

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 needed¹.

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.

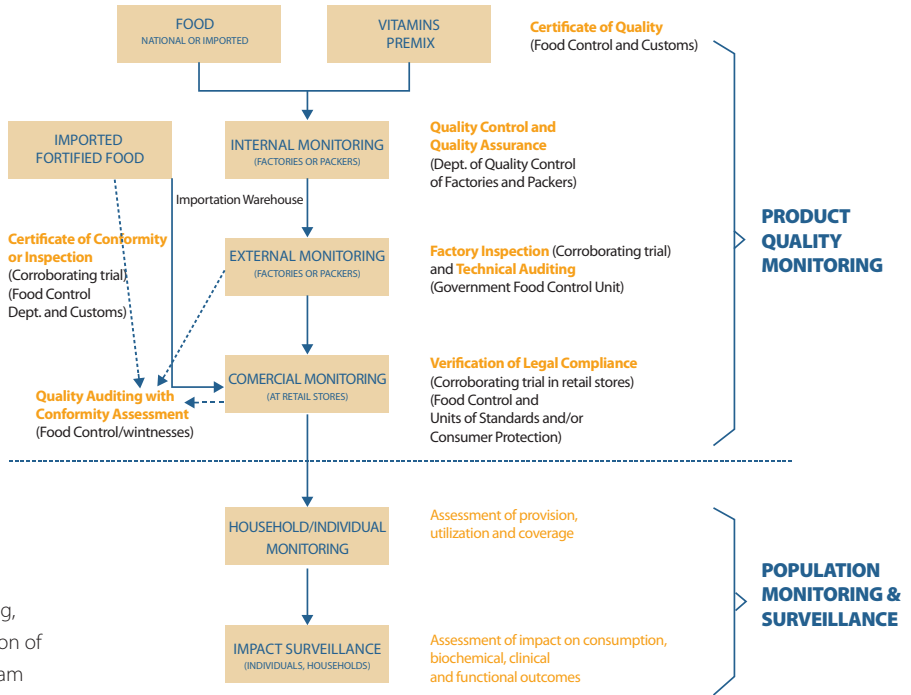


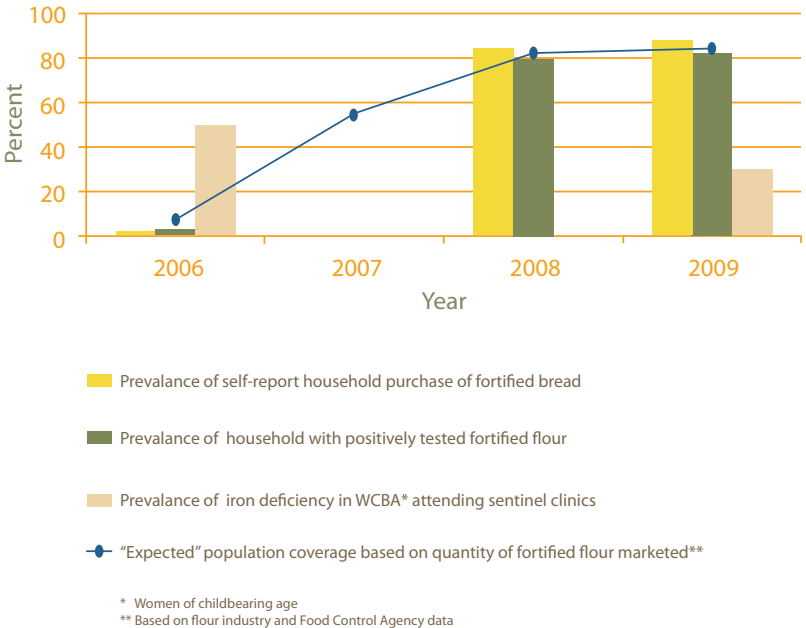
Figure 5.
Framework for monitoring,
surveillance and evaluation of
a food fortification program
(adapted from reference 2).

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 $\geq 80\%$ 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.

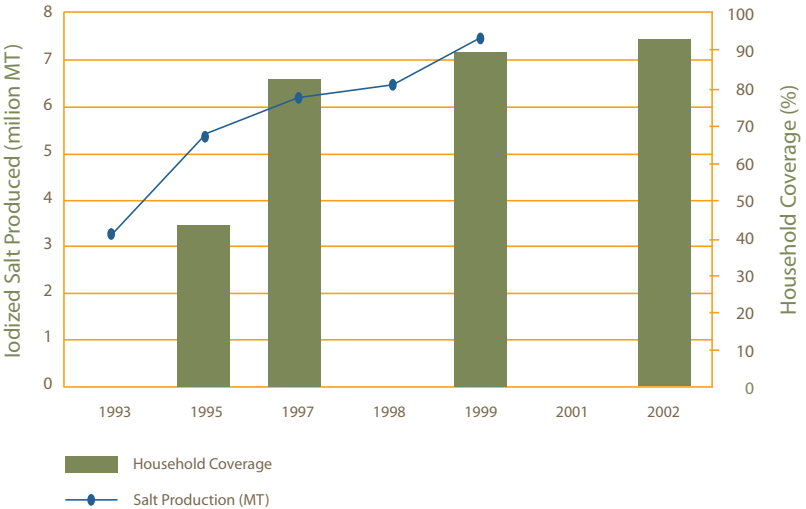


a. Data on “expected” population coverage of fortified flour (blue line), the “initial” household coverage of the product (yellow and green bars) and prevalence of iron deficiency in women of childbearing age (beige bars) are reported before the full-scale implementation of the fortification program 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 $\geq 80\%$ 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.

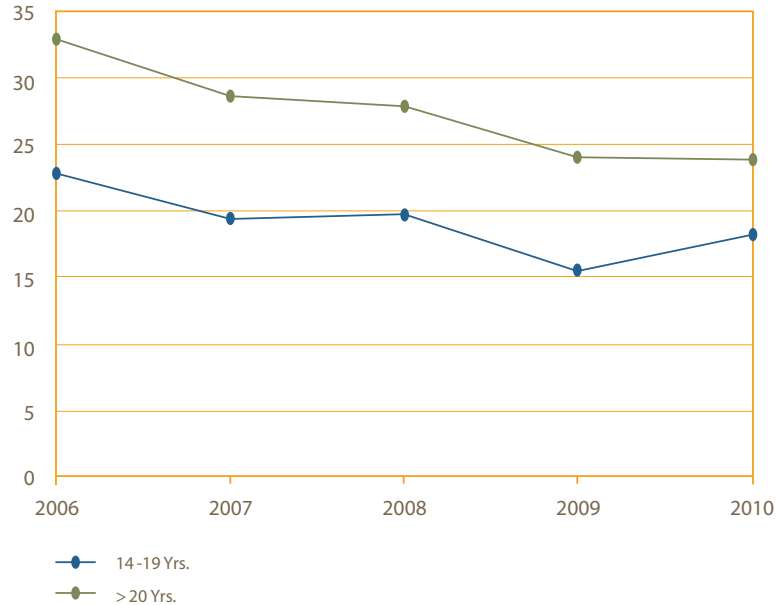
To give an example, one industrial mill in Kuwait produces about 75% of the low extraction flour consumed in the country (personal communication, Mr. Ebtihal Al Salem, Kuwait Flour Mills, April, 2011). That mill started mandatory fortification of the flour with electrolytic iron and folic acid in 2006 (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).



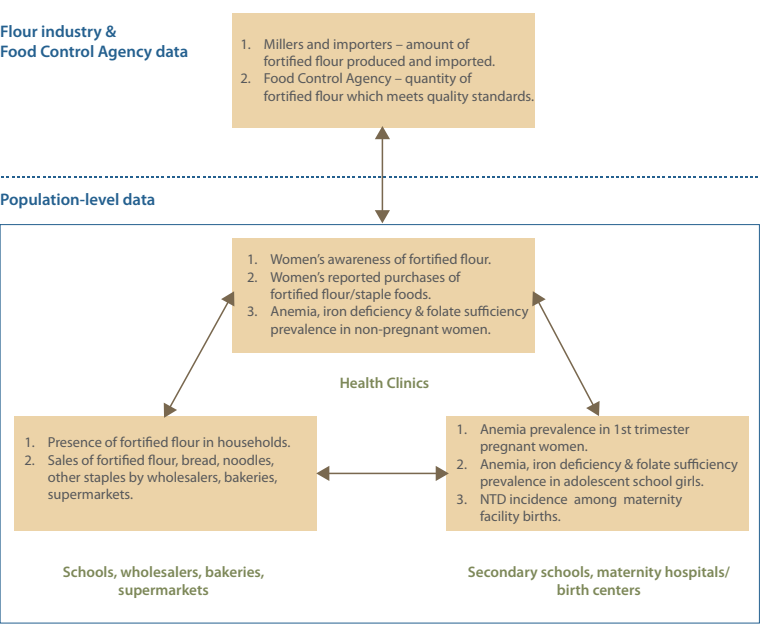
When there are opportunities to collect data on population coverage and impact of flour fortification through statistically representative population surveys, they should also be pursued. A few examples of such surveys are:

- 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 Toolkit².

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:

- 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.
- 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.
- Inform the program stakeholders and the population on the overall implementation and impact of flour fortification.

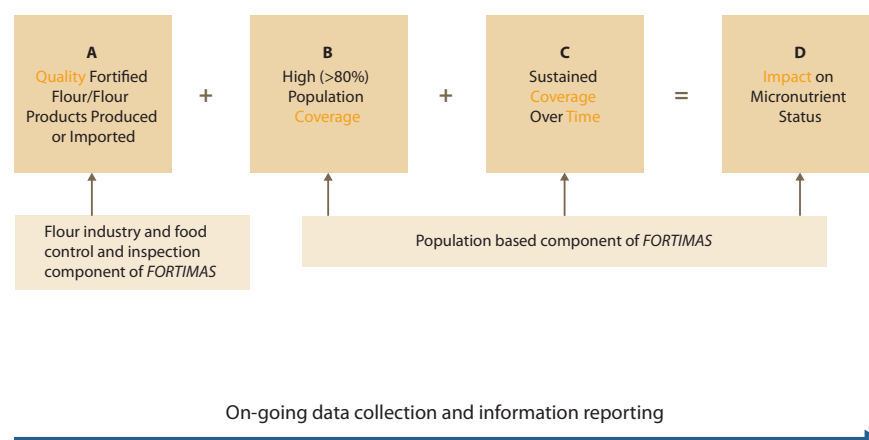
I. Sentinel Site and Purposive Data Collection and Convenience Sampling

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 “purposely” 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 homogeneous⁴ 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 same⁵. 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.