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Original Research

Flour fortification with iron: a mid-term evaluation

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Summary *Objectives:* Iron-deficiency anaemia is a major nutritional problem in Iran. A programme of flour fortification with iron was launched in 2001. A mid-term evaluation was conducted in 2004 to determine the effectiveness and coverage of this programme.
Methods: To determine the effectiveness of the program, a field trial was conducted in which blood hemoglobin and ferritin levels were measured in a sample population from Bushehr (intervention) and Fars (control) provinces. The target population was women aged 15–49 years. The coverage of the programme was determined using a cross-sectional study that measured iron content in samples of flour and bread from Bushehr province.
Results: Five hundred and sixty-seven and 296 women were studied in the intervention and control provinces, respectively. Women in the intervention province had a lower prevalence of low ferritin levels compared with women in the control province ($P = 0.04$). Women from the two provinces did not differ in terms of haemoglobin levels and iron-deficiency anaemia. The coverage of fortified flour and bread was 100% and 99.7%, respectively.
Conclusions: This mid-term evaluation found that the iron fortification programme in Iran has only had a beneficial effect on the prevalence of low ferritin levels. The final evaluation is likely to provide more useful information regarding the effect of this programme on a number of anaemia indicators.
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Introduction

Iron deficiency is the most common nutritional disorder in the world, and it is estimated that as many as 3.5 billion people could be affected. Iron

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deficiency is an important public health problem in both developed and developing countries.[1,2] According to World Health Organization (WHO) mortality data, around 0.8 million deaths (1.5% of the total) can be attributed to iron deficiency each year. In terms of the loss of healthy life, expressed in disability-adjusted life years (DALYs), iron-deficiency anaemia results in 25 million DALYs lost (or 2.4% of the global total).[3]

While more than half of anaemia cases worldwide are due to nutritional iron deficiency, subclinical iron deficiency resulting in functional disadvantages is as widespread as iron deficiency with anaemia.[4] Therefore, the prevalence of anaemia can be taken as an indicator of the extent and trends of iron deficiency. Maternal anaemia results in intra-uterine growth retardation, low birth weight, increased perinatal mortality, and increased maternal morbidity and mortality.[2,5–7] In developing countries, severe anaemia is the main causal factor in up to 20% of maternal deaths.[4,8,9] About one-fifth of perinatal mortality and one-tenth of maternal mortality in developing countries is attributable to iron deficiency.[10]

Iron-deficiency anaemia is also a serious public health problem in all countries comprising the Eastern Mediterranean Region of the WHO and comprising the Middle East and North Africa Region of the United Nations Children's Fund (UNICEF).[11]

Mandatory fortification of flour with iron has been practiced in developed countries for many years and has been reported to contribute to iron intake.[12–16] Food fortification may be an effective approach to combat iron deficiency.[17,18] Food fortification in Europe has been shown to contribute positively to micronutrient nutrition in adults[19] and children.[20]

Food fortification is one of four components of a cost-effective strategy for addressing micronutrient deficiencies; the other three components are supplementation, dietary diversification and public health measures such as promoting breast feeding and controlling parasitic infestations. Common food vehicles used around the world for iron fortification include processed cereals (e.g. wheat and corn), salt, sugar, condiments and other processed foods.[2,11]

Bread consumption is high in most countries of the Eastern Mediterranean Region of the WHO. Flour fortification offers an opportunity to deliver efficacious levels of iron to reduce the prevalence of iron deficiency and anaemia, and to cover a large part of the vulnerable population at low cost. This strategy is now being implemented in a number of countries in the region.[11]

In Iran, iron-deficiency anaemia is one of the most common nutritional problems. A national study conducted by the Ministry of Health and Medical Education and UNICEF in 1999 showed that 33.4% of Iranian women were anaemic according to haemoglobin levels, and 34.5% were iron deficient according to serum ferritin levels. The prevalence of iron-deficiency anaemia in Iranian women was 16.6%.[21,22]

Food fortification is considered to be an efficient strategy for combating iron deficiency in Iran. Cereals provide 63% of the total energy intake, the national per capita consumption of wheat was estimated to be 178 kg/year in 1993, and consumption of bread ranges from 230 to 505 g/person/day.[4] This dietary information indicates that wheat flour is an ideal vehicle for a fortification programme in Iran. The Iranian Ministry of Health and Medical Education launched a programme of flour fortification with iron on 31 May 2001 in Bushehr province. The iron-fortified flour premix is produced inside Iran and consists of 30 ppm ferrous sulphate and 1.5 ppm folic acid.

Quality assurance is the process of ensuring the adequacy and quality of fortified food products from production to consumption. A complementary activity is epidemiological surveillance, including monitoring and evaluation of the micronutrient status of the population to identify the impact of the intervention strategy.[23] In February 2004, a mid-term epidemiological surveillance of the flour fortification programme in Iran was conducted, and a final evaluation will be undertaken in 2007. The present study compared the mid-term data with baseline data gathered before the intervention in 2001 to determine the effectiveness of the iron-fortified flour programme.

Methods

The mid-term evaluation consisted of two studies. The first study was a field trial to determine the effectiveness of the programme. The intervention province (Bushehr) was compared with the control province (Fars) for anaemia indicators. The target population was women aged 15–49 years. Women of reproductive age were chosen because maternal anaemia results in increased perinatal and maternal morbidity and mortality. In each province, a cluster sampling method was used to sample the population.

The dependent variables were low haemoglobin level, low serum ferritin level, iron-deficiency anaemia, mean haemoglobin level and mean ferritin level. Low haemoglobin was defined as <12 g/dl in non-pregnant women, and <11 g/dl in pregnant women based on the WHO criteria.[24] Low ferritin was defined as $<10\,\mu g/l$ in women, according to the kit standard. Iron-deficiency anaemia was defined as both low haemoglobin and low ferritin.

Blood samples were taken from 900 women (600 from Bushehr province and 300 from Fars province) and tested for haemoglobin and ferritin. In addition, data were collected regarding characteristics that may be confounding, and logistic regression (for categorical variables) and linear regression (for numeric variables) were used to adjust for these confounders. P-values <0.05 were considered to be statistically significant. Analyses were conducted using Statistical Package for the Social Sciences software (SPSS Inc, Chicago, IL, USA), and the Explore procedure was used for outlier identification, resulting in ferritin levels $>400\,\mu g/l$ and haemoglobin levels $>20\,g/dl$ being excluded.

The second study was a cross-sectional investigation to determine coverage of the programme in Bushehr province. This study measured the iron content in 290 bread samples from households (one sample in each cluster), and in flour from 43 bakeries (from a systematic sampling of 430 bakeries). The dependent variables were iron concentrations in bread and flour.

The iron content was assayed using a spectrophotometric method (AACC 40-41B). This method determines iron content by reaction with orthophenanthroline and spectrophotometric measurement.[25] In terms of the iron level in bread (or flour), low was defined as 25–39.9 ppm, good as 40–65.9 ppm, acceptable as 66–79.9 ppm and high as $\geqslant 80$ ppm. These ranges were taken from the guidelines of the iron assay method.

Results

Study 1. Programme effectiveness

Baseline data (gathered prior to the intervention in 2001) were derived from 889 female subjects: 598 from Bushehr province and 291 from Fars province. The mid-term evaluation data were derived from 863 female subjects: 567 from Bushehr (intervention) province and 296 from Fars (control) province. The total number of samples assessed was less than the sample size due to clotting in some blood samples. In total, 29 subjects were excluded due to outlying haemoglobin levels (16 subjects in 2001 and 13 subjects in 2004), and 43 subjects were excluded due to outlying ferritin levels (28 subjects in 2001 and 15 subjects in 2004).

Subject characteristics are shown in Table 1. All indicators of anaemia were adjusted for significant characteristics in the logistic model and linear regression.

Prevalence of low haemoglobin levels

The prevalence rates of low haemoglobin levels in the intervention and control groups are shown in Table 2. Before the intervention, the prevalence of low haemoglobin levels was significantly lower in Bushehr women compared with Fars women (12.2% vs 20.1%; $P = 0.006$). After the intervention, the prevalence of low haemoglobin levels was still significantly lower in Bushehr women than Fars women (10.8% vs 21.4%; $P < 0.001$). The prevalence of low haemoglobin levels did not differ significantly between 2001 and 2004 in Bushehr women ($P = 0.5$) or Fars women ($P = 0.6$).

The change in prevalence of low haemoglobin levels between 2001 and 2004 in Bushehr women was compared with that in Fars women (Table 3). The difference between these changes was not significant (−1.4% vs 1.3%; $P = 0.5$). These data show that the intervention did not change the prevalence of low haemoglobin levels in Bushehr women.

Prevalence of low ferritin levels

The prevalence rates of low ferritin levels in the intervention and control groups are shown in Table 2. Before the intervention, the prevalence of low ferritin levels did not differ significantly between Bushehr women and Fars women (23% vs 25.5%; $P = 0.5$). After the intervention, the prevalence of low ferritin levels was significantly lower in Bushehr women compared with Fars women (21.3% vs 33.1%; $P = 0.001$). There was no significant difference in the prevalence of low ferritin levels between 2001 and 2004 in Bushehr women ($P = 0.4$) or Fars women ($P = 0.06$).

The change in prevalence of low ferritin levels between 2001 and 2004 in Bushehr women was compared with that in Fars women (Table 3). The difference between these changes was significant (−1.7% vs 7.6%; $P = 0.04$). These data show that the intervention decreased the prevalence of low ferritin levels in Bushehr women compared Fars women.

Prevalence of iron-deficiency anaemia

The prevalence rates of iron-deficiency anaemia in the intervention and control groups are shown in Table 2. Before the intervention, the prevalence of iron-deficiency anaemia was not significantly different between Bushehr women and Fars women (5.3% vs 9.1%; $P = 0.07$). After the intervention,

Table 1 Characteristics of women in the intervention and control groups at baseline (2001) and 3 years after the intervention (2004).

	Intervention group (Bushehr province)	Control group (Fars province)	*P*
Mean age ± SD (year)			
Baseline	31 ± 8.6	32.7 ± 9.1	0.005*
After intervention	30.6 ± 8.9	30.3 ± 8.8	0.5
P	0.5	0.001*	
Anaemia history (%)*			
Baseline	—	—	—
After intervention	13.4	16.9	0.2
P	—	—	
Regular use of ferrous sulphate (%)			
Baseline	7.9	10.7	0.2
After intervention	8.5	12.8	0.05
P	0.7	0.4	
Blood donor history (%)			
Baseline	0.7	0.0	0.3
After intervention	0.7	1.4	0.4
P	1	0.1	
Surgery history (%)			
Baseline	4.6	2.4	0.1
After intervention	2.3	2.7	0.8
P	0.04*	1	
Urban women (%)			
Baseline	53.8	38.5	< 0.001*
After intervention	54.7	40.2	< 0.001*
P	0.8	0.7	
Menstruation (%)			
Baseline	15.3	14.8	0.9
After intervention	18.5	20.3	0.5
P	0.2	0.8	
Menopausal status (%)			
Baseline	3	4.1	0.4
After intervention	3.2	3.7	0.7
P	1	0.8	
Marital status (%)			
Baseline	82.5	86.3	0.2
After intervention	78.8	76	0.4
P	0.3	0.007*	
Pregnancy (%)			
Baseline	5.9	4.4	0.5
After intervention	4.5	4.4	1
P	0.4	1	
Mean no. of pregnancy months ± SD			
Baseline	5.7 ± 2.3	4.8 ± 3.2	0.4
After intervention	5.8 ± 3.1	4.4 ± 2.4	0.2
P	0.8	0.7	

SD, standard deviation.
* *P*-values < 0.05 were considered to be statistically significant.

Table 2 Anaemia indicators by intervention and control groups.

	Intervention group (Bushehr province)	Control group (Fars province)	P*
Low haemoglobin (%)			
Baseline (2001)	12.2 (584)**	20.1 (289)	0.006
After intervention (2004)	10.8 (556)	21.4 (294)	<0.001
P*	0.5	0.6	
Low ferritin (%)			
Baseline (2001)	23 (575)	25.5 (286)	0.5
After intervention (2004)	21.3 (555)	33.1 (293)	0.001
P	0.4	0.06	
Iron-deficiency anaemia (%)			
Baseline (2001)	5.3 (568)	9.1 (285)	0.07
After intervention (2004)	3.7 (545)	11.3 (291)	<0.001
P	0.2	0.2	
Mean haemoglobin ± *SD* (g/dl)			
Baseline (2001)	13.6 ± 1.6 (584)	13.1 ± 1.5 (289)	<0.001
After intervention (2004)	13.5 ± 1.4 (556)	12.9 ± 1.4 (294)	<0.001
P	0.1	0.07	
Mean ferritin ± *SD* (μg/l)			
Baseline (2001)	31.2 ± 40.6 (575)	31.6 ± 45.7 (286)	0.96
After intervention (2004)	34.7 ± 35.4 (555)	33.3 ± 38.2 (293)	0.7
P	0.08	0.4	

SD, standard deviation.
*P-values < 0.05 were considered to be statistically significant. P-values adjusted for significant characteristics in logistic regression for categorical variables and in linear regression for numerical variables.
**n values in parentheses.

the prevalence of iron-deficiency anaemia was significantly lower in Bushehr women compared with Fars women (3.7% vs 11.3%; $P < 0.001$). The prevalence of iron-deficiency anaemia did not differ significantly between 2001 and 2004 in Bushehr women ($P = 0.2$) or Fars women ($P = 0.2$).

The change in the prevalence of iron-deficiency anaemia between 2001 and 2004 in Bushehr women was compared with that in Fars women (Table 3). The difference between these changes was not significant (−1.6% vs 2.2%; $P = 0.2$). These data show that the intervention did not affect the prevalence of iron-deficiency anaemia in Bushehr women.

Mean haemoglobin levels

The mean haemoglobin levels in the intervention and control groups are shown in Table 2. Before the intervention, the mean [standard deviation (SD)] haemoglobin level was significantly higher in Bushehr women compared with Fars women [13.6 (1.6) g/dl vs 13.1 (1.5) g/dl; $P < 0.001$]. After the intervention, the mean (SD) haemoglobin level was still significantly higher in Bushehr women compared with Fars women [13.5 (1.4) g/dl vs 12.9 (1.4) g/dl; $P < 0.001$)]. Mean haemoglobin levels in 2001 and 2004 were not significantly different in Bushehr women ($P = 0.1$) or Fars women ($P = 0.07$).

The change in mean haemoglobin levels between 2001 and 2004 in Bushehr women was compared with that in Fars women (Table 3). The difference between these changes was not significant [−0.1 (0.07) g/dl vs −0.2 (0.1) g/dl; $P = 0.5$)]. These data show that the intervention did not affect the mean haemoglobin level in Bushehr women.

Mean ferritin levels

The mean ferritin levels in the intervention and control groups are shown in Table 2. Before the intervention, the mean (SD) ferritin level did not differ significantly between Bushehr women and Fars women [31.2 (40.6) μg/l vs 31.6 (45.7) μg/l; $P = 0.96$)]. After the intervention, the mean (SD) ferritin level did not differ between Bushehr women and Fars women [34.7 (35.4) μg/l vs 33.3 (38.2) μg/l; $P = 0.7$)]. Mean ferritin levels in 2001

Table 3 Change in anaemia indicators by intervention and control groups before (2001) and after (2004) the intervention.

	Intervention group				Control group				Difference of changes	SE of difference	P
	2001	2004	Change	SE of change	2001	2004	Change	SE of change			
Low haemoglobin (%)	12.2	10.8	−1.4	1.9	20.1	21.4	1.3	3.4	2.7	3.8	0.5
Low ferritin (%)	23	21.3	−1.7	2.5	25.5	33.1	7.6	3.8	9.3	4.5	0.04*
Iron-deficiency anaemia (%)	5.3	3.7	−1.6	1.2	9.1	11.3	2.2	2.5	3.8	2.8	0.2
Mean haemoglobin (g/dl)	13.6	13.5	− 0.1	0.07	13.1	12.9	−0.2	0.1	0.1	0.1	0.5
Mean ferritin (μg/l)	31.2	34.7	3.5	2.3	31.6	33.3	1.7	3.5	1.8	4.2	0.7

SE, standard error.
*Change from baseline significantly different from that for control group.

and 2004 did not differ significantly in Bushehr women ($P = 0.08$) or Fars women ($P = 0.4$).

The change in mean ferritin levels between 2001 and 2004 in Bushehr women was compared with that in Fars women (Table 3). The difference between these changes was not significant [3.5 (2.3) μg/l vs 1.7 (3.5) μg/l; $P = 0.7$)]. These data show that the intervention did not change the mean ferritin level in Bushehr women.

Study 2. Programme coverage

Iron in bread

Two hundred and ninety bread samples from Bushehr province were analysed. The mean (SD) iron concentration in bread was 48.7 (8.5) ppm, which was defined as 'good'. The mean (SD) iron levels in bread in urban and rural regions were 48.5 (7.9) and 48.9 (9.2) ppm, respectively. This difference was not statistically significant ($P = 0.7$). The distribution of iron levels in bread in Bushehr province is shown in Table 4. The percentages of bread samples with high, acceptable, good and low levels of iron were 0%, 2.1%, 81.4% and 16.2%, respectively. One bread sample (0.3%) showed no evidence of fortification; this sample was rural and was not from a bakery. These data show that the coverage of bread fortified with iron was 99.7% in Bushehr province.

Iron in flour

Forty-three flour samples from Bushehr province were analysed. The mean (SD) iron level in flour was 52.8 (9.9) ppm, which was defined as 'good'. The mean (SD) iron levels of flour from the Alzahra and Borazjan mills, and from flour comprised of mixtures from various mills (mixed flour from Alzahra and Borazjan, or mixed flour from Bushehr and other provinces) were 52.6 (9.1), 56 (9.6) and 50.1 (10.6) ppm, respectively. There was no significant difference in mean iron levels in flour between mills ($P = 0.3$), and all mills had good iron levels. The distribution of iron levels in flour in Bushehr province is shown in Table 4. The percentages of flour samples with high, acceptable, good and low iron levels were 0%, 14%, 74.4% and 11.6%, respectively. The coverage of flour fortified with iron was 100% in Bushehr province.

Discussion

Iron fortification has been used to enhance iron intake in many developed countries for more than 50 years, but only in the last decade has this strategy been applied on a large scale to other parts of the world. Effectiveness and feasibility

Table 4 The distribution of bread and flour iron levels.

Iron level	Bread samples ($n = 290$)			Flour samples ($n = 43$)		
	n	%	Cumulative (%)	*n*	%	Cumulative (%)
High	0	0	0	0	0	0
Acceptable	6	2.1	2.1	6	14	14
Good	236	81.4	83.5	32	74.4	88.4
Low	47	16.2	99.7	5	11.6	100
None	1	0.3	100	0	0	100

studies are required to test the new technologies and processing/distribution systems.[26]

Flour fortification with iron is considered to be an efficient strategy for combating iron deficiency in Iran. The results of mid-term evaluation after 3 years of fortification showed that the coverage of fortified flour was 100%, indicating that fortified flour was available in all bakeries in Bushehr province. The coverage of fortified bread was 99.7%. While the coverage of fortified bread was high, particular attention needs to be paid to flour in rural areas as some of this flour may not be prepared from mills in Bushehr province.

For the past 60 years, fortification of wheat flour with iron and vitamins has been implemented in a number of countries to reduce the prevalence of anaemia and deficiencies. The present study in Iran found that the fortification programme decreased the prevalence of low ferritin levels in Bushehr (intervention) women compared with Fars (control) women. This finding shows that fortification had a beneficial effect on the prevalence of low ferritin levels. Interestingly, this mid-term study found that fortification had no effect on haemoglobin levels or the prevalence of iron-deficiency anaemia.

Haemoglobin measurements are important in the diagnosis of anaemia, but they are not sensitive to or specific for iron deficiency. In many developing countries, it is unlikely that all cases of anaemia are due to iron deficiency because other nutritional deficiencies, malaria, helminths and other inflammatory/infectious diseases also cause anaemia.[27] According to the Centers for Disease Control and Prevention, parts of Bushehr province were risk areas for malaria in 1996.[28] The Islamic Republic of Iran has three epidemiological zones of malaria. The annual parasite incidences in Zones 1, 2 and 3 were approximately 0.07, 0.11 and 2 per 1000 in 2002, respectively. Bushehr is in Zone 2 and it was established of two new foci in Bushehr and Fars provinces during 2002.[29] Therefore, in areas where anaemia is not mainly due to iron deficiency, iron supplementation and/or the fortification of food with iron will be inadequate by themselves to prevent and control anaemia. This means that blood haemoglobin is not an adequate proxy indicator for iron status in developing countries and a combination of various biochemical indicators of iron status, such as haemoglobin, serum ferritin, erythrocyte protoporphyrin, transferrin saturation and transferrin receptors, must be used.[30] The authors suggest that a proper biochemical indicator should be used to determine iron status in future studies.

Two national 'health and disease' surveys were conducted in 1989 and 1999 in Iran, and these studies showed that the prevalence of low haemoglobin levels was increasing in both Fars and Bushehr provinces (ferritin status was not measured). The present study showed that the prevalence of low haemoglobin levels is increasing in Fars province as indicated previously, but that the prevalence of low haemoglobin levels in Bushehr province is not increasing as shown previously. These data suggest that although the mid-term study showed that flour fortification had not altered the prevalence of low haemoglobin levels, fortification may be having a positive effect on haemoglobin levels by preventing further lowering. Although no significant changes in mean haemoglobin level and prevalence of low haemoglobin levels were observed between provinces in the mid-term evaluation, it is possible that the trend for haemoglobin is still emerging, and that the full-term study data will show increased haemoglobin levels as a result of the intervention. It is mentioned that haemoglobin is the last iron index to change in uncomplicated iron deficiency, and thus it may not provide information about early stages of iron storage depletion, which is reflected by decreased serum ferritin concentration.[31]

This mid-term evaluation showed that the iron fortification programme in Iran has only had a beneficial effect on the prevalence of low ferritin levels. Analysing the iron content of fortified flour determines whether the required level of iron is present, which is critical to the success of a flour fortification programme. It was estimated that the level of fortification used in the present work could increase the iron intake of the target population and improve anaemia status in Bushehr province. It should be noted that, in developing countries, the regular consumption of high phytate meals may promote anaemia because much of the iron ingested is unavailable for absorption.

The present study had the same limitations as any field trial. The target population was not paired before and after the intervention. In addition, field trials cannot control confounders in the same way as clinical trials, so the control community differed from the intervention community at baseline. Therefore, the populations of the provinces were matched in the analysis.

While flour fortification alone will not prevent iron-deficiency anaemia, it is an important component of a public health strategy.[2] In Sweden, at least 25% of the decline in the prevalence of iron deficiency was attributed to iron fortification, while the reminder was attributed to greater prescription of iron tablets and use of ascorbic acid supplements. This highlights the need for multiple strategies to prevent iron deficiency.[32] Therefore, the fortification programme alone should not be relied upon to reduce the incidence of anaemia or iron deficiency. It is the authors' belief that the final evaluation is likely to provide more useful information regarding the effect of this programme on a number of anaemia indicators.

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None.

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