

**FLOUR FORTIFICATION
IN THE ISLAMIC REPUBLIC OF IRAN:
SUSTAINABLE ROUTE TO IMPROVED HEALTH**



Lavash, a commonly eaten bread in Iran

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Executive Summary

In the mid 1990s, a series of events led Iranian public health officials, government leaders, and industry representatives to work together to improve the nutritional status of people in Iran. Regional workshops identified iron deficiency anaemia as a key public health concern throughout the Middle East, and health leaders in Iran included iron deficiency reduction as a key component of the country's nutrition strategy. At the same time, flour millers in Iran were adopting the latest technology for their industry and organizing a professional association.

Iran has one of the world's highest rates of wheat flour consumption, so flour fortification as a means of delivering extra nutrients to the population was an obvious health intervention to consider. A series of province-wide projects proved fortifying flour with iron was feasible and effective in improving iron status among Iranians. Following the example of several other countries, Iranian leaders decided to fortify flour with folic acid as well as iron. Folic acid reduces the incidence of neural tube defects (NTDs), which are permanently disabling or fatal birth defects.

It took several years for flour fortification to move from a concept to a reality in Iran, partly because the more than 335 flour mills in Iran each required fortification equipment and staff training. Planning a national strategy was also time-consuming because effective flour fortification requires consensus building among multiple parties. In Iran, a multisectoral committee was formed in 1999 to plan for flour fortification, and a working group was established to monitor activities from project design to impact analysis. The country's milling industry was evaluated in 2001 to determine its capacity for fortification, and the Federation of Iranian Associations of Flour Milling Industry began taking steps to prepare for fortification. The government of Iran passed a law in 2005 to require wheat flour fortification, and the law was implemented nationwide by 2007 (*see the decree in Appendix A*).

Iran successfully and systematically has moved from why to fortify, to what to fortify, to how to fortify, and finally to how to fortify effectively and sustainably.

Evaluations of provincial projects that paved the way for national fortification consistently reveal that the population's iron status improved after fortification began. Preliminary results from an unpublished study in Gorgan, the capital of the Golestan province, show a 30% reduction in NTD rates after fortification.

Iran is unique in that while most flour mills are privately owned, the government is involved in nearly every other aspect of wheat and flour production. Mill owners bought the equipment needed for fortification, and the government bears the on-going fortification expenses which average of 14'400 Iranian rial (IRR) or USD 1.60 per metric ton of flour.

The country's thorough work in studying health concerns, identifying a way to address them, establishing a sustainable fortification system, and developing an effective monitoring system is a noteworthy example for other countries considering this route to improved health.

Key to Acronyms

FFI	Flour Fortification Initiative
GCMRC	Gorgan Congenital Malformation Research Center
IAOM	International Association of Operative Millers
IRR	Iranian rial
MI	Micronutrient Initiative
MOHME	Ministry of Health and Medical Education
ND	Nutrition Department
NNFTRII	National Nutrition and Food Technology Research of Iran
NTD	Neural tube defect
NIMS	National Integrated Micronutrients Survey
ppm	parts per million
SSRC	Self Sufficiency and Research Center
TRoCA	Tabriz Registry of Congenital Anomalies
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Acknowledgements

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Introduction

Just as it only takes a touch of saffron to enhance the flavor of food, it only takes a small amount of nutrients added to flour to enhance the nutritional impact of bread, pasta, and any other food made with fortified flour.

Wheat naturally has vitamins and minerals such as iron, zinc, folate, riboflavin, and niacin in its outer bran and germ. These nutrients are mostly lost as wheat is milled into flour, however. Flour fortification replaces nutrients lost in milling or adds more nutrients as needed by the population. The objective is to increase the consumption of vitamins and minerals to improve nutritional status, leading to the prevention, control or elimination of dietary deficiencies and their disorders. Fortification has been carried out in several countries for more than 60 years, and the experiences of the United States¹ and Canada² have been documented for the benefit of other countries.

Vitamins and minerals are referred to as micronutrients because people need them in small daily quantities. Their impact on health is tremendous, however. Iron, for example, is essential for a child's physical and mental development. It is required for physical activity and work productivity at all ages and is critical for the health and survival of a pregnant mother and her unborn child.

"With Iran's nearly universal bread consumption and modern, centralized milling industry, flour fortification was an ideal way to deliver essential micronutrients to people of all ages and socio-economic backgrounds. These factors presented the Micronutrient Initiative with a good opportunity to work with different partners to implement simple and inexpensive fortification procedures and Government-legislated quality assurance measures to make flour fortification a success."

Venkatesh Mannar,

Micronutrient Initiative Executive Director

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Folate, also known as vitamin B9, helps produce and maintain new cells. This is especially critical for women who may become pregnant because folic acid, the form of folate used in supplements and fortification, is known to prevent up to 70% of NTDs if it is taken before conception and very early in pregnancy. The most common NTD is spina bifida in which the spine does not form correctly. In mild cases, permanent loss of some sensation or movement occurs. Severe cases include paralysis and varying degrees of loss of bowel and bladder control. Some spina bifida symptoms can be treated with surgeries and therapy, but spina bifida cannot be cured. Another NTD is anencephaly in which the brain does not form properly, and this causes the infant to die within a few days after birth. Countries with high rates of folate deficiency spend great resources caring for children born with these often preventable birth defects.

¹ Bishai, D. and Naluboa, R. *The history of Food Fortification in United States: the Relevance for Current Fortification Efforts in Developing Countries*. The University of Chicago, 2002.

² Lotfi, M. *Food Fortification in Canada, Experiences and Issues in Controlling Micronutrient Malnutrition*. The Micronutrient Initiative, Ottawa, Canada, 2002.

Countries frequently develop multiple strategies to address micronutrient deficiencies. Supplements and educational programs to encourage dietary diversity are often included. In addition, 60 countries now require fortification of at least one kind of flour. One advantage to flour fortification is that it does not depend on consumer behavior. In countries like Iran where wheat-based foods are widely consumed, and even in countries with moderate wheat flour consumption, wheat flour is an ideal means of delivering additional nutrients. Modern mills can accommodate the equipment required for fortification, and the central processing of most flour simplifies monitoring procedures.

What Generated Interest in Flour Fortification?

In 1994, nutrition experts and the Director of the Nutrition Department (ND) of Iran Ministry of Health and Medical Education (MOHME) developed a national nutrition strategy that included reducing iron deficiency as an important goal. The strategy included nutrition and public health education, dietary diversification, iron supplementation, and food fortification. Fortification alone cannot eliminate disorders such as anaemia and neural tube birth defects, but leaders determined that fortification as part of a complete health program could improve the nutritional and health status of Iran's 74 million³ people.

Activities by international organizations underscored the need to address iron deficiency. Regional leaders of the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) initiated a series of consultative meetings. One of the first such meetings, "Consultation on Strategies for the Control of Iron Deficiency Anaemia," was held by WHO and UNICEF in Tehran, Iran, in October 1995 to develop effective strategies to control iron deficiency. The strategies agreed upon were dietary improvements, iron supplementation for vulnerable groups, and food fortification.

The consultation led to a workshop in October 1996 in Muscat, Oman⁴ on the strategic development of food fortification, with special emphasis on flour fortification, followed by a joint workshop in Beirut Lebanon in 1998 to further define the strategy and develop country action plans. Both workshops were sponsored by the WHO, UNICEF, and the Micronutrient Initiative (MI). One outcome of the Beirut workshop was that MI developed a fund to help countries address obstacles to flour fortification and initiate a national flour fortification program. Terms of reference for awarding the fund were jointly developed by the WHO, UNICEF, and MI. The Eastern Mediterranean Regional Office of the WHO executed the fund, and Iran tapped into the fund's resources for a flour fortification pilot project. The WHO regional office also executed funds from the World Bank,⁵ which were a sub-component of a larger program. The World Bank funds helped Iran expand the fortification program to a national level.

³ Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat. *World Population Prospects: The 2008 Revision. Highlights*. New York: United Nations, 2009.

⁴ Fortification of flour with iron in countries of the Eastern Mediterranean Middle East and North Africa. Based on the joint WHO/UNICEF/ MI deliberations on strategic development workshop on food fortification with special reference to iron fortification of flour. Muscat, Oman, 26-30 October 1996. (WHO-EM/Nut/202/E/G).

⁵ Implementation Completion And Results Report On A Loan In The Amount Of US\$87.0 Million To The Islamic Republic Of Iran For A Second Primary Health Care And Nutrition Project, (http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2009/08/21/000333037_20090821000128/Rendred/PDF/ICR1110P06994311C0disclosed08119191.pdf) accessed June 2010.

Flour millers also generated interest as they learned the importance of fortification at international conferences and seminars such as meetings of the International Grain Council and the International Association of Operative Millers (IAOM). By 2004 when IAOM held a regional meeting in Tehran, Iran had been fortifying flour in some provinces. During a panel discussion on fortification, Mehrzad Jamshidi, chairman of KFF Mills in Iran, said the Federation of Iranian Associations of Flour Milling “knows that fortification is a noble and just cause for the people and for all of us involved... It will be effective and efficient.”⁶ Essa Al-Ghurair, chairman of the Al-Ghurair Food Group, moderated the panel discussion and said, fortification is “a cost to the industry, but in the long term, it is a benefit to the nation.”⁷ As a representative from nearly every Iranian flour mill was in the audience, the meeting helped accelerate flour fortification to the national level.

Why Iron and Folic Acid?

While many vitamins and minerals can be added to flour, the two most frequent health concerns addressed through flour fortification are iron and folic acid deficiencies. Iron is essential for an array of functions from energy metabolism to oxygen use. Consequences of iron deficiency include depressed work capacity and immune function, impaired cognitive functioning and temperature regulation, decreased school performance, compromised growth and development, increased lead and cadmium absorption, and increased risk of pregnancy complications including prematurity and fetal growth retardation.

Iron deficiency cannot always be equated with anaemia which occurs when low haemoglobin levels reduce the red blood cells’ capacity for carrying oxygen. About half of all cases of anaemia can be attributed to iron deficiency; other common causes are infections and genetic factors, according to the WHO. Severe anaemia is associated with 17% lower productivity in heavy manual labor, 5% lower productivity in other manual labor, and an estimated 4% loss of earnings due to lower cognitive skills.⁸

For a 2001 National Integrated Micronutrient Survey (NIMS) in Iran, the country was divided into 11 regions with similar epidemiological indicators. The study showed the prevalence of anaemia as measured by haemoglobin levels as well as iron deficiency based on ferritin levels. Ferritin is a common indicator of an individual’s iron status. Non-pregnant women of child-bearing age were not sampled separately in the survey. The results were as follows:⁹

⁶ Tehran Conference – October 2004 Panel Speakers. The Flour Fortification Initiative (<http://www.sph.emory.edu/wheatflour/Comm/Resource/CDs/Tehran04/content/panel.htm>, accessed 24 May 2010).

⁷ *ibid*

⁸ Horton, S.; Ross, J. The Economics of Iron Deficiency, *Food Policy*, 2003, 28:51-75.

⁹ Mahboob, S.; Abdollahi, Z.; Pouraram, H. National Plan on Iron Malnutrition and Flour/Food Fortification in Iran, Ministry of Health and Medical Education, Undersecretary for Health Nutrition Department and World Health Organization, 2006.

Age	% with anaemia	% with iron deficiency
Children 15-23 months	37.8	32.8
Children 6 years	21.6	25.7
Adolescents (14-20 years)	17.3	23.0
Pregnant women(≥ 5 months)	21.4	43.0
Adult women (50-60 years)	19.0	13.8
Adult men (45-60 years)	10.0	3.7

Depleted or low iron stores were found in low socioeconomic areas, such as the south and southeast [Sistan and Baluchestan, Hormozgan, Bushehr, Fars, Kerman], and also in the north and northwest [Gilan, Mazandaran, Golestan, East and West Azarbayejan and Ardebil] where the socioeconomic situation is better.

The percent of adult men with anaemia is significantly higher than the percent of adult men with iron deficiency. This in part may be due to existence of thalassemia major in the region. This inherited blood disorder represses haemoglobin production and can put people at risk of getting too much iron. The condition can be life threatening, however a report from the WHO Eastern Mediterranean Regional Office says fortifying food with iron does not create a risk for these individuals. The report says dietary iron contributes very little to total iron in people with thalassemia major, and the iron build-up from transfusion therapy far exceeds the iron that would be absorbed from the diet. In addition, treatment with iron chelators is now standard practice to offset iron overload which could be caused by the transfusions.¹⁰

The national survey did not measure folate status, but smaller studies in Iran did reveal folate deficiency. The results of a study in Golestan province showed a mean daily folate intake from food of 198 micrograms.¹¹ The recommended daily allowance of folic acid is 400 micrograms for women of child-bearing age.

Low folate among women increases the risk of children being born with a NTD. Countries report varying rates of NTDs such as 12.6 per 10,000 pregnancies, including terminated pregnancies, in Cuba, 9.6 per 10,000 in Norway, and 4.9 per 10,000 in Hungary.¹² Iran does not have a national birth defect monitoring system, but several studies indicate an incidence rate of about 28-32 per 10,000 births.¹³

¹⁰ Fortification of Flour to Control Micronutrient Deficiencies in the Eastern Mediterranean Middle East and North Africa: Thalassemia and Iron Fortification, Report of a joint WHO / UNICEF / MI / ISLI workshop, Beirut, Lebanon, 13-16 June 1998, Alexandria, Egypt.

¹¹ Abdollahi, Z., et al. Folate, Vitamin B 12 and Homocysteine Status in Women of Childbearing Age: Baseline Data of Folic Acid Wheat Flour Fortification in Iran. *Annals of Nutrition and Metabolism*, 2008, 53:143–150.

¹² Annual Report 2008 with data for 2006. Incidence of anencephaly, spina bifida, and encephalocele are included in the country's NTD rate. International Clearinghouse for Birth Defects Surveillance and Research, Roma, Italy, 2008.

¹³ Gosalipour, MJ; Mansourian, AR and Keshtkar, AA. Serum copper concentration in newborns with Neural Tube Defects in northern Iran: A case control study. *Iranian Journal of Pediatrics*, June 2009 19:(2), 130-134. Department of Embryology and Gorgan Congenital Malformations Research Center, Gorgan University of Medical Sciences, Gorgan, Iran.

Using medical records, a retrospective study¹⁴ in Ahwaz in southwestern Iran estimated prevalence of NTDs between March 2002 and March 2004 to be 42 in 10,000 births. The most common NTD was anencephaly which causes the brain and skull to incompletely form and is always fatal for the infant.

In northwest Iran, the Tabriz Registry of Congenital Anomalies (TRoCA) is a hospital-based registry covering all births in three university hospitals in the city of Tabriz. TRoCA, a member of the International Clearinghouse for Birth Defects Surveillance and Research, reported a NTD rate of 16.9 per 10,000 live births in 2005. Termination of pregnancy for birth defects was not reported.¹⁵ The rate of NTDs dropped to 7.0 per 10,000 in 2006,¹⁶ and more recent crude data (without statistical adjustment) shows a considerable decrease in NTD incidence in 2008 compared to before fortification (personal communication with Mahshid Lotfi). However, more analysis is required before this decline can be assumed to be a direct impact of folic acid fortification.

Flour fortification with folic acid is estimated to prevent 2388 cases of NTDs in Iran per year.

Bell and Oakley, 2006

A study funded by the Micronutrient Initiative has estimated how many NTDs could be prevented by fortifying flour with folic acid. Using worldwide statistics, it is estimated that 2388 NTDs will be prevented per year in Iran, based on the estimated annual prevalence of 3184 NTDs in Iran and a folic acid fortification of flour at the rate of 1.5 parts per million (ppm).¹⁷

Millers' organization and interest in fortification became one of the most important reasons for the program's success. Their willingness to learn and to initially install microfeeders at their own expense greatly facilitated their training and preparations for the national fortification of flour.

Why Fortify Flour?

The WHO/UNICEF/MI consultation held in 1998 noted that flour fortification improved iron intake in several countries, and considering the high per capita flour consumption in the region, flour fortification was recommended as a possible long-term strategy.¹⁸ The last nationwide National Nutrition and Food Technology Research Institute of Iran (NFTRII) food consumption survey in Iran conducted from 2000 to 2003

¹⁴ Behrooz Ahmad. Prevalence of neural tube defect and its relative factors in south west of Iran. *Pakistan Journal of Medical Sciences* July - September 2007, 23 (4):654-656. Department of Obstetrics & Gynecology, Ahwaz Jundi Shapur University of Medical Sciences.

¹⁵ Annual Report 2007 with data for 2005. Incidence of anencephaly, spina bifida, and encephalocele are included in the NTD rate. The Center of the International Clearinghouse for Birth Defects Surveillance and Research, Roma, Italy. 2007, 138-189.

¹⁶ 2008 Annual Report with data for 2006. Incidence of anencephaly, spina bifida, and encephalocele are included in the NTD rate. The Center of the International Clearinghouse for Birth Defects Surveillance and Research, Roma, Italy. 2008 119-120.

¹⁷ Bell KN, Oakley GP, Jr. Tracking the prevention of folic acid preventable spina bifida and anencephaly, *Birth Defects Research Part A: Clinical and Molecular Teratology* 2006, 76:654-657.

¹⁸ Fortification of Flour with Iron In Countries of the Eastern Mediterranean Middle East and North Africa, World Health Organization, Regional Office for the Eastern Mediterranean, 1998.

showed that bread and rice are the most commonly consumed grains and that the mean national consumption of bread is 320 grams per day.¹⁹

Bread was considered the more important food to fortify because it is less expensive than rice and consequently more widely consumed. People in Iran consumed 11.8 tonnes of wheat in various food products in 2003. That amounts to 416 grams of wheat per person per day, one of the highest wheat consumption rates in the world.²⁰ (*see Appendix B for types of wheat products common in Iran*).

Most wheat consumed in Iran is domestically grown which alleviates concerns about how to implement fortification standards on imported flour. For the five years from 2002 through 2006, the average wheat production in Iran was 13.9 million tonnes.²¹ Iran has more than 335 mills, according to the Federation of Iranian Associations of Flour Milling, and their combined milling capacity is more than 23 million tonnes annually.

Choosing flour as the food to fortify was simplified because Iran's milling industry is highly organized, uses modern equipment and is readily supportive of flour fortification efforts. Iran is unique in that to help ensure food security, all activities related to wheat and flour are under government regulation and control. This means that buying wheat from farmers, storing wheat in silos, transporting wheat to mills, covering processing costs, and delivering flour to bakeries are all at the government's expense. When the government opted to produce and supply fortified flour to all Iranians, it determined to do so at no additional cost to the consumer.²²

A 1990 industry seminar analyzed the country's milling infrastructure and described the latest technologies in the milling industry. The seminar was led by the Self-Sufficiency and Research Center (SSRC) which is affiliated with the Ministry of Industry and Mines. By the end of the decade, flour millers were organizing professional associations and by 2001, they had developed quality analysis and quality control procedures. With such interest and organizational support, millers became involved in developing a fortification strategy for Iran as industry representatives met with leaders from the Ministry of Health and Ministry of Commerce.

¹⁹ National Nutrition Institute. The comprehensive study on household food consumption survey and nutritional status of I.R. of Iran; 2000-2003.

²⁰ Food Supply, Crops Primary Equivalent, Food and Agriculture Organization of the United Nations, 2005 (<http://faostat.fao.org/site/609/DesktopDefault.aspx?PageID=609#ancor>, accessed 2 July 2010).

²¹ Production, Crops, Food and Agriculture Organization of the United Nations, 2008 (<http://faostat.fao.org/site/567/DesktopDefault.aspx?PageID=567#ancor>, accessed 7 August 2009).

²² Yazdjerdi, Hossein, National Plan on Flour Fortification: Assessment of Milling Industry and Cost Analysis, Sponsored by WHO, Tehran, December 2005.

What Steps Led to a National Policy?

Initial Efforts

In 1996 the MOHME conducted a pilot trial among 1250 people in the province of Isfahan.²³ The MOHME provided funding for iron premix which was added to flour at the bakery level. Six months later, the percentage of participants with low haemoglobin levels (below 12 grams per deciliter) had decreased from 9.1% to 4.4%, indicating improved iron status. While the results of this first trial were assessed to be of low precision and accuracy and could not be used to establish the feasibility of a national fortification program, they encouraged other relevant activities, including the following:

- formation of a national flour fortification committee
- planning of larger provincial studies, and
- preparation of the milling industry to begin national fortification

Formation of a National Flour Fortification Committee

Iran's successful salt iodization program demonstrated the capacity of the government system to effectively fortify a staple food, as well as the ability of the government and the private sector to work closely together to achieve an important goal. That experience eased the process for flour fortification and led the Nutrition Department of MOHME to form a multisectoral committee for national flour fortification in 1999. The committee was responsible for planning and making policy decisions. It was composed of representatives from all stakeholders including the Nutrition Department, Food Safety Department, Food and Drug Laboratory at the MOHME, Nutrition Research Institute, State Grain Organization, Bread Research Institute, Self Sufficiency and Research for Milling and Baking, Ministry of Commerce and other related industries.

A working group (or provincial subcommittee) was established to monitor and control all activities including project design, implementation, quality control and quality assurance as well as impact analysis and evaluation. It was headed by the Governor General and composed of officials from the MOHME (Nutrition Department, Food Control Department, Province Health Center, and Food Control Laboratories), Ministry of Commerce, Cereals Organization, Council for Bread and Flour, Baker's Union and Medical Sciences University in each province.

Planning and Impact of Large Provincial Studies

After the small pilot project in Isfahan, three larger studies were conducted in Bushehr, Fars, and Golestan provinces. These efforts were instrumental in revealing the feasibility and impact of fortifying flour in Iran. The country's mills already had very high standards for sanitation and cleanliness, and the provincial projects helped food safety authorities and industry leaders develop effective and sustainable quality control processes. Following is a description of each of the larger studies as well as the types of evaluations done and the outcomes.

²³ Tyler, V. *Reducing Iron Deficiency through Wheat Flour Fortification in the Middle East : Lessons from Efforts in Bahrain, Jordan, and Iran*. [thesis]. Atlanta, Emory University, 2005.

Bushehr

The MOHME submitted a proposal to MI for a provincial flour fortification trial. MI and UNICEF supported the trial which was seen as necessary to assess administrative issues and determine fortification efficacy before extending it to a national level (*see Appendix C for details of the grant application*).

The project was originally planned for the Semnan province, but the province had five mills and funding was only available for two microfeeders. Consequently, the trial was conducted in Bushehr province which had only two mills. (Microfeeders are equipment to add micronutrients to flour in large roller mills).

The Bushehr project began in June 2001. The neighboring Fars province was selected as a control group so that any health impact in Bushehr could be compared with a region where fortification was not taking place. With 700,000 people, the Bushehr province was appropriate for the project because it had laboratories which could perform quality control tests for iron in the fortified flour. In addition, the province had a high prevalence of iron deficiency and anaemia among women of child-bearing age, an efficient health management system, a high level of commitment, and a strong primary health care network. A baseline report of nutritional status was established with a 1997 study by the Nutrition Department of MOHME.

The Bushehr project helped establish an effective and sustainable monitoring system in Iran. The system enveloped a variety of activities including monitoring quality assurance data from mills, regular reporting of laboratory testing at the provincial level, and periodically collecting data on consumption of fortified flour and bread at market and household levels.²⁴ The success of the flour fortification in Bushehr could be primarily attributed to the design of this high level quality control and assurance system.

Bushehr Midterm Evaluation

A 2004 midterm evaluation in Bushehr showed significant improvements in serum ferritin levels in women compared to those in Fars province where flour was not yet fortified. Serum ferritin is a standard biochemical indicator which reflects the body's iron stores. Therefore an increase in ferritin means a decrease in iron deficiency, indicating positive impact of the intervention. While

One of the major achievements of the Bushehr project is the establishment of an effective and sustainable monitoring system, which encompasses monitoring quality assurance data from the mills, regular reporting of laboratory testing at the provincial level, and periodically collected data on consumption of fortified flour and bread at market and household level.²³

Dr. Mohamed Mansour
Iran Consultancy Report, 2004

²⁴ Mansour, Mohamed, MI/WHO Consultant, Iran Consultancy Report, 23-28 February 2004.

haemoglobin levels did not significantly change during the time period studied for the midterm evaluation, the study authors noted that fortification may be having a positive effect on haemoglobin levels by preventing further deterioration.²⁵

A second evaluation in Bushehr was completed in 2007, and its results were compared to baseline data in 2001. The results confirmed the findings of the first evaluation showing significant decrease in iron deficiency in men and women.

Another program evaluation of flour fortification in Bushehr was conducted in 2008. The prevalence of iron deficiency measured by ferritin significantly decreased in 2008 compared to 2001, confirming the first two evaluation results.²⁶

Fars

Fars province, which had been the control group for the Bushehr project, conducted a large-scale fortification program from 2004 to 2006. This was done in the province of more than 4 million people to examine the feasibility of extending the flour fortification program nationally. The province has 16 flour mills which together produce 3927 tons of flour a day. By then microfeeders were made locally, and micronutrient premix was produced in Iran. Mill owners purchased the equipment needed to fortify flour, and MI purchased the premix for the project.²⁷

This study further developed various components of a fortification program (program planning, implementation, management, quality control, consumer acceptance, monitoring and evaluation). The methodological approach included:

- Gathering data as baseline
- Establishing multi-sectoral provincial committee under the umbrella of Governor General (with relevant sectors such as Health, Commerce, Management & Planning Organization, Grain Research Center, and the Bakeries Association)
- Leading advocacy meetings
- Conducting training workshops
- Establishing a quality control system to monitor fortified flour and bread
- Increasing public awareness through mass media and field visits.

The average flour consumption in the province is 9.8kg per month. During the project, all flour mills fortified their flour (515,000 metric tons annually), and almost the entire population consumed fortified flour.

Monitoring steps included testing both premix and flour at mills. Personnel responsible for quality assurance recorded the date and time of each sample, results of the spot test to check for nutrients in

²⁵ Sadighi, J., et al., Flour Fortification with Iron: A Mid-Term Evaluation, Public Health 2008; 122:313-321.

²⁶ Sadighi, J. et al., Anaemia control: Lessons from the flour fortification programme. Public Health 2009, 123: 794-799.

²⁷ Final Narrative and Financial Report, Flour Fortification with Iron and Folic Acid in Fars Province, Iran, Micronutrient Initiative, 2004-06.

the fortified flour, and the weight of the microfeeders to ensure the premix was being distributed as expected. Spot tests were expected to be conducted at least once per shift while the mill was operating.

Fars Process Evaluation

This project showed that with collaboration of all stakeholders and relevant sectors, advocating with policy makers and implementing a high quality control system, the flour fortification program could be expanded throughout the country. The successful implementation of this project resulted in achieving political commitment from the Ministry of Commerce to allocate the necessary budget to fortify wheat flour in the country.

Golestan

Before the national program began, the MOHME launched a program to fortify flour in the northern province of Golestan where the NIMS survey showed a high prevalence of anaemia. Another report showed that 14.3% of 579 healthy women of child bearing age sampled in Golestan were folate deficient.²⁸ Fortification began in May 2006 before the nationwide program began in October that year. The program was evaluated in 2008 after 18 months of intervention.

Golestan Outcome Evaluation

The prevalence of iron deficiency significantly decreased in 2008 when compared to the 2006 baseline figures. Studies conducted by Gorgan Congenital Malformation Research Center (GCMRC) before fortification started in Gorgan, capital of the Golestan province, reported incidence of NTDs to be about 28-32 per 10,000 births.²⁹ In 2008 and after 18 months of fortification, the flour fortification program was evaluated, and unpublished preliminary results indicated that the rate of NTDs may have declined by about 30%.³⁰

Industry Steps to Implement and Monitor

A consultant for the WHO and MI performed a needs assessment in 2001 and evaluated the capacity of Iranian mills to begin flour fortification. The Federation of Iranian Associations of Flour Milling analyzed types of microfeeders and recommended four models for use in Iran. The Federation also compiled a list of equipment necessary to test flour and established a timetable for mills to be ready to begin fortification. The timetable was set by consulting the federation board members in discussion with provincial associations.

A key to the program's success was the emphasis on quality assurance. To monitor compliance, iron spot test methods were required and guidelines for conducting these tests were developed by a special

²⁸ Abdollahi, Z., et al. Folate, Vitamin B 12 and Homocysteine Status in Women of Childbearing Age: Baseline Data of Folic Acid Wheat Flour Fortification in Iran. *Annals of Nutrition and Metabolism*, 2008, 53:143–150.

²⁹ Gotalipour, MJ; Mansourian, AR and Keshtkar, AA. Serum Copper Concentration in Newborns with Neural Tube Defects in Northern Iran: A Case Control Study. *Iranian Journal of Pediatrics*, 2009, 19: (2), 130-134. Department of Embryology and Gorgan Congenital Malformations Research Center, Gorgan University of Medical Sciences, Gorgan, Iran.

³⁰ Abdollahi, Z.; Gotalipour MJ, Elmadfa, I. Effects of folic acid fortification of flour on the prevalence of neural tube defects, Preliminary Report, [PhD Research]. Vienna University. 2009.

committee consisting of the Ministry of Health and Standards Organization. Quality control at the mills included three steps:

1. Checking the feeder at regular intervals and adjusting the speed as needed to ensure that premix is being added to flour at the appropriate intervals
2. Performing spot tests at least once per shift during mill operation. The spot test uses a mixture of potassium thiocyanate and hydrogen peroxide to check for iron in the flour. If iron is present at sufficient levels in the flour, then it is assumed that other vitamins and minerals from the premix are distributed throughout the flour as well, making the iron spot test a proxy for other nutrients used in fortification.
3. Performing quantitative tests in the provincial laboratory using spectrophotometric methods to measure the proportion of iron in the random samples of fortified flour collected from the mills.

The Ministry of Health, under legislative authority, was charged with administering the fortification law and establishing detailed implementation regulations that included regular inspections and testing samples during production as well as at factories and retail stores.

The time from 2000 to 2001 was busy with training mill operators and laboratory technicians, procuring feeders and premix, and producing the premix locally. Bioavailability studies were conducted in cooperation with the department of pharmacology at the University of Tehran.

To prepare for national fortification, all mills in the country were divided into five groups based on their geographical locations and individual readiness. Geographical proximity was an important factor for training purposes. MOHME representatives conducted free classes to train millers in how to implement quality control and quality assurance measures. Furthermore, a deadline was set for each group to equip their mills and implement flour fortification with iron and folic acid.

By 2006, roughly 99% of mills were equipped with microfeeders and by August of that year, 84 mills in 10 of the 28 provinces had started fortifying flour. In October 2007, all mills throughout the country started flour fortification with iron and folic acid.

The integrated QC/QA system including testing schedules, testing procedures and information flow that was adopted by the mills and the responsible government departments has been very well designed and implemented for the start up phase of flour fortification.

Quentin Johnson

FFI Technical Coordinator who served as
WHO/MI consultant in Iran

Iran Consultancy Report, 6-18 December, 2005

Consumer Acceptance

Prior to developing a communications and social marketing plan, the MOHME conducted a rapid qualitative assessment of communities' understanding of the benefits of adding iron to flour. The MOHME then developed educational materials on iron deficiency anaemia and its adverse implications for health and well being. These materials were targeted to the general public and health workers as well

as to laboratory personnel. MOHME collaborated with the media regarding social marketing of fortified bread. Within a short period of time, relevant articles in popular newspapers appeared, and television and radio programs invited guests from the ministry to discuss availability of fortified bread and its nutritional and health benefits. The programs referred audiences to published information sheets and websites for more information. Several of the large provincial studies also conducted kick-off events and publicity campaigns to make people aware of the benefits of fortified flour.

Millers who were equipped to fortify flour and began to do so before the national mandate was in place labeled their product as fortified and successfully differentiated themselves from the others in the industry. Since there was no change in the taste or color, and there was no extra charge for the fortified bread, the consumers readily accepted the fortified product.

What Decisions Led to National Implementation?

Prior to program implementation, a needs assessment was conducted on a per-province basis. All mills around the country were equipped and millers trained – an achievement in its own right considering that Iran has more than 335 mills. Also, country leaders had to decide which flours to fortify, set fortification levels, and establish monitoring systems and calculate costs.

Iran decided to fortify flour with extraction rates between 80% and 88% which is about 88% of the flour in the country. Extraction rates refer to the amount of flour that is extracted from wheat in the milling process (*see Appendix B for extraction rates and types of bread in Iran*). Fortification of higher extraction flours, typically whole wheat flours, is not permitted according to the Iran protocol for flour fortification which was updated in 2009.³¹ Whole wheat flour may be fortified, however, if a province consumes a high rate of sangak bread made with this very high extraction rate flour. The Iran policy is flexible in this regard to ensure that fortified bread reaches at least 85% of the population.

Fortification rates were set at 1.5 parts per million (ppm) for folic acid and 30 ppm of ferrous sulfate, a form of iron. Ferrous sulfate was one of two iron compounds suggested for flour fortification based on consultations by the WHO Eastern Mediterranean Regional Office at the time. As bread has a short shelf life in Iran, and flour is used in less than two months, changes in color over time caused by the ferrous sulfate are not a problem.

Tests by the Food and Drug laboratory of the Ministry of Health determined that locally produced ferrous sulfate was of high quality and could be used in Iran's fortification efforts. Folic acid cannot be produced locally, so Iranian pharmaceutical companies were selected to mix imported folic acid and with locally produced ferrous sulfate. Premix quality is tested at each batch of 500 kilograms by testing three random samples at the national Food and Drug Laboratory. The testing guidelines were developed and provided by a special committee consisting of Ministry of Health and Standards Organization.

³¹ Government of Iran. Executive guidelines for conducting flour fortification with iron and folic acid at national level. Updated 2009.

Mill-related expenses for national flour fortification with iron and folic acid in Iran cost the government an average of IRR 14'400 (USD 1.60) per metric ton of flour.³² The cost analysis includes calculations for microfeeders, premix, electricity charges, additional labor, quality control, packaging and labeling. Other costs, such as marketing, advertising, and conducting seminars were at the government's expense and were not directly related to the mills (*see Appendix D for more detailed cost analysis*).

What Were the Challenges?

Iron Inhibitors

Implementation of a national program cannot be carried out without problems. One problem with bread's nutrient content was addressed in the Fars pilot project. Wheat naturally contains phytic acid which lowers iron and zinc absorption by humans. When bread is made with yeast, the phytic acid content is reduced which in turn improves people's ability to absorb those nutrients. When bread is made with sodium bicarbonate (baking soda), however, the phytic acid content is not as affected, and bakers in Iran commonly use sodium bicarbonate instead of yeast. In Fars, two experts from a local yeast producing factory traveled throughout the province to teach the method of making bread using yeast to the new generation of bakers. A provincial committee was created to follow up on the training along with an environmental health expert selected as the focal point.

As is evident in the Cabinet of Ministers decree (*see Appendix A*), reduction of sodium bicarbonate in baking bread has been given special attention by government officials. As a result, sodium bicarbonate is used at only about 30% of the country's bakeries. This figure is closer to 50% for bakeries in Tehran.³³

Safety Concerns

Initially some nutrition experts and university professors expressed concerns over the safety of flour fortification. They argued that because bread is inexpensive, low income people may consume more than a kilogram per day, leading to an iron overload.³⁴ They were also concerned that adding iron to flour may enhance zinc deficiency or prove to be harmful to specific individuals with certain diseases or medical conditions. Many supported simply replacing the iron that wheat loses during the milling process (restoration) as opposed to fortification. The Eastern Mediterranean Regional Office of the WHO suggested a one-day seminar conducted by international and local experts to discuss these concerns. Prior to this seminar, the Nutrition Department at the MOHME convened a special seminar for local experts and university professors to discuss the ministry's intent of expanding the flour fortification program to all other provinces where the prevalence of iron deficiency anaemia is high.

³² Yazdjerdi, Hossein, National Plan on Flour Fortification: Assessment of Milling Industry and Cost Analysis, Sponsored by WHO, Tehran, December 2005.

³³ Personal communications with personnel of Nutrition Department of MOHME.

³⁴ Middle East and North Africa Nutrition Association, Report on Middle East and African Nutrition Association General Assembly and Scientific Meeting, 21 and 22 December 2006, Cairo, Egypt. (<http://www.menana.net/Third.html>, accessed 17 July 2009).

The session was held in January 2003 where the most recent scientific research on flour fortification with iron was discussed and the results of the National Integrated Micronutrients Survey were presented.³⁵ At the meeting, the importance of integrating flour fortification as an intervention to combat iron deficiency into the overall nutrition plan was emphasized. In several meetings, the results of food consumption surveys were presented showing that 70% of Iranian households had inadequate iron intake. All research papers presented at nutrition conferences showed that iron deficiency anaemia is highly prevalent in Iran. Fortification has been shown to be an effective way to reach many people without requiring them to change their habits, but it was also emphasized that fortification is only part of a complete public health strategy. Evaluation results of the fortification programs in Bushehr and Golestan showed no adverse effects from fortification. Nevertheless, the issue of overload is under research. Preliminary data indicated no overload of iron occurs as the result of fortification of flour with iron. It was agreed that every public health intervention has advantages for a majority and may have some disadvantages for a minority.

What Contributed to the Program's Success?

The success and strengths of the flour fortification program in Iran can be attributed to a variety of factors. These include:

- Strong political commitments from national leadership and strong regulatory environment
- Government resources for capacity building and training
- Multi-sectoral committees and alliances with responsive participation of the private industry, including millers and premix suppliers, leading to open channels of communications
- Building of capacities at various levels, including millers from large operations who shared their knowledge with representatives from smaller mills who had little opportunity to attend workshops
- Collaboration in quality control/quality assurance and monitoring
- Communication and social marketing creating consumer acceptance of fortified bread
- Regular consultations and dialogue with stakeholders
- Acceptance of all millers to procure and install microfeeders by their own budget

What Was Achieved?

In the final assessment, national flour fortification in Iran was successful in both preparatory activities and final program outcomes. The outcomes are the results of multi-sectoral cooperation as seen in the National Fortification Committee and Provincial Fortification Committee. Multiple sectors also worked together on advocacy efforts based on medical documents and survey results. In about 10 years, the following was achieved in each of the sectors:

³⁵Nutrition Department of MOHME seminar for local experts and university professors to discuss suitability and benefits of flour fortification with iron and folic acid for Iran, 16 January 2003.

Public health

- A nutritional problem with adverse consequences on the country's health and wellbeing was identified and proven to be addressed with a simple intervention.
- The ability for people to absorb iron from bread was enhanced with reduction in sodium bicarbonate use.
- Cross sectional surveys were planned and conducted to determine program coverage and fortified food consumption.
- Iron deficiency was significantly reduced, preventing adverse consequences on health and wellbeing.
- Folic acid intake increased, resulting in fewer children affected by neural tube defects.
- While previous programs focused on increasing the quantity of foods, the fortification intervention turned policy makers' attention to the importance of improving food quality and not just its quantity. This has had, and will continue to have, a positive impact on programs to improve food and nutritional status of the country.

Government

- Government issued a decree mandating flour fortification.
- Leadership and policy makers were once again (following the salt iodization program) able to bring all technical and professional resources together.
- Flour/bread standards were defined for adding micronutrients to flour, and legislation was approved.
- It can be safely assumed that the government saved a tremendous amount of money and labor through the prevention of diseases, productivity enhancements and the overall health of its population.

Industry

- Food industry became more aware of its vital role in assuring health and wellbeing of consumers.
- Food laboratories were better equipped to perform food analysis, quality control and food inspection.
- Software for data analysis for monitoring purposes was designed.
- Educational material for the general public on the importance of iron and folic acid in daily diet was developed.
- Milling industry became better organized and equipped with the knowledge and tools to do a better and more efficient job.
- Guidelines were developed for rapid qualitative spot tests by a special committee with members from MOHME and Standards Organization.

- Self-sufficiency and Research Center (SSRC) affiliated with the Ministry of Industry and Mines was established.
- Country became more self-sufficient in making required tools and compounds, thereby avoiding import fees while boosting confidence.

What Are the Weaknesses and Next Steps?

- The practice of adding sodium bicarbonate instead of yeast for making bread, leaving behind high levels of phytate, is significantly reduced but is still practiced, particularly in Tehran. To further decrease its use and monitor compliance, improved inspection methods at bakeries are being proposed to better identify the presence of sodium bicarbonates in the dough and bread.
- Analysis of iron in fortified flour at factories and in breads sold at bakeries in both Bushehr and Golestan showed decreased levels of iron in 2009 compared to 2007 and 2004. Several factors can be responsible for reduced levels of iron in these samples. These may include, among others, a shortage in the number of personnel responsible for monitoring, a probable program slowing down due to changes at the ministry level, and some budgetary constraints. This observation emphasizes the importance of monitoring for continued benefit of flour fortification.
- Organizational changes, including program managerial replacements in the MOHME and moving the National Flour Fortification Committee from the then Nutrition Department of the Ministry to its Food and Drug Division, slowed down activities. This necessitated training of the new staff and those recently engaged in the program.
- Budget availability and allocation to purchase premix as well as other related costs need careful attention to avoid program discontinuation.
- The spot test mills use to evaluate iron content is a proxy for other micronutrients included in the premix, in this case, folic acid. Folic acid can be measured in the final food product, and Iran may want to consider doing this periodically as an additional quality assurance step.
- Iran does not have a national program to measure the incidence of neural tube defects. A national registry would be helpful in determining the extent of births affected by NTDs and helping the country know where more intervention is needed. Future health surveys in Iran could also include tests of serum or plasma folates to further refine populations at risk of pregnancies affected by NTDs.
- Fortification continues today with ferrous sulfate and folic acid. Flour fortification guidelines released in 2009, however, recommend sodium iron EDTA for the type of flour that Iran fortifies due to the iron's bioavailability. Sodium iron EDTA is more expensive than ferrous sulfate, and monitoring sodium iron EDTA in mills requires a different test than the spot test currently used in Iran. To reduce the cost of fortification with sodium iron EDTA but to secure the desired bioavailability, one promising alternative under study is using a mixture of sodium iron EDTA and ferrous sulfate.

- A cross-sectional survey in the Golestan province in February 2006 found insufficient vitamin B₁₂ in Iranian women of child bearing age,³⁶ and the 2001 NIMS found significant zinc deficiencies. Flour can be fortified with vitamin B₁₂ and zinc, but they are not included in Iran's current mandate. Iran may want to consider adding these vitamins to the milling premix if evidence continues to suggest vitamin B₁₂ and zinc deficiencies in the country. Studies are underway to research the feasibility of this, but the additional cost is a primary consideration.

What Lessons Were Learned?

- Realistic expectations regarding the impact of flour fortification on anaemia need to be clarified at the beginning of the fortification process. While studies consistently revealed that fortification improved serum ferritin levels and reduced NTDs, little difference in anaemia rates was observed, and this disappointed some leaders. Flour fortification can only address anaemia caused by iron deficiency, and it is not a curative intervention. Over time it can be expected to improve iron status in the population as a preventive measure so that people are less likely to develop iron deficiency anaemia. Flour fortification, however, is not likely to have an immediate impact on all anaemia rates.
- Involving the public sector, private sector, academia, and consumers from the very beginning of the process was a major factor in the success of the program and a very important lesson to be learned for all future programs. When all stakeholders are brought together early in the program's planning, win-win situations and a feeling of mutual trust can be fostered between the sectors.
- Funding needs to be secured as early as possible to ensure the long term success of the program with clear allocations to all sections and divisions involved. This will minimize potential conflicts between divisions and facilitate better budgeting and planning.
- More effective and practical ways to enforce regulations are required. For example, the use of yeast in place of sodium bicarbonate needs to be strongly advocated and enforced through better inspections.
- A lesson learned by the milling industry is the importance of sound and continuous training, and providing appropriate number of staff at factories to ensure sustained production of the highest possible flour quality.
- Before program implementation, it is very important to use all communication tools to better educate the public on the reasons and value of the program.

³⁶ Abdollahi, Z. et al. Folate, Vitamin B 12 and Homocysteine Status in Women of Childbearing Age: Baseline Data of Folic Acid Wheat Flour Fortification in Iran. *Annals of Nutrition and Metabolism*, 2008, 53:143–150.

Conclusion

Flour fortification has already had an impact in Iran by improving iron status and reducing neural tube defects. While the government's role in the wheat and flour industry in Iran is unique, the problems of iron deficiency and preventable birth defects are shared by countries across the globe. Iran's established system for adding micronutrients to flour serves as a model for other countries considering flour fortification as part of their national strategy to combat vitamin and mineral deficiencies.

Appendices

Appendix A

Official Iranian Cabinet of Ministers Decree for National Flour Fortification

Date 28/12/1384
(19 March 2006)

Emblem of Islamic Republic of Iran

Islamic Republic of Iran

Office of the President

Cabinet of Ministers Decree

In the Name of God

Ministry of Health and Medical Education

The Cabinet of Ministers in the session dated 28/12/1384 (19 March 2006), at the request number 301558 of the Ministry of Health and Medical Education and pursuant to the Article one hundred thirty eight of the Constitution of the Islamic Republic of Iran has mandated the following: (only relevant items below were translated - *Translator*)

Item #7: To eliminate micronutrient deficiencies and malnutrition, Ministries of Social Welfare, Education, Health and Medical Education, Management and Planning Organization and Imam Khomeini Committee should hold working groups sessions for execution of the programs to provide suitable snack foods for students with priority to poor areas and report the outcomes within two months.

Item #9: Management and Planning Organization of the Country, Ministries of Commerce (Professional Commercial Services Mother Company) and Health and Medical Education should make all the necessary arrangements for execution of the national fortification of flour with iron and folic acid as of the beginning of the year 1385 (21 March 2006).

Item #12: The Ministry of Health and Medical Education with cooperation of Ministry of Commerce should study the program of eliminating sodium bicarbonate from bread baking and submit the report to the Cabinet of Ministers to issue decree.

Parviz Davoodi
First Vice President

Copies to His Excellency Supreme Leader Office, Office of the President, Head of the Judicial Branch Office, First Vice President Office; Executive Vice President Office; Office of the Vice President for Legislative and Parliament Affairs; Chairman of the Expediency Discernment Council of the System Office; The Country Tribunal Accountability Office; The Tribunal Administrative Justice; The Acts Department of the Islamic Consultative Assembly (Majlis); The Country Inspection Organization; The Legal Administration; The Country Acts and Provisions Administration

All Ministries, organizations and government agencies; Structures of the Islamic Revolution; The Official Newspaper of the Islamic Republic of Iran; Secretariat of the Government Information Council, and the Office of the Government Council.

Appendix B

Specifications and Consumption of Flour Produced in Iran

Type of Flour	Extraction Rate	Relative Share of Consumption	Type of Products
Whole Wheat	93-97%	6%	Sangak Bread
Sabbos-gerefteh	86%	64%	Lavash Bread Taftoon Bread
Setareh	81%	24%	Barbari Bread
Nil or White Flour	50%	6%	Confectionary & Pasta

Source: Federation of Iranian Associations of Flour Milling

Appendix C

Grant Applications

To secure international funding, grant applications for pilot projects provided complete plans and budgets. Items covered in the proposal for the trial project in Bushehr province which was funded by the grantors included a plan of action and budget for:

- Iron deficiency anaemia survey
- Milling sector review
- Review of standards and legislation
- Policy level advocacy
- Baking trials and taste panels
- Communications research and focus groups
- Training, feeder purchase, premix procurement and quality assurance/ quality control system development
- Social marketing
- Program impact monitoring and evaluation

Appendix D

Cost Analysis

In a compressive cost analysis, Dr. Hossein Yazdjerdi, managing director of Iranflour, estimated that each mill would need two microfeeders. Additional considerations were:

- Annual maintenance costs were calculated at 10% of investment price.
- Electricity was estimated to require additional IRR 2'000'000 (USD 220) per year.
- Additional personnel were estimated to be one laboratory expert for quality assurance duties plus one operator per shift (3 shifts per day), thus totaling addition of four employees, with the estimated total cost of IRR 120'000'000 per year (USD13000).
- Laboratory equipment and supplies were estimated at IRR 2'000'000 (USD 220) per year.
- It was assumed that the equipment will become fully depreciated in 10 years.
- No construction costs were included as it was assumed that most mills have enough space to install microfeeders.

The above costs were considered to be fixed annual costs, since they will be spent by the mills regardless of production capacity. On the other hand, the price of premix and labeling are directly proportional to actual production. The analysis assumed that 80% of processed wheat is turned into flour and that mills were only operating at 50% of their capacity.