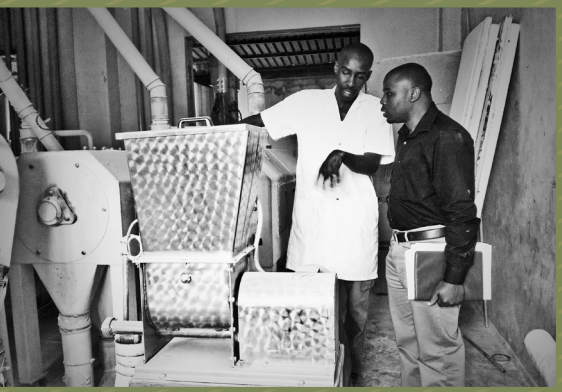
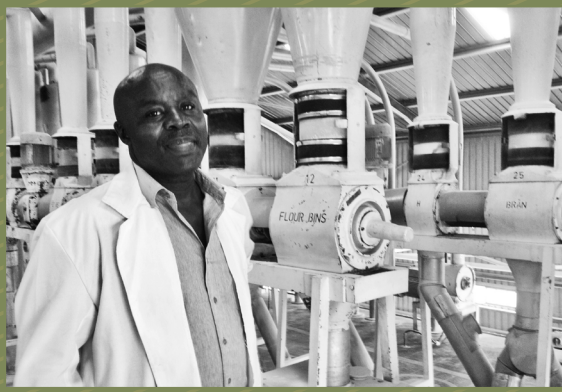
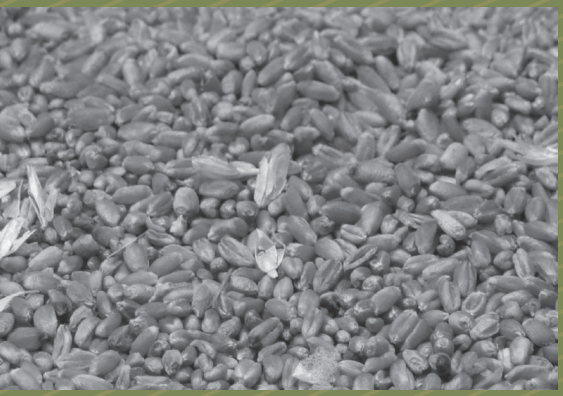




FORTIMAS

An Approach for Tracking the Population Coverage and Impact of a Flour Fortification Program



Acknowledgements

FORTIMAS (Fortification Monitoring and Surveillance) started as a response to those who requested guidance on a feasible method for assessing trends in selected indicators of population coverage and impact of a flour fortification program during the early stages of the intervention, between the statistically representative initial and first impact assessment surveys.

Ibrahim Parvanta was the main author of what started as "A Guide on Monitoring and Surveillance of Flour Fortification Programs" and remains the main author of FORTIMAS. However, the final version of the guide was greatly improved based on the inputs of many people in academia, international organizations, national agencies and NGOs throughout the writing process.

An initial version of the guide was reviewed in April 2011 by multi-sectorial country teams from Ethiopia, Kenya, Malawi, Mozambique, Rwanda, South Africa, Swaziland, Tanzania, Uganda and Zimbabwe at a workshop in Dar es Salaam, Tanzania. Their contributions enriched the subsequent draft that received further beneficial inputs from Deena Alasfoor (Ministry of Public Health, Sultanate of Oman), Christine Clewes (Global Alliance for Improved Nutrition - at time of review), Juan Pablo Peña-Rosas (World Health Organization), Laird Ruth and Mary Serdula (Centers for Disease Control and Prevention), and Brad Woodruff (International Health and Nutrition Consultant).

In March 2013, a follow-up meeting was held in Sandton, South Africa, to finalize the guide and develop it into a manual. The individuals listed below reviewed the revised document and gave invaluable advice on improving it for use at the country level. They also agreed to name the approach "FORTIMAS" for "Fortification Monitoring and Surveillance."
Ronald Afidra (Flour Fortification Initiative, Uganda), Ferima Coulibaly-Zerbo (World Health Organization, Burkina Faso), Maude de Hoop (National Department of Health, South-Africa), Pumla Dlamini (Global Alliance for Improved Nutrition, South-Africa), Esi Foriwa Amoaful (Ghana Health Service, Ghana), Svenja Jungjohann (Global Alliance for Improved Nutrition, Switzerland), George Kaishozi (Helen Keller International, Tanzania), Milla MacLachlan (Stellenbosch University - Faculty of Medicine and Health Sciences, South-Africa), Girma Mamo Bogale (Micronutrient Initiative, Ethiopia) , Eduarda Zandamela Mongói (Ministry of Industry and Trade, Mozambique), James Muwonge (Bureau of Statistics, Uganda), John Mwingira (Food and Drugs Authority, Tanzania), Alex Ndjebayi (Helen Keller International, Cameroon), Olugbenga A. B. Ogunmoyela (Bells University of Technology, Nigeria), Mawuli Sablah (Helen Keller International, Senegal), and Nigel Sunley (Sunley Consulting, South-Africa), and Lieven Bauwens (International Federation for Spina Bifida and Hydrocephalus, Belgium).

Throughout the entire process from the inception till finalization of FORTIMAS, Quentin Johnson (Coordinator for Training and Technical Support, Flour Fortification Initiative), Helena Pachón (Senior Nutrition Scientist, Flour Fortification Initiative), and Anna Verster (Senior Advisor Flour Fortification - Smarter Futures Flour Fortification Initiative / International Federation for Spina Bifida and Hydrocephalus) provided continual inputs and were in constant dialogue with the main author.

Last but not least, Becky Handforth (Europe Associate, Flour Fortification Initiative) edited the document with a fresh eye and mind. She worked closely with Ibrahim Parvanta in finalizing FORTIMAS into its current version.

FORTIMAS is a living document and will benefit from the experiences of its users.
Please contact info@smarterfutures.net to share your thoughts.

Smarter Futures, a partnership for Africa of the Flour Fortification Initiative, the International Federation for Spina Bifida and Hydrocephalus, Helen Keller International and Akzo Nobel gratefully acknowledges the financial support from the Government of the Netherlands towards the development of this guide.

Lieven Bauwens

Secretary General
International Federation for Spina Bifida and Hydrocephalus
Project Holder, Smarter Futures

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Preface

Worldwide, 77 countries require fortification of one or more types of wheat flour[1], and several countries in the Americas and Africa also fortify maize flour. However, many countries have struggled with how to assess the impact of this public health intervention over time. Some countries have included a micronutrient module when conducting Demographic and Health Surveys (DHS)[2]. However, the DHS and similar large surveys are quite expensive, usually require donor funding, and are only done at five to 10 year intervals. This approach does not allow for more frequent findings on the quality, population coverage and early evidence of the impact of a flour fortification program before investing in an "evaluation study".

In discussions with country and agency colleagues, representatives of the Flour Fortification Initiative (FFI) and Smarter Futures partner organizations were frequently asked for guidance on "lighter methods for assessing trends in selected impact indicators of a flour fortification program during the early stages of the program and in the interval between the base-line and first impact evaluation study". Therefore, Smarter Futures contracted Ibrahim Parvanta to develop a guide that would enable countries to assess trends in a limited number of program output and impact indicators in "easy-to-reach" target populations in countries that have embarked on flour fortification.

It is expected that flour fortification, implemented according to the latest guidance of the World Health Organization (WHO)[3], will improve the micronutrient status of populations that regularly consume staple foods made of adequately fortified flour. Thus, the purpose of this guide is to provide direction for the development of a feasible and sustainable Fortification Monitoring and Surveillance (FORTIMAS) approach to confirm high population coverage of quality fortified flour (i.e. flour that meets the national standard for added micronutrients) and detect the expected improvements in the micronutrient status of women of childbearing age (the primary target population) over time. Given that the majority of countries add iron and folic acid to fortified flour, the main impact indicators included in this guide pertain to measures of iron and folate status in the target population. However, users of the document may include additional indicators of program impact on the population's nutrient status based on other micronutrients that might be added to fortified flour.

The purpose of FORTIMAS is to track trends in the effectiveness of a flour fortification program over time in populations documented to regularly consume fortified flour – not necessarily to provide statistically representative cross-sectional estimates of the prevalence of micronutrient deficiencies in the population at any specific point in time. If such information is deemed necessary, statistically representative surveys may be carried out as needed and resources allow. It is also essential that countries take advantage of existing private and public data systems or sources to "triangulate" information on population coverage and impact of fortified flour on a continual basis.

1. http://www.ffinetwork.org/global_progress/index.php, accessed 24 July, 2013.
2. http://www.measuredhs.com/aboutdhs/. Accessed 4 February, 2013.
3. WHO. Recommendations on wheat and maize flour fortification meeting report: interim consensus statement. Geneva,Switzerland, 2009. (http://www.who.int/nutrition/publications/micronutrients/wheat_maize_fort.pdf)

The primary aims of the proposed FORTIMAS approach are to:

1. Determine if close to 80% or more of the population is covered by the flour fortification program in a given geographic area over time, based on the quantity of fortified flour produced and imported, and household purchases of fortified flour in sentinel communities.
2. Answer the question, "is the micronutrient status of those who regularly consume sufficient[4] quality fortified flour improving?"

The non-probabilistic sentinel site data collection approach described in this guide for tracking population coverage and nutritional impact of flour fortification is based on the following concepts:

a. Industrially milled flour is to be fortified because it has already been determined that such flour is a staple food that is regularly consumed by the vast majority of the population in a geographic area.
b. Regular intake of fortified flour that contains bioavailable forms of micronutrients, in particular iron, based on the expected per capita consumption of fortifiable (i.e. industrially milled) flour in the geographic area will improve the nutrient intake and status of its population.
c. When data on the annual quantity of adequately fortified flour marketed in a geographic area complement the finding of high population coverage of the product in selected sentinel communities in that geographic area, it may be assumed that the latter findings are "reflective" of the population coverage trends in the geographic area as a whole.
d. Sustained high population coverage of adequately fortified flour, combined with declining trends in the prevalence of the target micronutrient deficiency, indicate the likelihood that flour fortification has contributed to the improved micronutrient status of the population.

Although flour fortification is the focus of this guide, the principles and approaches could be used for monitoring and surveillance of other population-wide food fortification and nutrition programs (e.g. salt iodization, vegetable oil fortification, infant and young child feeding interventions, etc.). It would, however, be necessary to define and track appropriate indicators related to product quality, population coverage and impact of each intervention.

> The principles and approaches proposed in this FORTIMAS guide on flour fortification could be used for monitoring and surveillance of other population-wide food fortification and nutrition programs.

Finally, users of this guide are encouraged to share their experiences on monitoring and surveillance of flour fortification to the Smarter Futures secretariat in order to improve a future version of this manual.

4. According to the estimated per capita consumption of industrially produced (fortifiable) flour, which should determine the fortification standard.

Glossary of Terms

Term	Meaning
Adequately fortified flour	Fortified flour contains fortificant levels that meet the national standard, which in turn are based on the estimated per capita consumption of *fortifiable* flour per WHO interim recommendations on wheat and maize flour fortification.
Administrative sub-area	Capital and large cities and provinces in a country.
Convenience sampling	Non-probability sampling technique where subjects are selected because of their convenient accessibility.
Data collection point	An existing facility within a sentinel site where subjects are recruited for FORTIMAS data collection.
Expected population coverage	The proportion of the population thought to have regular access to fortified flour based on the annual quantity of fortified flour marketed and the estimated per capita consumption of such flour.
Flour fortification program monitoring	The ongoing and systematic collection and analysis of data and interpretation and use of the resulting *trend information* on *program outputs* (*i.e. fortified flour*) to assess how a flour fortification program is performing.
Flour fortification program 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 over time.
Flour fortification program evaluation	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.
Flour fortification standard	The quantity of specified micronutrients required to be added to fortified flour.
Fortifiable flour	Industrially milled flour produced by roller mills with ≥20 MT/day milling capacity.
(Initial) Impact	Detected change or improvement in an indicator of health or nutritional status in a population which results from an intervention.
Maximum sustained impact	Maximum improvement in health or nutritional status in a population due to a sustained intervention over a period of time … often a number of years.
Outcome	Long-term improved effects on society such as reduced maternal and child mortality, improved cognition and learning capacity of children, and higher work capacity and income in adults.
Per capita consumption (of fortified flour)	Estimated average intake of fortified flour (in grams or kilograms) per person in the population per defined time period (e.g. per day).

Term	Meaning
Population coverage (of fortified flour)	Proportion of the population that regularly consumes sufficient quantities of fortified flour (based on the quantity of fortified flour marketed and its estimated per capita daily consumption).
Preponderance of evidence	The weight of corresponding information from multiple sources of data supports the conclusion.
Purposive selection	Non-random determination of communities as sentinel data collection sites in selected geographic areas of the country where the expected population coverage of fortified flour is close to or more than 80% based on flour industry market data.
Quality assurance	A systematic approach and process to ensure the production of the best possible product (*i.e. industrially milled fortified flour*).
Quality fortified flour	Fortified flour with fortificant content that meets the national flour fortification standard which is in line with WHO recommendations of micronutrient addition levels based on estimated per capita intake of industrially milled flour.
Quality control	A systematic approach to verify that the product (*i.e. fortified flour*) meets the defined (*flour fortification*) standard.
Reflective (trend) data	The trends in findings based on non-probabilistic data "mirror", or would be expected to have a similar pattern, to findings based on probabilistic or statistically "representative" population data over time.
Sampling	The process of selecting units (e.g., individuals or household) among the target population.
Sentinel site	A community within a larger geographic sub-area where FORTIMAS data are collected.
Triangulation of information/findings	Analyzing data from more than one complementary source and cross-checking the findings.
Trends in population coverage and nutritional impact	Patterns in the trends of population coverage and impact (of an intervention, e.g. flour fortification) at multiple points over time.

Acronyms

CDC	Centers for Disease Control and Prevention
FAO	Food and Agriculture Organization
FCA	Food Control Agency
FFI	Flour Fortification Initiative
FORTIMAS	Flour Fortification Monitoring and Surveillance System
GMPs	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Point
Hb	Hemoglobin
HMIS	Health Management Information System
PHC	Primary Health Centers
NTD	Neural Tube Defects
QA	Quality Assurance (by flour mills)
QC	Quality Control (by Food Control Agency)
US	United States
WHO	World Health Organization

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:

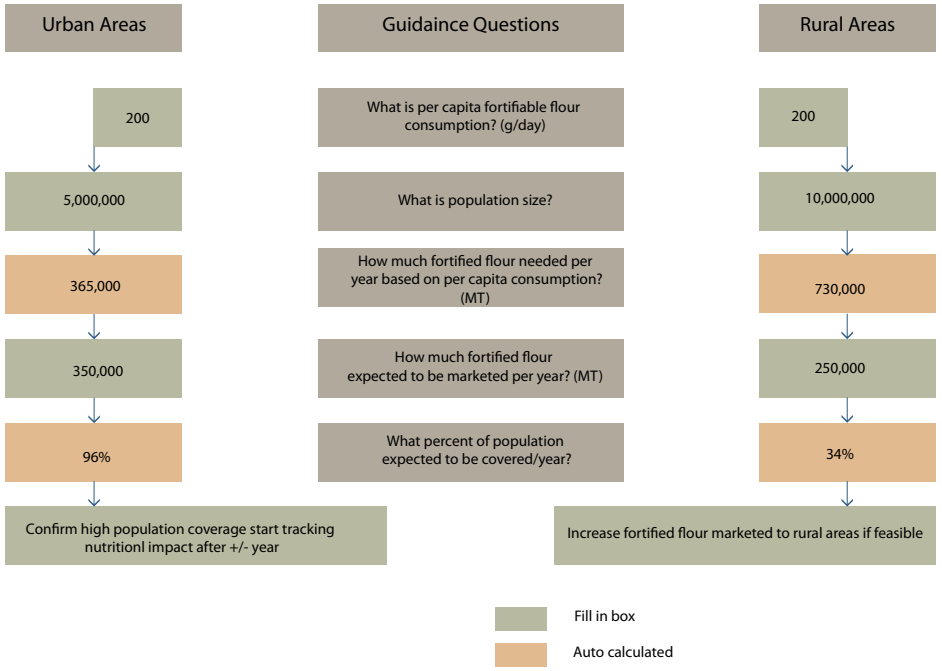
1. The industrial miller is the initial responsible party and must implement the appropriate QA/QC procedures to ensure adequate fortification of the flour supply according to the national standards. The minimum acceptable QA system that a miller should follow is Good Manufacturing Practices (GMPs). 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:

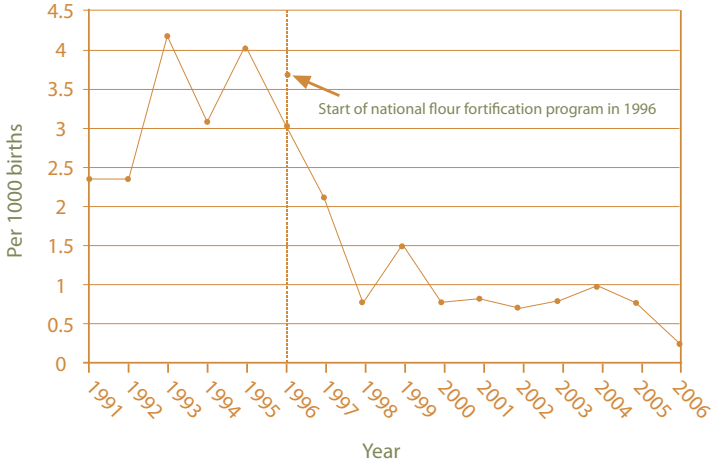
a. The estimated per capita consumption of *fortifiable* flour is about 200 g/day, in both urban and rural populations who utilize commercially purchased flour and/or flour-based products.

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.

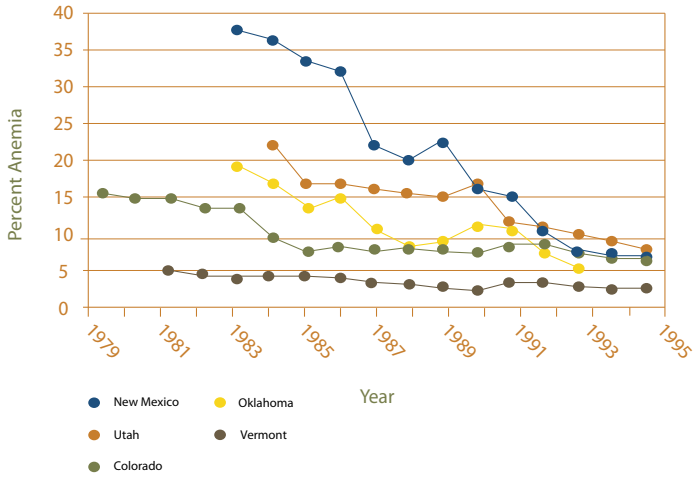
It should also be noted that effective flour fortification must be continued indefinitely to achieve *maximum sustained impact* on the nutritional and health status of the population. As shown in **Figure 1**, the birth prevalence of NTDs continued to decline in Oman during the decade since the inception 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).

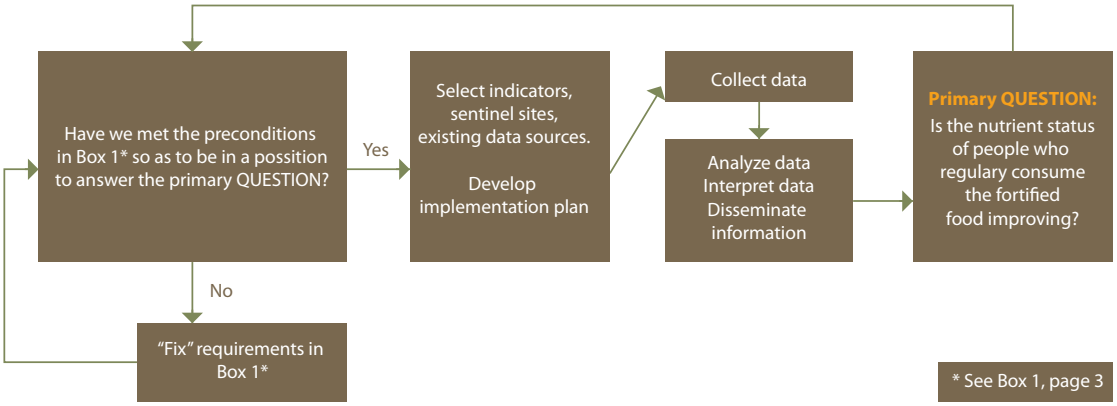


1. USDA. WIC - The Special Supplemental Nutrition Program for Women, Infants and Children. http://www.fns.usda.gov/wic/WIC-Fact-Sheet.pdf, accessed 20 January, 2013.

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 i*nformation 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).

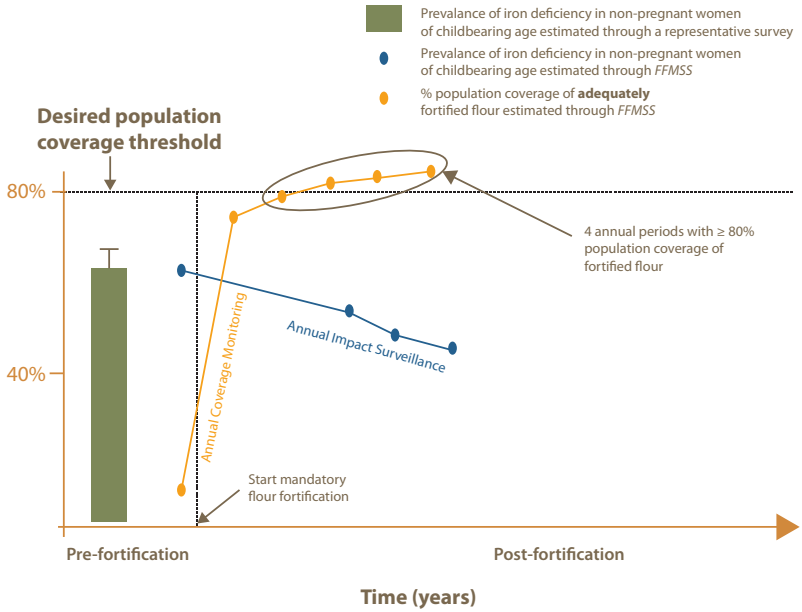
a. Pre-fortification data (green bar) indicate a very high prevalence of iron deficiency among women of childbearing age. Such data are usually available from population-based nutrition and health status surveys.

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

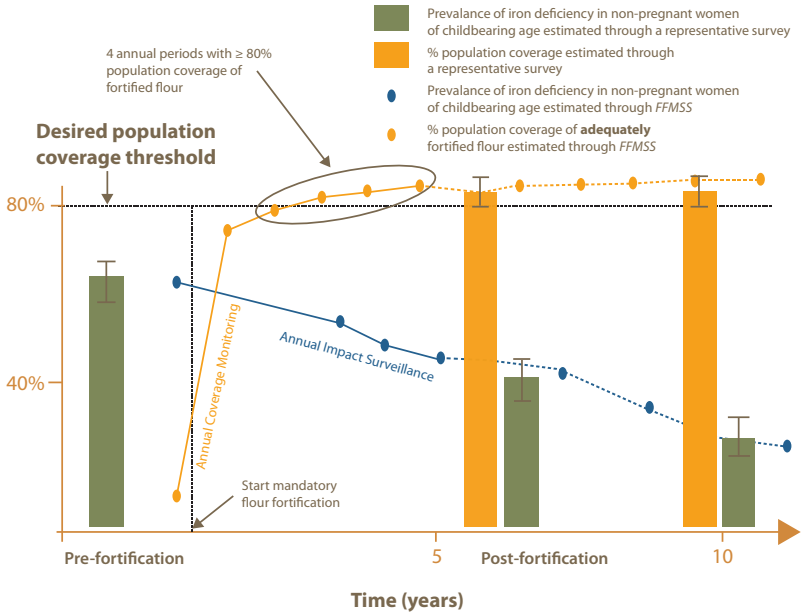
4. Adapted from: Patton MQ. Utilization-focused evaluation: The new century text. 3rd ed. Thousand Oaks, CA: Sage, 1997.

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!"

CHAPTER 2

Approach to FORTIMAS Data Collection

I. Sentinel Site and Purposive Data Collection and Convenience Sampling

As indicated in Chapter 1, for a flour fortification program to be successful and effective at improving the nutritional status of a population, it must first be confirmed that sufficient fortified flour of adequate quality is regularly marketed to meet the daily per capita consumption needs of the vast majority of the population in a specified geographic area. Furthermore, experience has shown that for flour fortification to make a sustainable impact, mandatory legislation on fortification of the most commonly consumed types of industrial flour is needed[1].

As illustrated above the dashed line in **Figure 5**, all food fortification programs must have internal and external QA/QC monitoring and reporting systems at the production, importation and market levels to ensure that consumers have access to adequately fortified foods. Once adequately fortified foods are marketed, it is necessary to determine (as shown below the dashed line in **Figure 5**) if the vast majority of the population has regular access to the target foods and whether the micronutrient status of that population is improving over time.

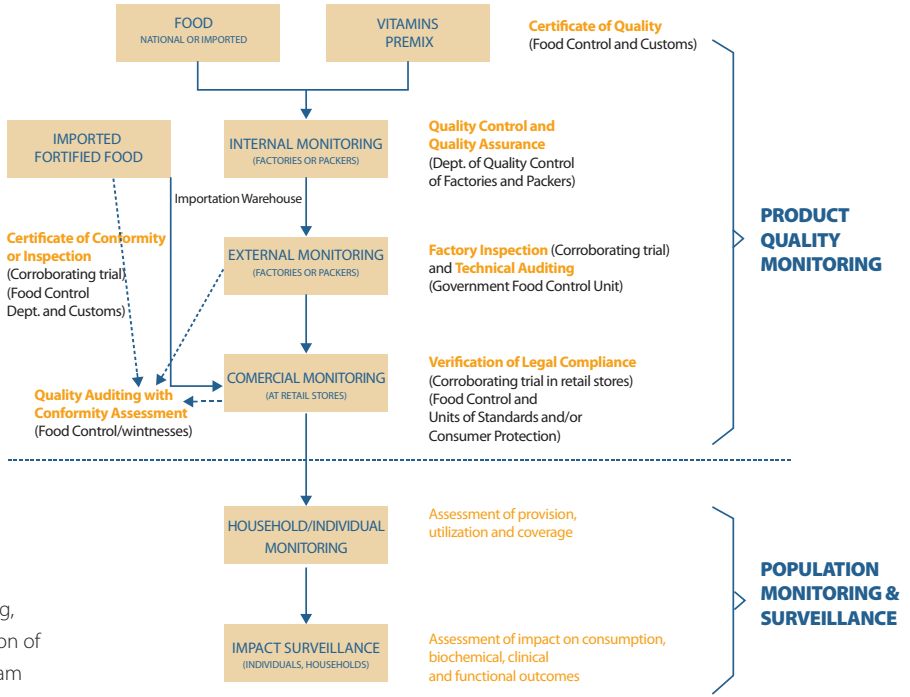


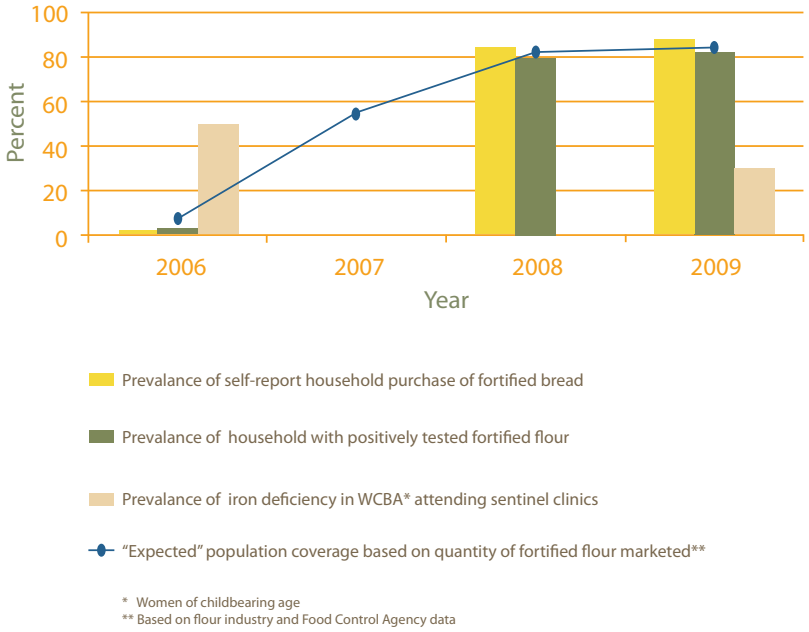
Figure 5.
Framework for monitoring, surveillance and evaluation of a food fortification program (adapted from reference 2).

1. Flour Fortification Initiative (http://www.ffinetwork.org). Accessed 20 January 2013.

A comprehensive FORTIMAS system should report annual data on the quantity of adequately fortified flour marketed in different geographic areas, as well as the trends in the micronutrient status of that population over time (once ≥80% population coverage is sustained). The provision of FORTIMAS data on the annual quantity of fortified flour marketed is the responsibility of the domestic industrial flour millers, importers and relevant regulatory and control agencies of the government (e.g. Food Control Agency and Customs Agency). The reporting of population level FORTIMAS data to confirm sufficiently high coverage of fortified flour, followed by decreasing trends in the public health burden of vitamin and mineral deficiencies over time, is generally the responsibility of a public health organization in the country.

Figure 6 illustrates findings from a hypothetical FORTIMAS system through "triangulation" of the following indicator trends: "expected" population coverage of fortified flour based on the quantity of fortified flour marketed, household coverage of fortified flour, and the prevalence of iron deficiency among women of childbearing age (see Chapter 3, **Table 4**).

Figure 6.
Example of findings from hypothetical FORTIMAS data used to confirm high population coverage of fortified flour for one year before reassessing iron deficiency in the target population.

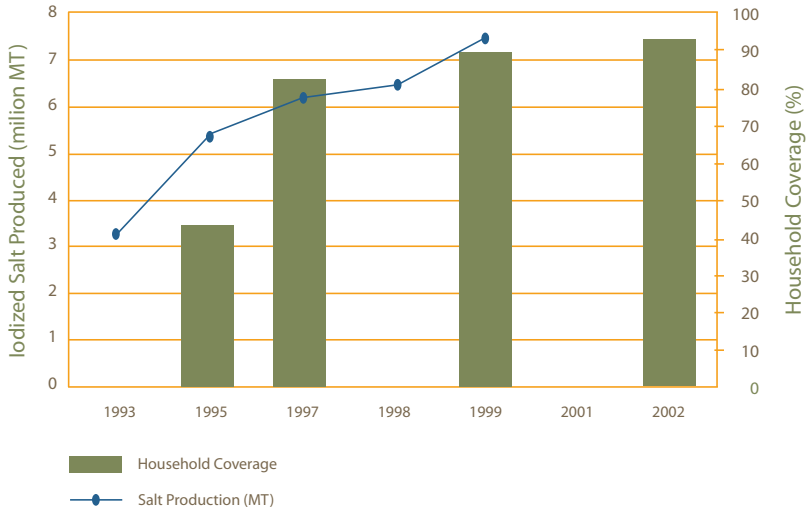


a. Data on "expected" population coverage of fortified flour (blue line), the "initial" household coverage of the product (yellow and green bars) and prevalence of iron deficiency in women of childbearing age (beige bars) are reported before the full-scale implementation of the fortification program in 2006. Where appropriate, the initial household coverage of fortified flour may be considered as close to zero, and there would be no specific need to collect primary data on that indicator.

b. In 2007, the quantity of fortified flour marketed is substantially increased. However, the "expected" population coverage of fortified flour is still estimated to be substantially less than 80%. Thus, primary population level data on household coverage of the product and the iron status of women of childbearing age are not collected (in order to avoid the expenditure of limited resources).
c. Because the flour industry data indicate an "expected" population coverage ≥80% in 2008 and 2009, population level FORTIMAS data on household coverage of fortified flour are also collected and confirm the high coverage of the intervention during those years.
d. Because independent, but complementary industry and population level data indicate sustained coverage of close to or more than 80% between 2008 and 2009, primary data on the iron status of women of childbearing age are again collected in early 2010. The indicate a decrease in the prevalence of iron deficiency after one year of sustained high coverage of fortified flour.

Figure 7 is an actual example of complementary findings on the trends in iodized salt production and household coverage in China. **Figure 4** (in Chapter 1) illustrates hypothetical FORTIMAS data combined with periodic surveys on population coverage and impact of a flour fortification program.

Figure 7.
Trends in annual production vs. household coverage of iodized salt in China.



Source: Zhao and van der Haar. Food & Nutr. Bulletin, Decembre 2004.

This guide is intended to advise on a feasible approach for the collection of population level monitoring and surveillance data to track the implementation and impact of a flour fortification program. Therefore, unless otherwise stated, the use of the abbreviation "FORTIMAS" in the remainder of this document relates to population level data collection to confirm that household coverage of fortified flour is close to 80% or more and to determine if the prevalence of vitamin and mineral deficiencies is decreasing over time (as expected) in population groups that have sustained access to the product.

It is important to note that it may not be always necessary to collect primary FORTIMAS data to track the population coverage and impact of a flour fortification program. Data on some key indicators may already be available through existing private and public sector networks and could be easily incorporated into the FORTIMAS information reporting system. For example, industrial flour mills and flour importers in a country already maintain records on the amount of fortified flour produced or imported and shipped to their major customers in different regions of the country. Similarly, flour wholesalers, bakeries and retail outlets usually maintain some form of records on the quantity of fortified flour and flour-based foods sold. Thus, it will be necessary for the public sector to partner with the flour industry and market sectors to include such data for FORTIMAS to allow for estimating the "expected" population coverage of fortified flour in specified sub-geographic areas of the country using the estimated population figures and per capita intake of *fortifiable* flour (see Chapter 3 for further discussion).

Furthermore, primary healthcare facilities and maternity hospitals/birth centers may routinely test pregnant women for anemia as part of their protocol for antenatal care services and record the findings in the patients' charts. Also, pregnancies that are medically terminated due to the detection of fetuses with NTDs (such as spina bifida and anencephaly) and/or babies born with such defects might also be recorded by healthcare facilities (see Chapter 3, **Table 4** for examples of program impact indicators). In such settings, data on the prevalence of anemia among 1st trimester pregnant women and birth prevalence of NTDs may already be available through the country's existing public health reporting systems, such as a Health Management Information System (HMIS) or vital statistics reporting system. If so, such secondary data could be incorporated into FORTIMAS for surveillance of the impact of flour fortification.

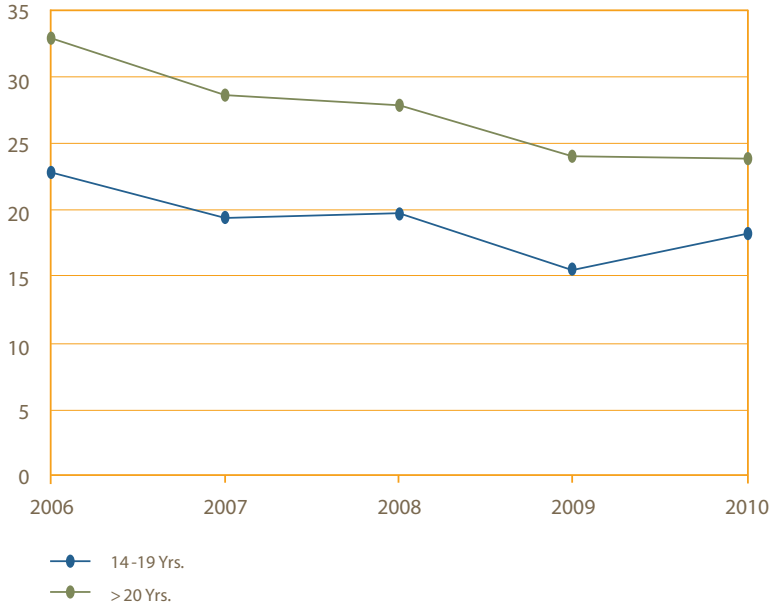
To give an example, one industrial mill in Kuwait produces about 75% of the low extraction flour consumed in the country (personal communication, Mr. Ebtihal Al Salem, Kuwait Flour Mills, April, 2011). That mill started mandatory fortification of the flour with electrolytic iron and folic acid in 2006 (personal communication, Dr. Nawal Al-Hamad, Kuwait Nutrition Department, April, 2011). Thus, it is expected that very close to 80% of the Kuwaiti population has been regularly consuming fortified flour products for the past number of years. The Kuwait Nutrition Surveillance System, which is based on data from a network of sentinel health facilities and girls' high schools across that country, illustrates the impact the flour fortification program in Kuwait over time (Figure 8). Based on the declining trend in the prevalence of anemia (a proxy indicator of iron deficiency) among adult women in sentinel health clinics and adolescent girls in sentinel schools, screened for hemoglobin (Hb) between 2006 and 2010, together with the sustained fortification of the vast bulk of low extraction

flour, it may be surmised that the intervention has contributed to improved iron status of women of childbearing age in Kuwait (**Figure 8**).

If relevant data are not currently available through health facilities or the existing public health data systems, it may be possible to support all or selected facilities to systematically collect and submit data on selected indicators to help track the population coverage and impact of fortified flour across different communities over time (see Chapter 3 for discussion on sentinel site data collection).

Figure 8.
Anemia trends among Kuwaiti females by age group following flour fortification with electrolytic iron and folic acid. Kuwait Nutrition Surveillance System*.

* Source: Dr Nawal Al-Ahmad. Kuwait Department of Nutrition (personal communication, April, 2011).



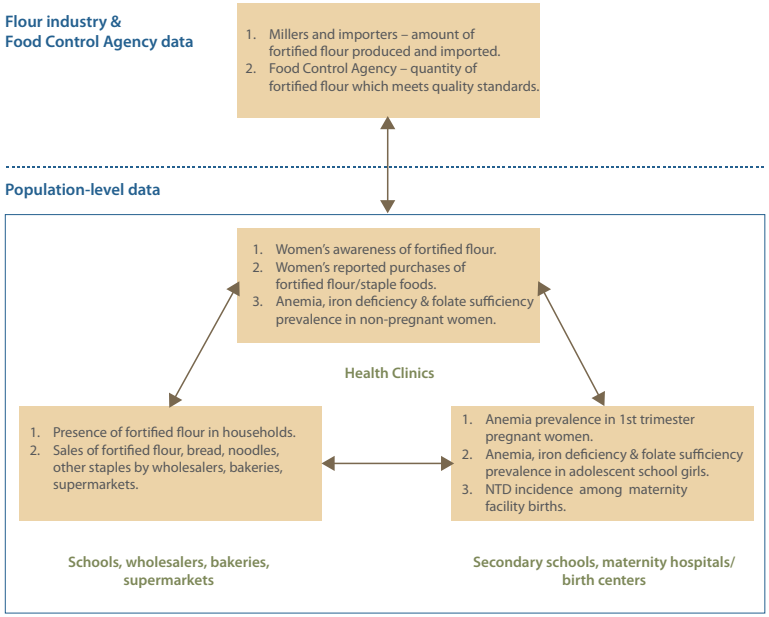
When there are opportunities to collect data on population coverage and impact of flour fortification through statistically representative population surveys, they should also be pursued. A few examples of such surveys are:

- National Vulnerability Assessment Survey
- National Household Expenditure Survey
- Multiple Indicator Cluster Survey
- Demographic and Health Survey
- Stand-alone nutrition survey

When the assessment of a flour fortification program is an objective of any of the above national surveys before fortified flour is sufficiently marketed nationwide, it is essential to collect appropriate stratified data in those sub-areas of the country where high population coverage of fortified flour (based on flour industry production and marketing data) is expected. For example, in countries where urban populations primarily consume fortified flour, the aforementioned surveys should target urban areas to obtain representative data on household coverage and the impact of flour fortification. Excellent guides are available on the design and implementation of such surveys; one example is the Nutrition Survey Toolkit[2].

The purpose of population level FORTIMAS data is to confirm sustained high population coverage of fortified flour in defined geographic areas, and to track trends in a limited number of nutrition and health impact indicators (see Chapter 3, **Table 4**) among women of childbearing age in those areas as a measure of the effectiveness of the flour fortification program. Regardless of the data collection approach, a robust and reliable FORTIMAS system should include data from different but complementary sources to allow for "triangulation" and interpretation of information on population coverage and impact of the intervention. **Figure 9** includes examples of existing entities, such as flour millers, markets, health facilities and schools that could potentially serve as sources of complementary FORTIMAS data to help track the population coverage and impact of a flour fortification program. Some of the population level data could be obtained in sentinel (selected) sites using non-probability (or non-random) population sampling approach (15).

Figure 9.
Schematic of a potential *Flour Fortification Monitoring and Surveillance System* using data from complementary sources to track fortified flour production/ imports and population access and impact.



2. Nutrition Survey Toolkit. http://www.micronutrient.org/nutritiontoolkit/ (accessed 11 July, 2013).

The purpose of FORTIMAS is to confirm sustained high population coverage of fortified flour in defined geographic areas, and to track trends in a limited number of nutrition and health impact indicators among women of childbearing age in the same areas as a means to assess the effectiveness of the flour fortification program.

In summary, a well-functioning FORTIMAS should:

a. Have a systematic process for on-going collection of reliable data, using existing private and public sector sources and networks. Only if necessary, a separate system for the primary collection of FORTIMAS data should be implemented.
b. Report overall information based on appropriate "triangulation" and interpretation of findings on the production, population coverage, and impact of the flour fortification program so that corrective measures are taken as needed.
c. Inform the program stakeholders and the population on the overall implementation and impact of flour fortification.

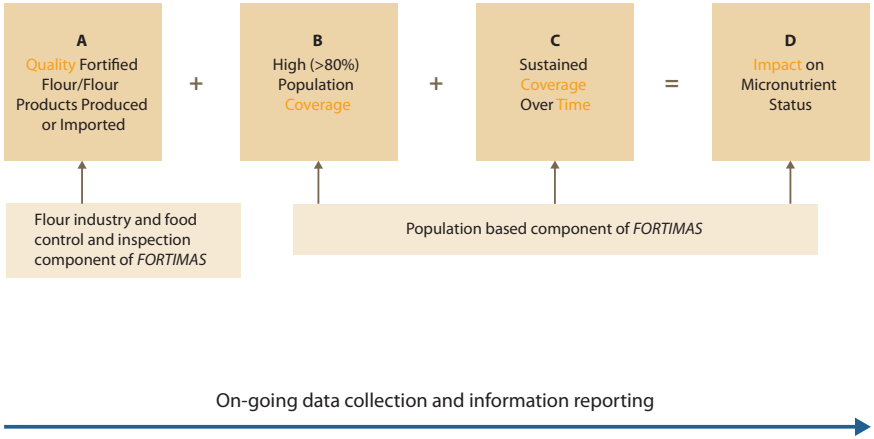
I. Sentinel Site and Purposive Data Collection and Convenience Sampling

The public health success of an effective flour fortification program could be described by the "formula" illustrated in **Figure 10**. Ensuring the availability of quality fortified flour and flour-based products is the responsibility of flour millers, importers, food producers, and the regulatory inspection authorities (depicted in Box "A" in **Figure 10**). The monitoring of population level coverage of fortified flour and impact surveillance of the intervention over time (depicted by boxes "B", "C" and "D") is usually the responsibility of the public health sector. Sentinel site and purposive data collection and convenience sampling of target subjects and households using existing data systems and networks is one feasible approach to the design and implementation of FORTIMAS.

The term "sentinel" refers to "watching over"[3] selected areas or population groups. To help confirm that the vast majority of the population in specific geographic areas has sustained access to fortified flour, a few communities within those areas of a country are "purposively" and strategically selected as *sentinel data collection sites* (16). Thus, sentinel sites are selected in a number of sub-areas of the country where ≥80% of the population are expected regular access to fortified flour. Within each sentinel site or community, one or more *sentinel data collection points* are identified. These might include primary health centers (PHCs), maternity hospitals and birth centers, schools, houses of worship, large worksites or other existing networks where "average" or "typical" target subjects could be conveniently recruited for data collection in a timely manner; hence the term "*convenience sampling*".

3. Merriam-Webster thesaurus. http://www.merriam-webster.com/thesaurus/sentinel, accessed May 2, 2010.

Figure 10.
"Formula" to describe the public health success of an effective flour fortification program.



Once population coverage of close to 80% or higher is confirmed by flour industry data flour industry and household data for at least one year, surveillance data on the impact of flour fortification may be collected through a number of sentinel sites. Again, it should be noted that if relevant data on population coverage or impact indicators of flour fortification are already collected through existing processes at *sentinel data collection points* (e.g. PHCs or maternity hospitals), such secondary data should be incorporated into the FORTIMAS system first. Then, the opportunity to collect primary FORTIMAS data through the relevant network of *sentinel data collection points* should be explored. For example, primary data on the presence of fortified flour or flour-based products in households could be collected by having students bring product samples for testing at their schools within the sentinel sites (refer to Chapter 3, Section V, 2).

The sentinel site and purposive data collection approach described in this guide does not provide *statistically representative* population level data on the coverage and impact of a flour fortification program. However, the methodology can be used to track the implementation and impact of the intervention in a country based on the following premises:

1. Industrially milled flour has already been documented to be consumed regularly by the vast majority of the population in the specified geographic area(s); i.e., there is a relatively homogeneous[4] use of fortified flour as a staple food. Thus, unless there is a compelling reason for only those recruited in sentinel sites for FORTIMAS data collection to consume fortified flour, it is most likely that others who do not have the chance to be recruited also consume fortified flour and benefit nutritionally. Therefore, the trends determined from data on the "sentinel" subjects would be expected to be reflective of (or mirror) the trends in the overall population of the broader area where each sentinel site (community) is selected.

4. http://changingminds.org/explanations/research/sampling/convenience_sampling.htm; accessed 02/04/2013.

2. The strength of a well-implemented FORTIMAS using such a non-random data collection approach is that it detects *trends* in the indicators of interest over time. The primary aims of the system are to confirm the "expected" high population coverage of fortified flour over time, and to detect declining trends in the prevalence of selected nutritional impact indicators, not necessarily to determine (with statistical precision) the actual population coverage and burden of micronutrient deficiency at any point in time.

3. To help minimize costs, data are collected in the fewest necessary sentinel sites within a larger geographic area based on a good understanding of important socio-demographic characteristics and flour consumption patterns of population groups in the larger area, as well as their current and potential future access to fortified flour (further discussed in Chapter 3 below). For example, it is known that in Tanzania 90% of urban households purchase industrially milled wheat flour based foods. In contrast, only 55% of rural Tanzanian households do the same[5]. Thus, it is likely that the nutritional impact of fortified flour would be detected more readily in urban areas than in rural areas where access to and consumption of fortified flour is less homogeneous As such, resources might be better expended to increase the availability of fortified flour across rural communities, before expanding program monitoring and surveillance activities in those areas (this concept was also illustrated in Chapter 1, **Box 2**).

4. The preponderance of evidence from complementary findings through "triangulation" or "cross-checking" of information from more than one source of data strengthens the confidence in the overall findings of the FORTIMAS.

An essential requirement of a sentinel site data collection approach described in this guide is to train the appropriate staff within the *sentinel data collection points* to systemically collect reliable data on a minimum number of indicators and submit them to the "FORTIMAS Office" for computer entry, processing, analysis, interpretation and dissemination. This eliminates the need to periodically mobilize a central data collection team(s), usually from the capital city, to travel to various locations across the country to collect primary FORTIMAS data. Sentinel data collection also helps to build human capital within selected communities and stimulates "ownership" and interest in FORTIMAS and its findings at the local level. With this in mind, sentinel sites should not be changed for each cycle of FORTIMAS data collection. However, if substantial secular changes are expected (e.g. in key demographic characteristics or fortified flour consumption patterns), new sentinel sites may be added while some earlier ones might be eliminated. Regardless, it is essential that all those involved with the operation of FORTIMAS, including those responsible for the analysis and reporting of the findings, are trained and re-trained regularly to maintain the needed skills to collect reliable data and report actionable information. The latter should also be trained to carefully monitor the quality of the data received from the different sources and provide feedback to the relevant personnel and entities to help ensure reliable FORTIMAS data quality.

5. http://www.ffinetwork.org/plan/documents/Jorgensen_Considerations_in_calculating_flour_consumption.pdf; accessed 01/20/2013.

The types of information that multiple sources of data and use of non-probability population level data collection can and cannot provide are listed in **Table 2**.

Table 2. Examples of information that FORTIMAS data based on multiple sources and using sentinel site data collection can and cannot provide.

Can	Cannot
Provide trend findings that are reflective of population coverage and impact of flour fortification.	Provide statistically representative findings on population coverage and impact of flour fortification at each point in time.
Adequately show that flour fortification is or is not contributing to improved micronutrient status of the population.	Provide statistically plausible or probable conclusion that flour fortification led to improved micronutrient status of the population.
Contribute to flour fortification program evaluation.	Be used alone for evaluating a flour fortification program.
Utilize existing data systems, e.g. records of production of flour mills, sales figures of fortified flour products in selected supermarkets, antenatal care anemia test results, birth outcome data from maternity hospitals and birthing centers, etc., to track relevant flour fortification program monitoring and surveillance indicators.	

The FORTIMAS Office, with appropriate technical capacity, may be hosted within a relevant government agency or not-for-profit technical institute. It is expected that the FORTIMAS Office would receive data and report information on the status of the fortification program based on the quality and quantity of fortified flour produced and imported, as well as sentinel site population coverage monitoring and impact surveillance data. In many countries, a National Fortification Alliance (NFA) has been established to develop and implement the national flour or food fortification program. The FORTIMAS Office should report to or be a sub-committee of the NFA. This strategy will increase the long-term commitment of the NFA to fortification, ensure appropriate dissemination of the FORTIMAS data, and allow for "early warning" and timely alerts as needed.

In summary, a sentinel site and purposive data collection approach will not provide statistically representative findings on the population coverage and impact of flour fortification. However, through triangulation of flour industry and FCA information on the quantity and quality of fortified flour marketed in the broad geographic area of interest, and confirmatory findings of sustained high population coverage

of the product in selected communities, combined with detection of declining trends in micronutrient deficiency indicators across the FORTIMAS sentinel sites, it can be adequately concluded (12) that flour fortification has been effective in improving the nutritional status of the population. If deemed necessary and resources are available, a statistically representative evaluation study may be performed to confirm the impact of the flour fortification program in specific geographic areas. Importantly, if the FORTIMAS findings indicate deficiencies in fortified flour quality, or the findings on household coverage of fortified flour at the community level do not match the flour industry figures, or the expected improvements in micronutrient status is not detected, appropriate investigations must be conducted in order to correct the situation in a timely manner. FORTIMAS will thus strengthen the capacity of the NFA to follow the program's progress and respond to possible challenges.

Photos: David Synder.

CHAPTER 3

Planning and Implementing a Sentinel Site Flour Fortification Program Monitoring and Surveillance System

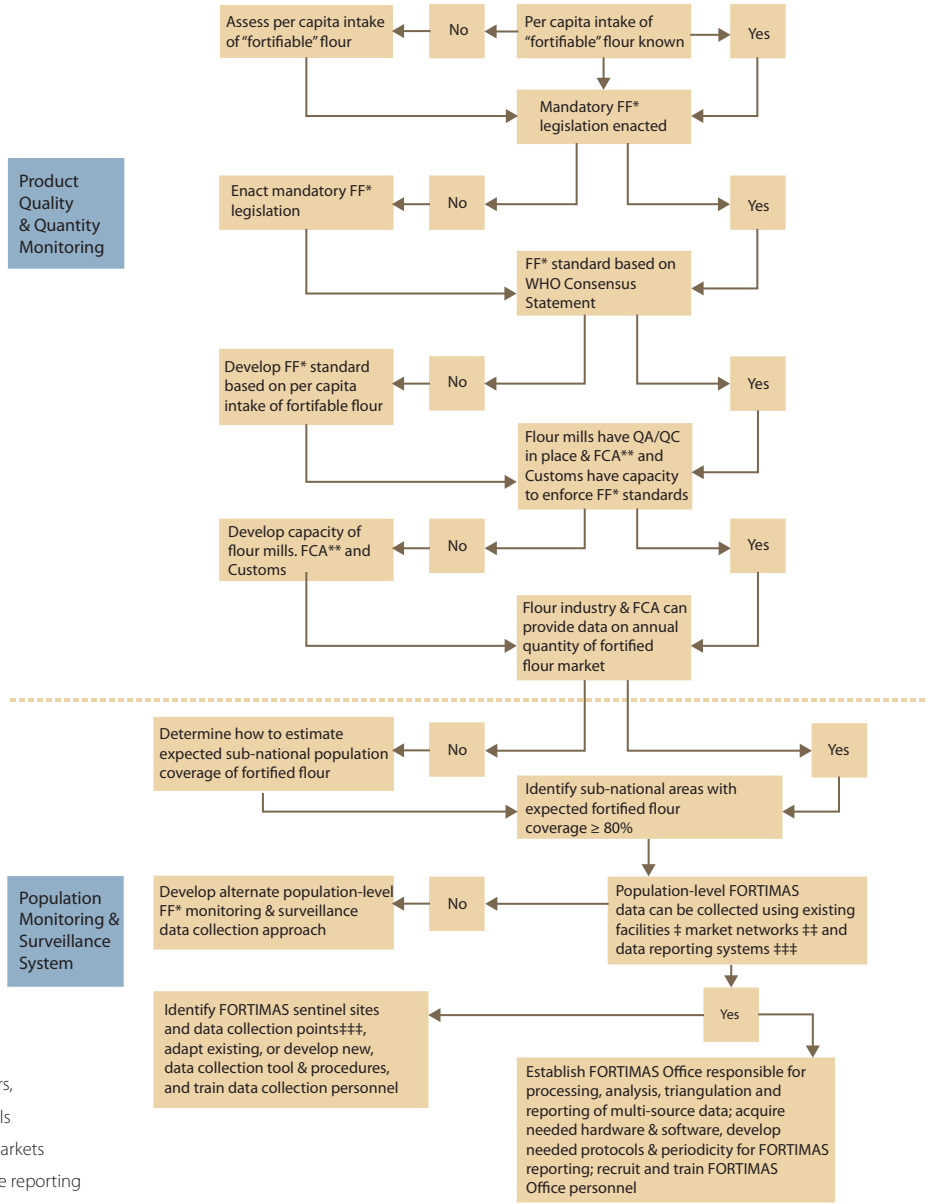
As illustrated in Chapter 2, **Figure 10**, the public health effectiveness of a flour fortification program depends on a quality intervention defined by the sustained production and marketing of adequately fortified flour that is regularly consumed by the vast majority of the population. This chapter will address the planning and implementation of a FORTIMAS system using sentinel and purposive data collected through existing data systems or networks, as much as feasible, for the regular and systematic collection of data on population coverage monitoring and impact surveillance of a flour fortification program.

Flow Diagram 2 (below) could be used to determine if all the pre-conditions have been met for a successful flour fortification program. It also describes the broad steps to be considered for the implementation of a sentinel site FORTIMAS approach described in this guide. In **Flow Diagram 2**, the population-level data collection component of FORTIMAS is illustrated in the section below the dashed line. To reiterate, it is essential to ensure that the production and imports of sufficient and adequately fortified flour and its QA/QC monitoring are in place before embarking on the collection of population-level data.

An important point to note is that often countries estimate per capita consumption of total flour using data from the Food and Agriculture Organization of the United Nations (FAO). This statistic includes all sources of flour available for the population – *fortifiable* and *non-fortifiable* combined. If *non-fortifiable* flour accounts for a substantial proportion of per capita flour intake, the fortification standard based on total flour intake could be set too low to impact the nutritional status of the population (4, 5). Thus, for each of the four conditions listed in **Table 3**, the answer under the "situation" column should be "yes" in order to ensure that the fortified flour contains the appropriate concentration of the fortificant nutrients, and is regularly accessible to the vast majority of the population so the desired nutritional impact is achieved. If for any of the conditions listed, the answer in the "situation" column is "no", then corrective actions must be taken by the appropriate stakeholders to enable flour fortification to be effective. Until then, additional resources should not be expended to collect impact surveillance data.

Flow Diagram 2.

A conceptual framework to help guide the development of a successful flour fortification program and its monitoring and surveillance.



Legend

* Flour Fortification

** Food Control Agency

‡ e.g. primary health centers, maternity hospitals, schools

‡‡ e.g. wholesalers, supermarkets

‡‡‡ e.g. HMIS, birth outcome reporting

Table 3. Conditions needed for an effective flour fortification program.

Condition	Situation	Corrective Action Needed
1. There is a good estimate of per capita intake of *fortifiable* flour for the area where fortified flour will be marketed.	Yes	
	No	Conduct a rapid study to assess per capita intake of *fortifiable* flour – to set fortification standards.
2. The national standard for each micronutrient to be added to fortified flour is based on the estimated per capita intake of *fortifiable* flour (refer to WHO recommendations)[i].	Yes	
	No	Modify the national fortified flour standards accordingly - it is especially important that a bioavailable form of iron is used allow adequate absorption of this nutrient[ii].
3. Flour mills have adequate QA /QC systems, and food control and customs agencies have the capacity to enforce the fortification standards to ensure the marketing of quality fortified flour.	Yes	
	No	The flour fortification program stakeholders should work to enable the implementation of needed QA and QC procedures.
4. Sufficient fortified flour is marketed to meet the per capita intake need of close to or more than 80% of the population in the geographic area.	Yes	
	No	Work with the flour millers and importers to increase access to fortified flour among the population.

I. Potential Indicators to Measure

Table 4 includes a list of potential flour fortification program output and impact indicators, sources of data, and the numerators and denominators to calculate the appropriate ratios of the measure to track coverage of fortified flour and the expected impact in nutritional status. A brief description of each indicator follows:

i. WHO. Recommendations on wheat and maize flour fortification meeting report: interim consensus statement. Geneva, Switzerland, 2009.

ii. The millers tool kit on fortification. http://www.ffinetwork.org/implement/documents/English_Tool_Kit_March_2011.pdf. Accessed, 20 January 2013.

a. **Total annual quantity of fortified flour (marketed) in geographic area per year** – the overall tonnage of domestically produced and imported fortified flour (marketed in specified geographic area) in a one year period.

   Although flour millers and importers are responsible to provide data on the total quantity of fortified flour marketed annually, the national FCA should confirm if the product consistently conforms to the national fortification standard (i.e. is adequately fortified). If substantial proportions of fortified flour do not meet the national standard (especially when fortificant levels are too low), it is unlikely that the expected nutritional impact would be achieved. Thus, appropriate steps should be taken to ensure that a sufficient quantity of quality fortified flour is regularly marketed and accessible. Once the flour industry's QA/QC processes and reporting protocols are well developed, it may be possible to rely on data from the mills alone to estimate the amount of adequately fortified flour marketed.

   Using the annual quantity of adequately fortified flour marketed in a geographic area, the population of that area, and their estimated per capita consumption of industrial flour, the "expected population coverage" of fortified flour can be calculated. If the expected coverage is close to or more than 80%, then population level FORTIMAS data may be collected to confirm that such high coverage is sustained over time.

b. **Prevalence of households that purchase fortified flour/flour** – based staple food - adult women from different households who attend sentinel PHCs complete or are administered a brief standard questionnaire.

c. **Prevalence of households that use fortified flour** – age-appropriate students in sentinel secondary schools are instructed to bring to school on a specified date, samples of flour from their homes. Those samples are tested by trained teachers for the presence of fortificant using the iron spot-test, and the findings submitted to the FORTIMAS office for analysis.

   Note: If feasible, in addition to the above two potential indicators, sales patterns of fortified flour and/or flour-based staple foods could also be tracked at the community level as a complementary indicator of population coverage. For example, in South Africa, sales of fortified flour products were tracked through the use of electronic product bar codes (personal communication, Dr. Philip Randall, milling consultant). Also, it may be possible to partner with a few wholesalers in selected sentinel sites (cities or provinces) to monitor the sales trends for fortified flour and/or flour-based staple foods.

d. **Prevalence of consumers with positive attitude about consuming fortified flour** – data for this program impact indicator may be collected by interviewing adult women recruited in sentinel PHCs. The primary purpose of this indicator is to help assess if the social marketing and promotion efforts are successful in encouraging the population to accept mandatory fortification of flour and flour-based staple foods (e.g. bread, noodles, etc.).

e. **Prevalence of consumers who recognize fortification logo** – data for this program impact indicator may be collected by interviewing adult women recruited in sentinel PHCs. It is a measure of the effectiveness of the health communication and social marketing components of the flour fortification program.

Table 4. Proposed output and impact indicators and their potential sources of data to track the progress of a mandatory flour fortification program.

	Indicator	Type	Measure	Data Source	Numerator	Denominator
a	Total annual quantity of fortified flour (marketed) in geographic area per year	Output	MT/year	Flour millers' and importers' data on amount of flour marketed, and FCA[1] quality control inspection findings	Total amount of industrial flour produced and imported in a 12-month period	12 months (1 year)
b	Prevalence of households[2] reporting purchase fortified flour/flour-based staple food	Output	Percent	FORTIMAS participating primary health facilities	Total number of women in sentinel health facilities who report household purchase of fortified flour or flour based staple foods	Total number of women interviewed in sentinel health facilities
c	Prevalence of households that have fortified flour	Output	Percent	Household flour samples tested in sentinel schools	Number of flour samples from homes of students of sentinel schools that test positive for fortification	Total number of household flour samples tested (1 per student)
d	Prevalence of consumers with positive attitude about consuming fortified flour	Impact	Percent	Non-pregnant or pregnant women interviewed in sentinel primary health centers	Number of women with positive attitude about their families consuming fortified flour	Total number of women interviewed FORTIMAS participating primary health facilities
e	Prevalence of consumers who recognize fortification logo	Impact	Percent	Non-pregnant or pregnant women interviewed in sentinel primary health centers	Number of women who correctly identify fortification logo	Total number of women interviewed FORTIMAS participating primary health facilities

1. FCA – Food Control Agency.
2. Each household represented by individual women recruited for data collection in each sentinel health clinic.

Table 4. Continued

	Indicator	Type	Measure	Data Source	Numerator	Denominator
f	Prevalence of anemia in non-pregnant women	Impact	Percent	Test Hb[3] levels in non-pregnant women and adolescent female students in sentinel primary health centers and/or secondary schools	Number of non-pregnant women or 1st trimester pregnant women testing positive for anemia (Hb <12 mg/dL)	Total number of women tested for anemia in FORTIMAS participating primary health facilities
g	Prevalence of iron deficiency in non-pregnant women	Impact	Percent	Test serum ferritin levels in non-pregnant women and adolescent female students in sentinel primary health centers and/or secondary schools	Number of non-pregnant women testing positive for iron deficiency (serum ferritin <15 ng/mL)	Total number of women tested for iron status in FORTIMAS participating primary health facilities
h	Prevalence of folate sufficiency in non-pregnant women	Impact	Percent	Test serum folate concentration non-pregnant women and adolescent female students in sentinel primary health centers and/or secondary schools	Number of non-pregnant women testing positive for folate sufficiency (serum folate >7 ng/mL)	Total number of women tested for folate status in FORTIMAS participating primary health facilities+
i	Birth prevalence of neural tube defects	Impact	Per 10,000 births/year	Report NTD[4] cases and total live and stillbirths in maternity hospitals & birthing centers	Total number of babies born with spina bifida or anencephaly per year in maternity facilities	Total number of births in maternity facilities per year

3. Hb – hemoglobin.
4. NTD – Neural tube defects.

f. **Prevalence of anemia in non-pregnant women** – Anemia, based on low Hb, could be used as a proxy indicator of iron deficiency if biochemical assessments of iron status (e.g. serum ferritin) are not available. In populations where a large proportion of anemia is caused by factors other than iron or folate deficiency, the prevalence of anemia may not be reduced very much through flour fortification, even if the iron and folate status of the population do improve.

g. **Prevalence of iron deficiency in non-pregnant women** – Data for this indicator could be collected by testing the serum ferritin concentration of non-pregnant women (and/or those in first trimester of pregnancy) recruited in sentinel PHCs. Findings of low serum ferritin together with low Hb indicate iron-deficiency anemia. The prevalence of iron deficiency (and anemia) could also be assessed among adolescent female students in grades 10 to 12 of sentinel secondary schools.

h. **Prevalence of folate sufficiency in non-pregnant women** – Folate sufficiency refers to a level of serum folate (≥10 ng/ml)[1] that is protective against the development of a NTD in the fetus. It is also a measure of effectiveness of a flour fortification program that includes folic acid. Data for this indicator could be collected by testing serum folate concentration in non-pregnant women and adolescent girls recruited in sentinel PHCs and/or sentinel secondary schools.

i. **Birth prevalence of NTDs** – Data for this indicator are reported by maternity hospitals and birthing centers. The number of NTD-affected births and the total number of live and stillbirths during a year are used to report NTD birth prevalence (as per 10,000 births/year). Data on at least 20,000 births annually are needed per target geographic area. Ideally, NTD-affected pregnancies that are medically terminated would also be included when determining the birth prevalence of NTDs. However, this information is reliant upon strong antenatal care systems, which are not available in many countries.

II. Selection of Large Administrative Sub-Areas of a Country in which to Track theProgress of Flour Fortification

The first phase of setting up the population-level component of a FORTIMAS system is to select the appropriate large administrative sub-areas in the country such as regions, provinces or large urban centers where sentinel data will be collected. Subsequently, a minimum number of smaller administrative communities, such as districts within a large city or towns in urban and rural areas of a province within the sub-areas should be determined as sentinel data collection sites. The third phase involves the selection of data collection points (or facilities) within the sentinel sites where individuals can be recruited for data collection. This section of the guide addresses the selection of large administrative sub-areas, sentinel sites and data collection points.

1. Personal communication. Dr. Godfrey Oakley. Emory University School of Public Health, Atlanta, Georgia, USA. March, 2013.

It is recommended that representatives of the relevant government, industry and civil society stakeholders of the flour fortification program work together to develop a "situation map" using the best estimates of the quantity of fortified flour expected to be available in different large sub-areas of the country. Based on that information and the estimated per capita intake of flour, the expected population coverage of the product in those sub-areas can be determined. From among all the sub-areas, a few are then selected as broad areas for tracking household coverage of fortified flour based on distinct socio-demographic and environmental factors that might influence the impact of the flour fortification program among the populations.

Sub-area = a large sub-national administrative area of the country; e.g. large cities and provinces
Sentinel site = a community within a larger geographic area where FORTIMAS data are collected.
Sentinel data collection point = existing facility within a sentinel site where relevant data on subjects already are, or could easily be, collected (e.g. primary health centers, maternity hospitals, and schools).

Table 5 is an example of a hypothetical flour fortification program "situation mapping" worksheet that:

1. Lists the major administrative sub-areas of a country where fortified flour is or will be marketed.
2. Calculates the estimated amount of fortified flour needed in each sub-area annually based on the population size and the per capita consumption of industrially milled flour that was used to develop the national fortification standard.
3. Specifies the annual quantity of fortified flour marketed in each sub-area.
4. Calculates the "expected" population coverage of fortified flour in each sub-area based on the quantity of the marketed product and actual amount needed according to the per capita consumption.
5. Identifies sub-areas with varying prevalence of iron deficiency (or anemia) in women of childbearing age (if data are not available, estimate if the prevalence might be similar to, higher or lower than the national prevalence).
6. Identifies sub-areas based on socio-economic status and other major factors (e.g. malaria prevalence; antenatal iron/folic acid supplementation coverage, hookworm infection and/or intervention coverage, etc.) that might also influence the population's micronutrient status.
7. Identifies the primary source (market vs. home) of bread (or other appropriate flour-based staple food) for the majority of the population in the sub-areas.
8. Is used to identify (based on the above information) the fewest number of sub-areas in the country to adequately track the progress of the flour fortification program. (Note: The final decision about the sub-areas for data collection purposes should be based on balancing the need for obtaining sufficient data to help guide the implementation of the flour fortification program vs. the available resources and capacity to regularly collect, analyze and report FORTIMAS findings. Sometimes, political issues may also necessitate where FORTIMAS data are collected.)

Table 5. Example of a hypothetical geographic "mapping" worksheet for a national flour fortification program.

	Population	Per Capita *Fortifiable* Flour Intake (g/Day)	FF Needed Annually (Milion MT)	FF Marketed Annually (Milion MT)	Expected Population Coverage of FF (%)	Prevelance of Iron Deficiency in WCBA* (%)	Socio-Economic Level** (Low, Same, High)	Seasonal Malaria Incidence in WCBA*	Other Relevant Factor	Bread Source	Establish Sentinel Sites Within Sub-Area
Country name	36,000,000	200	2,628,000	1,300,00	49	50					
Capital City	10,000,000		730,000	600,00	82	40	High	Low		Market	Yes
Province 1	6,000,000		438,000	350,000	80	42	Medium	Low		Market	
Urban Areas	2,000,000		146,000	115,000	79		High	Low		Market	No
Rural Areas	4,000,000		292,000	235,000	80		Low	Low		Market	No
Province 2	4,000,000		292,000	240,000	82	52	Medium	Medium			
Urban Areas	1,500,000		109,500	90,000	82		Medium	Low		Market	Yes
Rural Areas	2,500,000		182,500	150,000	82		Low	Medium		Homemade	Yes
Province 3	3,500,000		255,500	70,000	27	59	Low	Low			
Urban Areas							Medium	Low		Market	Low Coverage
Rural Areas							Low	Low		Homemade	
Province 4	2,500,000		182,500	40,000	27	61	Low	Medium			
Urban Areas							Medium	Medium		Market	Low Coverage
Rural Areas							Low	High		Homemade	

* WCBA – Women of Childbearing Age.
** Compared to the national level.
*** For example, high iron/folic acid supplementation coverage; high prevalence of hookworm infection.

In the hypothetical example in **Table 5**, the quantity of fortified flour marketed is expected to meet the per capita needs of close to 80% or more of the population in the capital of the country and across Province 1 and Province 2. Therefore, Province 3 and Province 4 would be excluded from selection as potential FORTIMAS data collection sub-areas until the fortified flour marketed in those areas is sufficiently increased to cover the needs of the vast majority of their populations. However, if resources allow, surveillance data on flour fortification impact indicators could also be collected in one province that lacks adequate coverage to compare findings with the trends in the high coverage areas over time.

In the **Table 5** example, three sub-areas of the country: the capital city of the country, and an urban and a rural area of Province 2 are chosen in the first "selection" phase, based on the following criteria:

- The capital city comprises nearly a third of the national population that would have high coverage of fortified flour. Also, the malaria prevalence is low.
- The prevalence of iron deficiency in Province 2 is 12% higher than in the capital city (the prevalence in Province 1 is similar to that in the capital). There is a seasonal difference in malaria prevalence among the urban and rural populations of Province 2. While the urban population of Province 2 mostly purchases bread from the market, the rural households bake bread at home using industrially milled flour.
- The malaria prevalence and source of bread for the urban and rural populations of Province 1 are similar to that of the urban population in Province 2. Thus, the trends in the impact of flour fortification in urban areas of Province 2 would likely be reflective of Province 1.
- Therefore, tracking the progress of the flour fortification program in the capital city and the urban and rural areas of Province 2 would allow for the most varied population sources of data using the fewest number of sub-areas that have expected coverage of close to 80% or more.

A hypothetical "situation map" for Tanzania can be viewed in **Figure 11**. The areas highlighted on the map could be designated as potential sub-areas of the country where sentinel FORTIMAS data collection sites (or communities) would be selected because close to 90% of the populations in those sub-areas are expected to have access to industrially milled flour.

Figure 11.
Geographic areas of Tanzania expected to have high population coverage of fortified flour.

Source: Courtesy of Dr. Anna Verster, Smarter Futures.

III. Selection of FORTIMAS Sentinel Sites and Data Collection Points

Once the large administrative sub-areas of the country, where the coverage and impact of fortified flour is to be tracked, are determined, then a few communities (e.g. districts) within those sub-areas are selected as sentinel data collection sites. There is no set rule or "formula" to decide how many sentinel sites to select. The decision should be based on balancing the need for data from a sufficient number of sentinel sites to generate reliable trend data over time that would be "reflective" of the pattern in population coverage and impact of flour fortification in the sub-areas of interest, with the availability of personnel and financial resources needed to implement a sustainable FORTIMAS system.

If the availability and consumption of fortified flour is expected to be relatively similar across the large administrative sub-areas, and there are no geographically distinct sub-groups with socio-demographic or other factors that might affect the expected impact of fortification, then two to three sentinel communities (e.g. urban and rural sites) within each sub-area should be sufficient. In a different setting, where data on indicators of population coverage or impact of flour fortification are already collected as a routine component of services delivered through primary health centers (e.g. data on purchase or consumption of fortified flour/foods are routinely recorded in patient forms, or NTD births are regularly reported by maternity facilities), then data from as many such data collection points could be included in FORTIMAS as feasible. Thus, data from collection points in many more sentinel sites could be relatively easily incorporated into FORTIMAS findings. In contrast, if the collection of population coverage and impact of fortified flour has to be added to the existing portfolio of PHCs or schools, etc., then it's likely that fewer sentinel sites and data collection points within them could be supported to collect reliable FORTIMAS data on a continuing basis.

Keep in mind that whenever possible, findings from existing data collection systems such as HMIS or vital statistics reporting systems should be incorporated into the overall FORTIMAS findings and reports to avoid expending unnecessary resources by collecting duplicate data from various sentinel data collection points. Instead, FORTIMAS resources should be utilized on feasible approaches to collect essential complementary data to help improve the reliability of the overall findings on population coverage of adequately fortified flour and the associated reduction in the burden of micronutrient deficiency. With regard to NTD surveillance, data should be collected from as many maternity facilities as possible in target sub-geographic areas with high population coverage of fortified flour (see also Section IV, below).

Other practical considerations for the selection of sentinel sites and data collection points are:

- The data collection points within the sentinel site should have, or should be easily supported to acquire, the minimal infrastructure and human capacity to collect reliable data and submit them for analysis in a timely manner, e.g.

    - Administer brief questionnaires (see Appendices B – D as basic examples).
    - Arrange for collection of household flour or bread samples and test them for fortificant presence or appropriately submit them for such testing.
    - Collect and test blood specimens for selected micronutrient status indicators or appropriately submit them for such testing (e.g. can assure adequate cold chain for storage and transfer of specimens).

- The population of the sentinel site should be large enough to ensure that the data collection points are accessed regularly (on daily or weekly basis) by a significant number of people (e.g. mothers who bring children for immunization or preventive health checkups, pregnant women seeking antenatal care, students in the highest grades in secondary school). This will facilitate the recruitment of the target number of subjects (refer to Section IV below) within about two weeks for each round of FORTIMAS data collection.

    - Two neighboring communities could be combined to cover a larger population if necessary and considered as a single sentinel site to allow using the same type of data collection points (e.g. antenatal care clinics or schools) to allow for timely recruitment of the needed subjects.

- Administrators and staff of the potential sentinel sites and data collection points are supportive and willing to collect FORTIMAS data systematically and regularly with relatively moderate additional incentives or resources.
- The data collection points are relatively easy to access for periodic monitoring of their FORTIMAS related activities.

From the list of potential communities that meet the above criteria, the minimum needed number of sentinel sites (e.g. from one to three) in each large sub-area can be selected randomly or purposively. In either case, the methodology for the selection of FORTIMAS sentinel sites and data collection points should be transparent and fully described.

IV. How Many Subjects to Recruit for Each FORTIMAS Data Collection Round?

Data on population coverage and impact of flour fortification do not need to be collected on the same individuals or households for each round of FORTIMAS data collection. Rather, the FORTIMAS findings are based on the collection of data on groups of "typical" residents and households in selected communities (sentinel sites) within larger geographic areas. The decision on the minimum number of subjects or households from which to collect data depends on balancing resource availability with the need for sufficient data to allow for reliable prevalence estimates of program coverage and impact indicators for each sub-geographic area in the country over time. The estimation of resource needs should also include the cost of data entry and processing.

FORTIMAS in not intended to collect data on the same individuals, but rather to track groups of people, such as residents of selected sentinel sites over time

1. Coverage monitoring

Once population coverage of fortified flour in a geographic area is "expected" to be close to 80% or more based on information from the flour industry on the quantity of the product marketed, the high coverage could be "confirmed" through the collection of relevant data (see proposed set of "output" indicators in **Table 4**) on convenience groups (i.e. samples) of subjects and/or households selected through the designated FORTIMAS data collection points (refer also to Section V below).

The number of subjects or households selected must be large enough to generate reliable prevalence estimates of fortified flour coverage in the target sub-geographic areas of the country annually. A single survey sample size calculator, such as one provided by the Micronutrient Initiative[2] (http://www.micronutrient.org/nutritiontoolkit/sampling.htm), could be used to determine the "minimum" number of women (see indicator "b" in **Table 4**) or households (see indicator "c" in **Table 4**) to recruit for data collection per FORTIMAS sentinel site to "confirm" a close to 80% or higher "expected" coverage of fortified flour and/or flour-based staple foods each year. Thus:

2. MI. Nutrition survey toolkit. http://www.micronutrient.org/nutritiontoolkit/. Accessed 02/10/2014.

- Based on an 80% prevalence of household coverage, a 10% desired precision of the estimate, and "survey design effect" of 1.0 (given sentinel site and convenience sampling approach), a minimum sample size of 62 subjects or households would be required in each sentinel site for each round of FORTIMAS data collection.
- In order to generate more robust findings on fortified flour coverage for each sentinel site annually, the actual sample size could be increased to 100 subjects (or households); such a minimum sample size is also used by the Centers for Disease Control and Prevention (CDC) to generate prevalence estimates for each site that reports data for the Pediatric Nutrition Surveillance System and the Pregnancy Nutrition Surveillance System[3].
- Furthermore, a sample size of 100 would allow for a "more precise" (~7 – 8%) estimate of the prevalence of household coverage for each sentinel site.
- If requiring spot-tests of 62 to 100 household flour samples in each FORTIMAS sentinel school (see indicator "c" in **Table 4**) is too costly, then the number of household flour samples could be divided across each target school in the sub-geographic areas so as to have data on total of 100 samples per area.
- Because flour fortification is an essential public nutrition intervention in the country, querying and counseling women about its use should be a routine component of primary health care nutrition services. Furthermore, since collecting data on household purchases of fortified flour and/or fortified flour-based staple foods is not very costly, it would be best to report such data on ALL non-pregnant women served by primary health facilities, and certainly on all women served by facilities designated as FORTIMAS data collection points.

2. Impact surveillance

As already indicated, the aim of FORTIMAS is to detect the expected declining trends in the prevalence of micronutrient deficiency overtime rather than to generate statistically "representative" estimates of the prevalence of a micronutrient deficiency in the target population each year. Such analysis of the trend (e.g. over four to five years) in the prevalence of micronutrient deficiency allows for collection of data on smaller numbers of subjects each year, than would be needed to "statistically" compare prevalence estimates between two specific years. To guide decisions on sample size for surveillance of the impact of flour fortification, use the "expected percent reduction" in the prevalence of the impact indicator (see indicators "d" to "h" in **Table 4**) from year-to-year. As illustrated in **Figure 2** (Section I), larger annual reductions could be anticipated when the prevalence of the micronutrient deficiency indicator is high, and the rate of the reduction would decrease as the micronutrient status of the population improves over time. Also, a smaller sample size is needed to adequately detect a larger reduction in the prevalence of an indicator than a smaller reduction. Therefore, the FORTIMAS sample size would be expected to grow larger as an effective flour fortification program is sustained over time and the rate of reduction in the prevalence of impact indicators decrease with improving micronutrient status of the population (refer to **Figure 2**, Section I).

[3] CDC. Pediatric and Pregnancy Nutrition Surveillance System. http://www.cdc.gov/pednss/how_to/read_a_data_table/table_basics.htm. Accessed 02/04/2013.

A potential approach to guide decisions related to the FORTIMAS sample size necessary to track the impact of the flour fortification program over time is described below using the prevalence of anemia as an impact indictor. A similar approach would be used to determine sample sizes to track the prevalence of iron deficiency or folate sufficiency (note that the prevalence of folate sufficiency would be expected to increase overtime) based on their "baseline" prevalence.

For example, in a hypothetical country, the initial round of FORTIMAS data (before full scale implementation of flour fortification) indicates that the "baseline" prevalence of anemia among non-pregnant women is about 50% on average across the target sub-geographic areas. Furthermore, it is expected that the prevalence of anemia would be reduced to about 40% after one or two years of sustained high population coverage of quality fortified flour. Using the "two surveys" option of the sample size calculator spreadsheet (http://www.micronutrient.org/nutritiontoolkit/sampling.htm)[4]:

a. With 50% in the "survey 1" column and 40% in the "survey 2" column, a 1.0 in the "design effect" column (given sentinel site and convenience sampling approach), and 100% in the "individual response rate" column (because subjects would be recruited in the sentinel health facilities until the "minimum" number is reached), 388 subjects would be needed per site for which surveillance findings are to be reported.
b. If anemia screening (based on low Hb) is a routine service provided at each FORTIMAS sentinel health facility, the Hb test results for all the non-pregnant women served by the facility during the year (i.e. more than 388) should be used to report the annual prevalence of anemia among the women in that sentinel site. The cumulative Hb data from all FORTIMAS sentinel health facilities in each sub-geographic area would yield findings on prevalence of anemia by sub-geographic area and the national level.
c. If anemia screening is not a routine service of the primary health facilities, but sufficient FORTIMAS funds are available to do Hb tests on 150 target women in each sentinel health facility (i.e. FORTIMAS data collection point) this reduced sample size would allow for adequate detection of an approximately 16% reduction in the prevalence of anemia in the sentinel site (i.e. from ~50% to ~ 34%). If there are at least two sentinel sites and health facility data collection points in each sub-geographic area (e.g. a province or large city), combining the Hb data from two sites (i.e. 300 subjects) would allow for detection of a 12% decrease in the prevalence of anemia (i.e. from 50% to 38%) between the "baseline and follow up reporting period. However, However, as indicated earlier, if there is sustained high coverage of quality fortified flour and a steady decrease in the prevalence of anemia over four or five years in each sentinel site, then using a "reasonably" reduced sample size would also allow for concluding that the prevalence of anemia is indeed decreasing in the sentinel communities. However, if it is decided that prevalence estimates of anemia should be provided for each sentinel site, then the recommendation of collecting Hb data on at least 100 subjects per site[5] should be considered.

4. MI. Nutrition survey toolkit. http://www.micronutrient.org/nutritiontoolkit/. Accessed 02/10/2014.
5. CDC. Pediatric and Pregnancy Nutrition Surveillance System. http://www.cdc.gov/pednss/how_to/read_a_data_table/table_basics.htm. Accessed 02/04/2013.

d. The analysis of the cumulative annual Hb data from all FORTIMAS data collection points would allow the detection of a smaller reduction in anemia prevalence (i.e. <10%) among non-pregnant women residing in all high fortified flour coverage areas in the country.

To track the birth prevalence of NTDs, which is usually reported as the number of cases per 10,000 births per year, data on about 20,000 births (live or stillbirth) per year would be needed for each target sub-geographic area[6]. Thus, NTD and total births data from multiple maternity facilities within large sub-geographic areas with sustained high coverage of fortified flour in the country would be needed to generate reliable annual estimates on the birth-prevalence of NTDs. For additional guidance, refer to the recent publication by the WHO, CDC and the International Clearinghouse for Birth Defects Surveillance and Research (ICBDSR), entitled *Birth defects surveillance: a manual for programme managers*[7].

In summary, the number of sentinel sites, data collection points and subjects to include in as robust a FORTIMAS data collection system as possible, depends on the resources needed to sustain the collection, processing, analysis and reporting of data over many years. Thus, each country would need to determine its own feasible approach to implementing FORTIMAS based on local capacity and resource availability, while considering the minimum numbers of subjects and households to collect data on in order to generate reliable prevalence estimates on the coverage and impact of the flour fortification program.

V. How to Recruit Subjects for Each FORTIMAS Data Collection Round?

Proposed approaches for recruiting subjects in a timely manner through FORTIMAS data collection points such as PHCs, schools and maternity facilities are described below.

1. Sentinel Primary Health Centers

Based on informed consent[8], adult women who visit the sentinel PHCs should be recruited for FORTIMAS data collection using convenience sampling. For example:

- Consenting mothers who bring their young children to the PHCs for immunization or well-child examinations and pregnant women who seek antenatal care could be administered a brief questionnaire to collect data on their attitudes towards fortified flour/flour-based staple foods and their families' practices related purchasing and consuming those products.

6. Dr. RJ Berry, Centers for Disease Control and Prevention, Atlanta, Georgia, USA. Personal communication. December, 2013.
7. http://www.who.int/nutrition/publications/birthdefects_manual/en/.
8. Local regulations should be followed regarding informed consent procedures for recruiting subjects for FORTIMAS data collection.

- Non-pregnant women could also be tested for laboratory measures of micronutrient status in the initial round of FORTIMAS data collection (prior to full implementation of flour fortification) and again when high population coverage has been confirmed in the sub-area and sentinel site for at least a one year period.

A proposed convenience sampling approach to recruit the minimum number of women for each data collection period is to:

- Specify a fixed set of dates for when each selected PHC must collect the FORTIMAS data. To not overload a central laboratory responsible for testing biological specimens for micronutrient status (e.g. serum ferritin or serum folate), a staggered schedule of data collection for groups of PHCs may be warranted within a defined short time period. This would depend on the laboratory's capacity to process such samples.
- Each designated data collection point should determine the number of days needed to recruit the recommended number of subjects based on the facility's expected average daily caseload. **Table 6** below could be used as a tool to determine the number of days needed (the first row is filled in as an example).
- Designate the range of consecutive working dates when all the subjects are to be recruited for each round of FORTIMAS data collection.

    a. During the predetermined dates, a standard FORTIMAS data collection form (see example in Appendix A) should be completed on each adult woman who visits the PHC for any reason other than illness and agrees to participate in FORTIMAS.

If deemed helpful, it might be possible to utilize medical, nursing or health science students from universities, or upper secondary school students to serve as FORTIMAS data collectors. Such an approach should be based on formal agreements with the relevant educational institutions to ensure that student data collectors are available throughout the data collection periods. To encourage such student participation, their FORTIMAS-related work could be included as a recognized academic activity.

Table 6. Tool to estimate the number of days needed to recruit at least 105 target women per sentinel data collection point.

A	B	C	D	E	F
Primary Health Center No.	Average daily facility caseload of target women (N)	Expected refusals (%)	Number of refusals per day (N)	Number of days to recruit 105 women (Days)	Add two extra days to ensure enough subjects (Total Days)
1	10	10	1	**12**	**14**

Column C = Column A* (Column B/100)
Column D = 120/ (Column A - Column C)
Column E = Column D + 2

2. Sentinel Schools

Secondary schools within the FORTIMAS sentinel sites could serve as data collection points to help track the household availability of fortified flour and/or staple foods made from fortified flour.

If the majority of the population in a sub-area purchases industrially milled flour to prepare flour-based staple foods at home, students could periodically be instructed to bring samples of flour from their homes to be tested for the presence of fortificants. A potential approach may be as follows:

a. About 100 – 105 students who attend sentinel schools would be instructed to bring flour samples (minimum of 150 grams; equivalent to a 250 ml cup of flour) from their homes on a specified date during the school year. The students would also complete a very brief questionnaire (see example in Appendix B). Note: it would likely be necessary for each selected school to provide the designated students with appropriate-sized containers for their flour samples.
b. Each flour sample would be tested by the chemistry, science, or other appropriate teacher(s) in the school for the presence of iron using the iron spot test (see Appendix C for instructions on testing flour expected to be fortified with ferrous sulfate, ferrous fumarate or electrolytic iron, and Appendix D for flour expected to be fortified with sodium iron-EDTA). The presence of iron fortificant in a flour sample also indicates that the other required nutrients (e.g. folic acid) are present in the flour because a quality fortificant premix contains all the nutrients in their proportionate concentrations.

– The teacher records the findings in a log sheet (see Appendix F), which is submitted to the FORTIMAS office for data entry and processing.
– If it is not feasible to test flour samples at the schools, the possibility of transferring the samples for testing at the sentinel PHC in the community should be explored. This approach was successfully carried out in Morocco.
– If testing of flour samples is not feasible at all, the students could be instructed to only complete a very brief data form about the type of flour in his/her home, including the brand name and/or presence of a fortification logo.

If the majority of households in the target area purchase staple flour products (e.g. bread) from the market:

a. Students should be instructed to complete a brief questionnaire about the purchased bread in their homes, including the name or location of the bakery from which it was purchased.
b. The top two to three most commonly reported bakeries could then be inspected by the appropriate local office of the FCA to ascertain if fortified flour is used.

In countries where the industry QA/QC and/or regulatory inspection procedures for domestic and imported fortified flour are reliable and confirm that the flour produced or imported is consistently and adequately fortified, testing of household or commercial bakery flour may not be necessary. In such cases, questionnaire data on self-reported purchase of fortified flour/flour based staple foods (e.g. bread or pasta) through sentinel PHCs would likely be sufficient to assess population coverage.

3. Maternity Hospitals and Birthing Centers

As indicated above, essentially all the maternity hospitals and birthing centers, especially those that serve populations in the geographic areas with >80% population coverage for fortified flour, should be encouraged to account for every case of NTD birth in the facility and report the number of cases together with the total number of births per year to the FORTIMAS Office for analysis as an indicator of the impact of the fortification program. A more advanced NTD surveillance system would also account for pregnancies terminated due to the detection of NTDs. Outcomes of at least 20,000 births per year should be included in order to generate reliable statistics on birth prevalence of NTDs.

VI. How Often to Collect and Report FORTIMAS Data?

As with the number of sentinel sites and data collection points to select, and the number of subjects or households to include, the periodicity of data collection and reporting of FORTIMAS findings also depends on the local situation, human and technical capacity, and other resources. Since the overall purpose of FORTIMAS is to help guide the sustained and effective implementation of flour fortification in a country, the FORTIMAS data collection and reporting frequency should be determined at the country level.

Although the focus of this guide is on the population-based component of FORTIMAS (i.e. boxes B, C and D in **Figure 10**), until the adequate quality and sufficient quantity of production of fortified flour is achieved, it would not be necessary to expend resources to actively track the coverage and impact of the intervention among the population. Therefore, the flour millers must implement the appropriate QA/QC procedures as described elsewhere(8). Similarly, the national food control and customs agencies must establish appropriate regulatory monitoring systems to assure the quality of imported fortified flour also. For the population-based component of FORTIMAS, the following recommendations are proposed regarding the frequency of data collection and reporting of findings based on the local situation (**Table 7**).

Table 7. Options for frequency of data collection for the population-based component of FORTIMAS.

Indicator Type	Situation	Frequency of Data Collection	Frequency of Information Reporting
Program coverage	Collection of data on fortified flour coverage monitoring is to be added to the activities of sentinel PHCs and schools (where appropriate).	- Annually when flour industry data indicate that sufficient fortified flour is marketed to meet the per capita intake needs of close to 80% or more of the population in a sub-area.	- Annually when flour industry data indicate that sufficient fortified flour is marketed to meet the per capita intake needs of close to 80% or more of the population in a sub-area.
Program impact	Data on selected impact indicators (e.g. Hb of adult women or NTD-affected births) are already collected through PHCs and maternity facilities.	- Continue the routine frequency of data collection, and work to ensure the quality and reliability of the data.	- Annually when population coverage of fortified flour is sustained at >80%.
	Data on selected impact indicators (e.g. Hb of adult women or NTD affected births) is to be added to activities of sentinel PHCs and maternity facilities.	- Data on sufficient number subjects are collected to provide the needed annual statistics - After a steady decline in prevalence of target micronutrient deficiency indicators is detected, data may be collected every 2 – 3 years	- Annually during the initial 4 to 5 years of sustained high coverage of fortified flour. - May be reduced to every 2 to 3 years once there is steady decline in micronutrient deficiency prevalence.
	NTD case reporting to be initiated	- On all births	- Annually

CHAPTER 4

Additional Considerations for Implementing a Sustained Flour Fortification Program Monitoring and Surveillance System

I. Engage All the Stakeholders of the Flour Fortification Program

II. Describe the Scope of the Flour Fortification Program and Define its Objectives

III. Focus the Design of FORTIMAS

IV. Collect Credible Data

V. Justify the Conclusions - Analyze Data and Interpret Findings Transparently

VI. Share the Lessons Learned and Include Specific Action Recommendations

VII. Finalize the FORTIMAS Design

In addition to the topics and issues discussed in the previous chapters, the following six steps of the Centers for Disease Control and Prevention's (CDC) *Framework for Program Evaluation in Public Health* (17) could help to guide the design of FORTIMAS. Those steps are:

a. Engage stakeholders;
b. Describe the scope of the program;
c. Focus the monitoring and surveillance system;
d. Collect credible data;
e. Justify the conclusions; and
f. Ensure that the lessons learned are shared and used.

I. Engage All the Stakeholders of the Flour Fortification Program

The "stakeholders" of the flour fortification program are individuals and organizations that are invested in fortification, are able to influence the success of the intervention, and/or may be interested in the quality, coverage and impact findings of FORTIMAS. In many countries, these stakeholders are already part of a National Fortification Alliance (NFA) or Committee that was involved in the development and implementation of the fortification program. Important stakeholders include:

- Relevant branches of the ministries of health, industry, agriculture, commerce and others;
- Private sector entities such as flour millers, importers and wholesalers, bakers, pasta or confectionary producers and fortificant suppliers;
- Scientific and academic groups;
- United Nations and donor agencies;
- Media representatives; and
- Civil society and consumer groups.

The roles and contributions of different stakeholders may include the following (also see **Table 8** below):

- Serve as members of the "FORTIMAS technical committee" which would advise on the methodology and tools for data collection, analysis and interpretation. A FORTIMAS committee could be established as a sub-committee of an existing NFA.
- Collect data, assist with data analysis and/or help disseminate the findings.
- Take specific actions based on the findings of FORTIMAS - for example, if the flour industry records indicate sufficient production of quality fortified flour but the population coverage monitoring system finds an unexpectedly high prevalence of unfortified household flour samples in selected sentinel sites, the FCA should be informed of the discrepancy and follow up accordingly.

Additional benefits of closely engaging the flour fortification program stakeholders in FORTIMAS are as follows:

- Involvement of appropriate public sector agencies, health professionals, academics, and civil society organizations in the planning of the FORTIMAS system helps to legitimize the data collection methodology and the information reported.
- Engaging relevant milling and baking industry and market sector representatives in the design of the FORTIMAS system helps overcome potential misunderstandings and resistance by the private sector and may even bring additional resources to help sustain FORTIMAS.
- Different public and private sector entities may already be collecting relevant data that could be incorporated as part of overall FORTIMAS findings, or they may be willing to adapt their systems to help collect the needed data; for example:

    - Supermarkets with electronic scanners may be able to provide data on sales of fortified flour products, as was done in South Africa (personal communication, Dr. Philip Randall, milling consultant).
    - Flour wholesalers likely have data on the quantity of different types of flour and bread or noodles they sell in the local markets; periodic analysis of those data would show if fortified flour and/or flour product sales have increased in various geographic areas over time. This information can then be used to estimate the population coverage of fortified flour in different areas of the country.
    - Maternity hospitals may already keep record of the number of NTD-affected births. Thus, such data would only need to be compiled, analyzed and reported periodically.

- Engaging the stakeholders early in the planning of FORTIMAS will help to gain their trust, buy-in, and cooperation. When the stakeholders have a sense of "ownership" or engagement, they are more likely to accept the findings of FORTIMAS and take the needed follow-up actions (7).
- Whenever feasible, stakeholders can support FORTIMAS by incorporating relevant indicators in periodically-conducted national surveys (e.g. Demographic and Health Surveys, Multiple Indicator Cluster Surveys, Household Expenditure Surveys, etc.).
- Wherever possible, FORTIMAS should become an integral part of the NFA structure and its responsibilities. This may necessitate inviting additional members to join the NFA.

Table 8. Examples of flour fortification program stakeholders and their potential roles in the planning and implementation of the FORTIMAS system.

Stakeholder	Sector	Role
Flour industry association	Private	1. Reports total quantity of adequately fortified flour marketed – domestically milled and imported. 2. Informs on quantities of adequately fortified flour marketed in different areas of the country (*to help determine where to establish FORTIMAS sentinel sites*).
Food Control Agency	Public	1. Reports on the quantity of domestically produced and imported flour that meets fortification standards on an annual basis (*to help determine when the coverage of adequately fortified flour has reached 80% or more*).
Food wholesalers' association	Private	1. Reports sales of fortified flour in local markets.
Maternal and Child Health Department and/or Health Management Information System Department	Public	1. Identifies primary health clinics as data collection points in sentinel sites. 2. Formalizes guidelines on hospital reporting of NTD births.
Association of NTD-affected families	Civic	1. Advocacy.
Technical and donor agencies	Public/Civic	1. Technical support and advocacy. 2. Funding support.

1. Different public and private sector groups may already record relevant data that could be incorporated into FORTIMAS or their data systems could be adapted to help collect needed data.

2. Involving the stakeholders of the flour fortification program early in the planning of the FORTIMAS will help get their **trust**, **buy-in**, and **cooperation**.

II. Describe the Scope of the Flour Fortification Program and Define its Objectives

The collection, analysis and interpretation of FORTIMAS data on monitoring of population coverage and nutritional impact surveillance of a flour fortification program cannot be done in isolation. Information on flour production and imports, market distribution of flour and flour products across a country, and consumer purchasing and consumption habits must also be considered when designing the FORTIMAS data collection system. Examples of a flour fortification program goal and objectives are presented in **Box 3**.

Box 3. Examples of the goal and output and impact objectives of a hypothetical wheat flour fortification program.

Program Goal: Reduce the burden of micronutrient malnutrition.

Output objective 1: The national wheat flour industry produces and/or imports sufficient flour fortified according to the national standards to meet the estimated per capita flour consumption needs of >80% of the population (in the target geographic area) within 3 years of program implementation.

Output objective 2: Fortified flour is used to prepare all commercially baked bread (in the target geographic area).

Output objective 3: At least 80% of households (in the target geographic area) regularly purchase fortified flour or flour products within 3 years of program implementation.

Impact objective 1: Decrease the prevalence of anemia (Hb <12 g/dL) among women of childbearing age by 20% relative to the pre-fortification level within 5 years of program implementation.

Impact objective 2: Decrease the prevalence of iron deficiency (serum ferritin <15 ng/mL) among women of childbearing age (in the target geographic area) by 30% relative to the pre-fortification level within 5 years of program implementation.

Impact objective 3: Increase the prevalence of folate sufficiency (serum folate >7 ng/mL) among women of childbearing age (in the target geographic area) by 50% relative to the pre-fortification level within 5 years of program implementation.

Impact objective 4: Decrease the birth prevalence of neural tube defects (in the target geographic area) by 40% relative to the pre-fortification level within 5 years of program implementation.

Examples of questions to answer in order to guide the development of the FORTIMAS system are:

1. Is sufficient fortified flour (domestic and imported) expected to be marketed in the target geographic area so that close to 80% of the population will have regular access?

    - If not, focus on increasing the quantity of fortified flour marketed in the area to support equitable public health impact.

2. Will fortified flour and/or flour-based foods be labeled or branded with a logo so that consumers can identify them easily?

    - If not, how will consumers identify the fortified products?

Information on flour production and imports, market distribution of flour and flour products across a country, and how most consumers access and prepare fortified flour products must be considered when designing the FORTIMAS system.

3. Does the majority of the population in the target area prepare flour-based staple foods (e.g. bread) at home or purchase them from the market? (Note: It may be that most urban households in a sub-region purchase fortified flour-based foods while their rural counterparts buy fortified flour and prepare the foods at home). If they prepare the foods at home:

    - Is fortifiable flour typically mixed with non-fortifiable flour to make bread or another common flour-based staple food? If so, the fortification standard for fortifiable flour may need to be adjusted accordingly to ensure adequate intake of the target micronutrients.

4. Are the primary flour-based staple foods (e.g. bread or pasta) in the target geographic area produced by large-scale producers or by many small producers in each community (e.g. neighborhood bakeries)?

    - If a limited number of large-scale producers supply most of the staple foods using industrial flour in the target area, a system should be developed to periodically inspect those entities to confirm their use of fortified flour.
    - If there are many small bakeries, consider partnering with a limited number of flour wholesalers that distribute flour to those bakeries to periodically obtain data on the quantity of fortified flour sold in the target geographic area.

III. Focus the Design of FORTIMAS

Once the scope, characteristics and objectives of the flour fortification program are described, determine the most important monitoring and impact surveillance indicators that should be tracked through the FORTIMAS system. A useful approach to planning is to develop a log-frame which addresses the following:

a. What feasible indicators would provide the needed information?
b. What methods should be used to collect the data?
c. What should be the primary target group for data collection?
d. How should the target group be accessed?
e. Who should collect the data?
f. How often should the data be collected?
g. Who should compile and analyze the data?
h. To whom should the data be disseminated?

The sample log-frames below present a potential FORTIMAS design where data are collected via sentinel health clinics, secondary schools and large maternity hospitals. The primary questions about population coverage and nutritional impact of flour fortification are written at the top of each log-frame. The questions in bullets a – h above appear as the headings of each column of the log-frames. The rows of the log-frames describe (in abbreviated form) the guidance presented in Section V of this document. However, before expending resources on the implementation of the population component of the FORTIMAS, the NFA and relevant stakeholders of the flour fortification program must first ensure that the conditions listed in Chapter 1, **Box 1** and Chapter 3, **Table 3** are met.

The focus of the FORTIMAS system will likely change over time as the flour fortification program matures and becomes better established. In the early stages, the main focus will be on monitoring trends in the population's use of fortified flour and flour-based staple foods. Once high population coverage of fortified flour is sustained in the defined geographic area, collection of surveillance data on micronutrient status of the target population can be initiated.

Before expending a lot of resources on the implementation of the population component of the FORTIMAS, the National Fortification Alliance and relevant stakeholders must first focus on flour production and imports and ensure that the fortification standards are based on per capita consumption of industrially milled flour according to the WHO recommendations (5).

Log-Frame A: Primary Question: Has the threshold in population coverage of fortified flour been sustained annually?							
Indicator	Method	Primary target group	How to access the target group?	Who collects the data?	How often to collect the data?	Who compiles and analyzes the data?	Who should receive and act on the information?
Proportion of population reporting purchase of fortified flour/ bread	Subjects are asked about the type of flour they purchase using a standard questionnaire	Women of childbearing age	Interview mothers of children seen for well-child & immunization visits at sentinel health facilities	Sentinel health facility staff trained to collect *FORTIMAS* data	1. Prior to or within first month of the start of the mandatory fortification program. 2. Annually when flour industry and the FCA report sufficient quantity of fortified flour marketed to meet the needs of ≥80% of population in defined geographic area.	*FORTIMAS* data processing office	National Fortification Alliance
Proportion of population that recognizes flour fortification logo (or label)	Assess recognition of fortification logo (or label) on target food product(s)	Women of childbearing age	Interview mothers of children seen for well-child & immunization visits at sentinel health facilities	Sentinel health facility staff trained to collect *FORTIMAS* data	1. Six months after start of mandatory fortification program. 2. Annually when flour industry and FCA report sufficient quantity of fortified flour marketed to meet the needs of ≥80% of population in defined geographic area.	*FORTIMAS* data processing office	National Fortification Alliance

Log-Frame A: Continued

Indicator	Method	Primary target group	How to access the target group?	Who collects the data?	How often to collect the data?	Who compiles and analyzes the data?	Who should receive and act on the information?
Proportion of households which use fortified flour	Subjects report if fortified flour/ flour based staple foods in their homes carry the fortification logo or label	Households in sentinel site	Secondary school students complete household data form	School science or chemistry teachers trained to collect *FORTIMAS* data	1. Prior to or within first month of the start of the mandatory fortification program. 2. Annually when flour industry and FCA report sufficient quantity of fortified flour marketed to meet the needs of ≥80% of population in defined geographic area.	*FORTIMAS* data processing office	National Fortification Alliance
	Household flour samples are tested for iron fortificant	Households in sentinel site	Secondary school students bring flour samples from home for testing	School science or chemistry teachers trained to collect *FORTIMAS* data		*FORTIMAS* data processing office	National Fortification Alliance

Photo: Philip Randall.

Log-Frame B: Primary Question: Is the prevalence of anemia and/or iron deficiency decreasing and folate sufficiency increasing?							
Indicator	Method	Primary target group	How to access the target group?	Who collects the data?	How often to collect the data?	Who compiles and analyzes the data?	Who should receive and act on the information?
Prevalence of anemia (Hb <12 g/dL)	Blood Hb test	Non-pregnant women of childbearing age	Mothers of children seen for well-child & immunization visits at sentinel health facilities	Sentinel health facility staff trained to collect *FORTIMAS* data	1. Prior to or within first month of the start of the mandatory flour fortification. 2. Annually after ≥80% household coverage is sustained for at least 12 months.	*FORTIMAS* data processing office	National Fortification Alliance
Prevalence of iron deficiency (serum ferritin <15 ug/dL)	Serum ferritin test	Non-pregnant women of childbearing age	Mothers of children seen for well-child & immunization visits at sentinel health facilities	1. Trained sentinel health facility staff collect serum samples. 2. Biochemistry laboratory performs tests.	1. Prior to or within first month of the start of the mandatory flour fortification. 2. Annually after ≥80% household coverage is sustained for at least 12 months.	*FORTIMAS* data processing office	National Fortification Alliance
Prevalence of folate sufficiency (serum folate >7 ng/mL)	Serum folate testl	Non-pregnant women of childbearing age	Mothers of children seen for well-child & immunization visits at sentinel health facilities	1. Trained sentinel health facility staff collect serum samples. 2. Biochemistry laboratory performs tests.	1. Prior to or within first month of the start of the mandatory flour fortification. 2. Annually after ≥80% household coverage is sustained for at least 12 months.	*FORTIMAS* data processing office	National Fortification Alliance

Log-Frame C: Primary Question: Is the birth prevalence of neural tube defects (NTD) decreasing?							
Feasible Indicator(s)	Method	Primary target group	How to access the target group?	Who collects the data?	How often to collect the data?	Who compiles and analyzes the data?	Who should receive and act on the information?
NTD birth prevalence per 10,000 births	Maternity hospitals and birthing centers report NTD births	All babies born in maternity hospitals and birthing centers	NTD reporting by all or the largest maternity hospitals & birthing centers in high-fortified flour coverage areas.	Staff of facilities where babies are delivered	1. Prior to or within first month of the start of the flour fortification program. 2. Annually	National vital statistics agency or *FORTIMAS* data processing office	National Fortification Alliance

Photo: David McKee.

The periodicity of data collection will also vary over time. For example, data on the population's attitudes about mandatory flour fortification and coverage of fortified flour and flour-based products may need to be collected more frequently (e.g. quarterly or semi-annually) during the first year or two of the program as social marketing activities promote acceptance of the intervention. Once consumer concerns about fortified flour are alleviated and high population coverage is sustained over four to five years, the frequency of data collection to confirm high population coverage may be reduced to every two or three years.

The frequency of data collection on nutritional and health impact indicators would also vary based on how quickly the indicator is expected to respond to fortification. For example, experience has shown that serum folate levels increase rapidly and may be detected within four to six months of regular consumption of fortified flour (personal communication, Dr. Godfrey Oakley, Emory School of Public Health). On the other hand, a year or more may be required to notice improvements in iron or hemoglobin status (6). Detecting significant reductions in the birth prevalence of NTDs will likely take one to two years of sustained high population coverage of fortified flour and flour-based products (9, 10). Overall, provided that close to 80% population coverage of fortified flour is sustained, micronutrient status indicators may be tracked annually in the first three to five years of the flour fortification program. After a number of years when the decline in the trends in prevalence of micronutrient deficiency in different regions of the country converge toward a "maximum sustained impact" of the flour fortification program (see Chapter 1, **Figure 3** as an example related to pediatric anemia trends), the frequency of impact surveillance data collection may also be reduced.

If substantial variation is not anticipated in the distribution, marketing, or consumption of fortified flour across a country or sub-geographic areas within a country, and there is substantial confidence that the flour industry will rapidly and regularly produce sufficient quality fortified flour, it may not be necessary to monitor population coverage in the target areas. Instead, after collecting an initial or "baseline" round of micronutrient status data prior to the start of the fortification program, the FORTIMAS can focus on tracking the impact of the program about one year after mandatory fortification goes into full effect. For example, the flour industry in Australia began mandatory fortification with folic acid in September 2009. Because the flour industry in that country is well developed, and it was expected that all the flour would be rapidly and adequately fortified according to the national standards, no specific population coverage monitoring system was implemented. Instead, as they had been doing before flour fortification, researchers focused on continuing to test serum folate in hospital patients across that country, and found a 77% relative drop in the percent of subjects with low levels about 7 months after flour fortification began (10). Similarly, the initial assessment of flour and cereal products fortification in the U.S. was done by assessing folate status of hospital patients and the birth prevalence of NTD births before fortification, during the voluntary fortification period and after the mandatory fortification law went into full effect.

In summary, multiple questions about relevant indicators, target groups and data collection, analysis and dissemination should be considered when developing the FORTIMAS system. Spending sufficient time on the planning stage will ensure that the indicators for the flour fortification program are tracked well. This will in turn help the stakeholders assess whether or not the objectives of the fortification program are being met.

As the fortification program matures, the overall focus of the FORTIMAS system will shift. At the outset, FORTIMAS will primarily direct attention to output indicators followed by impact indicators once high sustained population coverage of fortified flour is achieved in specified sub-areas. In the same way, FORTIMAS may gradually incorporate new target areas in line with the scale-up activities of the fortification program. For example, fortified flour may be primarily marketed in urban areas of a country initially. However, as the market share of industrial flour substantially increases in rural areas, FORTIMAS activities should be modified to also track population coverage and nutritional impact of the flour fortification program among rural populations of the country.

IV. Collect Credible Data

The credibility and utility of the FORTIMAS will depend on the ability of the system to:

- Track the coverage and impact of the flour fortification program in the target population groups;
- Collect reliable data on population coverage and impact indicators over time; and
- Meet the information needs of the flour fortification program stakeholders in a timely manner to help strengthen the effectiveness of the intervention

The collection of accurate and precise data is integral to the credibility of the FORTIMAS system, and the following are helpful toward that end:

a. Clearly define all the indicators.
b. Develop well-designed data collection tools that are easily understood and completed by respondents; promptly enter data or transfer it to a computer database with minimal errors (for a manual data entry system, a double data entry process is highly recommended).
c. Develop clear instructions and procedures for all phases of data collection, including standardizing how subjects are recruited: where, when, how often, and by whom.
d. Establish a systematic training approach for all FORTIMAS data collectors (e.g. nurses in sentinel clinics, teachers in sentinel schools, and staff of delivery wards and nurseries in maternity centers, etc.). It is also necessary to periodically re-train all data collectors and monitor data collection in "the field", so any data quality problems can be corrected early on.
e. Ensure that the laboratories designated to perform biochemical tests of micronutrient status have appropriate QA/QC procedures, including external quality control through a standard laboratory.
f. Prepare appropriate procedure manuals for all phases of data collection, computer entry and analysis.

g. Correct computer data entry errors and eliminate any outlier values prior to final analyses, which should in turn be carefully interpreted to ensure that the results are "logical" before final publication of the findings.
h. Unless the estimate of per capita consumption of industrial flour, especially among women of childbearing age, is based on recent assessments, such data could be collected in the initial round of FORTIMAS data collection and every five to 10 years thereafter or when there are indications that consumption levels may have substantially changed since the initial estimates. For example, only "bread" flour is required to be fortified in South Africa. However, it is now believed that since the start of the national flour fortification program in that country, the market share for cake flour (which is not fortified) has grown from 15% to about 40%[1]. Furthermore, small bakeries in South Africa now blend both types of flour to make bread due to consumer preference. Because the nutritional impact of the flour fortification program may be negatively impacted due to the changes in the flour market and consumer choice, the flour fortification standard in South Africa may need to be adjusted based on updated estimates of per capita consumption of *fortifiable* flour.

   Household Income and Expenditure Survey data[2] as well as the Fortification Rapid Assessment Tool (FRAT)[3] are also potential approaches toward estimating the per capita intake fortifiable flour.

i. When:

   a. The per capita consumption of *fortifiable* flour is known, and essentially all industrial flour is mandatorily fortified;
   b. Fortified flour production and imports are readily and reliably certified as of adequate quality, and;
   c. The stakeholders of the flour fortification program are confident that the bulk of the *fortifiable* flour in the markets across the geographic area is fortified;

   Then population coverage of fortified flour may be estimated on the industry data alone; i.e. it may not be necessary to confirm the coverage through active data collection at the population level.

   If it is necessary to track population coverage of fortified flour or flour products, the least costly approach is likely to collect data on self-reported household purchases of fortified flour/flour-based staple foods, and to "triangulate" the findings with data on the quantity of fortified flour marketed in the geographic area. An important limitation of such data is the ability of consumers, especially illiterate ones, to identify fortified flour/flour-based staple foods in the market, if not all types of flour are fortified. The legal use of an easily recognizable "fortification logo" or label would help consumers select fortified products.

1. http://ffinetwork.org/about/calendar/2011/documents%202011/SouthAfricaMS.pdf. Accessed 8 February, 2013.
2. Dary, O and Imhoff-Kunsch, B. Guide to estimating per capita consumption of staple foods using Household Income and Expenditure Survey (HIES) data. ECSA/A2Z M&E Workshop, Kampala, Uganda, July 5-7, 2010.
3. http://www.micronutrient.org/nutritiontoolkit/ModuleFolders/3.Indicators%5CDietary%5CTools%5CFortification_Rapid_Assessment_Tool_and_Guidelines.pdf. Accessed 8 February, 2013.

j. When testing household flour samples through sentinel schools is included to assess coverage of fortified flour, the selected schools have to be supplied with the appropriate materials and reagents, and the relevant teachers well trained to perform the flour spot tests. The teachers should also be provided with standard log sheets to record the test results and minimal additional data about the brand of flour (see an example in Appendix F).

Some important questions that FORTIMAS findings should answer are (see also **Box 3**):

1. Is the trend in population coverage of fortified flour/flour-based staple foods increasing based on flour industry and sentinel site data?
2. Is population coverage of fortified flour sustained at >80% or more across the country or in any of its sub-regions?
3. Is the prevalence of iron deficiency and/or anemia decreasing among women of childbearing age in the areas where sufficient population coverage has been sustained?
4. Is the prevalence of folate sufficiency increasing among women of childbearing age where sufficient population coverage has been sustained?
5. Is the birth prevalence of NTDs decreasing where sufficient population coverage has been sustained?

If other interventions to raise the iron and/or folic acid status of the population (e.g. supplementation programs or deworming interventions etc.) have not been ongoing in the geographic areas prior to the start of flour fortification, and substantial improvements in the implementation and coverage of the other interventions do not take place after flour fortification starts, then any substantial improvements in the iron or folate status of the population after sustained high population coverage of fortified flour is achieved, could be attributed to the flour fortification program. For example, the proportion of preconception iron/folic acid supplementation coverage among women of childbearing age did not change substantially after mandatory folic acid fortification of flour and cereals was initiated in the United States. Thus, the increase in serum folate levels of the population, as well as the decrease in the birth prevalence of NTD detected about one year after the start of folic acid fortification were attributed to the fortification program (9).

The credibility of FORTIMAS findings could be further enhanced by comparing them with other relevant information such as findings from household expenditure or nutrition surveys that may be implemented. **Table 9** below summarizes some potential issues and proposed solutions related to credible data collection.

When reporting the findings:

- Clearly describe the methodology of data collection and analysis.
- Compare and contrast the findings with reports from other sources, including from neighboring countries that have implemented flour fortification, and suggest possible explanations for similarities or differences.
- Describe how the information addresses the objectives of the flour fortification program.

- Clarify the limitations of the information, including potential biases; explore and present potential alternate explanations for the findings.

The format for reporting the FORTIMAS findings depends on the audience. Those in academic and technical fields will likely want the details of the analysis methods with detailed tabulations of the results. High level administrators and the media may be more interested in a less technical report with graphic or pictorial summaries of the findings (see **Figures 4** and **8** as examples).

Table 9. Potential issues that could affect the quality and credibility of FORTIMAS based on purposive and convenience sampling methodology.

Factor	Issues to Consider	Potential Solutions
Type of FORTIMAS data to collect	How to assess reported purchase of fortified flour or flour products, especially among illiterate subjects?	Ask women to identify the "Fortification Logo" from among three to five other common food product logos in the market.
	How to assess if a commercial flour product (e.g. bread) is made from fortified flour?	1. Monitor fortified flour use in bakeries if most of the flour products in the geographic area are produced by large facilities. 2. Monitor sales of fortified flour among a few flour wholesalers in the sentinel sites. 3. Monitor use of fortified flour in the most commonly used small retail bakeries in the sentinel community identified through interviews of women in sentinel health clinics or reported by sentinel school students.
	How to assess the proportion of fortified flour in mixed flour samples used to bake homemade bread?	1. Conduct iron spot tests on the following types of flour samples used for baking bread: - 3 to 4 typical blends of fortified and non-fortified flou;r - fortified flour only; - non-fortified flour only. 2. Take pictures of the resulting spot tests which can then be used to identify types of blended as well as non-blended samples of household flour from homes of students of sentinel schools.

Table 9. Continued

Factor	Issues to Consider	Potential Solutions
Type of FORTIMAS data to collect	How to ensure reliable laboratory results of biological tests of micronutrient status?	1. Assess QA/QC procedures of the local laboratory related to required tests. 2. Send biological samples to external certified laboratory for testing. 3. Train all sentinel PHC staffs on standard procedures to collect blood samples (capillary blood collection methods may be more feasible).
	How to track NTD birth prevalence?	1. Work with the Ministry of Health to require reporting of all NTD births in maternity hospitals. 2. Work with trained midwives to establish an NTD surveillance system if the majority of babies are born at home.
Data collection process	How to ensure that the self-reported purchases of fortified flour/flour-based staple foods is accurate?	1. Work with a local academic institution to develop an appropriate set of questions to assess self-reported purchases of fortified flour/flour-based staple foods. 2. In the test phase of FORTIMAS perform a few cross-checks on self-reported purchases of fortified products. First, document purchases by interviewing women at sentinel clinics. Then confirm the presence of fortified products in the home by conducting house visits. 3. Develop a continuous training and standardization system for sentinel clinic staff.
	How to test household flour samples?	Work with and train sentinel site school teachers to test household flour samples brought by students and report the results to the FORTIMAS office.
	How to account for non-responders?	Keep track of the number of sentinel clinic subjects or other respondents who decline to participate and the reasons for non-participation.
Data analysis	Quality of data analysis	1. Develop easily understood data collection forms and ensure good training of data collectors. 2. Incorporate automatic data entry check process to prevent entry of potentially incorrect data (e.g. out of range values). 3. Implement double data entry process to identify and correct data entry errors.

V. Justify the Conclusions – Analyze Data and Interpret Findings Transparently

"Data analysis is the process of calculating, tabulating, and classifying the results; interpreting and presenting the information generated in an understandable manner; and making appropriate action recommendations to different stakeholders." (7). A key purpose of FORTIMAS is to enable the stakeholders of the flour fortification program to sustain successful components of the intervention and improve weaker ones. Therefore, the social and political context of the flour fortification program and the needs of various stakeholders should be considered in the design of the data collection system and the analysis and presentation of the findings, without compromising the integrity and credibility of the FORTIMAS system.

VI. Share the Lessons Learned and Include Specific Action Recommendations

A few essential points to help sustain FORTIMAS are:

1. Regularly and consistently report findings and information, including specific actionable recommendations.
2. Share FORTIMAS reports with all stakeholders, especially those who collect the data so that they can appreciate the importance of their role in the overall flour fortification system and the efforts to improve the nutritional status and health of the population.
3. Ensure that FORTIMAS reports, with specific recommendations, are shared with the flour and baking industries in the country. Additionally, the role of those industries in improving the population's nutritional and health status should be specifically and clearly acknowledged.
4. Publish the FORTIMAS findings in peer-reviewed public health and nutrition journals and present them at national and international public health and industry conferences.

Engaging the flour fortification program stakeholders in the planning and design of the FORTIMAS system (as described above), and regularly sharing the findings along with actionable recommendations promotes a sense of "ownership" with the overall intervention, which is intended to improve and protect the nutritional status of the population. Such inclusiveness could also facilitate further involvement by all parties, including a willingness to take corrective action as needed to improve the fortification program.

Share findings of FORTIMAS with those who collect the data at the sentinel sites so that they can appreciate the importance of their role in the overall flour fortification system and the efforts to improve the nutritional status and health of the population.

Information from FORTIMAS must also be regularly provided to flour and flour based food producers in the country, and their role in improving the nutritional status of the population should be clearly acknowledged.

VII. Finalize the FORTIMAS Design

Through the entire FORTIMAS design and planning process it is important to answer the following questions and modify the approach and methods accordingly:

- Can the data be easily and sustainably collected over time?
- Is the cost of collecting the data reasonable given the available funds and human resources?
- Will the resulting findings and information be useful for documenting progress toward the program's public health objectives?
- Will the data for the selected indicators inform the stakeholders about the key output and impact measures of the program?

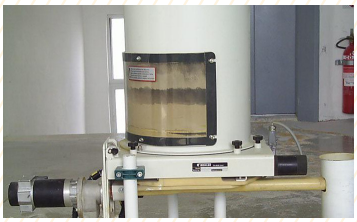
The design of FORTIMAS will undergo a number of iterations or revisions before the system is implemented. Furthermore, the FORTIMAS objectives, processes and procedures may need to be modified from time to time as the data and information needs change over time.

To adapt the proposed FORTIMAS methodology to the local setting, the following steps are recommended:

- Conduct an appropriate situation assessment to determine if the proposed approaches to purposive and convenience sampling are feasible for a sustainable FORTIMAS system. If so, ensure that all the program stakeholders have a good understanding of:

    1. **The time, effort, and resources needed to implement FORTIMAS**: it is absolutely essential to have sufficient, dedicated and trained staff to coordinate the design, planning and implementation of the FORTIMAS system. The FORTIMAS staff should also have the needed resources and support to continuously strengthen their capacity to do the job well.
    2. **The data collection system and process**: who will collect the data; where and how the data will be cumulated and processed; who will analyze the data and report the information; and who will have access to the "raw" data (address any concerns about individual and institutional privacy).
    3. **Reporting the FORTIMAS findings**: how often will the findings will be published and disseminated; what format will be used (e.g. hard-copy vs. web-based documents); and what kind of information will be available at various points in time (e.g. what would be included in quarterly vs. semi-annual vs. annual reports).
    4. **Utilization of the FORTIMAS information**: if the information is not shared with or useful for decision-making by the stakeholders of the flour fortification program, it will be difficult to justify expending resources to sustain FORTIMAS.

Conduct a "pilot" or "test run" of FORTIMAS, from data collection through data entry and analysis. Then, adjust and improve procedures and data flow, including altering the design of certain components of the system as needed. Finally, it is reiterated that the NFA members should be appropriately engaged throughout the development and evolution of FORTIMAS. It is important to acknowledge that the NFA will help provide the necessary continuity to the system by ensuring that all stakeholders and sectors understand their roles in the "flour fortification system" and have access to the findings of FORTIMAS. FORTIMAS thus becomes part and parcel of a successful fortification program.


Photos: Pholip Randal

APPENDICES

Appendix A – Example of a sentinel clinic data collection form

Appendix B – Example of a household flour information form to be completed by sentinel school students

Appendix C – Semi-quantitative spot test for iron as ferrous sulfate, ferrous fumarate, or electrolytic iron

Appendix D – Semi-quantitative spot test for iron as Sodium Iron EDTA: Adaptation of the AACC 40-40 spot test

Appendix E – Example of a flour fortificant test long-sheet for sentinel school teachers

Appendix A – Example of a sentinel clinic data collection form[1].

Sentinel Clinic Name (or *FORTIMAS* assigned code): _____

Date dd/mm/yyyy	Woman's age (Years)	Please identify fortification logo	How much industrial flour do you buy for your household per week*? (kg)
	1 = Yes 2 = No 3 = Don't Know	1 = Recognizes logo 2 = Does not recognize logo	
__ __/__ __/__ __ __ __	__ __	__	__
__ __/__ __/__ __ __ __	__ __	__	__
__ __/__ __/__ __ __ __	__ __	__	__
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[1] Results of serum ferritin and serum folate tests would be entered later by the biochemistry laboratory where the tests would be performed.

* Replace "industrial flour" with "bread" if the general practice in the society is to purchase bread instead of baking it at home, and convert the bread's weight to flour equivalent by multiplying it by the appropriate factor based on the type of bread (French bread – 0.65; US-style white loaf – 0.60; Arabic style flat bread – 0.85). Also, modify the time period to fit the typical purchasing frequency.

** Perform tests only in the first round of *FORTIMAS* data collection and annually when population coverage of fortified flour is ≥80%.

How Many family members >5 years old?	Hb** (g/dL)	Measure of serum ferritin**	Measure of serum folate**
	99.9 = Did not consent	99.9 = Did not consent	99.9 = Did not consent
__ __	__ __. __	__ __. __	__ __. __
__ __	__ __. __	__ __. __	__ __. __
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__ __	__ __. __	__ __. __	__ __. __

Appendix B – Example of a household flour information form to be completed by sentinel school students.

1. Student number: __ __ __

   (3-digit pre-coded from 001 – 100)

2. Date: __ __/ __ __ __ __ (MM/YYYY)

3. Household usually buys market flour __ (1= Yes; 2= No)

   If Yes:

   a. What is flour brand name? _____

b. Does sack carry fortification logo? __ (1= Yes; 2 = No; 3 = Don't know)

4. Household flour stored in: __ (1= original sack; 2= in household container)

(If both fortified and unfortified flour are marketed, it is possible for the two types of product to be mixed when stored in a household container. Such a household flour sample would yield a "false negative" or "false low" fortification quality)

Appendix C – Semi-quantitative spot test for iron as ferrous sulfate, ferrous fumarate, or electrolytic iron.

I. Reagents

Hydrochloric acid, HCl, 37% Merck 317
Hydrogen peroxide, H2O2, 30%, Merck 7209
Potassium thiocyanate, KSCN, Merck 5124 or 5125

II. Solutions

KSCN - 10%: Dissolve 10 g of KSCN in 100 ml distilled water.
HCl - 2M: To a 500 ml beaker, add 100 ml distilled water, then 17 ml concentrated HCl and, finally 83 ml distilled water.
H2O2 - 3%: Add 9 ml concentrated H2O2 (30%) to 81 ml distilled water.

Reagent 1

Immediately before using, mix equal amounts of 10% KSCN and 2M HCl. Mark the levels of 20 and 40 ml on a flask, using a pipette. Add 2M HCl up to the 1st mark and then add 10% KSCN up to the 2nd mark. This is reagent 1. Use within 1 day. Discard the remaining.

Reagent 2

3% H2O2. Discard remaining solution at the end of the day.

III. Materials

Watch glass
Droppers

IV. Procedure

1. Take a sample of 100 g of flour and place it on the watch glass. With the lower part of another watch glass, press on the flour sample so that it forms a flat surface.
2. Add 5 drops of reagent 1 with the dropper so that it covers an area of 4x4 cm (1.5x1.5 inches). Let stand for 15-30 seconds.
3. Add 5 drops of reagent 2 on the surface covered by reagent 1. Let stand for 1-2 minutes.

V. Interpretation

The appearance of red colored spots indicates the presence of iron. The number of spots is a broad estimation of the amount and homogeneity of iron in the sample. If a more accurate estimation is required, testing with known concentrations of iron (30, 60, and 90 ppm) is recommended in order to compare results of these samples with those of the flour being tested.

Appendix D – Semi-quantitative spot test for iron as Sodium Iron EDTA: Adaptation of the AACC 40-40 spot test.

Procedure

The protocol used is identical to that used for ferrous sulfate, ferrous fumarate, or electrolytic iron **with the exception of the use of Reagent 2** – the use of reagent 2 will produce a negative result even in the presence of NaFeEDTA – so follow steps 1 and 2 of part IV Procedure above and wait for 2 minutes

The appearance of red colored spots indicates the presence of NaFeEDTA

Note: As NaFeEDTA is added in significantly smaller quantities than other iron sources fewer spots appear; hence the larger test surface recommendation.

Appendix E – Example of a flour fortificant test log-sheet for sentinel school teachers.

Sentinel school name (or FORTIMAS assigned ID number) _____

Date: __ __/ __ __ __ __ (MM/YYYY)

Student Number	Flour Brand* (FORTIMAS assigned code)	Test Result 1 = Positive 2 = Negative
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_
_ _ _	_	_

* As indicated in each student's completed form submitted with the flour sample.

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