

CHAPTER 3

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

- I. Potential Indicators to Measure
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Sub-Areas of a Country in which to Track
the Progress of Flour Fortifications
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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.

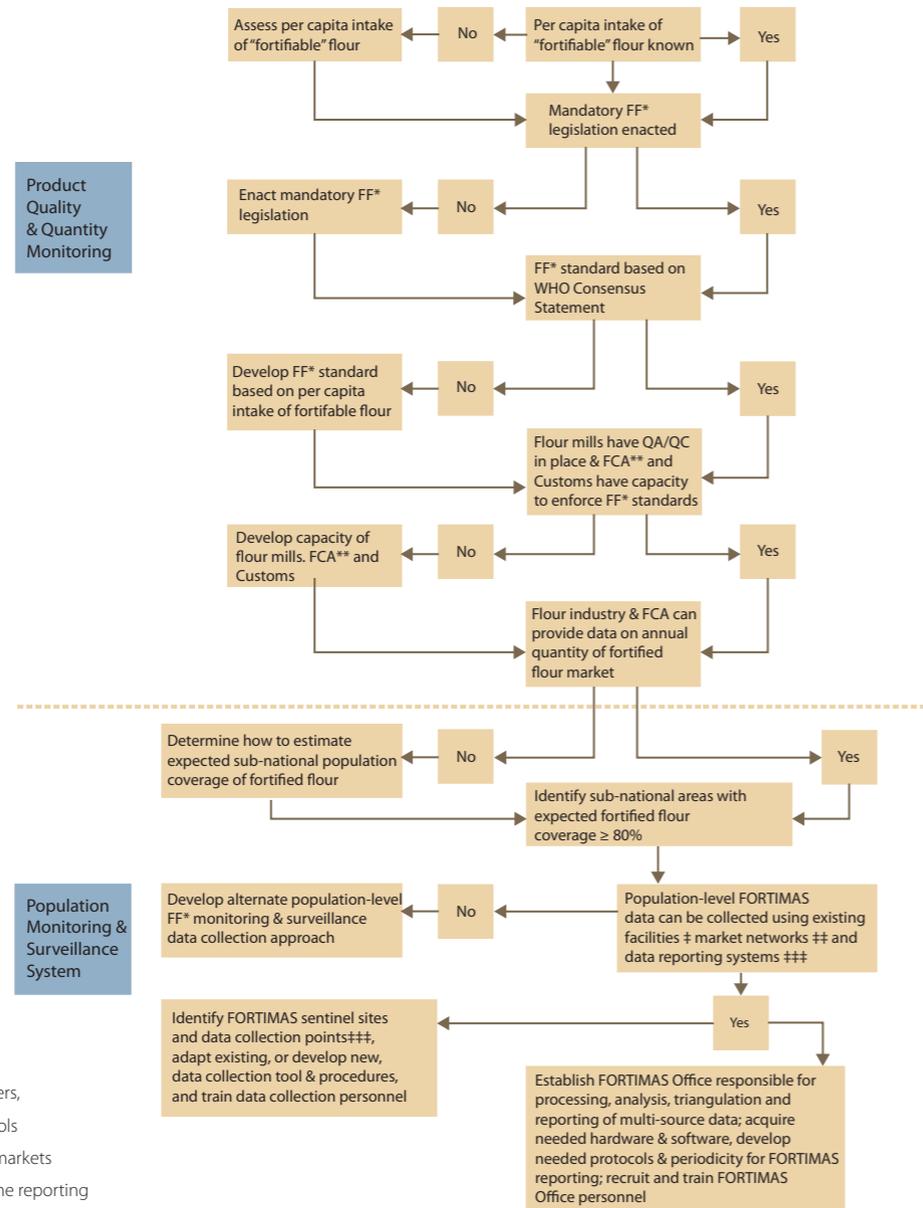


Table 3. Conditions needed for an effective flour fortification program.

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).	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 ⁱ .
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.ffnetwork.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 the Progress 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 (Million MT)	FF Marketed Annually (Million MT)	Expected Population Coverage of FF (%)	Prevalence 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 is 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 Initiative² (<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 System³.
- 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 indicator. 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:

- 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.
- 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.
- 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, 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 site⁵ 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 area⁶. 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 consent⁸, 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.

- 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.

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.

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:

- 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.
- 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:

- 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.
- 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