Guide for Developing a Flour Fortification Program Monitoring and Surveillance System:

Overview

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Introduction
Minimum Conditions for a Successful Flour Fortification Program

• Good estimate is available on average per capita intake of **fortifiable** flour (i.e. flour produced in roller mills with \( \geq 20 \) MT/day capacity) - not total flour - in a defined geographic area.
  – Essential for determining the standard for concentration of vitamins and minerals to be added to fortified flour.

• With regard to iron fortification, a **bio-available** form of fortificant (sodium iron EDTA, ferrous sulfate, ferrous fumerate, or electrolytic iron) must be used - NOT *atomized, reduced, and hydrogen-reduced elemental iron powders*
  – Amount of iron fortificant must be based on extraction level of the flour.
Minimum Conditions for a Successful Flour Fortification Program (cont.)

• Good QA/QC procedures are in place at the flour mills, along with regulatory inspections and enforcement by the food control and/or customs agencies to ensure that quality (adequately) fortified flour is marketed.

• Sufficient fortified flour containing fortificant levels consistent with WHO guidance is accessible to meet the daily per capita intake needs of the vast majority of the population in the geographic area.

• Good social marketing and BCC are implemented to encourage the population to accept mandatory fortification of industrially milled flour.
• Regular and transparent collaboration between public health sector, food and/or customs control, and flour industry (millers and importers) is critical for effectiveness of flour fortification and its successful monitoring, surveillance and evaluation.
Distinguish Between Two Questions

• Is micronutrient status improving among people in the country that regularly consume quality fortified flour (foods)?

• What is the micronutrient status of the population of the country?
Key Terms

- Flour is staple product
- Fortifiable flour
- Per capita consumption
- Population coverage (penetration)
- Trends in population coverage and impact
- Initial impact
- Maximum sustained impact
- Reflective trend data
- Purposive selection
- Convenience sampling
- Triangulation of information
- Preponderance of evidence
Background
Average levels of nutrients to add to fortified wheat flour based on extraction, fortificant compound, and estimated per capita *fortifiable flour* consumption.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Flour Extraction</th>
<th>Compound</th>
<th>Level of nutrients to be added (ppm) by estimated per capita fortifiable wheat flour availability (g/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>&lt;75</td>
</tr>
<tr>
<td>Iron</td>
<td>Low</td>
<td>NaFeEDTA</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ferrous Sulfate</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ferrous fumarate</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Electrolytic iron</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>NaFeEDTA</td>
<td>40</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>Low or High</td>
<td>Folic Acid</td>
<td>5.0</td>
</tr>
<tr>
<td>Vit. B12</td>
<td>Low or High</td>
<td>Cyanocobalamin</td>
<td>0.04</td>
</tr>
<tr>
<td>Vit. A</td>
<td>Low or High</td>
<td>Vit. A Palmitate</td>
<td>5.9</td>
</tr>
<tr>
<td>Zinc</td>
<td>Low</td>
<td>Zinc Oxide</td>
<td>95</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Zinc Oxide</td>
<td>100</td>
</tr>
</tbody>
</table>

Adapted from WHO Interim Consensus Statement, 2009.
Framework for monitoring, surveillance and evaluation of a food fortification program.
“Formula” to Describe Public Health Success of an Effective Flour Fortification Program

A + B + C = D

A: Quality Fortified Flour/Flour Products Produced or Imported
B: High (>80%) Population Coverage
C: Sustained Coverage Over Time
D: Impact on Micronutrient Status

Industry and food Control based component of FFMSS
Population based component of FFMSS

On-going data collection and information reporting
Flour fortification must be continued indefinitely to achieve maximum sustained impact on the nutritional and health status of the population.

Declining trends in anemia prevalence in low-income children <5 years old in five states in the United States.

Trends in the incidence of spina bifida and other birth defects in Oman.


Source: Personal communication; Ms. Deena Alasfoor, Oman Director of Nutrition.
Flour Fortification Monitoring vs. Surveillance vs. Evaluation
Flour Fortification Program Monitoring

• The ongoing and systematic collection and analysis of data and interpretation and use of the resulting trend information on program inputs, implemented activities, and outputs to assess how a flour fortification program is performing compared to predefined criteria.
  – Focus of this guide is on tracking the quantity and sufficient population coverage of adequately fortified flour as output indicator.
  – No need to track coverage data on fortified flour at population level until flour industry and Food Control Agency report that sufficient quality fortified flour is marketed to meet the per capita intake of close to 80% or more of the population in the designated geographic area.
Flour Fortification Surveillance

• The ongoing and systematic collection, analysis, and interpretation of data and dissemination of the trend information on micronutrient and health status of a population with regular access to fortified flour, to help strengthen and sustain a flour fortification program as impact indicators.
  – Focus of this guide is on tracking iron and folate nutrition and NTD incidence as impact indicators.
Flour Fortification Program Evaluation

• Is the systematic collection and analysis of data and information about the activities, characteristics, and impact of the flour fortification program to assess (and improve) its effectiveness and inform decisions about its continuation or expansion.
  – FFMSS data and information informs program evaluation.
  – Additional data (quantitative and/or qualitative) may need to be collected; e.g. a population-based statistical survey.
  – May be conducted every 5 – 10 years.
  – Most public nutrition programs are evaluated at adequacy level – i.e. the preponderance of evidence indicates that the program has (or has not) helped improve nutritional status of the population.
Important Points to Remember about Indicators

- *If you do not know what to do with findings, no need to collect the data for it!*
- *Just because you can measure it doesn’t mean you have to!*
Purpose of Guide

• To provide guidance on developing a feasible and sustainable *Flour Fortification Monitoring and Surveillance System (FFMSS)* to confirm trends in high population coverage of adequately fortified flour, followed by impact on micronutrient status of a population over time.
  
  – *Different, but complementary data sources are needed to strengthen the overall information obtained through the FFMSS.*
Schematic of a Potential FFMSS Using Complementary Sources of Data

1. Presence of fortified flour in households.
2. Sales of fortified flour, bread, noodles, other staples by wholesalers, bakeries, supermarkets

**Population-level data**

- Women’s awareness of fortified flour.
- Women’s reported purchases of fortified flour/staple foods.
- Anemia, iron deficiency & folate sufficiency prevalence in non-pregnant women.
- Anemia prevalence in 1st trimester pregnant women.
- Anemia, iron deficiency & folate sufficiency prevalence in adolescent school girls.
- NTD incidence among maternity facility births

**Flour industry & Food Control Agency data**

- Millers and importers – amount of fortified flour produced and imported.
- Food Control Agency – quantity of fortified flour which meets quality standards

**Health Clinics**

- 1. Women’s awareness of fortified flour.
- 2. Women’s reported purchases of fortified flour/staple foods.
- 3. Anemia, iron deficiency & folate sufficiency prevalence in non-pregnant women.

**Secondary schools, maternity hospitals/birth centers**

- 1. Presence of fortified flour in households.
- 2. Sales of fortified flour, bread, noodles, other staples by wholesalers, bakeries, supermarkets

**Schools, wholesalers, bakeries, supermarkets**
**Hypothetical example of trends in fortified flour production and household coverage, and iron deficiency among women of childbearing age**

- **Prevalence of self-reported household purchase of fortified bread**
- **Prevalence of households with positively tested fortified flour**
- **Prevalence of iron deficiency in WCBA* attending sentinel clinics**
- **Quality fortified flour marketed**

*Women of childbearing age*

**Based on flour industry and Food Control Agency data**
- Prevalence of iron deficiency in non-pregnant women of childbearing age estimated through a representative survey.
- Prevalence of iron deficiency in non-pregnant women of childbearing age estimated through FFMSS.
- % population coverage of adequately fortified flour estimated through FFMSS.

Desired population coverage threshold

80%

40%

Start of mandatory flour fortification

Annual Coverage Monitoring

Annual Impact Surveillance

4 annual periods with ≥80% population coverage of fortified flour

Pre-fortification

Post-fortification

Time (years)
Desired population coverage threshold

4 annual periods with ≥80% population coverage of fortified flour

- Prevalence of iron deficiency in non-pregnant women of childbearing age estimated through a representative survey.
- % population coverage estimated through a representative survey.
- Prevalence of iron deficiency in non-pregnant women of childbearing age estimated through FFMSS.
- % population coverage of adequately fortified flour estimated through FFMSS.

Start of mandatory flour fortification

Annual Coverage Monitoring

Annual Impact Surveillance

Pre-fortification

Post-fortification

Time (years)
Sentinel Data Collection and Purposive and Convenience Sampling Approach
“Sentinel” refers to “watching over”.

Sentinel data collection involves purposively selecting a few communities within a larger geographic area (expected to have high population coverage) as **sentinel data collection sites** such that:

- Data trends from the sites are expected to reflect (mirror) trends in household coverage and impact of flour fortification in the broader geographic area.

Exiting health clinics, schools, worksites, houses of worship, etc. within each **sentinel site** could serve as **data collection points**.

Once the FFMSS documents the desired trends in population and impact, more detailed assessment and evaluation of the flour fortification program could be performed.
NTD Surveillance

• All maternity hospitals and birthing centers should report data on NTD births; live or still-born.
  – Ideally a thorough NTD surveillance system accounts for every NTD affected pregnancy, including medical termination of pregnancies.
Details on how to design a sentinel site system to collect population level data for tracking population coverage and impact of flour fortification will be addressed through group work in the next couple of days.