

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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1. Reports sales of fortified flour in local markets.
Maternal and Child Health Department and/or Health Management Information System Department	Public	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1. Advocacy.
Technical and donor agencies	Public/Civic	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> Prior to or within first month of the start of the mandatory fortification program. 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

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	<ol style="list-style-type: none"> Prior to or within first month of the start of the mandatory flour fortification. 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	<ol style="list-style-type: none"> Trained sentinel health facility staff collect serum samples. Biochemistry laboratory performs tests. 	<ol style="list-style-type: none"> Prior to or within first month of the start of the mandatory flour fortification. 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 test	Non-pregnant women of childbearing age	Mothers of children seen for well-child & immunization visits at sentinel health facilities	<ol style="list-style-type: none"> Trained sentinel health facility staff collect serum samples. Biochemistry laboratory performs tests. 	<ol style="list-style-type: none"> Prior to or within first month of the start of the mandatory flour fortification. Annually after ≥80% household coverage is sustained for at least 12 months. 	FORTIMAS data processing office	National Fortification Alliance



Photo: Philip Randall.

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	<ol style="list-style-type: none"> Prior to or within first month of the start of the flour fortification program. Annually 	National vital statistics agency or FORTIMAS data processing office	National Fortification Alliance

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.



Photo: David McKee.

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 data² 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/folate 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?	<ol style="list-style-type: none"> 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?	<ol style="list-style-type: none"> 1. Conduct iron spot tests on the following types of flour samples used for baking bread: <ul style="list-style-type: none"> - 3 to 4 typical blends of fortified and non-fortified flour; - 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?	<ol style="list-style-type: none"> 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?	<ol style="list-style-type: none"> 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?	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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: Philip Randal