CHAPTER 1

Background

I. Components of an Effective Flour Fortification Program

II. Monitoring vs. Surveillance vs. Evaluation of a Flour Fortification Program

Vitamin and mineral deficiencies are among the world's most serious health risk factors (1) and contribute to reduced productivity and socioeconomic development of populations. Mass fortification of widely consumed food staples, such as wheat or maize flours, is considered a safe, economically feasible and sustainable strategy to help protect populations from such deficiencies (2). Various factors regarding milling processes, market distribution of industrially milled flour, and whether consumers mainly purchase flour or staple foods made of it, affect fortification standards and the approaches used to assess the overall effectiveness of a flour fortification program.

Thirty-three countries were fortifying flour in 2004 when the Flour Fortification Initiative (FFI) (http://www.ffinetwork.org/), a network of public, private and civic sector organizations, companies and institutions, was formed to help promote and accelerate the fortification of industrially milled flour around the world. The added efforts of the FFI network have led to an increase in the number of countries implementing flour fortification and the annual tonnage of fortified flour produced. As of July 2013, 77 countries required fortification of at least one type of wheat flour with at least iron and/or folic acid[1]; flour fortification standards in a number of countries also included the addition of thiamin, riboflavin, and niacin (3).

In order to provide up-to-date recommendations for effective flour fortification, an international technical workshop, convened under the auspices of FFI, issued guidance on the formulation and concentrations of iron, zinc, folic acid, vitamin A and vitamin B_{12} to add to low and high extraction wheat and maize flour based on the estimated per capita consumption of industrially milled "fortifiable" flour (i.e. produced by industrial roller mills with ≥20 MT/day milling capacity) (4). The outcome of that workshop served as the basis for the World Health Organization (WHO) consensus statement on wheat and maize flour fortification published in 2009 (**Table 1**) (5). The technical workshop also acknowledged the need for appropriate and on-going quality assurance (QA) and quality control (QC) processes and enforcement to ensure that adequately fortified flour is marketed. Furthermore, it was acknowledged that on-going epidemiological assessment of the impact of flour fortification is needed to inform and guide programs (4).

Fortifiable flour is defined as commercially milled flour produced by roller mills with ≥20 MT/day milling capacity.

Where staple foods made with industrially milled flour are widely consumed, flour fortification is a public health intervention intended to improve the micronutrient status of populations. To be successful and effective, flour fortification should be mandated by law and implemented through transparent collaboration between the public and private sectors. The quality of fortified flour depends on the addition of appropriate levels of micronutrients (as prescribed by the national standard) during the milling process. Those standards, in turn, must be developed according to the estimated per capita consumption of *fortifiable* flour (5).

1. http://www.ffinetwork.org/global_progress/index.php, accessed 24 July, 2013.

Table 1. Recommended levels of selected minerals and vitamins to add to low and high extraction flour by fortificant type and estimated per capita intake of industrial flour. (Ref. 5).

Nutrient	Extraction Level of Flour	Fortificant	Level of nutrient to be added to flour (parts per milion) By per capita fortifiable flour intake			
			<75 g/day	75-149 g/day	150-300 g/day	>300 g/day
Iron	Low	NaFeEDTA Ferrous Sulfate Ferrous Fumarate Electrolytic	40 60 60 NR[1]	40 60 60 NR[1]	20 30 30 60	15 20 20 40
	High	NaFeEDTA	40	40	20	15
Zinc	Low	Zinc Oxide	95	55	40	30
	High	Zinc Oxide	100	100	80	70
Folic Acid	Low or High	Folic Acid	5.0	2.6	1.3	1.0
Vitamin B12	Low or High	Cyancobalamin	0.04	0.02	0.01	0.008
Vitamin A	Low or High	Vitamin A palmitate	5.9	3.0	1.5	1.0

[1] NR – Not recommended

Once flour fortification is initiated, it is important to verify that the flour is fortified according to the national standards and that the product and staple foods made with it (e.g. bread or pasta) are marketed or otherwise accessible to the vast proportion of the population in a geographic area in order to reduce the public health burden of vitamin and mineral deficiencies.

I. Components of an Effective Flour Fortification Program

The public health effectiveness and success of a flour fortification program essentially consists of two main components:

1. Production and marketing of sufficient quality fortified flour to meet the daily intake needs of the vast majority of the population in a specified geographic area.
2. Sufficient consumption of staple foods made from quality fortified flour by the specified population so as to substantially improve micronutrient intake and status.

The minimum conditions for a flour fortification program are listed in **Box 1**. Before the impact of flour fortification on the nutritional and health status of the population is assessed, an adequate level of operational performance is necessary to ensure that sufficient quality fortified flour is marketed (2). Thus:

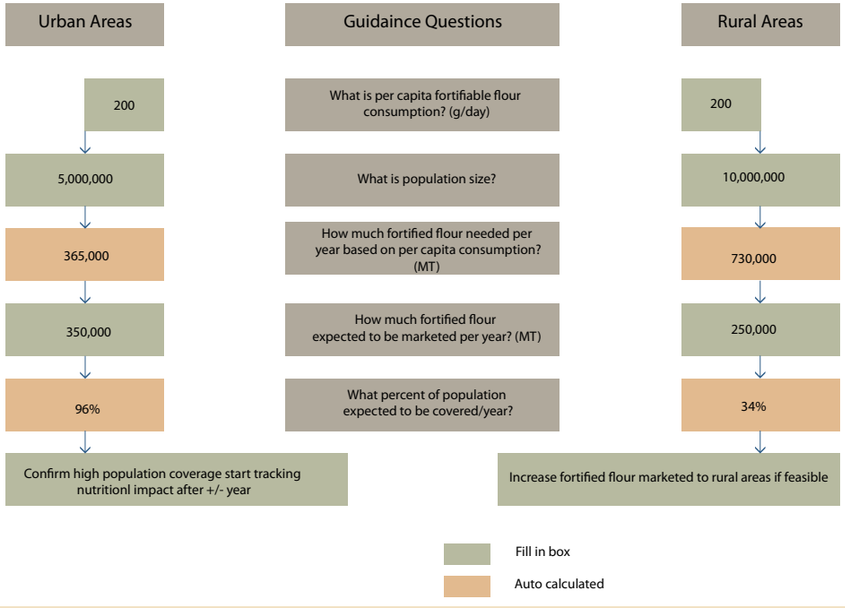
1. The industrial miller is the initial responsible party and must implement the appropriate QA/QC procedures to ensure adequate fortification of the flour supply according to the national standards. The minimum acceptable QA system that a miller should follow is Good Manufacturing Practices (GMPs). In several countries, Hazard Analysis and Critical Control Point (HACCP) systems are followed (8).
2. Each importer must provide a "certificate of conformity" to assure that the total quantity of fortified flour imported meets the national fortification standards.
3. The official Food Control Agency (FCA) and the customs agency must conduct regular QC inspections. For the FCA, this entails auditing of fortification records and testing of the flour at the mills. The customs agency should ensure that adequately fortified flour enters the country by inspecting the "certificate of conformity" that must accompany each shipment of the product, and if at all feasible, through rapid testing of the flour at the points of entry.
4. To readily detect a reduction in the prevalence of selected vitamin and mineral deficiencies or health conditions (e.g. neural tube defects) in a population, sufficient fortified flour should be marketed to meet the daily per capita consumption needs of close to 80% or more of the population in the geographic area for about one year (4, 7).

Box 1. Minimum conditions needed for an effective flour fortification program.

- The national standard for the concentration of vitamins and minerals to be added to fortified flour is determined based on the estimated per capita consumption of *fortifiable* flour (i.e. flour produced in roller mills with ≥20 MT/day capacity) - not total flour - in a defined geographic area (4, 5).
- With regard to fortification with iron, a bio-available form of iron fortificant, as specified by the World Health Organization (WHO) (5), is used and the amount added is based on the extraction level of the flour; *atomized, reduced, and hydrogen-reduced elemental iron powders must not be used since they have been shown to be ineffective in improving iron status when added to flour* (6).
- Appropriate quality assurance (QA) procedures are in place at the flour mills, and there are adequate quality control (QC) inspections and enforcement by the food control and/or customs agencies to ensure that quality fortified flour is produced and/or imported and marketed.
- Sufficient fortified flour with added nutrient levels consistent with those recommended by WHO (5) is accessible to meet the daily per capita consumption needs of close to 80% or more of the population in the specified geographic area (2, 7).
- Appropriate social marketing and behavior change communication interventions are implemented to encourage the population to accept mandatory fortification of industrially milled flour used for making staple foods.

Box 2 below illustrates how information on flour consumption, population size, and projections about the quantity of fortified flour, and the estimated per capita intake of *fortifiable* or fortified flour can be used to determine population groups in the country expected to substantially benefit nutritionally from a flour fortification program.

Box 2. Example of the use of relevant data to determine the expected population coverage of fortified flour in urban vs. rural populations in a hypothetical country.



The interactive version of this sheet can be downloaded from www.Smarterfutures.net/FORTIMAS

In the hypothetical example above:

a. The estimated per capita consumption of *fortifiable* flour is about 200 g/day, in both urban and rural populations who utilize commercially purchased flour and/or flour-based products.

b. Based on the respective urban vs. rural populations of the country, 365,000 MT and 730,000 MT of fortified flour would be needed per year to meet the daily consumption needs of each population group, respectively (i.e. ((200 x population size)/1,000,000 g/MT) x 365 days/year).

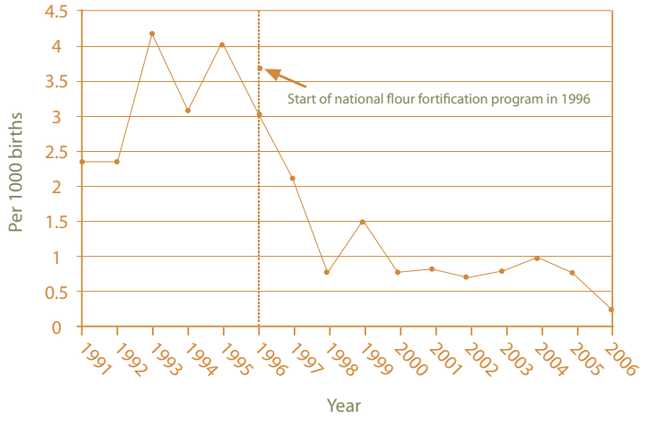
c. The actual expected amount of fortified flour to be marketed in urban areas annually is 350,000 MT.
   - This would meet the daily consumption needs of 96% of the urban population.
   - If the flour is regularly fortified according to the national standard, which in turn is in line with the WHO recommendations (5), then the initial impact of the flour fortification program could be detected within 1 – 2 years of full implementation in urban areas.

d. In contrast, the 250,000 MT of fortified flour expected to be marketed in rural areas would meet the daily needs of only 34% of that population.
   - It would be very difficult to identify the 34% of rural people who would have regular daily intake of fortified flour at 200 g/day throughout a year.
   - Marketing of fortified flour in rural areas should not be stopped. Rather, stakeholders of the flour fortification program should explore options to increase the quantity of fortified flour marketed in those areas over time.

In the United States (9), Australia (10) and Oman (11), where staple foods made from industrial flour were accessible to essentially the entire population of each country, the mandatory addition of folic acid to fortified flour resulted in high population coverage of the product very rapidly, followed by significant increases in serum folate levels among the population and/or reduction in the birth prevalence of neural tube defects (NTDs) within one to two years.

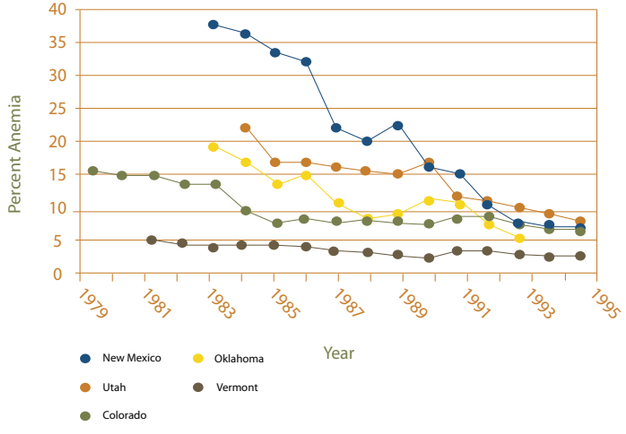
It should also be noted that effective flour fortification must be continued indefinitely to achieve *maximum sustained impact* on the nutritional and health status of the population. As shown in **Figure 1**, the birth prevalence of NTDs continued to decline in Oman during the decade since the inception of that country's national flour fortification program. Recent data indicate that the decrease in birth prevalence of NTD in Oman has been sustained (personal communication, Ms. Deena Alasfoor, Oman Ministry of Health, August, 2011).

Figure 1.
Trends in the birth prevalence of babies born with spina bifida and other neural tube defects – Oman Ministry of Healthneural tube defects reporting system (data source: ref. 11).



It should be noted that the rate of decline in the prevalence of a micronutrient deficiency and/or NTDs often differs between countries and even sub-areas within a country. The degree of impact of a flour fortification program is largely dependent on the extent of the problem in each setting prior to the start of the intervention. **Figure 2** provides an example for this concept. Across the United States, low-income preschool children received benefits through an essentially similar nutrition intervention program[1]. Despite programmatic consistency across the country, states with a higher public health burden of pediatric anemia (as proxy for iron deficiency) had higher rates of decline in the prevalence of the condition.

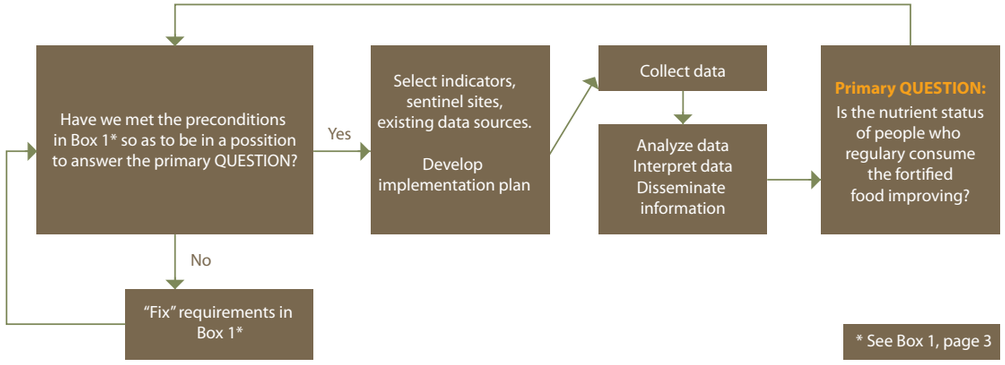
Figure 2.
Declining trends in anemia prevalence in low-income children <5 years old in various States in the United States (data source: Sherry, B. et al. Pediatrics 107:677, 2001).



1. USDA. WIC - The Special Supplemental Nutrition Program for Women, Infants and Children. http://www.fns.usda.gov/wic/WIC-Fact-Sheet.pdf, accessed 20 January, 2013.

As stated in the Preface, the primary aim of the guide is to propose a population-level data collection approach to help answer the question, "is the micronutrient status of those who regularly consume sufficient quality fortified flour improving?" During the planning stages of FORTIMAS, it may be useful to "work backwards" from the ultimate aim and review the issues that need to be addressed to achieve it. **Flow Diagram 1** illustrates this approach. Also, keep in mind that **Box 1** (above) lists the essential preconditions for an effective flour fortification program that must be met before embarking on collecting primary data or using existing data to track the population coverage and impact of the intervention.

Flow Diagram 1.
"Working backwards" from the primary question to be answered in order to facilitate the success of a flour fortification program.



When linking the flow diagram to the guide, please note that Chapter 4 (Sections IV, V, and VI) describes data collection, analysis, interpretation and dissemination. Chapter 3, Section I and **Table 4** list potential indicators to track. Chapters 2 and 3 (sections II to IV) discuss the selection and use of sentinel sites and data collection points to collect population-level data. Chapter 3, sections V and VI, and Chapter 4, section VII as well as several annexes assist in developing the FORTIMAS implementation plan.

II. Monitoring vs. Surveillance vs. Evaluation of a Flour Fortification Program

1. What is Flour Fortification Program Monitoring?

Once a flour fortification program is initiated, it is important to know if sufficient quantities of adequately fortified flour are produced and/or imported, and if a high enough proportion of the population consumes fortified flour products, tto have a public health impact. Thus, *Flour Fortification Program Monitoring*

is intended to track key *processes* (or implementation) of the program related to the production and consumption of fortified flour, and may be defined as "the ongoing and systematic collection and analysis of data, and interpretation and use of the resulting *information on program inputs, activities*, and *outputs* to assess how the flour fortification program is performing compared to predefined criteria"[2].

Some examples of flour fortification program-related inputs and activities include: purchasing sufficient quantities of vitamin and mineral premix; procuring premix feeders; training millers on feeder installation and use; training millers and food control agents on QA/QC procedures and regulatory inspection methods; developing and implementing communication and social marketing messages to encourage consumer acceptance of fortified flour; training FORTIMAS data collectors and analysts; and acquiring the needed computer hardware and software for entry, cleaning and analysis of FORTIMAS data.

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. The focus of this guide is on monitoring the sufficiency of the output of adequately fortified flour.

With regard to flour fortification program monitoring, the focus of this guide is on tracking the quantity of fortified flour as an output measure that determines the expected proportion of the population with access to sufficient quality fortified flour and flour-based staple foods (e.g. bread and pasta). Proposed examples of trends of output indicators of a flour fortification program that should be tracked at defined intervals over time include those listed below (also refer to Chapter 3, **Table 4** and Chapter 4, **log-frame A**):

a. Total quantity of fortified flour produced and/or imported annually (data to be provided by the flour industry and customs agency).
b. Proportion of flour which meets national fortification standards (data to be provided by the food control agency).
c. Quantity of fortified flour available in wholesale markets (data provided by selected flour wholesalers may be more practical as there are typically far fewer of them compared to retailers in a geographic area).
d. Quantity of fortified flour used for commercial production of bread and/or pasta.
e. Prevalence of households that report purchasing fortified flour and/or flour based staple foods.
f. Prevalence of households that have fortified flour and/or flour based staple foods in the home at the time of data collection.

[2] Adapted from: Pena-Rosas JP, Parvanta I, Van der Haar F, Chapel T. Monitoring and evaluation in flour fortification programs: design and implementation considerations. Nutr Review 2008; 66 (148-162).

It would not be necessary to track the presence of fortified flour or flour-based staple foods in communities and households until the flour industry and the Food Control Agency report that sufficient quality fortified flour is marketed to meet the per capita consumption of close to 80% or more of the population in a designated geographic area.

2. What is Flour Fortification Program Surveillance?

Tracking the impact of flour fortification on the nutritional and health status of the population is referred to as *Flour Fortification Program Surveillance* and may be defined as "the ongoing and systematic collection, analysis, and interpretation of data and dissemination of the trends in micronutrient and health status of a population with regular access to fortified flour, to assess the impact of, and help strengthen and sustain an effective flour fortification program"[3]. Examples of nutritional impact surveillance indicators to track after the program monitoring data indicate sustained high population coverage of fortified flour over time are presented in Chapter 3, **Table 4**.

Flour Fortification Program Surveillance is the on-going 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 assess the impact of, and help strengthen and sustain a flour fortification program.

Because flour fortification is carried out as a private-public partnership, surveillance of the impact of the intervention should also be performed as collaboratively and transparently as possible between the two sectors. In fact, the design and implementation of the population-level component of FORTIMAS very much depends on information from the flour industry (i.e. industrial millers and importers) to direct where and when to collect surveillance data on the impact of the intervention. Thus, when a flour fortification program is initiated in a country, the FORTIMAS system could start tracking the impact of the intervention once the industry data indicate expected high population coverage of the product annually.

Figure 3 depicts the chronological manner in which data are hypothetically collected using the FORTIMAS approach. In order to use resources wisely, nutritional impact surveillance should only be conducted after industry sources indicate an expected annual population coverage of quality fortified flour that is close to or more than 80%, and subsequent population level monitoring confirms that estimate. However, some "baseline data" prior to the full-scale implementation of flour fortification may be necessary to substantiate the progress and impact of the program. Here are some key points to guide interpretation of the chart in **Figure 3**:

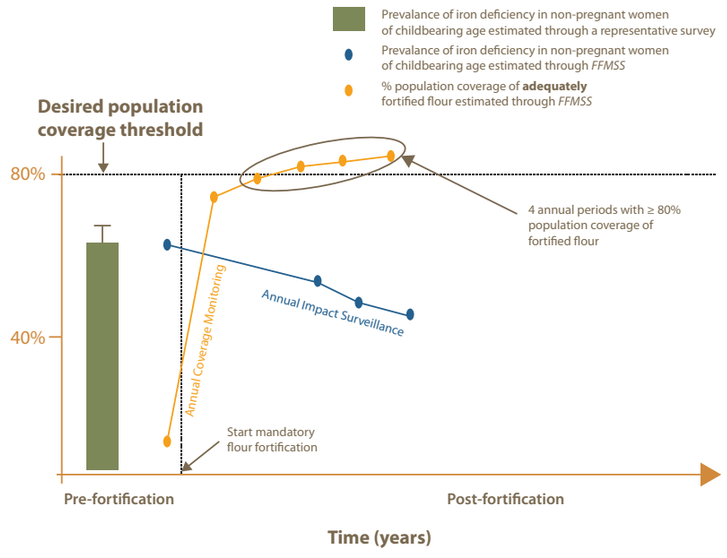
[3] Adapted from: Centers for Disease Control and Prevention. Updated guidelines for evaluating public health surveillance systems: recommendations from the guidelines working group. MMWR 2001;50 (No. RR-13).

a. Pre-fortification data (green bar) indicate a very high prevalence of iron deficiency among women of childbearing age. Such data are usually available from population-based nutrition and health status surveys.
b. Prior to the start or full-scale implementation of a mandatory flour fortification program, "initial" or "baseline" FORTIMAS data are collected on population coverage of fortified flour (first orange circle) and the prevalence of iron deficiency (first blue circle) in women of childbearing age using the FORTIMAS methodology that is carried out over time to generate trend information for those parameters.

   Unless contrary information exists, the baseline population coverage of fortified flour may be assumed to be negligible (or 0%).

Figure 3.
Illustration of the chronology of hypothetical FORTIMAS* data collection to track fortified flour coverage vs. impact on iron status in the population.

* FORTIMAS – Flour Fortification Monitoring and Surveillance System



c. Population coverage of fortified flour sustained at around 80% for at least one year indicates that the fortification program may be having the desired health impact. Thus, surveillance of iron deficiency among women of childbearing age is started. A decreasing trend in the prevalence of iron deficiency in the target group indicates an effective intervention.

Note:

- When there is continued and reliable marketing of quality fortified flour for a few years, population coverage of the intervention may be estimated based on the quantity of the product marketed alone. Furthermore, it may be sufficient to report impact surveillance findings every two or three years instead of annually until maximum impact or reduction in the level of the specific nutrient deficiency is achieved through flour fortification. After that, it may be appropriate to just ensure continued marketing of quality fortified flour and actively track the "sustained impact" of flour fortification every five years or more.
- In a country where the marketing of adequately fortified flour evolves gradually, population level FORTIMAS data collection on coverage and impact of the program may be initiated in those sub-areas where the vast majority of the population has regular access to the product annually.
- An on-going, thus successful, FORTIMAS system is in large part dependent on a cycle of minimal data collection, timely data processing and analysis, and regular dissemination of the information and related action recommendations to all stakeholders of the fortification program, including those who collected and submitted the needed data for analysis. It is also essential to acknowledge the primary role of flour millers and importers in the improvement of nutritional and health status of the population due to quality flour fortification.
- In many countries, a variety of data on health and nutrition status are collected consistently through existing systems. Where possible, the FORTIMAS approach should be to identify and extract the most useful data from those systems to incorporate into FORTIMAS analyses and reports.

3. What is Flour Fortification Program Evaluation?

Once the FORTIMAS system documents sufficient production of adequately fortified flour, sustained high population coverage of the product, and decreasing trends in the prevalence of micronutrient deficiencies, a more detailed assessment and review of the program could be carried out to assess its overall implementation, public health impact and value to continue. This is referred to as *Flour Fortification Program Evaluation*, which is defined as the "systematic collection and analysis of data and information about the activities, characteristics, and impact of a flour fortification program to assess (and improve) its effectiveness and inform decisions about its continuation or expansion"[4]. Thus, the findings of a well-implemented FORTIMAS system will inform decisions about when and how to best evaluate a flour fortification program.

> 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.

The eventual approach to a full evaluation of the flour fortification program will be dictated by the specific purpose of the study and by the availability of resources. The level of precision required to satisfy the needs of decision-makers regarding the effectiveness of the program is another important factor to consider when selecting the evaluation design. The impact of most public nutrition programs is evaluated at the *adequacy* level (12); i.e. the preponderance of evidence (taking into account possible confounders and

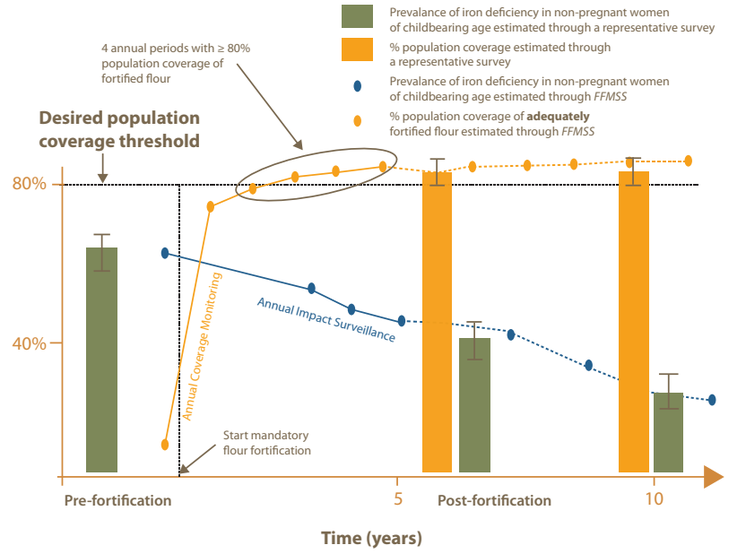
4. Adapted from: Patton MQ. Utilization-focused evaluation: The new century text. 3rd ed. Thousand Oaks, CA: Sage, 1997.

contributions by complementary interventions) indicates that the program has (or has not) improved the nutritional and health status of the population.

Evaluation of a flour fortification program may be conducted every five to 10 years. In contrast, FORTIMAS is an on-going data collection system. **Figure 4** describes, as a hypothetical example, how the FORTIMAS data may be combined every few years with more detailed representative surveys toward periodic evaluation of the flour fortification program:

1. For four consecutive years, the FORTIMAS system has indicated sufficient population coverage of (quality) fortified flour, combined with a decreasing trend in the prevalence of iron deficiency among women of childbearing age in a specified geographic area.
2. A representative survey is carried out in the geographic area around the 6th year of the program and confirms (with statistical precision) high population coverage of (quality) fortified flour (orange bar) and a significant reduction in the prevalence of iron deficiency among women of childbearing age (green bar). At this stage, additional quantitative and qualitative data are also collected to evaluate the fortification program's strengths and weaknesses, as well as its associated costs, to help sustain the intervention in the long-term.
3. Since the flour fortification program is well-established after about five years of implementation, FORTIMAS continues to confirm a high population coverage of (quality) fortified flour, primarily based on industry production and import data, together with regulatory QC information from the FCA. The data system also tracks the annual (or bi-annual) prevalence of iron deficiency among women of childbearing age.
4. When funds are available, another representative health and nutrition survey is carried out about 10 years after the start of the flour fortification program. The survey confirms the FORTIMAS data on continued high population coverage of fortified flour (2nd orange bar) and sustained "maximum reduction" in the prevalence of iron deficiency achieved through flour fortification (3rd green bar).

Figure 4.
Chronology of a hypothetical FORTIMAS combined with periodic representative surveys for the evaluation of a flour fortification program.



A note about "baseline" data:

As shown in **Figures 3** and **4**, there are essentially two types of "baseline" or "initial" flour fortification program monitoring and surveillance data. In most countries, the decision to fortify flour or other foods is based on evidence of a high prevalence of vitamin and mineral deficiencies, usually obtained from a population based nutrition survey (e.g. DHS, Multiple Cluster Indicator Survey, stand-alone nutrition survey, etc.). Such "baseline" data is shown by the left-most green bar in **Figures 3** and **4.** The "initial" FORTIMAS data on population coverage and prevalence of iron deficiency in non-pregnant women of childbearing age (shown as the left-most orange and blue circles, respectively in **Figures 3** and **4**) would be used to compare on-going trends in population coverage monitoring and impact surveillance of the flour fortification program.

4. What are Flour Fortification Program Monitoring and Surveillance Indicators?

Flour fortification monitoring and surveillance indicators included in this guide are parameters that can be assessed to track the trends in output and impact indicators of the flour fortification program in a geographic area (see Chapter 3, **Table 4**). The analysis of data on those indicators will enable the private, public and civic sector stakeholders of the flour fortification program to gauge progress toward the program objectives related to population coverage of adequately fortified flour and reductions in specific nutritional and health conditions. By comparing the value of an indicator (e.g. metric tons of adequately fortified flour

produced, percent of households that purchase fortified flour, percent of women of childbearing age who are iron deficient, birth prevalence of NTDs, etc.) over time, it is possible to assess the expected success of the flour fortification program.

The appropriate program output and impact indicators to track through the FORTIMAS approach should be (13):

- **Valid** – correctly measure what they are intended to measure. For example, serum ferritin has been shown to be a valid indicator of iron status, whereas anemia, based on low hemoglobin (Hb), is a proxy indicator of iron deficiency (14). The prevalence of anemia decreases in a population when widespread iron deficiency is alleviated through increased iron intake. However, because results of serum ferritin and Hb tests are affected by malaria infection, such surveillance data should be collected in the low transmission season. Another option is to collect data on inflammatory response indicators (e.g. C-reactive protein or alpha-1-acid glycoprotein) to allow for appropriate interpretation of the findings related to changes in iron status of the target population.
- **Simple and measurable** – can be feasibly assessed. For example, the label or logo on a sack of fortified flour or package of bread could be a simple indicator of a quality fortified product if the millers and bakers are trusted to apply the approved fortification label/logo according to the national regulations.
- **Reliable** – provide accurate and reproducible results on repeat measurements; i.e. the indicators and data collection methodology are robust and expected to yield similar findings if repeated.
- **Timely** – can be assessed within an appropriate timeframe so that necessary actions can be taken based on the findings. For example, fortified flour production and import data may be available rapidly to estimate population coverage, especially in the early stages of the flour fortification program.
- **Comparable** – data are collected systematically across geographic areas and time, using the same methodology and tools, so that the results can be compared between different groups or at different points in time.
- **Programmatically important** – help guide and improve the program. For example, regulatory quality control monitoring data confirm that sufficient quality fortified flour is produced and/or imported to meet the needs of the target population.

Cost will largely dictate the continuation of FORTIMAS over time. Thus, only the fewest necessary indicators to track population coverage and nutritional impact of the flour fortification program should be measured. The motto to guide the selection of indicators is, "there is no need to collect any data that will not be readily used to guide and improve the program" (7). Another way to say it is, "if you do not know what to do with the findings, do not collect the data!"