PAKISTAN FOOD FORTIFICATION SCOPING STUDY

Photo: Aga Khan University – Farheen Ayub Khan

Pakistan Food Fortification Study Team

APRIL 2014

Maximising the Quality of Scaling up Nutrition Programmes (MQSUN)

MQSUN aims to provide the Department for International Development (DFID) with technical services to improve the quality of nutrition-specific and nutrition-sensitive programmes. The project is resourced by a consortium of seven leading non-state organisations working on nutrition. The consortium is led by PATH.

The group is committed to:

- Expanding the evidence base on the causes of undernutrition;
- Enhancing skills and capacity to support scaling up of nutrition-specific and nutrition-sensitive programmes;
- Providing the best guidance available to support programme design, implementation, monitoring and evaluation;
- Increasing innovation in nutrition programmes;
- Knowledge-sharing to ensure lessons are learnt across DFID and beyond.

MQSUN partners are:

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Executive Summary

Findings from the 2011 National Nutritional Survey reveal that very little progress has been made with respect to micronutrient deficiencies among women and children in Pakistan, with the exception of gains in iodized salt use and large reductions in moderate to severe urinary iodine deficiency rates. One in five pregnant and lactating women and one in three children under the age of 5 were anemic due to iron deficiency in 2011. Night blindness affected 16% of pregnant women, and more than 50% of children were vitamin A deficient. About 40% of women and children were deficient in zinc, and 70% of pregnant women and 40% of children were deficient in vitamin D. Moreover, persistent high rates of stunting (44%) and wasting (15%) among children under 5 are an important reminder that this could be a major bottleneck in addressing child survival in Pakistan.

Food fortification is safe and cost-effective in the prevention of micronutrient deficiencies and has been widely practiced in developed countries for well over a century. Commissioned by the UK Department for International Development (DFID) Pakistan, the scoping study presented here was undertaken by an international team of consultants to investigate and compare options for food fortification initiatives in Pakistan. The study focused on three areas: the regulatory environment for food fortification, the private sector role, and potential agricultural solutions. Phase 1 of the study was a descriptive analysis to map the current landscape for food fortification, Phase 2 included the appraisal of selected options for fortification with respect to evidence on potential impact and feasibility of implementation, and Phase 3 included an economic analysis of these options.

Landscape analysis

The regulatory environment

Successful implementation of a sustainable food fortification programme requires a regulatory environment in which appropriate government legislation is enacted and systems exist through which compliance can be effectively monitored and enforced.

In Pakistan, fortification of edible oil was mandated by legislation at the federal level in 1965 and has been retained in the provincial food laws in all four provinces. No provincial legislation is in place for wheat flour fortification. Currently only Sindh legislates the compulsory iodization of salt, but Khyber Pakhtunkhwa and Balochistan both mandate salt iodization province-wide through amendments to the regulations that attend the provincial food laws, and the majority of districts in Punjab have implemented by-law amendments to the same effect.

Monitoring and enforcement frameworks for food quality and safety are outlined in the provincial food laws. Primary responsibility is assigned to the district-level representatives of the Provincial Health Department, or the new Punjab Food Authority in Punjab, but a range of other actors are involved in the monitoring and enforcement process.

In addition to the lack of legislation, other constraints on fortification monitoring and enforcement that were identified in the landscape analysis include:

- Limited quantity and technical capacity of food inspectors, and lack of standardized protocols for inspection and sample collection from manufacturers and markets;
- Limited quantity and analytical capacity of public sector and other accredited laboratories for testing food samples, particularly with respect to micronutrient characteristics of wheat flour and edible oil/ghee;
- Coordinating capacity for monitoring and enforcement activities is inconsistent and varies across districts and provinces, with additional lack of clarity on specific institutional roles in some areas;
- Inconsistent penalties for non-compliance that vary by jurisdiction, and fines may be less than the costs incurred for fortification.

Various potential actions for improving the regulatory environment for food fortification were identified, including continued advocacy for legislation standards, expanding and improving inspection and food sample collection capacity and laboratory analytical capacity, and investigating the barriers to effective prosecution for non-compliance.

The role of the private sector

Compulsory fortification of staple foods obliges private-sector food producers to adapt their manufacturing and quality control processes, requiring financial and technical resources. In the context of the privately owned wheat flour and edible oil/ghee industries in Pakistan, the barriers to implementing fortification cluster in two main areas at the level of the manufacturing unit are:

- Procurement of additional production inputs, including:
  - Fortificant premixes
  - Capital equipment
- Establishing sufficient internal quality control, including:
  - Equipment calibration and appropriate premix storage and dispensing
  - Internal analytical capacity for sample testing
  - Independent external laboratory analyses

A range of potential actions to address these barriers was identified, including detailed supply chain analyses, supporting procurement of premixes, equipment and plant-level lab consumables through subsidies or revolving funds, and investment in private-sector laboratories.

In addition to fortification in the wheat flour and edible oil/ghee industries, other private-sector areas in which fortification initiatives could be pursued include:

- Wheat flour fortification by small-scale *Chakki* millers
- Fortification of commercial complementary foods for infants and young children
- Fortification of dairy foods

Potential agricultural solutions

As alternatives or complementary to fortification of staple foods, various agricultural strategies could be pursued to improve the micronutrient profiles of staple crops, and potentially, the nutritional status of women and children in Pakistan. Biofortification through plant breeding techniques is one such strategy. The Ministry of National Food Security and Research is currently prioritizing the development, production and consumption of biofortified high-zinc wheat, and HarvestPlus has been developing and testing biofortified wheat seed in Pakistan since 2009 in collaboration with the National Agricultural Research Centre. There are currently three candidate varieties under development, with approval for the most advanced line expected in 2015.

With about 80% of the cultivated area in Pakistan deficient in zinc, the use of zinc-fortified fertilizer is another agricultural strategy for increasing the micronutrient content of staple crops, and potentially, the nutritional status of women and children. At present, some farmers in Pakistan use micronutrient fertilizers for fruit orchards and for rice crops, but there is a history of adulterated or fake fortified fertilizers being marketed in Pakistan, and this constrains uptake on a larger scale. In Punjab, a government task force has now been constituted to monitor manufacturing processes at fertilizer production facilities, including licensing, in-house laboratory analysis, and final product testing.

Appraisal of the selected options

Building on the preceding landscape analysis, four options were selected for appraisal with respect to the existing evidence of their effect on micronutrient status and the prospects for implementation and scale-up in Pakistan: 1) wheat flour fortification with iron, 2) edible oil/ghee fortification with vitamin A and D, 3) biofortification to address iron and zinc content of wheat, and 4) zinc-fortified fertilizers. Prospects for implementation and scale-up were considered in terms of capacity (e.g., regulatory mechanisms, infrastructure, partnerships and previous experience) and demand (e.g., existing demand or prospects for demand creation).

There is good evidence to suggest that wheat flour fortification can improve population iron status. Per capita wheat consumption in Pakistan is among the highest in the world, making wheat an ideal candidate staple for fortification, and previous in-country experience has already demonstrated that industrial wheat flour fortification at considerable scale is possible. However, legislation for wheat flour fortification is still not in place in any province, and monitoring and enforcement capacity is limited. In collaboration with the Government of Punjab, Global Alliance for Improved Nutrition (GAIN)-supported wheat flour fortification activities resumed in October 2013, with a renewed focus on legislation as well as on capacity development in quality assurance and mill-level quality control.

Strong programmatic evidence for the effect of fortifying staple foods with vitamin A comes from Central America, where sugar fortification has been implemented widely in several countries for several decades, and dramatic reductions in vitamin A deficiencies in children have been shown. The evidence for vitamin A-fortified oil is more mixed, however. Legislation for the mandatory fortification of edible oil/ghee with vitamin A has been in place for decades in all four provinces, but with very low industry compliance; the rest of the regulatory framework is lacking. However, rapid test technology for detecting vitamin A in oil has recently become available and could be incorporated into sample collection protocols, at least for initial screening by food inspectors. Prospects for scaling up edible oil/ghee fortification are improved by the fact that oil fortification is a technologically simple process requiring no additional industrial equipment. Also, because some edible oil/ghee producers in Pakistan already do fortify their products, there is some market intelligence available on the consumption characteristics of fortified oil/ghee, including consumers' sensitivity to price and their response to branding and marketing.

Much of the evidence on biofortification to date has focused on demonstrating the feasibility of breeding strategies, with further evidence now accumulating on the efficacy of biofortified crop consumption for improving micronutrient status. However, evidence for the effectiveness of biofortification is still very limited, and so far focused only on vitamin A-rich orange-fleshed sweet potato. It has been proposed that, once approved, the biofortified wheat seed be multiplied and marketed through private seed companies and the state-run Punjab Seed Corporation (PSC), thereby making use of already existing facilities and sales networks. HarvestPlus and its partners anticipate that, with the higher-yield characteristic and the 'invisibility' of the additional zinc, farmer uptake and consumer acceptance will both be high.

Field trials conducted across seven countries, including Pakistan, have shown that addition of zinc fertilizer to soil in combination with foliar application can increase zinc concentration in grains by 48%. However, no evidence appears to be available yet on the efficacy or effectiveness of zinc-fortified fertilizer for improving micronutrient status in humans. A pilot project has been recently proposed to test the application and effects of the use of fortified fertilizer on 4,000 acres of wheat fields owned by 2,000 farmers in Pakistan over four years, to provide empirical evidence for the effectiveness of increasing zinc levels in the body. Because quality fortified fertilizer has yet to be marketed reliably in Pakistan, the degree of acceptability and future uptake by farmers is unknown. Efforts underway in Punjab to improve market surveillance may restore some farmer confidence.

Economic analysis

For the economic appraisal of the four options, a counterfactual approach was used whereby the modeled benefits and costs of the interventions at target levels of coverage were compared with the modeled benefits and costs at estimated current levels of coverage. Benefits included the number of child and maternal lives saved and the future economic consequences from morbidity and/or mortality that were averted. At target levels of coverage, the estimated benefit:cost ratios were 7.2:1 for wheat flour fortification, 9.8:1 for edible oil/ghee fortification; 0.11:1 for biofortification, and 0.06:1 for zinc-fortified fertilizer.

Further to the counterfactual-based analyses of intervention cost-effectiveness, the projected costs of increasing fortification coverage to target levels over five and ten year periods were calculated for wheat flour and for edible oil/ghee. The estimated cost to scale up wheat flour fortification from the assumed current coverage of 0% to the target coverage of 85% in urban areas and 65% in rural areas was US$114.7 million over five years and $183.3 million over ten years. To scale up edible oil/ghee fortification from the assumed 20% current coverage to 85% coverage in urban areas and from 10% to 75% in rural areas, the estimated cost was $16.6 million over five years and $26.8 million over ten years.

Appraisal summary

To quantitatively summarize the overall appraisal, scores were assigned to each of the four options with respect to the existing evidence of the effect of the intervention on improving micronutrient status, the prospects for its implementation and scale-up of Pakistan, and the estimate of its cost-effectiveness. Relatively, wheat flour fortification scored strongly, edible oil/ghee fortification scored moderately, and both zinc biofortification of wheat and zinc-fortified fertilizer scored weakly.

Conclusions

Finally, these analyses of options for scaling up fortification are a step towards a holistic national nutrition strategy targeting major groups at risk, especially women of reproductive age and young infants and children. Our findings clearly support the utilization of food fortification strategies at scale, which could build on the recent success of the iodized salt programme. Given the widespread prevalence in Pakistan of deficiencies in iron and in vitamins A and D, food fortification strategies offer a tangible option for delivering these micronutrients on a large scale. Zinc deficiency is also highly prevalent in Pakistan, but for zinc, agriculture options are a more feasible strategy than alternative supplementation options, but these still require further evaluative work. However, overall success would also require closer attention to strategies for improving infant and young child feeding as well as quality of complementary foods for young children.

1.0 Background

1.1 Undernutrition and micronutrient deficiencies in Pakistan

To set the context for the discussion of potential opportunities for food fortification in Pakistan in the following sections of this report, this section briefly presents the trends and current status of key indicators on undernutrition and micronutrient deficiencies in women and children in Pakistan. Iron deficiency anemia and deficiencies of vitamin A, iodine, zinc and vitamin D are highlighted, all of which are directly relevant to food fortification.

1.1.1 Nutritional status of children under 5 years

Standard indicators of malnutrition in children include stunting (low length/height-for-age), wasting (low weight-for-height) and underweight (low weight-for-age). Tables 1 and 2 present the trends in these indicators over time in Pakistan, and by urban/rural location and province in 2011.

Table 1. Prevalence of malnutrition in children <5 years, 1965-2011

	1965	1977	1985-7	1990-4	2001	2011
Stunted	49.0%	43.3%	41.8%	36.3%	41.6%	43.7%
Wasted	11.0%	8.6%	10.8%	11.8%	14.9%	15.1%
Underweight	-	53.3%	47.9%	40.1%	31.5%	31.5%

Table 2. Prevalence of malnutrition in children <5 years by province and age, 2011

	Pakistan		Punjab	Sindh	KP	Balochistan
	Urban	**Rural**				
Stunted	36.9%	46.3%	39.2%	49.8%	47.8%	52.2%
Wasted	12.7%	16.1%	13.7%	17.5%	17.3%	16.1%
Underweight	26.6%	33.3%	29.8%	40.5%	24.1%	39.6%
	0-6m	**7-12m**	**13-24m**	**25-36m**	**37-48m**	**49-60m**
Stunted	23.8%	30.3%	47.9%	54.7%	52.3%	38.4%
Wasted	26.3%	23.2%	15.8%	14.5%	11.2%	13.9%
Underweight	29.0%	33.3%	32.1%	35.3%	28.6%	27.1%

While the prevalence of underweight among children in Pakistan has generally declined over the past 45 years, trends in the other indices are less encouraging, with stunting and wasting having both increased over the past decade. Approximately 44% of children are now stunted and about 15% are wasted, both very high levels of malnutrition with respect to global norms.

1.1.2 Nutritional status of women aged 15-49 years

Standard indicators of malnutrition in adults include body mass index (BMI), with normal values ranging from 18 to 25. Trends in BMI among women of reproductive age in Pakistan are presented in Table 3, showing an increase in average BMI from 21 in 2001 to 23 by 2011. This shift reflects a decrease in the proportion of women underweight as well as an increase in the proportion women overweight, including a doubling of the proportion of women classified as obese (BMI ≥30) since 2001.

Table 3. BMI distribution and average BMI among women 15-49 years

BMI	2001	2011
< 17	13.9%	7.5%
17 > 20	33.7%	23.9%
20 > 25	35.5%	39.8%
25 > 30	12.2%	19.3%
≥ 30	4.7%	9.5%
Average BMI	20.9	23.0

1.1.3 Iron deficiency anemia

Iron deficiency anemia prevalence among women in 2011 is presented in Figure 1. Nationally, about 20% of women were anemic due to iron deficiency, with less than 1% having severe iron deficiency anemia. There was little difference in prevalence between urban and rural areas. Khyber Pakhtunkhwa had the lowest prevalence of iron deficiency anemia among women at 7%, followed by Balochistan at 15%, and prevalence was highest in Sindh province at about 23%.

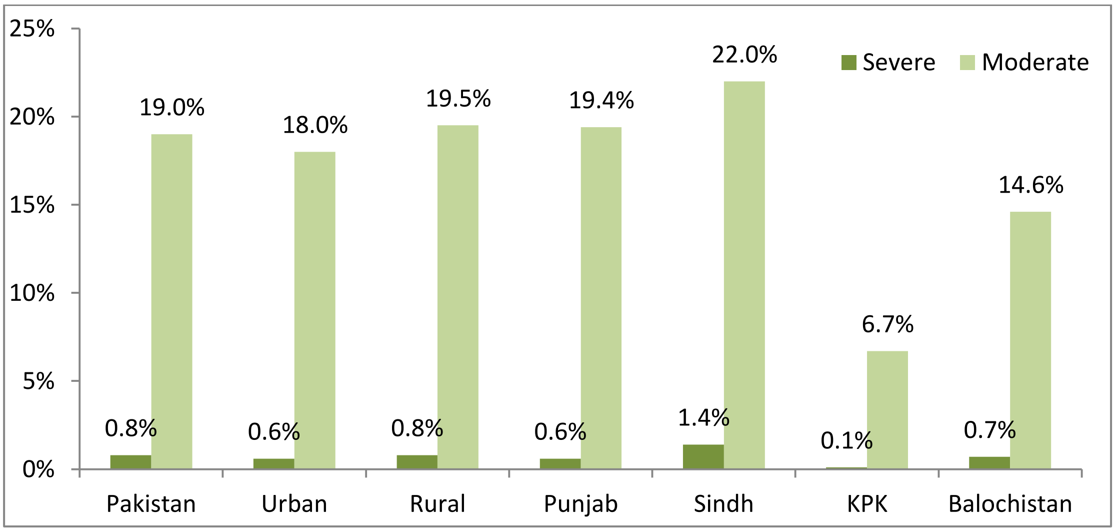

Figure 1. Iron deficiency anemia prevalence among women, 2011

Approximately one-third of all children under the age of 5 in Pakistan were anemic due to iron deficiency in 2011, with about 2% having severe iron deficiency anemia (Figure 2). As among women, there was little difference between urban and rural areas in iron deficiency anemia prevalence among children. Prevalence was lowest in Khyber Pakhtunkhwa (14%) and Balochistan (19%), and highest in Punjab province (36%).

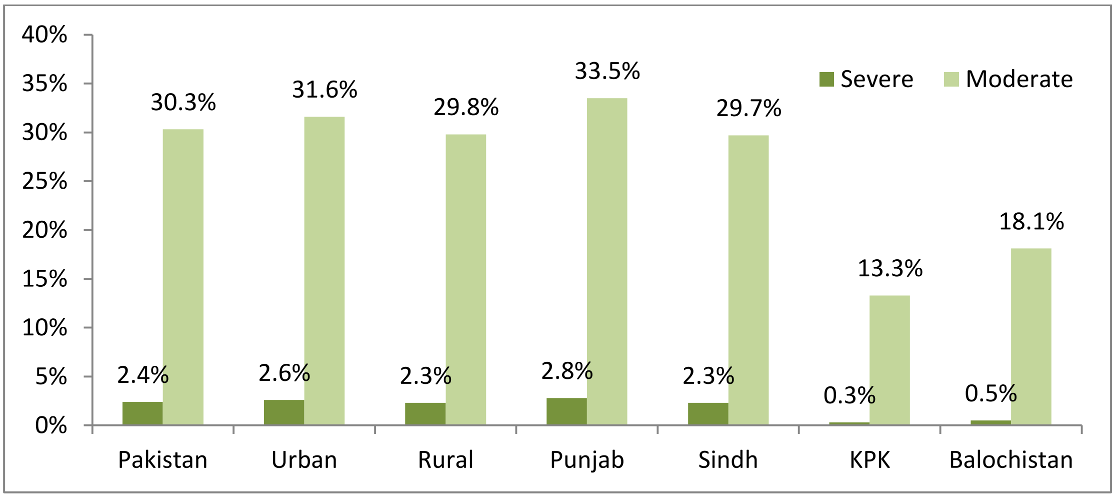

Figure 2. Iron deficiency anemia prevalence among children under 5 years, 2011

1.1.4 Vitamin A deficiency

Night blindness is a clinical sign of vitamin A deficiency. Trends in the prevalence of night blindness among pregnant women are presented in Figure 3, nationally and by urban/rural areas, and further stratified by current and last pregnancy. Nationally and in all strata considered, the prevalence of night blindness increased between 2001 and 2011.

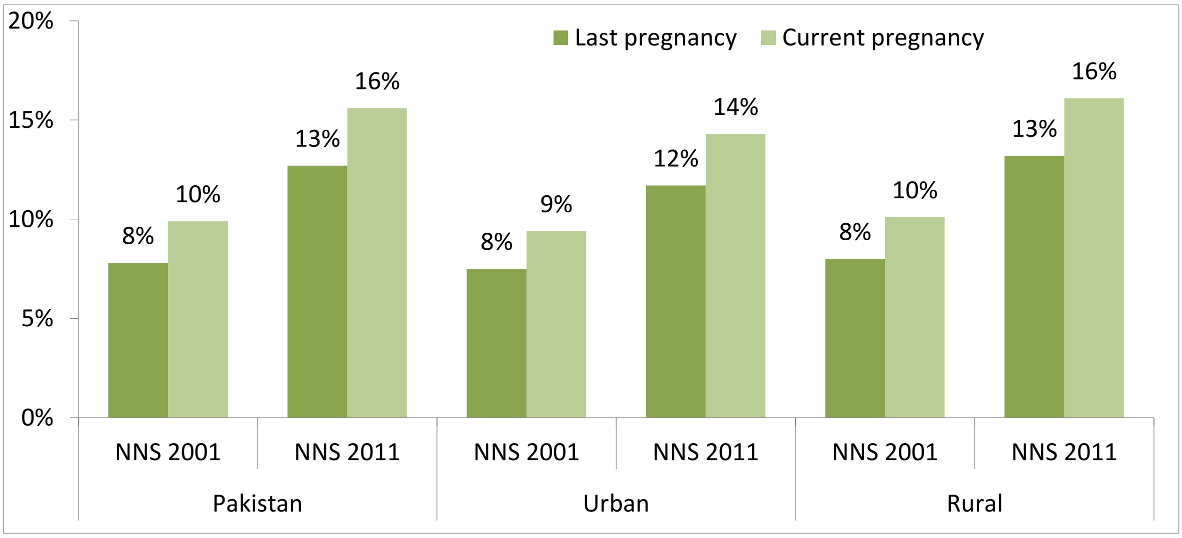

Figure 3. Prevalence of night blindness among pregnant women

Among children under 5, prevalence of vitamin A deficiency in 2011 was four times as high as it was a decade earlier, with one-third of all children moderately deficient in 2011 and about 20% severely deficient (Figure 4). This national trend was similar in both urban and rural areas.

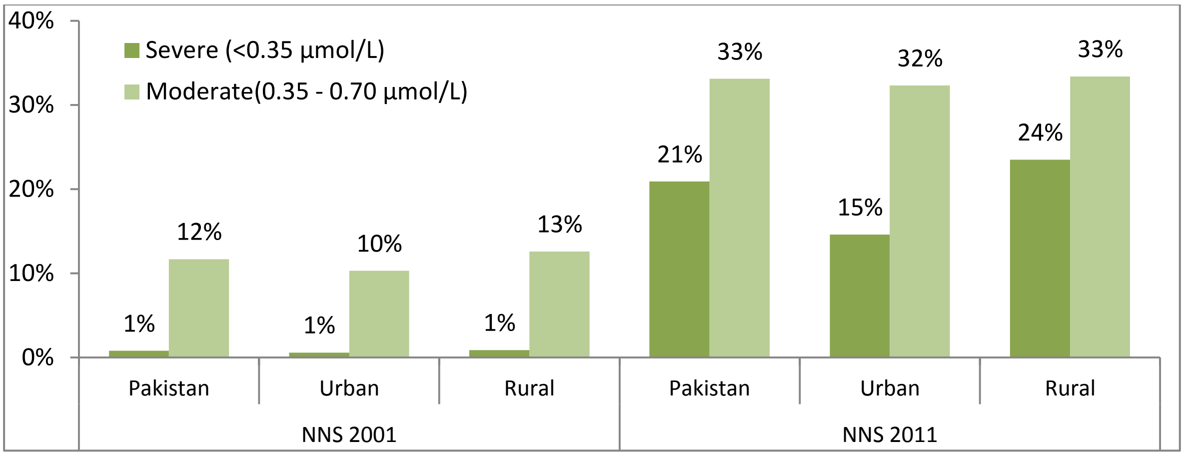

Figure 4. Vitamin A deficiency among children under 5 years

1.1.5 Iodine deficiency

Trends in the prevalence of clinical and biochemical indicators of iodine deficiency are presented in Table 4, for women and school-aged children, and stratified by severity of biochemical iodine deficiency (determined from urinary iodine excretion). Very large reductions in both clinical and biochemical indicators of iodine deficiency appear to have been achieved over the past decade, with maternal goiter prevalence declining from 21% in 2001 to 3% 2011 and biochemical iodine deficiency declining from 57% to 18% and from 40% to 12% in mothers and school-aged children, respectively.

Table 4. Prevalence of goiter and biochemical iodine deficiency , 2011

	Clinical Goiter		**Biochemical Iodine Deficiency**			
	2001	**2011**	**2001**		**2011**	
			Moderate	*Severe*	*Moderate*	*Severe*
Children 6-12 years	6.5%	-	17.0%	22.9%	10.0%	2.1%
Mothers 15-49 years	21.2%	2.9%	20.0%	36.5%	14.2%	3.9%

1.1.6 Zinc deficiency

There has been no improvement in zinc deficiency over the past decade, with prevalence actually increasing slightly from 41% in 2001 to 42% in 2011 among non-pregnant women and from 37% to 39% among children under 5 (Figure 5).

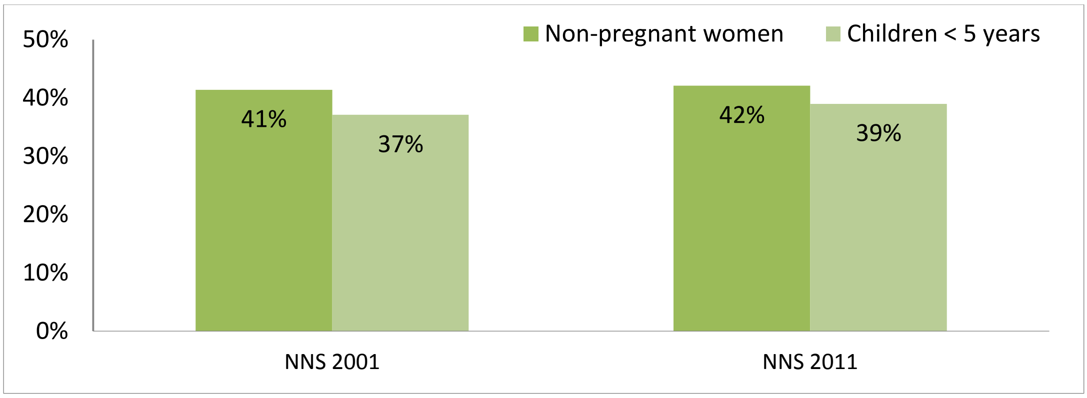

Figure 5. Prevalence of zinc deficiency among non-pregnant women and children under 5 years

1.1.7 Vitamin D deficiency

Vitamin D deficiency among pregnant women in 2011 is presented in Figure 6. Nearly 70% of pregnant women were vitamin D deficient in Pakistan in 2011, with about one-quarter being severely deficient. Prevalence was slightly higher in urban compared to rural areas, and was considerably lower in Balochistan compared to the other provinces.

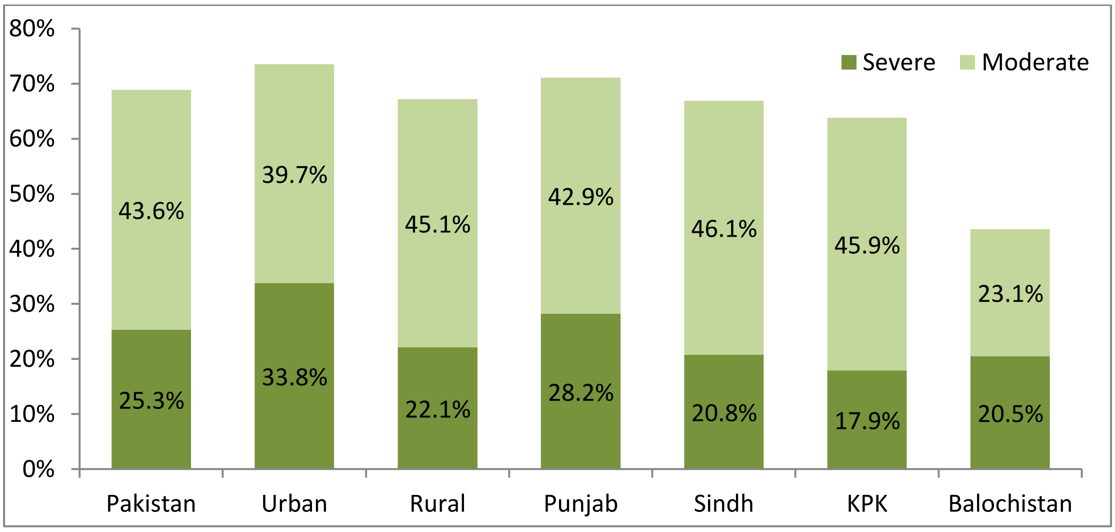

Figure 6. Prevalence of Vitamin D deficiency among pregnant women, 2011

About 40% of all children under 5 in Pakistan were vitamin D deficient in 2011, including about 9% with severe deficiency (Figure 7). As among women, prevalence was higher in urban compared to rural areas. Balochistan had the highest prevalence of child vitamin D (43%), while Khyber Pakhtunkhwa had the lowest (29%).

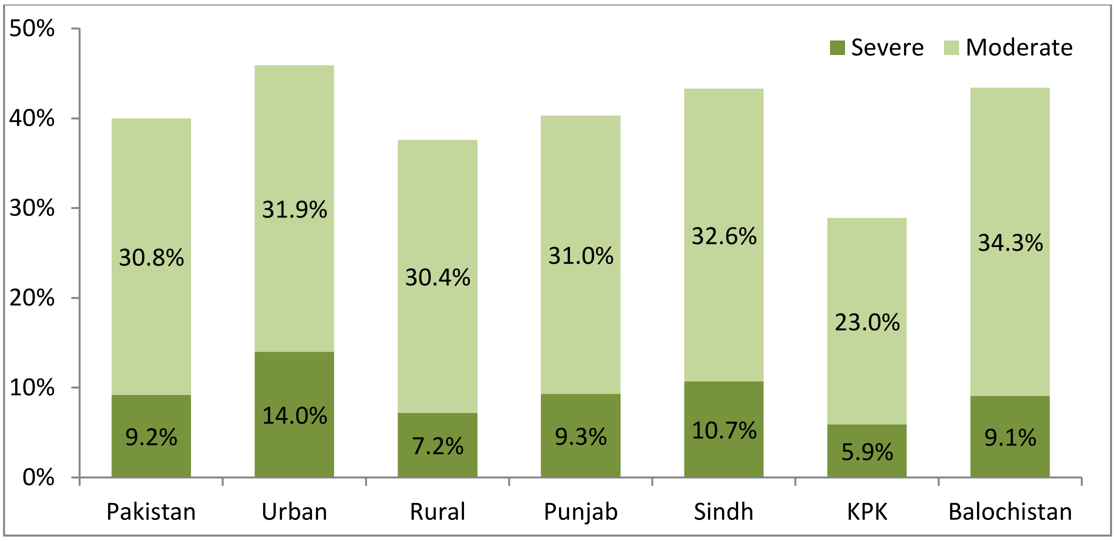

Figure 7. Prevalence of Vitamin D deficiency among children under 5 years, 2011

Overall, very little progress has been made with respect to micronutrient deficiencies among women and children in Pakistan, with the exception of gains in iodized salt use and large reductions in iodine deficiency rates. One in five pregnant and lactating women and one in three children under 5 were anemic due to iron deficiency in 2011. Night blindness affected 16% of pregnant women and more than 50% of children were vitamin A deficient. About 40% of women and children were deficient in zinc on biochemical analysis, while 70% of pregnant women and 40% of children were deficient in vitamin D. Moreover, persistent high rates of stunting and wasting among children under 5 are an important reminder that this could be a major bottleneck in addressing child survival in Pakistan.

1.2 The role of fortification globally and in the context of Pakistan

Food fortification is safe and cost-effective in the prevention of micronutrient deficiencies and has been widely practiced in developed countries for well over a century. Foods may be fortified at three levels: mass or universal, targeted, and at household level. Mass or universal fortification, ideally legislated and mandatory for industries, has the potential of producing fortified foods and food products that are widely consumed by the general population (e.g., salt iodization and wheat flour fortification with iron and folate). This is by far the most cost-effective nutrition intervention, particularly when produced by medium- to large-scale industries. Targeted fortification (e.g., nutrient-fortified complementary foods for children 6-24 months) is important for nutritionally vulnerable population subgroups such as infants, young children, women of reproductive age, and populations in emergency situations whose nutrient intake is insufficient through available diets. Targeted fortification is also effective in resource-poor settings where family foods lack animal sources that are typically necessary to meet the nutrient requirements of young children. As in other countries in the region, such as India, the traditional food vehicles used for fortification in Pakistan include wheat flour, table salt and vegetable oils/ghee.

Biofortification of food crops (enhancing micronutrient content using plant breeding techniques) is an alternative to more common fortification interventions and is rapidly advancing in technology with considerable success, particularly with regard to increasing iron, provitamin A, zinc, and folate contents in staple foods. Given the large agricultural sector in Pakistan and its robust agriculture research programme dating back over half a century, there is much interest in biofortification as well as micronutrient-fortified fertilizers.

2.0 The regulatory environment for food fortification in Pakistan

Successful implementation of a sustainable food fortification programme requires a regulatory environment in which appropriate government legislation is enacted and systems through which compliance can be effectively monitored and enforced.

In this section, we first describe the current status of legislation in Pakistan relevant for food fortification and the associated monitoring and enforcement mechanisms currently in place. We then identify existing barriers to effective regulation for food fortification in Pakistan and draw lessons for success from previous fortification experience. Finally, this section identifies activities and processes through which a more conducive regulatory environment for food fortification in Pakistan could be pursued.

2.1 Legislation

Pure Food Laws and national standards

Legislation on food quality and safety in Pakistan comprises a series of ordinances and acts adopted and amended over time, with concomitant rules defining the procedures by which the laws are to be implemented, monitored and enforced. In each province, current food quality and safety law is derived from the West Pakistan Pure Food Ordinance of 1960, its amendment Act in 1963, and the associated Rules promulgated in 1965. These federal instruments were subsequently adopted and enacted as provincial legislation and have since been amended further by provincial governments variously. In Punjab, the Pure Food Ordinance of 1965 was fully repealed and replaced by the Punjab Food Authority Act in 2011, along with new Punjab Pure Food Rules.

In all provinces, the existing food quality and safety laws focus on preventing the adulteration of food items across a range of categories, including dairy products, edible oils and fat products, beverages, food grains and cereals, spices and condiments, and fruits and vegetables. Rules define individual food items and stipulate their mandatory, allowable or proscribed characteristics, including the quantity and nature of additives and preservatives. Where applicable, they also specify regulations on labeling, packing and storage. Technical regulations set out in the Pure Food Rules may, but not necessarily, reflect national standards notified by the federal Pakistan Standards and Quality Control Authority (PSQCA).

Established in 2000 under the Pakistan Standards and Quality Control Act of 1996, the PSQCA is mandated to formulate, promote and support compliance with national standard specifications in various industrial and service areas, including agriculture and food. With respect to standards relevant for the fortification of staple foods, the PSQCA has issued Pakistan Standard Specifications for fortified wheat flour, for edible oils and ghee (in which the addition of vitamin A is specified for all products), and for iodized salt.

2.1.1 Current status of legislation on the fortification of wheat flour

There is currently no provincial legislation in place for the mandatory fortification of wheat flour. A national standard specification has been developed, distinguishing fortified flour from regular flour by the addition of one or more of vitamins or minerals: calcium carbonate, iron, thiamine, riboflavin and niacin. Folic acid is not listed. A permissible range for the addition of calcium carbonate is given, but no further specification on fortification levels is included.

2.1.2 Current status of legislation on the fortification of edible oil/ghee

The fortification of edible oils and ghee with vitamin A was mandated under the West Pakistan Pure Food Rules of 1965 and this provision has been retained in the Pure Food Rules in all provinces. The current Pakistan Standard Specification requires the addition of 33,000 international units of vitamin A per kilogram of finished product, and this national standard is reflected across the provincial Pure Food Rules.

2.1.3 Current status of legislation on salt iodization

The provincial government of Sindh passed the Compulsory Iodization of Salt Act in 2013, prohibiting the manufacture, processing or import of edible salt with an iodine content less than 30 parts per million (ppm). This is consistent with the national standard for iodized salt, which specifies a minimum iodine content of 30ppm at the manufacture level and 15ppm at the retail level. There is still no provincial legislation for mandatory salt iodization in place in Punjab, Khyber Pakhtunkhwa or Bolochistan (Table 5). However, Khyber Pakhtunkhwa and Balochistan both mandate salt iodization province-wide through amendments to their provincial Pure Food Rules, and in Punjab, district by-law amendments to the provincial Pure Food Rules have made iodization mandatory in the majority of districts.

Table 5. Current status of provincial legislation and national standards development for fortified staple foods in Pakistan

	Wheat flour	Edible oil/ghee	Salt
Provincial legislation in place?			
Punjab	No	Yes	No
Sindh	No	Yes	Yes
Khyber Pakhtunkhwa	No	Yes	No
Balochistan	No	Yes	No
National standard in place?	Yes	Yes	Yes

Advocacy for further amendments to the provincial Pure Food Rules is ongoing in Punjab, not only for salt iodization, but also aiming to mandate fortification of wheat flour with iron and folic acid, and fortification of edible oil/ghee with vitamins A and D.

2.2 Monitoring and enforcement framework

Role of the Provincial Health Department

A monitoring and enforcement framework for food quality and safety is outlined in the Punjab Food Authority Act 2011 and in the Pure Food Ordinance in other provinces. Responsibility for enforcement of the pure food laws is assigned to the representative of the Provincial Health Department in each district, the Executive District Officer (EDO) Health. District Health Officers and other local functionaries, where needed, are appointed by the EDO Health as inspectors and are empowered to enter and inspect any premises in which food items are manufactured, processed or sold, and to collect samples for laboratory analysis by a Public Analyst.

The Public Analyst produces a certificate documenting the analytical results and an opinion on conformity with the standards prescribed under the pure food laws. This certificate may then be used as evidence for legal prosecution against the manufacturer, retailer, or other source from which the sample was obtained. Penalties for contravention are also outlined in the pure food laws, including ranges for fines and imprisonment terms.

The operationalization of this legislated monitoring and enforcement framework varies by district and province. In districts with limited Health Department personnel, the EDO Health may draw human resource support from sub-district authorities. The Tehsil/Taluka Municipal Administration (TMA) does not have a legislated role in the enforcement of food quality and safety, but TMA officers may be temporarily appointed as food inspectors by authority of the EDO Health.

In Punjab, a new cadre of food inspectors has been established to include functionaries outside of the Health Department, appointed by the new Punjab Food Authority (PFA) established in 2011. The EDO Health, however, currently retains responsibility for enforcement of food quality in most jurisdictions in Punjab as the organizational structure and enforcement mechanisms of the PFA are being rolled out across the province in stages, first to major urban centres.

Functional Public Analyst Laboratories of the Provincial Health Department are currently established at Lahore and Multan (Punjab), Hyderabad (Sindh), and Peshawar (Khyber Pakhtunkhwa). In contexts in which access to a Public Analyst Laboratory is constrained, food samples collected by inspectors may be sent to other public-sector laboratories or to accredited private-sector laboratories authorized by the EDO Health to act in the capacity of Public Analyst. In Punjab, Public Analyst Laboratories may fall under the jurisdiction of the Punjab Food Authority in future, rather than the Provincial Health Department. However, technical capacities for micronutrient analyses in the public-sector laboratories remain limited. In particular, despite the existence of legislation supporting vitamin A fortification of oils, there is virtually no capacity for high-performance liquid chromatography (HPLC) analysis of food and fluid samples for this analyte or carotenoids in public-sector laboratories. Some capacity exists in agriculture and industrial laboratories (e.g., PCSIR laboratories), but to date has not been utilized for this purpose. However, rapid test technology for detecting vitamin A in edible oil is now available (e.g., Bioanalyt's iCheck™ CHROMA test kit) and could be incorporated into sample collection protocols, at least for initial screening.

Role of the Provincial Food Department

Although it has no legal role in regulating food quality and safety, the Food Department in each province is involved in monitoring the quality of wheat flour. The primary role of the Food Department is to manage government procurement and storage of wheat grain, and its subsequent release to industrial flour millers via a quota system. Through its standard operating procedures and network of specialist laboratories, it also collects and conducts analyses on grain and flour samples, profiling grain characteristics during the procurement process and testing flour for compliance with standards, particularly with respect to moisture content.

Role of the Pakistan Standards and Quality Control Authority

In addition to developing and promoting national standards, the PSQCA is authorized to inspect and analyze samples for compliance with standards designated as mandatory. Compliance with the majority of the 15,000 national standards currently in place is voluntary, but those cited in legislation are compulsory.

Other institutions supporting monitoring and enforcement

Several other public-sector institutions and agencies support the monitoring and enforcement of food quality and safety in Pakistan, including the following:

- ***Pakistan Council for Scientific and Industrial Research***: primarily mandated to provide scientific support to industry, but also a *Focal Institution* for investigating and resolving disputes on quality and authenticity of raw and finished foodstuffs and drugs.
- ***National Institute of Health***: involved in public health-related activities such as diagnostic services, research and production of biological vaccines, but also a *Reference Laboratory* for analyzing iron and folic acid content in wheat flour samples, as well as a *Public Analyst Laboratory* for the Islamabad Capital Territory. The laboratory has undertaken some food analysis in the past for vitamin A content using the older titration method.
- ***Nutrition Research Laboratory, Aga Khan University***: a *Focal Institution* for clinical analysis of micronutrients in blood serum which is the only national laboratory certified by the US Centers for Disease Control and Prevention (CDC) for micronutrient analyses and undertook key micronutrient analyses for the National Nutrition Surveys in 2001 and 2011. The Aga Khan University laboratory

also evaluated ghee and oil samples for vitamin A by HPLC in 2001, the only such analysis to date in Pakistan.

- ***National Institute of Food Science and Technology, University of Agriculture***: a *Focal Accredited Laboratory* for resolving issues related to foodstuff purity in accordance with the hazard analysis and critical control points (HACCP) approach to food safety and other national standards.
- Some capacities for fortified food sample analysis exist in a few other university departments of food sciences and dietetics (e.g., University of Karachi), but these have not been utilized for this purpose at any scale.

2.3 Critical success criteria for effective regulation of food fortification

As highlighted in the 2006 World Health Organization (WHO)/Food and Agriculture Organization (FAO) guidelines on food fortification, an effective regulatory monitoring system for food fortification requires internal, external and commercial monitoring, underscored by appropriate legislation. Efforts to mandate fortification of wheat flour and salt are underway in Punjab, salt iodization is already mandatory in other provinces, and edible oil/ghee fortification is compulsory in all provinces. Additionally, a framework incorporating internal, external and commercial monitoring is currently in place in all provinces, along with judicial enforcement mechanisms.

However, existing constraints within each regulatory component have implications for current food quality and safety assurance and as well as for effective implementation of future food fortification programmes.

2.3.1 Existing constraints on effective regulation

Through document review and stakeholder interviews, five key constraints on monitoring and enforcement have been identified:

1. Lack of legislation for mandatory wheat flour fortification;
2. Limited quantity and technical capacity of food inspectors, and lack of standardized protocols for inspection and sample collection from manufacturers and markets;
3. Limited quantity and analytical capacity of public sector and other accredited laboratories for testing food samples, particularly with respect to micronutrient characteristics of wheat flour and edible oil/ghee;
4. Coordinating capacity for monitoring and enforcement activities is inconsistent and varies across districts and provinces, with additional lack of clarity on specific institutional roles in some areas (especially in Punjab, since promulgation of the Punjab Food Authority Act in 2011);
5. Inconsistent penalties for non-compliance that vary by jurisdiction and fines may be less than the costs incurred for fortification.

2.3.2 Regulatory lessons learned from previous fortification experience in Pakistan

Guidance in overcoming some of the existing constraints on effective regulation of food fortification may be drawn from the ongoing, and largely successful, Universal Salt Iodization (USI) programme in Pakistan as well as from previous country experience with wheat flour fortification.

- *Universal Salt Iodization Programme*

With initial support from the Micronutrient Initiative (MI) and further support from the World Food Programme (WFP), the United Nations Children's Fund (UNICEF), and GAIN, the USI programme was initiated in 2005, building on earlier programmes in Pakistan to prevent and control iodine deficiency disorders (IDD). A recent overview of the challenges faced and progress made by the USI programme suggests that advocacy with policymakers for iodization legislation was important in the programme's success, with technical and lobbying support from implementing partners initially enabling by-law amendments to the Pure Food Rules at the district level (Masuood, 2013). Ongoing training of inspectors for monitoring and quality control, the appointment of District Focal Persons for the programme, and the convening of IDD Control Committees at district and provincial levels to oversee monitoring activities have also been key components. Monitoring capacity has been further strengthened by establishing a dedicated quality control laboratory for quantitative analysis of iodine content in every district. Nonetheless, entrenching a truly effective and sustainable regulatory system for salt iodization remains a significant challenge for the USI programme. The extent and intensity of the USI programme activities that were needed to develop the regulatory system to its current level of effectiveness should inform future programming for wheat flour and edible oil/ghee fortification.

- *National Wheat Flour Fortification Programme*

The National Wheat Flour Fortification Programme (NWFFP) was launched in 2005, with funding support from GAIN, technical support from MI, and substantial industry commitment from the Pakistan Flour Mills Association (PFMA). By the time the NWFFP was suspended in 2010, about 125 flour mills had started fortifying flour, mostly with mill-purchased microfeeders and GAIN-subsidized premix. Programme operations were suspended with the dissolution of the federal Ministry of Health, the legal entity to which GAIN provided support, as a consequence of the 18th Constitutional Amendment in April 2010 that devolved multiple federal ministries to provincial governments.

A key lesson learned from the NWFFP with respect to improving the regulatory environment for food fortification was on the importance of legislation to mandate fortification. With support from NWFFP advocacy initiatives, a national standard specification on fortified wheat flour was developed and notified by the PSQCA in 2008, but no national legislation had been enacted by time of devolution and the programme's suspension. In a 2009 commissioned evaluation report on the NWFFP (Zafar, 2009), the crucial role of legislation for ensuring the future success of wheat flour fortification initiatives in Pakistan was strongly emphasized, highlighting its dual function in compelling millers to fortify their wheat flour and in providing the legal framework within which quality assurance standards are enforceable. The evaluation report includes recommendations to pursue provincial legislation as a primary aim, but also to advocate in the interim for amendments to existing Pure Food Rules by order of provincial chief ministers, or by orders at the district or municipal level as has been done in the USI programme.

In collaboration with the Government of Punjab, GAIN-supported wheat flour fortification activities resumed in October 2013, with a renewed focus on legislation as well as on capacity development in quality assurance and mill-level quality control.

2.4 Strategies for improving the regulatory environment for food fortification

The preceding landscape mapping and analysis of the regulatory environment for food fortification in Pakistan highlights the legislative and monitoring and enforcement domains in which further action to improve the regulatory environment could be pursued. We present a range of potential actions in Table 6.

Table 6. Potential actions to improve the regulatory environment for food fortification in Pakistan
Legislation and standards
• Advocate with parliamentarians and legislators for mandatory wheat flour fortification in all provinces
• Revise national standard for fortified wheat flour pending further research on appropriate iron compounds and fortification levels, and including folic acid and other micronutrients in compliance with current WHO/FAO recommendations
• Advocate with parliamentarians and legislators for addition of vitamin D to national standards for edible oil/ghee
Monitoring and enforcement
Inspection and sample collection
• Revise protocols and standard operating procedures to ensure adequate range and frequency of producer/market inspection and sample collection by District Health Officers or other appointed food inspectors
• Review and revise food inspector training protocols to increase and maintain capacity for effective inspection and sample collection
• Establish and strengthen data management protocols for systematic recording and reporting of inspection and sample collection process data and results
• Establish new district-level positions and committees for food fortification oversight, modeled on the District Focal Person and the IDD committee roles established for the USI programme
Analytical capacity
• Map the functional capacity (including staffing, equipment and workflow) of all Public Analyst Laboratories, other public-sector laboratories and accredited private-sector laboratories to identify opportunities for network improvement with respect to sample testing
Regulation of internal quality control capacity
• For wheat flour and edible oil/ghee mills, make internal fortification quality control processes and sample testing capacity a requirement for operational licensing
• For wheat flour mills, make internal fortification quality control processes and sample testing capacity a requirement for receipt of government wheat quota
Prosecution and penalties
• Identify and address barriers to effective prosecution for non-compliance with pure food laws and assess adequacy of existing penalties for deterring non-compliance

3.0 Private sector interventions for food fortification in Pakistan

Compulsory fortification of staple foods obliges private-sector food producers to adapt their manufacturing and quality control processes, requiring financial and technical resources. In this section, we outline the structure of the wheat flour and edible oil/ghee industries in Pakistan and the markets they supply. We then examine the key constraints on fortification implementation within these industries and identify potential activities and processes by which to address these constraints. Finally, we consider potential opportunities for promoting fortification in other private-sector domains, including among small-scale *Chakki* millers, among commercial producers of complementary foods for infants and young children, and within the dairy industry.

3.1 Staple food industries and markets

- Wheat flour industry and markets

Domestic wheat production in Pakistan was estimated at 23.5 million metric tonnes (MT) in 2012, with 75% of all wheat produced in Punjab province, and about 0.8 million MT of wheat exported, mostly to Afghanistan (GAIN, 2013b). Domestic food consumption of wheat was estimated at 21.8 million MT in 2012 (Prikhodko and Zrilyi, 2013), with a per capita consumption of about 121 kg/year or 332g/day.

There is heavy government involvement in the wheat market in Pakistan, aimed at increasing wheat production and farm incomes and maintaining affordable retail wheat flour prices geographically and throughout the year. Producer prices are set annually, with the federal Pakistan Agricultural Storage and Services Corporation and Provincial Food Departments together procuring about 25% to 30% of total wheat production. Government procures wheat during the harvest from April to June and releases it via quota to industrial millers at a set price during the non-harvest period from September to March.

The wheat flour milling industry in Pakistan is privately owned. About 1,200 wheat flour mills are registered with the Pakistan Flour Mills Association (PFMA), the main industry representative body, with a collective installed capacity of 200,000 MT per day. Many mills operate at only a fraction of their installed capacity, with many smaller ones processing only their wheat quota, which is sufficient for three hours of milling. The wheat flour produced by industrial mills, mostly high-extraction *atta* flour, is estimated to meet the consumption needs of about 50% of the population. The remaining demand is met by small-scale traditional millers, or *Chakkis*, operating in both rural and urban areas throughout the country and producing whole wheat flour.

Table 7 presents the size distribution of industrial flour mills by province.

Table 7. Provincial and size distribution (by installed capacity) of industrial wheat flour mills currently registered with the Pakistan Flour Mills Association

	Number of industrial wheat flour mills, by installed capacity			
	Small <80 MT/day	Medium 80-200 MT/day	Large >200 MT/day	Total
Punjab	81	387	364	832 (69%)
Sindh	4	120	49	173 (14%)
KP	3	123	27	153 (13%)
Balochistan	9	25	10	44 (4%)
Total	97 (8%)	655 (55%)	450 (37%)	1,202 (100%)

Source: Pakistan Flour Mills Association

Government sets the price of wheat flour produced from its released stock, with input from the PFMA and other stakeholders involved in national wheat policy. Flour produced from wheat procured on the open market is priced 9% to 10% higher.

Wheat flour marketing is diversified, with millers selling their products variously to wholesalers, direct to retailers and to export traders. Mills located near the Afghanistan border sell most of their product for export. In the 2012-2013 market year, an estimated 500,000 MT of wheat flour was officially exported from Pakistan to Afghanistan, most of it from Punjab, with perhaps up to a further 250,000 MT exported informally (GAIN, 2013a). Given an estimated food consumption of wheat in Afghanistan of around 5 million MT, Pakistani wheat may therefore supply some 10% to 15% of wheat flour demand in Afghanistan.

Imports from Pakistan comprise the majority of the wheat flour supply in the major markets of Kandahar and Jalalabad, about half of the supply in Kabul, and at least 10% of the supply in Mazar and Herat (RASTA, 2013). Most of the informal wheat flour import occurs along the border between Afghanistan's Central Eastern provinces and Pakistan's Federally Administered Tribal Areas (RASTA, 2013).

- Edible oil/ghee industry and market

Pakistan is a net importer of edible oil, with domestic production of 1.5 million MT in 2012 meeting only about 40% of domestic consumption (GAIN, 2013c). Domestically produced oils are derived mostly from cottonseed (43%), rapeseed (33%) and sunflower (24%). Imported palm oil, estimated at 2.2 million MT in 2012, meets the bulk of the remaining demand and is generally processed and sold in semi-solid hydrogenated form, or *vanaspati ghee*.

An estimated 100 industrial units are involved in edible oil processing and ghee manufacturing, selling their products through wholesalers. About 70 solvent extraction plants produce edible oil, located mostly in Punjab and Sindh provinces, with almost all selling their semi-refined oil to ghee mills; very few solvent extractors market a refined oil product. The primary manufacturing associations in the industry are the Pakistan Vanaspati Manufacturers' Association and the All Pakistan Solvent Extractors' Association. Both associations participate in policy formulation processes for the industry.

Retail prices for edible oil/ghee are set by the market, reflecting competition between brands as well as the international price of palm oil and import costs. Higher prices in northern Pakistan reflect additional transport costs.

Domestic food consumption of edible oil was estimated at 3.4 million MT in 2012 (GAIN, 2013c), representing a per capita intake of about 19kg/year or 52g/day.

3.2 Constraints on food fortification in the wheat flour and edible oil/ghee industries and opportunities for intervention

In the context of industrial staple food production, barriers to implementing mandatory fortification at the level of the manufacturing unit cluster in two main areas:

1) Procurement of additional production inputs
2) Establishing sufficient internal quality control

Within each of these areas, barriers and opportunities for intervention are similar across the wheat flour and edible oil/ghee industries in Pakistan.

1) Procurement of additional production inputs

Adapting existing food production processes to enable fortification requires a reliable supply of an appropriate fortificant premix and the infrastructural and technical capacity with which to incorporate it into the food vehicle.

Fortificant premixes

Vitamin and mineral premixes typically account for the majority of the incremental total costs associated with fortification. In addition to the cost of the micronutrient compounds, premixes attract import duties and sales taxes in Pakistan (currently 5% and 17%, respectively) in the absence of negotiated exemptions, and entail shipping and other charges. Appropriate storage and efficient distribution systems are further considerations, often posing significant logistical challenges.

No domestic supply of iron and folic acid premix for wheat flour fortification is currently available; it needs to be sourced internationally. The current in-country cost of the iron (NaFeEDTA) and folate premix is estimated at $9 to $10/kg, or $1.35 to $1.50/MT of wheat flour. Once procured, however, the distribution of premix to the widely dispersed, large number of flour mills might be facilitated through the existing networks for wheat distribution via the quota system administered by Provincial Food Departments.

For fortifying edible oil/ghee, vitamin A premix is currently available for purchase domestically through suppliers such as BASF and DSM, currently at about $55/kg, or $1.82/MT oil. The main constraint on procurement of premix for edible oil/ghee producers is high prices. Distribution may be another consideration; however, the relatively small number of edible oil/ghee mills and their established systems for purchasing other chemical inputs for refining and manufacturing are both favourable for premix procurement.

Capital equipment for adding premix

In wheat flour fortification, fortificant premix is added to flour towards the end of the milling process through a premix feeder. Feeder technologies are relatively simple and can normally be incorporated into existing mill infrastructure with minimal disruption. Some domestic capacity exists for manufacturing premix feeders in Pakistan, but its exact scale is unknown; there are several international suppliers. Depending on the size and type, the current cost of a feeder ranges from $3,000 to $35,000 (see: www.ffinetwork.org/implement/toolkit.html), with feeders suitable for most existing Pakistani mills ranging from $3,000 to $10,000. In addition to the initial outlay for the feeder unit, costs for routine and unplanned equipment maintenance are involved.

No specialized equipment is needed for fortifying edible oil/ghee. Fortificant premix is added during the manufacturing process in the same way as other chemical inputs typically used.

Potential interventions for procurement of additional production inputs

Support to industry for procurement of premixes and premix feeders could take several forms, addressing both coordination and financing (Table 8). Within both the wheat flour and edible oil/ghee industries, detailed supply chain analyses and engagement with suppliers and industry representatives to investigate and coordinate pooled procurement opportunities would address both cost and logistics considerations.

With respect to wheat flour fortification particularly, feasibility studies on opportunities for domestic production of premixes and especially premix feeders, followed up with financial and technical business development support where appropriate, could increase fortification programme sustainability. In the initial programme phase, costs for feeder equipment could be subsidized wholly or in part, to ensure infrastructural capacity is acquired and installed immediately. Subsidies for recurrent premix costs could also be considered, but these may have limited incentive effect in the context of largely controlled wheat flour prices. Alternately, a time-limited revolving fund mechanism could ensure liquidity for, and timely settlement of, recurrent premix costs and could also facilitate more effective pooled procurement.

Short-term subsidies for edible oil/ghee premix might incentivize manufacturers to begin fortifying their products, but more effective monitoring and enforcement of the longstanding legislation on mandatory edible oil/ghee fortification may be equally effective. Additionally, advocacy and technical support could be provided to representatives of both industries to effectively lobby for import duty and tax exemptions on premixes.

2) Establishing sufficient internal quality control

Effective internal quality control processes are essential for private-sector producers of fortified foods, not only for ensuring compliance with food quality and safety laws but also for maintaining the reputational capital that derives from product quality, including its adequate fortification. In addition to internal measures such as accurate premix feeder calibration and appropriate premix storage and dispensing, internal analytical capacity for sample testing and external laboratory analyses are important components of fortification quality control at the production level.

Internal capacity to adequately analyze samples enables timely identification and correction of problems during the fortification process. Acquiring this internal analytical capacity poses a challenge for wheat flour millers and edible oil/ghee manufacturers. Simple testing protocols such as the Iron Spot Test can be used to determine the presence of added iron in wheat flour. While this test cannot quantify the fortification level, it remains the most appropriate internal testing protocol currently available for wheat flour fortification, requiring minimal equipment and a limited number of laboratory consumables. For edible oil/ghee, rapid test technology is now available for detecting added vitamin A (e.g., Bioanalyt's iCheck™ CHROMA test kit).

Sophisticated laboratory techniques are required for comprehensive quantitative analyses of the micronutrient characteristics of food samples, including spectrophotometry for wheat flour and high-performance liquid chromatography (HPLC) or edible oil/ghee. To obtain independent analyses of their fortified products, and in the absence of internal capacity for quantitative testing, food producers must procure analytical services from accredited commercial laboratories with regular frequency. Reliable access to these external analytical services is another potential challenge for wheat flour millers and edible oil/ghee, specifically in terms of where these services are located and what their fee structures are.

Potential interventions for establishing and maintaining internal quality control

Many of the strategies for supporting the procurement of fortificant premixes and premix feeders, outlined above, could also be pursued to help develop effective internal quality control systems for fortification in wheat flour and edible oil/ghee mills, particularly with respect to procurement of production-level sample testing equipment and materials (Table 8). An additional area for potential intervention with respect to production-level quality control is in improving access to external laboratory services for sample analysis. Mapping the existing functional capacity of accredited commercial laboratories by province and engagement with wheat flour and edible oil/ghee industry representatives to develop coordinated procurement of laboratory services are two potential strategies.

Table 8. Potential private-sector interventions for wheat flour and edible oil/ghee fortification in Pakistan
Fortificant premix
• Conduct detailed analysis of possible supply chains for premixes
• Develop procedures for efficient tendering, purchase, quality control and distribution of premixes
Engage industry representatives on feasible pooled procurement procedures
Engage suppliers directly (e.g., BASF, Fortitech, DSM) or through pooled procurement mechanism (e.g., GAIN Premix Facility)
Engage local logistics firms to procure and distribute premix
Engage Provincial Food Departments on feasible premix storage and distribution procedures, based on current wheat distribution system
• Support premix procurement
Subsidize cost of premix
Develop revolving fund for premix procurement (managed by an independent, nonprofit organization)
Support advocacy for reduced import duties and VAT on premix
• Investigate feasibility for developing domestic premix production capacity
Equipment for adding premix (for wheat fortification only)
• Conduct detailed analysis of current and possible supply chains for premix feeders
• Develop procedures for efficient tendering, purchase and distribution of feeders
Engage PFMA on feasible procedures for pooled procurement of feeders
Identify and engage domestic manufacturers of feeder equipment
• Support procurement of feeders
Subsidize cost of feeders
Support advocacy for reduced import duties and VAT on feeders
• Support development of domestic feeder manufacturing capacity
Equipment and materials for internal quality control
• Conduct detailed analysis of current and possible supply chains for in-plant laboratory equipment and consumables
• Develop procedures for efficient tendering, purchase and distribution of in-plant laboratory equipment and consumables
• Support procurement of in-plant laboratory equipment and consumables
Subsidize cost of in-plant lab equipment
Develop revolving fund for procurement of lab consumables
Support advocacy for reduced duties and tax on lab equipment and consumables
• Conduct detailed mapping of existing capacity for sample analysis in accredited private-sector laboratories
• Develop procedures for efficient tendering and purchase of private-sector laboratory services for sample analysis
• Support further development of private-sector laboratory networks for sample analysis

3.3 Further opportunities for promoting food fortification in the private sector

In addition to the opportunities for private sector interventions to promote food fortification in the wheat flour and edible oil/ghee industries, there are at least three other areas in which further opportunities could be pursued.

- ***Wheat flour fortification at the village level***

Industrial mills supply about 45% to 50% of the demand for wheat flour in Pakistan, with industrially milled flour being consumed by 60% to 70% of the population in urban areas and by 25% to 30% of the rural population. Demand for industrially milled flour will continue to grow, but flour produced by small-scale *Chakki* mills will continue to supply a large proportion of domestic demand for some time.

There are an estimated 30,000 to 50,000 *Chakki* mills in operation throughout the country, present in both rural and urban areas, and with a typical individual milling capacity of 500 to 1,500 kg of flour per day. Largely unorganized and informal, the *Chakki* mill sector is not associated with the Pakistan Flour Mills Association and is unlikely to be targeted by industrially focused wheat flour fortification programming.

However, appropriate technology for village-level wheat flour fortification does exist (e.g., small-scale, semi-automatic premix microfeeders for use with grind stone techniques), and effective efforts to disseminate and encourage uptake of these technologies could improve wheat flour fortification coverage significantly. Possible interventions to initiate and support such efforts include:

- Geographical mapping of *Chakki* mills and assessment of their infrastructural capacity for small-scale fortification
- Identify local capacity for manufacturing premix microfeeders for use in *Chakki* mills
- Implement microfinance initiatives to support procurement of equipment and fortificant premix by *Chakki* millers
- Encourage registration and the formation of associations among *Chakki* millers

- ***Fortification of complementary food for infants and young children***

Infants and young children in Pakistan do consume wheat flour porridges, but the weaning foods most commonly prepared are not wheat-based; rather, traditional foods made from rice and other non-wheat grains are more widely consumed. Consumption of commercially produced complementary foods among infants and young children is increasing, however, and this trend offers an opportunity for targeting fortification to this nutritionally vulnerable subpopulation. Possible interventions to promote fortification in this area include:

- Market research to identify popular commercial products and brands of complementary foods consumed in Pakistan and to identify target domestic and multinational companies for potential engagement in fortification initiatives.
- Support product development and marketing initiatives for fortified complementary foods. Lessons could be drawn from ongoing domestic production of the World Food Programme's AchaMum and WawaMum products, ready-to-use supplementary foods for preventing malnutrition in children.

- *Fortification of dairy foods*

Foods and beverages made from milk are widely consumed by both adults and children in Pakistan, yet the dairy sector is not yet featured in food fortification programme planning. A comprehensive assessment of the dairy industry and its capacity for undertaking fortification initiatives would identify potential opportunities for intervention.

4.0 Agricultural interventions for food fortification in Pakistan

4.1 Biofortification

Biofortification is the development and dissemination of staple crop varieties that have been enhanced with micronutrients using plant breeding techniques. Naturally occurring variation exists in the germplasm of wheat, which provides options for incorporating higher levels of iron, zinc and β-carotene into wheat grains (Hoisington, 2002). In 1997-1998, the International Maize and Wheat Improvement Center (CIMMYT) in Mexico identified several wheat varieties with 25% to 30% higher grain iron and zinc concentrations than known varieties. Wild relatives of wheat have been found to contain a source of the highest iron and zinc concentration in the grains, although these accessions are often low yielding and have poor grain quality. In such cases, backcrossing to breed varieties would enhance the grain production and quality (Johns, 2007).

To date, biofortified wheat seed is not available for consumption. However, other nutrient-rich crops, such as vitamin A-rich orange sweet potato, maize and cassava, and iron-rich beans are being planted and consumed by 400,000 farming families in Africa. Iron-rich pearl millet has also reached 30,000 Indian farming families. All biofortified varieties of staple food crops currently being tested by HarvestPlus (wheat, rice, maize, pearl millet, sweet potatoes, beans and cassava) have been developed through conventional breeding methods and therefore technology of genetic engineering has not been used.

In Pakistan, the breeding programme for the development of biofortified wheat started in 2009 (when the first breeding material of HarvestPlus was received from CIMMYT) in the form of segregating lines at National Agricultural Research Centre (NARC), Islamabad. Advanced nursery lines were tested at two further locations in Pakistan: Wheat Research Institute, Faisalabad and Regional Agricultural Research Institute, Bahawalpur. This testing programme led to the selection of the three best lead lines (NR-419, NR-421, and NR-439), which are adapted under both irrigated and rain-fed conditions (Table 9). They not only contain more than 37 mg kg^{-1} of zinc in their grains (compared to an average of 25 micrograms of zinc per gram of grain in current wheat varieties), but are high yielding and resistant to stem rust disease (Ug99).

In 2012-2013, the first biofortified wheat variety, NR-421, completed its first year of testing in the National Uniform Wheat Yield Trails (NUWYT) where it was planted in 115 locations. It is currently undergoing its second year of testing and is anticipated to be officially released by fall 2015 for general cultivation. NR-421 will also be registered under the provisions of Pakistan Seed Act 1976. NR-419 is in its first year of testing under NUWYT, and NR-439 is in its first year of agronomic performance tests and trials.

Table 9. Characteristics of candidate wheat varieties under development in Pakistan
NR-421 (Candidate Wheat Variety) • Contains zinc > 37 microgram per gram, iron > 70 microgram per gram, and high in protein content • In early maturing, resistant to Ug99 and high yielding at par with other mega varieties • Best suited for irrigated areas and late planting situations • In its second year of evaluation in NUWYT and the seed is being multiplied simultaneously; it will be approved and released for commercial cultivation during 2015-2016 crop season
NR-419 (Candidate Wheat Variety) • Contains > 37 microgram zinc per gram and >70 microgram iron per gram, resistant to Ug99, high yielding equivalent to other mega varieties • Currently in its first year of testing under NUWYT (2013-2014) in irrigated areas
NR-439 (Potential Wheat Line) • Contains > 37 microgram zinc per gram and sufficient quantity of iron, resistant to Ug99 • Currently being tested for its suitability under irrigated and rain-fed areas • In its first year of test and trials for agronomic performance during crop cycle 2013-2014

Source: National Agricultural Research Centre, Islamabad

While NR-421 is undergoing testing for the second year during the 2013-2014 Rabi season, its nucleus seed will be multiplied to produce 'Breeder's Seed'. The breeder's seed will be multiplied during 2014-2015 season to produce a 'Basic Seed'. After the variety is approved in 2015, its certified seed will be produced under the schedule given in Table 10.

Table 10. Seed multiplication scheme for biofortified wheat variety (NR-421)

Crop Season	Available seed (tons)	Area planted for seed multiplication (acres)	Quantity of seed produced (tons)
2015-2016	1.0	25	30
2016-2017	30.0	600	720
2017-2018	720.0	14,400	17,280
2018-2019	17,280	345,600	414,720
2019-2020	414,720	Sufficient to plant 8.0 million acres	

Source: HarvestPlus Pakistan

During the 2018-2019 crop cycle, it is anticipated that 17,280 tons of seed will be made available for sowing on an area of 345,600 acres, which will translate into the production of 414,720 tons of seed. During the next season (2019-2020), there will be sufficient seed to sow more than 8 million acres or cover about 37% of the total wheat area during 2019-2020 crop season. NR-419 and NR-439 are expected to have a similar multiplication scheme.

The achievement of biofortification of staple crops in Africa has been successfully demonstrated, while breeding programmes are underway in several countries, including Pakistan, for genetically improving staple food crops. Although biofortification is initially capital intensive and time consuming to reach the delivery stage, once it is achieved it is highly cost-effective and can be delivered on a large scale equitably. However, the degree to which biofortification will be accepted and adopted in Pakistan is still unclear. Biofortified wheat does not differ in appearance or taste from regular wheat varieties, but farmers will still need to be convinced to purchase the biofortified wheat seed.

- Marketing development of fortified seeds and products

It is proposed that the biofortified wheat seed may be multiplied and marketed largely through the private seed companies and also involving the Punjab Seed Corporation, the only state-run seed organization. This system will facilitate to use not only the huge seed multiplication facility available in private sector, but also use their sales network for marketing of this seed. The participating seed companies may also be encouraged to launch special campaigns for marketing of biofortified seed. At the same time, federal and provincial governments may be approached to launch awareness campaigns for the use of biofortified wheat flour through print and electronic media to reduce micronutrient malnutrition. The Ministry of National Food Security and Research of the Government of Pakistan is giving a high priority towards development, production and consumption of biofortified high-zinc wheat. This programme is proposed to be included in the 11th 5-Year Development Plan (2013-2018) and also Pakistan Vision-2025.

4.2 Seed financing

During the 2012-2013 financial year in Pakistan, 3,900 agriculture-designated branches of 27 financial institutions advanced Rs 231 billion to the agricultural sector. The 19 commercial banks disbursed Rs 124 billion, with Zari Trakiati Bank alone disbursing Rs 38 billion. Agriculture loan disbursement increased by 17% compared to the previous year. In addition, these banks financed Rs 1445.6 million in development loans to private seed companies for improving their facilities for the production of quality seed. Individual farmers can obtain production loans of up to Rs 20,000 per acre of wheat crop, including Rs 3,000 per acre for the purchasing of seed. This amount is sufficient for purchasing high-quality seed from the open market.

4.3 Micronutrient fertilizers

In Pakistan, 70% to 80 % of the 22.43 million hectares of cultivated area is deficient in zinc (Rafique, 2006; Ryan, 2013). Deficiency in zinc and other micronutrients (boron, iron, copper, manganese, molybdenum and chloride) cause considerable reduction in crop yield and quality. Such deficiencies are the result of continuous mining of micronutrients by intensive cropping, the cultivation of high-yielding varieties, the use of more NPK (nitrogen, phosphorus, and potassium) fertilizers, decreased use of organic manures and inappropriate agronomic practices adopted by the farming community (Khattak, 1995).

Micronutrient fertilizers, straight or blended with other macronutrients, can be applied to soils to ameliorate their micronutrient deficiencies. Blended micronutrient fertilizers are currently being manufactured in India as zincated urea and zincated super phosphate (2.5%) (Singh, 2001). Turkey is also using single/straight micronutrient fertilizers, producing more than 3 million tons of zincated compound fertilizers (Cakmak, 2012). In addition, a mix of two or more micronutrient fertilizers in liquid form is also available for foliar spray.

Given the high population prevalence of zinc deficiency in Pakistan and the country's reliance on wheat as the main staple food, zinc fertilizer is arguably the most appropriate micronutrient fertilizer, as it can also improve the productivity of wheat crop by more than 15%. Field trials conducted across seven countries, including Pakistan, revealed that the addition of zinc fertilizer in the soils in combination with foliar application increased zinc concentration in grains by 48%, from 27 to 48 mg / kg (Zou, 2012). The replenishment of soils with macro- and micro-nutrients offers the potential opportunity for increasing food as well as feed crop production by more than 50%. Rafique et al. (2006) reported that zinc content in wheat and rice grains could be increased two-fold with a concurrent increase in grain yield, by the application of zinc sulfate at the rate of 3 kg zinc per hectare. Zinc toxicity in soil is not a problem *per se* and a large dose of zinc nutrient remains effective for a number of subsequent crops. Other micronutrient fertilizers, such as boron, iron, copper and manganese, also have been shown to increase the level of micronutrients and crop yields.

By the estimation of one key informant for the present study, about 95,000 tonnes of zinc-fortified fertilizer would be required to supplement the total zinc-deficient area in Pakistan, but only about 5% of that volume is actually used. At present, some farmers in Pakistan use micronutrient fertilizers for apples and citrus orchards, and about 80% of the total zinc-fertilizer use in Pakistan is for rice crop. However, adoption on a large scale has the potential to produce a positive impact on human capital and economic development. In addition, the adoption of improved agricultural practices such as green manuring and the use of composted organic matter result in improving soil structure, fertility and crop productivity. These practices also increase soil water-retention capacity, improve fertilizer efficiency and enhance the quality of produce. These improved agricultural practices are complementary to the use of micronutrient-fortified fertilizers, and technical support to farmers for adopting these practices should supplement interventional strategies for increasing micronutrient fertilizer uptake.

In Pakistan, zinc fertilizers currently marketed are often adulterated or fake, with market surveillance reporting samples containing less than 1% elemental zinc compared to the 23% to 35% claimed on the bags in which they are sold. The Government of Punjab has expressed concern with the current sale of adulterated and fake fertilizers and has given high priority to controlling malpractice in marketing these fertilizers. A ‘Rapid Task Force’ has now been constituted to monitor the manufacturing process at production facilities, including licensing, in-house laboratory analysis, the testing of finished products. This surveillance and enforcement system is regulated by Department of Agriculture (Extension Wing), which has an extensive network at the grassroots level for sample collection and well-equipped divisional laboratories for analyzing a range of nutrients. In case of non-compliance with standards, the company or supplier is heavily fined and their license can be revoked.

4.4 Crop diversification

Approaches to crop diversification are horizontal or vertical in nature. Through a horizontal approach, indigenous or exotic high-value crops are added to the existing cropping system, while through a vertical approach, activities to add more value to crop products are carried out, such as processing, local branding, packaging and merchandizing. These approaches are complementary, and could be pursued in tandem.

Crop diversification can improve nutrition by introducing high-quality foods into the diet. Additionally, its practice can reduce risks faced by monoculture producers, whose livelihoods are vulnerable to environmental, social and economic factors. Diversification also helps to improve soil fertility, reduce erosion, control insects, pests and weeds, and reduce farmers’ reliance on chemical fertilizers. It can also increase soil water-utilization capacity and ultimately crop yield, and thereby net profits (Peel, 1998).

While crop diversification and rotation is one of the oldest and most effective cultural control methods of land degradation, uptake by farmers has been limited, as farmers require additional planning and management skills to diversify, increasing the complexity of farming. Awareness-raising activities and the provision of additional technical support to farmers could increase the uptake of this practice.

4.5 Reducing rice milling and polishing time

In Pakistan, brown rice is passed through two huller machines to remove the outer bran layers from the grains, and then polished by a brushing machine in order to increase its shelf-life and appearance. The polished white rice may be coated further with glucose to increase its lustre.

The polishing process improves the market value of rice but reduces its quality, becoming 95% starch, 5% to 7% protein and 0.5% to 1.0% lipids (Fitzgerald, 2009). Because of the additional milling, the polished rice grain loses vitamins and minerals, specifically protein (23%), fat (76%), dietary fiber (49%), ash (51%), calcium (20%), phosphorus (49%), iron (32%), thiamine (B1) (69%), riboflavin (B2) (36%) and niacin (B3) (47%). However, such nutritional losses can be reduced by adopting parboiling technology, as the polishing of parboiled rice does not reduce its quality.

Parboiled rice is produced through a hydrothermal process carried out in three stages: soaking the paddy in water at 70^{o}C to 80^{o}C for eight to ten hours; steaming the soaked paddy to gelatinize the starch; and drying the rice prior to milling. The rice is parboiled to soften the kernel, which allows the surface starch, bran and other components to commingle with endosperm (FAO, 1993). While brown rice in its most natural form provides the most nutrients, parboiled rice retains all minerals except for vitamins B1, B2 and B3, and serves as a healthier alternative to milled rice.

Alternatively, the loss of nutrients in the milling process could be replenished during processing by coating or dusting the rice kernels with vitamin and mineral fortificants.

In addition, recent advances in extrusion technology have led to the development of ‘Ultra Rice’, a high-vitamin simulated grain. It is blended with white rice at a 1 to 100-blend ratio, resulting in fortified rice, and has been successfully trialed by PATH in Brazil and India. Furthermore, such losses in vitamin and minerals could also be minimized by reducing milling time and improving milling and parboiling techniques, in combination with rice fortification. Such alternatives should be targeted in Punjab and Sindh regions, where approximately 10% to 20% of the population regularly consumes rice as a staple food.

4.6 Commodity storage

Covered storage space for food grain in the public sector is insufficient in Pakistan. In 2012, 5.79 million MT of wheat grain was procured and stored by provincial governments and the Pakistan Agricultural Storage and Services Corporation (PASSCO), exceeding the amount of available covered storage space by 1.45 million MT. Overflow grain was packed in gunny bags and stacked on raised beds under waterproof tarpaulins in uncovered grounds of storage facilities and in fields near highways. Table 11 provides a breakdown of wheat procurement and storage capacity by province.

Table 11. Procurement and storage capacity of wheat in Pakistan, 2011-2012

Province	Wheat procured (million MT)	Covered storage capacity (million MT)	Unused covered storage capacity (million MT)
Punjab	2.78	2.48	- 0.30
Sindh	1.15	0.71	- 0.44
Khyber Pakhtunkhwa	0.32	0.37	0.05
Balochistan	0.11	0.22	0.11
PASSCO	1.43	0.56	0.87
Total	5.79	4.34	1.45

Source: Agricultural Statistics of Pakistan 2011-12, Ministry of National Food Security & Research

In storage, grains absorb moisture from the ground and atmosphere, which provides the foundation for grain damage. Because wheat grain stored in open space is subjected to environmental hazards including rains, floods, harsh temperatures and fungal diseases, such storage can lead to significant grain damage both in terms of quantity and quality. In addition, infestation with rodents, sparrows, moles and insects can cause significant grain loss during storage. During heavy infestation, grain can be reduced to frass, presenting a sickly appearance and giving a foul odour. Flour made from such stock has an unpleasant smell, bitter taste and lower baking quality.

Wheat grain loss under farm level and public storage facilities is estimated at 5.2% and 3.5%, respectively (Baloch, 1986). Grain may remain vulnerable to pests and insect infestations during transportation and processing, but additional losses can be minimized by storage in elevated, fumigated bins or silos. Expansion of public-sector covered storage capacity could be pursued in collaboration with the private sector, on the 'build, operate and transfer' model or through leasing and public-private partnership arrangements.

A summary of potential areas for action within the agricultural sector is presented in Table 12.

Table 12. Potential agricultural interventions for improving nutritional value of staple food crops
Genetic biofortification of staple food crops
• Intensive research and development (R&D) programme to develop the biofortified nutrient-dense staple food crops through conventional plant breeding techniques
• Mass multiplication of biofortified wheat seed
• Advocacy for the consumption of biofortified wheat
Promotion and application of micronutrient fertilizers
• Application of micronutrient fertilizers on the basis of soil test analysis
• Quantify the impact of micronutrient fertilizers on raising the nutrients and vitamin content in food crops
• Development and marketing of blended fertilizers with micronutrients, in partnership with private-sector fertilizer companies
• Necessary legislation for manufacturing of micronutrient fertilizers, revamping the micronutrient fertilizer manufacturing system, and strict enforcement in marketing for quality control
Crop diversification and cropping pattern
• Diversification of crops through the promotion of short-season high-value vegetables and fruit crops for small-scale land holdings, and adoption of inter- and relay-cropping in the irrigated areas
• Massive-scale adoption of 'Tunnel Farming Technology' for the availability of farm-fresh nutritious food supplies
• Advocacy for the cultivation of pulses, oilseeds crops in the rain-fed areas
• Enhancing the productivity of food crops by improving management and growing these in the best agro-ecological niche areas
Improvement and maintenance of nutritional value in rice and wheat
• Adoption of parboiling method in rice to retain nutritional value as well as lengthening the storage period
• Reduce the milling process to reduce the loss of nutrients and vitamins in rice
• Fortification of rice with minerals during milling process
• Large-scale construction of silos, for storage of wheat grain to avoid loss in quantity and quality
• Advocacy to fumigate wheat grains stored in bins by household in the rural areas
Commodity storage
• Expand public-sector coverage storage capacity, possibly through public-private partnerships

5.0 Appraisal of intervention options

Building on the preceding analysis of the current landscape for food fortification in Pakistan, this section first presents an assessment of various intervention options with respect to existing evidence of their effect on micronutrient status and the prospects for implementation and scale-up in Pakistan. Prospects for implementation and scale-up are considered in terms of capacity (e.g., regulatory mechanisms, infrastructure, partnerships and previous experience) and demand (e.g., existing demand or prospects for demand creation). Estimates of the projected impact and cost associated with the scale-up of each option are then presented. The overall appraisal of options is summarized quantitatively at the end of this section.

5.1 Evidence of effect and prospects for implementation and scale-up in Pakistan

Wheat flour fortification with iron and folic acid

Globally, wheat flour fortification is practiced widely, with some 75 countries currently mandating the fortification of wheat flour with at least iron and folic acid (see: www.ffinetwork.org/global_progress). Establishing causality in the assessment of food fortification programmes is methodologically difficult, but evidence from before-and-after studies in Central Asia (Tazhibayez et al., 2008), Venezuela (Layrisse et al., 2002) and Iran (Sadighi et al., 2009) suggests that the wheat flour fortification can significantly improve population iron status, measured by serum ferritin levels. Pooled analyses of randomized and quasi-experimental studies of iron-fortified staple food consumption among children show significant increases in serum ferritin levels and hemoglobin concentrations, and lower anemia prevalence, with some studies also showing an effect on cognition (Das et al., 2013). Similarly, significant positive effects of iron-fortified staple food consumption are shown on serum ferritin, hemoglobin and anemia among women. Pooled analyses of before-and-after studies of mass flour fortification with folate show significant impact in reduction of neural tube defects, including spina bifida and anencephaly.

With per capita wheat consumption in Pakistan among the highest in the world, wheat flour is an excellent candidate staple for food fortification, and current trade patterns suggest that fortified Pakistani wheat flour could also meet some 10% to 15% of wheat flour demand in Afghanistan. Previous in-country experience has already demonstrated that fortification of industrially produced wheat flour at considerable scale is possible. The mill-level technology required for flour fortification is relatively simple and can be incorporated into existing industrial milling processes relatively easily, as shown by the 125 mills functionally equipped to fortify flour in 2005-2010 through the NWFFP. Additionally, there is a significant level of organization/coordination within the privately owned flour-milling industry (likely a consequence, at least in part, of the heavy government involvement in the wheat and wheat flour markets), and this could be advantageous with respect to pooled procurement of fortification inputs; for example, existing wheat quota distribution networks might facilitate the efficient distribution of consumable fortificant supplies. In the PFMA, there also exists an active industry association that is publicly supportive of mandatory wheat flour fortification and is formally engaged in the operational planning for large-scale wheat flour fortification in Punjab. No legislation for mandatory wheat flour fortification is currently in place in Pakistan, but the province of Punjab appears to be considering such legislation seriously.

Despite these strengths in local capacity for implementing wheat flour fortification, some significant constraints remain. While legislation on mandatory fortification may be enacted in the near future, the rest of the regulatory framework is currently characterized by limited food inspection capacity, limited laboratory analytical capacity, and uncoordinated monitoring and enforcement (including inconsistent judicial penalties) across districts and provinces. However, at least with respect to human resource and lab capacity, these limitations could be addressed relatively easily with sufficient investment.

The large proportion of total wheat flour demand currently being met by *Chakki* millers poses another serious challenge for any proposed wheat flour fortification programme, not necessarily for its initial implementation, but almost certainly for its scale-up. While studies have identified no concerns with respect to the palatability and local acceptance of fortified flour in Pakistan (Mahmood et al., 2007), consumer preference for wholegrain *Chakki* flour remains strong, including in urban areas. In the absence of programmes promoting fortification in the *Chakki* sector, intensive advocacy efforts to encourage uptake of industrially produced fortified flour will likely be needed. From the previous NWFFP, the industry has at least some experience with branding and marketing fortified industrial wheat flour, and further insight into effective domestic strategies for promoting fortified products could be drawn from the salt industry, including strategies to counter disincentives from potentially higher retail prices for fortified products.

Fortification of edible oil/ghee with vitamin A

Strong programmatic evidence for the effect of fortifying staple foods with vitamin A comes from Central America, where sugar fortification has been implemented widely in several countries for several decades, beginning with Guatemala. An evaluation of the initial Guatemala programme showed that it was associated with a dramatic reduction in the prevalence of vitamin A deficiency among pre-school-aged children (Arroyave et al., 1981). With respect to the vitamin A fortification of oil and oil products, a large and significant reduction in vitamin A deficiency prevalence was shown in an efficacy trial among pre-school-aged children in the Philippines consuming fortified margarine daily over a period of six months (Solon et al., 1996).

However, in a later trial among a similar population of Filipino children, intake of vitamin A-fortified cooking oil showed no effect on serum retinol levels compared to non-fortified oil, unless taken together with other vitamin A-rich foods (Candelaria et al., 2005).

Legislation for the mandatory fortification of edible oil/ghee with vitamin A has been in place for decades in all four provinces; however, as discussed above with respect to flour fortification, the rest of the regulatory framework needed to entrench and sustain fortification initiatives is lacking. In the case of vitamin A fortification, laboratory analytical capacity is a particular problem. Almost no labs are equipped for the high-performance liquid chromatography, the gold standard for determining vitamin A content in food samples, making the monitoring and enforcement of the existing legislation on oil fortification difficult. However, this issue could be addressed with sufficient investment, and rapid test technology for detecting vitamin A in oil has recently become available.

Low industry compliance likely stems from weak enforcement of the existing legislation, but it may also be due, at least in part, to misinformation about the value and viability of adding vitamin A to their products. Until sufficient monitoring and enforcement capacity can be established, advocacy to promote 'voluntary' fortification among edible oil/ghee producers and their industry representative bodies will be needed to generate initial fortification momentum. Here, insight could be drawn from the Universal Salt Iodization programme as well as from the motivation of the PFMA to support wheat flour fortification.

The prospects for implementing and scaling up edible oil/ghee fortification in Pakistan are improved by the fact that fortification of oil products is a technologically simple process and requires no additional industrial equipment. Additionally, in contrast with the large number of widely dispersed wheat flour mills, the number of industrial units involved in edible oil/ghee production is small and relatively concentrated, which may better enable pooled procurement and efficient distribution of the vitamin A fortificant.

Also, because some edible oil/ghee producers in Pakistan already do fortify their products, there is already some market intelligence available on the consumption characteristics of fortified oil/ghee, including consumers' sensitivity to price and their response to branding and marketing. This will be an advantage for the industry as it seeks to increase its production of fortified oil/ghee.

Biofortification of wheat with zinc

Much of the evidence on biofortification to date has focused on demonstrating the feasibility of breeding strategies, with further evidence now accumulating on the efficacy of biofortified crop consumption for improving micronutrient status.

However, evidence for the effectiveness of biofortification is still very limited, so far focused only on vitamin A-rich orange-fleshed sweet potato (Ruel et al., 2013).

HarvestPlus has been developing and testing biofortified wheat seed in Pakistan since 2009, in collaboration with the National Agricultural Research Centre in Islamabad. Breeding trials are currently in progress for three lead lines, with approval expected for the first line in 2015, and for the next two lines shortly thereafter. However, because biofortified wheat is still under development, readiness for implementation and potential rates of scale-up in Pakistan can only be surmised.

It has been proposed that the biofortified wheat seed be multiplied and marketed through private seed companies and the Punjab Seed Corporation (PSC), the only state-run seed organisation. Partnering with PSC would enable usage of its already existing seed multiplication facility and sales network.

Several large-scale activities are planned to promote the biofortified wheat seed nationally. Fauji Fertilizer Company (FFC), the largest fertilizer company in Pakistan, will establish demonstration plots in all four provinces in the 2015-2016 season to demonstrate the effects of mixing high-zinc wheat seed with fortified fertilizer and weedicides. HarvestPlus and FFC plan to organize field days to jointly promote the cultivation of the biofortified wheat seed among farmers and create awareness about the benefits of consuming biofortified wheat for their families. Moreover, other national and multinational seed companies, nongovernmental organizations (NGOs) and Farmers Associations have also expressed interest to HarvestPlus in producing and marketing the biofortified wheat varieties, including participating in training programmes and field days.

The Ministry of National Food Security and Research is currently prioritizing the development, production and consumption of biofortified high-zinc wheat, and proposed to be included in Pakistan's 11th 5-Year Development Plan (2013-2018) and Vision 2025 document.

The degree to which consumers will accept biofortified wheat seed also remains uncertain. However, HarvestPlus and its partners anticipate acceptance to be high, as the additional zinc is invisible and does not alter the taste of the wheat.

Fortification of fertilizer with zinc

Field trials conducted across seven countries, including Pakistan, have shown that addition of zinc fertilizer to soil in combination with foliar application can increase zinc concentration in grains by 48% (Zou et al., 2012). Given the high population prevalence of zinc deficiency and the country's reliance on wheat as the main staple food, zinc fertilizer is arguably the most appropriate micronutrient fertilizer for use in Pakistan. However, no evidence appears to be available yet on the efficacy or effectiveness of zinc-fortified fertilizer for improving micronutrient status in humans.

A further pilot project has been recently proposed to test the application and effects of the use of fortified fertilizer on 4,000 acres of wheat fields owned by 2,000 farmers in Pakistan over four years. The project is intended to provide empirical evidence for the effectiveness of increasing zinc levels in the body. Simultaneously, the project is expected to generate practical evidence and data for politicians, policymakers, administrators, media and NGOs, and to develop local ownership of the programme.

In addition to increasing crop zinc content, studies have shown that adding zinc sulfate to soil can increase wheat yield by as much as 120% (Ahmad et al., 2012). However, while 70% to 80% of the soil in the cultivated area in Pakistan is zinc-deficient, and despite nearly universal use of NPK (nitrogen, phosphorus, and potassium) fertilizers among Pakistani farmers, the adoption of zinc or other micronutrient fertilizers has been limited. The zinc sulfate fertilizer that is used in Pakistan is either mixed locally or imported blended from China, but much of it is adulterated or totally fake.

The Government of Punjab has expressed concern with the current sale of adulterated and fake fertilizers and has given high priority to controlling malpractice in marketing these fertilizers. A 'Rapid Task Force' has now been constituted to monitor the manufacturing process at production facilities, including licensing, in-house laboratory analysis, and the testing of finished products. This surveillance and enforcement system is regulated by the Department of Agriculture (Extension Wing), which has an extensive network at the grassroots level for sample collection and well-equipped divisional laboratories for analyzing a range of nutrients.

Since quality fortified fertilizer has yet to be marketed reliably in Pakistan, the degree of acceptability and future uptake by farmers is unknown.

5.2 Projected benefits and costs

For the economic appraisal of intervention options, we used a counterfactual approach whereby the modeled benefits and costs of fortification interventions at target levels of coverage were compared with the modeled benefits and costs at estimated current levels of coverage (Table 13) (Bhutta et al., 2013; Stein et al., 2005).

Coverage was defined as the percentage of the population consuming the fortified staple of interest. We assumed there is currently no production, and thus no consumption, of wheat flour fortified with iron and folic acid in Pakistan or of wheat fortified with zinc through either biofortification or the use of zinc-fortified fertilizer. Accounting for a higher proportion of wheat flour demand met by *Chakki* millers in rural areas, and assuming a small but steady secular shift towards industrial wheat flour consumption, we set a high-coverage target for iron and folic acid-fortified wheat flour of 65% in rural areas and 85% in urban areas. For comparability, we used the same coverage targets for the two agricultural options for fortifying wheat with zinc.

While vitamin A fortification of edible oil/ghee is mandatory in Pakistan, previous market surveillance studies and reports of industry interviews suggest that compliance with this legislation is very low, with vitamin A being added at insufficient levels or, most often, not at all (Berger and Head, 1995; Abraham and Paracha, 2004). For our models, we therefore assumed current coverage of sufficiently fortified edible oil/ghee to be about 20% in urban areas and 10% in rural areas, and we set target coverage at an increase of 65% in both areas.

While salt iodization is not one of the focal interventions of this overall appraisal, we have included this intervention in our economic analyses for reference. Estimates of the current coverage of iodized salt were taken from the 2011 National Nutrition Survey in Pakistan (NNSP, 2011). Given the success of the national salt iodization programme to date, we assumed an effectively universal target coverage of 99% across the whole population.

Table 13. Coverage levels used to assess the benefits and costs of fortification interventions in urban and rural areas of Pakistan

	Urban		Rural	
	Current	Target	Current	Target
Wheat flour fortification with iron and folic acid	0%	85%	0%	65%
Fortification of edible oil/ghee with vitamin A	20%	85%	10%	75%
Fortification of salt with iodine	72%	99%	68%	99%
Biofortification of wheat with zinc	0%	85%	0%	65%
Fortification of wheat with zinc-fortified fertilizer	0%	85%	0%	65%

Global evidence of impact of fortification on major functional and health outcomes in women and children is limited, as most studies have been at limited scale (Das et al., 2013). However, some inference can be drawn from impact estimates in representative populations on micronutrient status and manifestations such as anemia. Relevant effect estimates were drawn from the epidemiological literature and applied within the widely used *Lives Saved Tool* (LiST) to project mortality impacts of fortification among women and children (Walker, 2013). We additionally estimated the mortality impact of improving vitamin A status in children under 6 months, a pathway that is not currently modelled in LiST. Existing evidence suggests that improving vitamin A status in newborns can reduce mortality at 6 months by 14% (Haider et al., 2013), and is possibly related to maternal vitamin A status. Given the widespread vitamin A deficiency in Pakistan among women and infants, we feel this is a key intervention and its potential effects need to be captured in the impact modeling. In addition to the mortality impacts modeled within and outside of LiST, we also estimated the effects of increasing iron and iodine fortification coverage on the prevalence of child and adult anemia and maternal goiter, respectively.

Estimates of the economic consequences averted through fortification reflect the present value of the avoided loss of future wage income due to death as well as reduced productivity from anemia (Horton & Ross, 2003). A discount rate of 3% was used for all economic consequence models.

Further detail of the pathways and effect estimates incorporated into the impact modeling are given in Appendix 1. The final impact estimates are presented in Table 14.

Table 14. Potential impact of fortification interventions at target coverage compared to current coverage

	Additional child lives saved	Additional maternal lives saved	Additional averted economic consequences from morbidity and/or mortality (‘000 000)
Wheat flour fortification with iron and folic acid	3,285	491	$261.0
Fortification of edible oil/ghee with vitamin A	2,951	-	$50.0
Fortification of salt with iodine	-	-	$190.9
Biofortification of wheat with zinc	403	-	$6.8
Fortification of wheat with zinc-fortified fertilizer	806	-	$13.7

At target levels of coverage, wheat flour fortification with iron and folic acid could potentially save the most lives and avert the greatest loss of future wage income from both morbidity and mortality. Despite having no effect on mortality, salt iodization could have a very large economic impact given the substantial risk of cognitive impairment and consequent productivity loss among children born to women with goiter. The modeled impacts of edible oil/ghee fortification with vitamin A and of wheat fortification with zinc through biofortification or zinc-fortified fertilizer are considerably lower, in part because it is assumed that loss of future income in these three scenarios is a consequence of mortality only.

To estimate the incremental costs associated with scaling up fortification interventions from current coverage, the unit cost of fortifying one metric tonne (MT) of the relevant staple was first developed for each option and then multiplied by the additional volume of fortified staple consumption at the target level (i.e., net of the volume at current consumption).

An 'ingredients' approach was used to derive unit costs for wheat flour and edible oil/ghee fortification, accounting for the costs of fortificants and any capital equipment needed to add them, internal quality control at the producer level, external quality assurance, and social marketing/promotion. For fortified salt, the unit cost was based on the widely used per capita cost estimate for salt iodization (Bhutta, 2013; Horton, 2010), which was applied to the estimated per capita salt consumption in Pakistan to give a unit cost per MT. For biofortification, the unit cost was constructed from budget and production projections associated with the ongoing HarvestPlus biofortification development programme. Projections from the HarvestPlus pessimistic/low-impact scenario were used to estimate the average unit cost over the next ten years, including breeding and delivery (including advocacy) costs, but excluding R&D and other costs incurred prior to 2014. Similarly, budget and production projections from ongoing research initiatives were used to construct the unit cost for the zinc-fortified fertilizer option. These data were used to estimate the average unit cost over the next ten years, including fortificant, logistics and advocacy/promotion costs.

The estimated unit costs and total costs for increasing fortification coverage from current to target levels are presented in Table 15, along with the estimated benefit-cost ratio for each intervention and the cost per life saved, where applicable.

Table 15. Estimated incremental costs and cost-effectiveness of fortification interventions at target coverage compared to current coverage				
	Unit cost (per MT of staple)	Total incremental cost ('000 000)	Benefit-cost ratio	Cost per additional life saved
Wheat flour fortification with iron and folic acid	\$2.24	\$36.0	7.2 : 1	\$10,973 (child) \$73,423 (maternal)
Fortification of edible oil/ghee with vitamin A	\$2.29	\$5.1	9.8 : 1	\$1,735 (child)
Fortification of salt with iodine	\$11.32	\$3.3	58.0 : 1	-
Biofortification of wheat with zinc	\$4.04	\$65.0	0.11 : 1	\$161,238 (child)
Fortification of wheat with zinc-fortified fertilizer	\$13.69	\$220.3	0.06 : 1	\$273,187 (child)

The estimated benefit-cost ratios for the conventional food fortification options are consistent with other recent studies that present economic analyses of fortification, including the 2013 *Lancet Series on Maternal and Child Nutrition* (Bhutta et al., 2013) the 2010 *Scaling Up Nutrition* report (Horton et al., 2009), and the 2008 *Copenhagen Consensus* project (Horton et al., 2009). As expected, salt iodization ranks highest with a benefit-cost ratio of nearly 60:1, followed by vitamin A fortification of edible oil/ghee at nearly 10:1 and wheat flour fortification with iron and folic acid at about 7:1.

Conversely, the effectiveness estimates for the two agricultural options suggest that the costs of biofortification and zinc-fortified fertilizer far outweigh their potential benefits with respect to reducing child mortality. These estimates must be interpreted with caution, however, as these technologies are still under development and remain relatively untested; their efficient costs and their actual effectiveness with respect to improving micronutrient status therefore remain unknown. Previous estimates in the literature ascribe high cost-effectiveness to zinc biofortification of wheat in Pakistan (benefit-cost ratios of 54:420; Meenakshi et al., 2007) but the methods, outcomes and underlying assumptions of those estimates differ from those presented here. The cost-effectiveness of the two agricultural fortification options considered here is assessed with respect only to the potential mortality impact of increased zinc intake; it is possible that additional benefits may be realized through other pathways (for example, cognitive benefits from reduced stunting), but there is currently insufficient evidence on which to model such benefits.

5.3 Appraisal summary

A quantitative summary of the overall appraisal of the intervention option under consideration is presented in Table 16. Scores were assigned to each option with respect to the existing evidence of the effect of the intervention on improving micronutrient status, the prospects for its implementation and scale-up of Pakistan, and the estimate of its cost-effectiveness. Feasibility of implementation and scale-up is considered in terms of local capacity for implementation (e.g., regulation, infrastructure, and previous experience) and local demand (e.g., existing demand or prospects for demand creation).

Table 16. Feasibility appraisal of intervention options for food fortification in Pakistan

	Evidence of effect	Prospects for implementation		Cost-effectiveness
		Capacity	*Demand*	
Wheat flour fortification with iron and folic acid	3	3	2	3
Fortification of edible oil/ghee with vitamin A	2	2	2	3
Biofortification of wheat with zinc	2	3	1	0
Fortification of wheat through zinc-fortified fertilizer	1	3	1	0
Score: 0=very weak/very low; 1=weak/low; 2=moderate; 3=strong/high				

Overall, wheat flour fortification scores strongly, edible oil/ghee fortification scores moderately, and both zinc biofortification of wheat and zinc-fortified fertilizer score weakly.

Further to the counterfactual-based analyses of intervention cost-effectiveness presented above, the projected costs of increasing fortification coverage to target levels over five- and ten-year periods were calculated for wheat flour and for edible oil/ghee (Table 17).

To achieve target coverage in five years, annual coverage increases of 17% (urban) and 13% (rural) were assumed for wheat flour fortification, and an annual increase of 13% was assumed for edible oil/ghee fortification in both all areas. To achieve target coverage over ten years, the assumed annual coverage increases were the

8.5% (urban) and 6.5% (rural) for wheat flour fortification and 6.5% for edible oil/ghee fortification.

Costs were derived by applying the estimated unit cost of fortification per MT of staple ($2.24 for wheat flour, $2.29 for edible oil/ghee) to the estimated fortified staple consumption each year, netting out the estimated current level of fortified staple consumption (0% for fortified wheat flour; 20% and 10% fortified edible oil/ghee consumption in urban and rural areas, respectively).

Factor costs were derived from the proportion that each factor is estimated to contribute to the total unit cost of fortification for each staple. The estimated unit cost for wheat flour fortification reflects 64% fortificant costs, 5% capital costs, 14% in-mill quality control (QC) and other recurrent costs, 10% public quality assurance (QA) costs and 7% public advocacy costs. For edible oil/ghee fortification, 80% of the total unit cost derives from fortificant costs, 4% from in-mill recurrent costs, 8% public QA costs and 8% public advocacy costs. Fortificant premixes included are iron (NaFeEDTA) plus folic acid for wheat flour fortification and vitamin A palmitate for edible oil/ghee. Feeder equipment comprises the capital cost for wheat flour fortification, with the feeder cost amortized over ten years; no capital costs are assumed for edible/oil ghee fortification. For wheat fortification, in-mill quality control costs include on-site personnel and materials for sample testing, while other recurrent costs include maintenance of feeder equipment. For edible oil/ghee fortification, mill-level sample testing is assumed to be mostly through external commercial testing. The combined public-sector costs for QA (monitoring and enforcement) and advocacy to promote fortification are assumed to be 20% of the private-sector costs.

Table 17. Projected costs of scaling up fortification coverage to target levels over five and ten years, by cost factor (‘000 000)

	Fortificant	Capital	In-mill QC /other recurrent	Public QA	Public advocacy	Total
Wheat flour fortification						
5 years	$73.4	$5.7	$16.1	$11.5	$8.0	**$114.7**
10 years	$117.3	$9.2	$25.7	$18.3	$12.8	**$183.3**
Edible oil/ghee fortification						
5 years	$13.2	$0.0	$0.7	$1.3	$1.3	**$16.6**
10 years	$21.5	$0.0	$1.1	$2.1	$2.1	**$26.8**

Finally, these analyses of options for scaling up fortification are a step towards a holistic national nutrition strategy targeting major groups at risk, especially women of reproductive age and young infants and children. Our findings clearly support the utilization of food fortification strategies at scale, which could build on the recent success of the iodized salt programme. Given the widespread prevalence in Pakistan of deficiencies in iron and in vitamins A and D, food fortification strategies offer a tangible option for delivering these micronutrients on a large scale. Zinc deficiency is also highly prevalent in Pakistan; for zinc, however, agriculture options are a more feasible strategy than alternative supplementation options, but these still require further evaluative work. Overall success would also require closer attention to strategies for improving infant and young child feeding as well as quality of complementary foods for young children.

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7.0 Appendices

Appendix 1. Impact model parameters and assumptions

Table A1.1. Impact model effectiveness assumptions

Intervention	Pathway modelled	Effectiveness estimates applied (% reduction)	Notes/Source
Wheat flour fortification with iron and folic acid	Reduced child mortality (from congenital anomalies and via reduced small-for-gestational-age [SGA])	Congenital anomaly mortality: 35%	LiST default value
Wheat flour fortification with iron and folic acid	Reduced child mortality (from congenital anomalies and via reduced small-for-gestational-age [SGA])	SGA: 2%	Assumed to be 1/3 of the LiST default value for IFA supplementation
Wheat flour fortification with iron and folic acid	Reduced maternal mortality (via reduced anemia)	Anemia: 32%	Das et al., 2013
Wheat flour fortification with iron and folic acid	Reduced maternal mortality (via reduced anemia)	For maternal mortality, RR if anemic = 1/0.71 = 1.41	Black et al., 2013
Wheat flour fortification with iron and folic acid	Reduced child anemia prevalence	Anemia: 32%	Das et al., 2013
Wheat flour fortification with iron and folic acid	Reduced adult anemia prevalence	Anemia: 32%	Das et al., 2013
Fortification of edible oil/ghee with vitamin A	Reduced child mortality (from diarrhea in children 6-59m and from all causes in children <6m)	Diarrh mortality (6-59m): 16%	Assumed to be 1/3 of the LiST default value for vitamin A supplementation
Fortification of edible oil/ghee with vitamin A	Reduced child mortality (from diarrhea in children 6-59m and from all causes in children <6m)	All-cause mortality (0-5m): 5%	Assumed to be 1/3 of the vitamin A supplementation effect reported in Haider et al., 2013
Fortification of salt with iodine	Reduced number of births affected by maternal goiter	Goiter prevalence: 95%	Authors' assumption
Biofortification of wheat with zinc	Reduced child mortality (from diarrhea and pneumonia and from other infectious diseases via reduced stunting; 6-59m)	Diarrh mortality: 5%	Assumed to be 1/10 of the LiST default values for zinc supplementation (based on quantity of added zinc)
Biofortification of wheat with zinc	Reduced child mortality (from diarrhea and pneumonia and from other infectious diseases via reduced stunting; 6-59m)	Pneumo mortality: 5%	Assumed to be 1/10 of the LiST default values for zinc supplementation (based on quantity of added zinc)
Biofortification of wheat with zinc	Reduced child mortality (from diarrhea and pneumonia and from other infectious diseases via reduced stunting; 6-59m)	Stunting: 1%	Assumed to be 1/10 of the LiST default values for zinc supplementation (based on quantity of added zinc)
Fortification of wheat through zinc-fortified fertilizer	Reduced child mortality (from diarrhea and pneumonia and from other infectious diseases via reduced stunting; 6-59m)	Diarrh mortality: 10%	Assumed to be 1/5 of the LiST default values for zinc supplementation (based on quantity of added zinc)
Fortification of wheat through zinc-fortified fertilizer	Reduced child mortality (from diarrhea and pneumonia and from other infectious diseases via reduced stunting; 6-59m)	Pneumo mortality: 10%	Assumed to be 1/5 of the LiST default values for zinc supplementation (based on quantity of added zinc)
Fortification of wheat through zinc-fortified fertilizer	Reduced child mortality (from diarrhea and pneumonia and from other infectious diseases via reduced stunting; 6-59m)	Stunting: 2%	Assumed to be 1/5 of the LiST default values for zinc supplementation (based on quantity of added zinc)

Table A1.2. Impact model outcome measures			
Intervention	**Effect**	**Outcome measure: mortality**	**Outcome measure: economic consequence**
Wheat flour fortification with iron and folic acid	Reduced child mortality	Number of additional deaths averted at target vs. current coverage	Additional averted lost future income due to mortality, at target vs. current coverage
	Reduced maternal mortality		
	Reduced child anemia prevalence	-	Additional averted lost future income due to reduced productivity from anemia
	Reduced adult anemia prevalence	-	
Fortification of edible oil/ghee with vitamin A	Reduced child mortality	Number of additional deaths averted at target vs. current coverage	Additional averted lost future income due to mortality, at target vs. current coverage
Fortification of salt with iodine	Reduced maternal goiter prevalence	-	Additional averted lost future income due to reduced productivity among children born to women with goiter
Biofortification of wheat with zinc	Reduced child mortality	Number of additional deaths averted at target vs. current coverage	Additional averted lost future income due to mortality, at target vs. current coverage
Fortification of wheat through zinc-fortified fertilizer	Reduced child mortality		