

FOLATE TASK TEAM

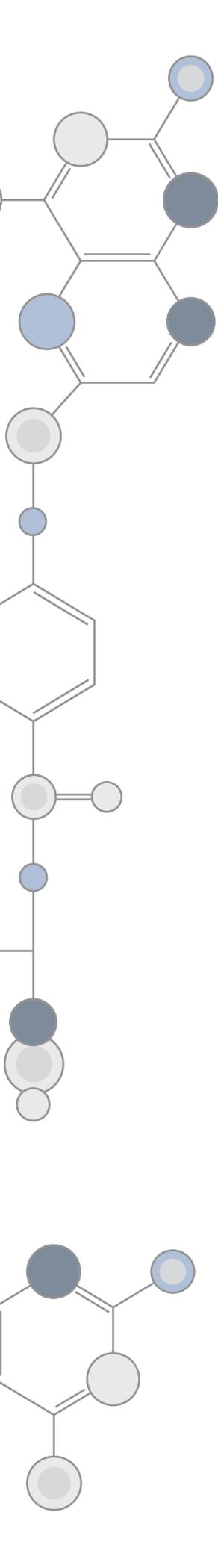
THE POLICY ENVIRONMENT FOR FOLIC ACID INTERVENTIONS TO PREVENT NTDS: UNDERSTANDING SUPPLEMENTATION, AND LAYING THE GROUNDWORK FOR FORTIFICATION

KNOWLEDGE BRIEF



Nourish Life





This brief was developed in partnership with the International Federation for Spina Bifida and Hydrocephalus. The Folate Task Team would like to express its gratitude to Lieven Bauwens, Martine Austin, and Renée Jopp for their contributions.

ABOUT THE FOLATE TASK TEAM

The Folate Task Team comprises a group of global experts and partners under the leadership of Nutrition International (NI) through NTEAM (Nutrition Technical Assistance Mechanism), all joined together to identify priority actions to reduce folate-sensitive neural tube defects, build laboratory capacity for the assessment of folate status, support research in this critical area and to facilitate access to folate-related knowledge products.

Through NTEAM, NI shares its expertise globally to support the scale-up of nutrition for the most vulnerable. We believe that knowledge, rigorously obtained and generously shared, is key to effective progress for nutrition. NTEAM convenes global experts to tackle key nutrition issues and encourage broad use of knowledge by translating technical information and research into accessible guidance, tools and resources. We also work with countries and agencies, sharing expertise through timely and coordinated technical assistance.

ABOUT THE INTERNATIONAL FEDERATION FOR SPINA BIFIDA AND HYDROCEPHALUS

The International Federation for Spina Bifida and Hydrocephalus (IF) was founded by people with spina bifida and hydrocephalus (SBH) and their families in 1979. Over the years, it has grown from a voluntary association into a professional disabled people's organization (DPO) with global coverage, democratic structure and transparent and accountable processes.

The majority of IF member organizations are led and governed by adults with SBH or parents of children with SBH. Children are active participants in our members' activities: they are involved in child-led activities, training workshops on independence and holiday camps. Nowadays, many young people with SBH have taken over the leadership of their organizations. In most cases, IF members choose close cooperation with medical and education professionals and researchers, given the importance of these professions to children and adults with SBH for their survival and development.

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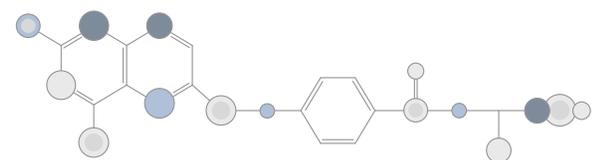
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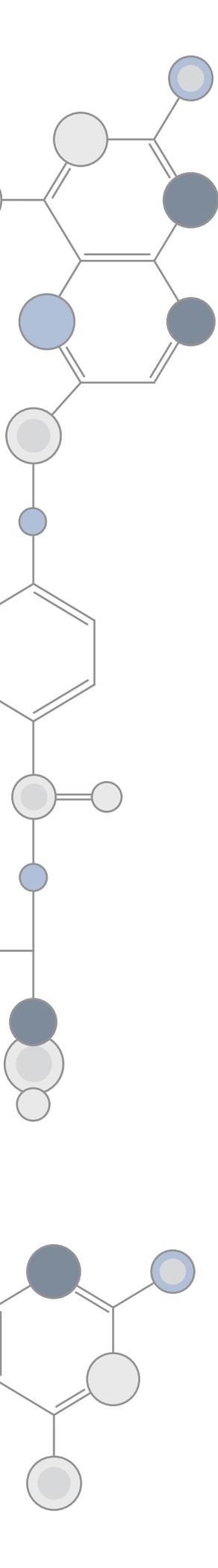
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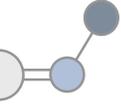




INTRODUCTION

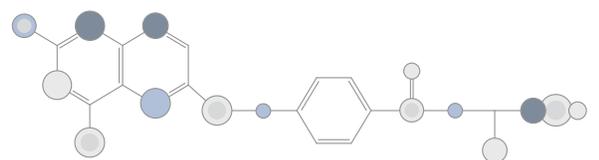
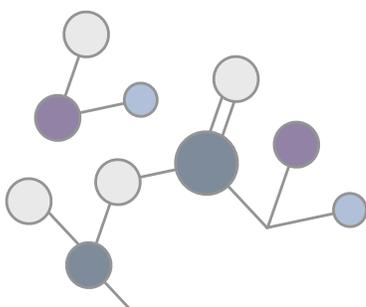
Neural tube defects (NTD) are a group of serious birth defects that occur within the first 28 days of a pregnancy. While NTDs are multifaceted conditions that can occur for several reasons, since 1991, it has been scientifically established that folate insufficiency is a known risk factor for NTDs.¹ Even in the presence of a healthy, balanced diet it is often not possible to meet the requirement for daily folate needed to support a healthy pregnancy from dietary sources alone. Mandatory fortification of food with folic acid is a cost-effective measure to reduce this risk, and it requires no change in diet or behaviour. The World Health Organization (WHO) has also recommended that all women should take a daily supplement containing 400 mcg of folic acid from the time they start trying to conceive until the twelfth week of their pregnancy. However, there are various challenges with regard to using supplementation as a primary intervention for improving the nutrition status of a population. These include: costs; availability; accessibility; unplanned pregnancy; limited understanding about the importance of folic acid tablets and when to take them (a 400 mcg supplement of folic acid must be taken daily from at least eight weeks before conception, and continued until the twelfth week of pregnancy); lack of adherence; and, resistance towards taking tablets due to cultural beliefs. Research and evidence show that fortifying food with folic acid—the synthetic form of folate—is a successful intervention that improves folate levels for women of reproductive age (WRA) **before they get pregnant** to a level that provides the maximum preventive protection against NTDs.

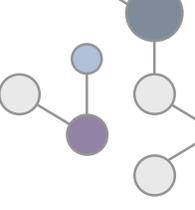
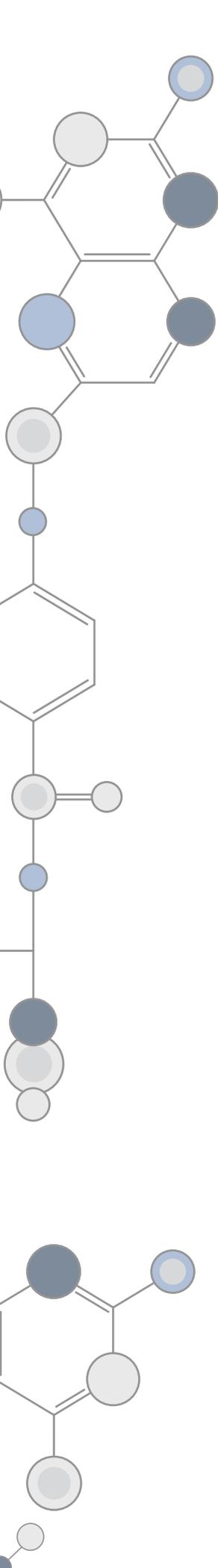
As a result of the research, 80 countries around the world are fortifying one or more foods with folic acid. But many countries do not—including many low- and middle-income countries (LMIC) where the NTD burden is highest. In 2015, it was estimated that there were 260,100 pregnancies affected by NTDs world-wide, resulting in 57,800 still-births and 117,900



under-five deaths.² While the majority of babies may survive the newborn period, more than three-quarters of those born in LMIC die before the age of five. Those who survive often present lifelong disabilities.

The purpose of this knowledge brief is to introduce the policy environment surrounding interventions with folic acid, including supplementation and fortification. This enables countries to make informed decisions to improve folate status in their populations as a way to reduce the risk of folate-sensitive NTDs. Understanding the international conventions and legislations developed based on research conducted by reputable organizations such as the United Nations, Nutrition International (NI), the International Federation for Spina Bifida and Hydrocephalus (IF,)the Food Fortification Initiative (FFI), and Global Alliance for Improved Nutrition (GAIN) will help decision-makers and health officials implement successful prevention strategies and folic acid fortification programs.





POLICY ENVIRONMENT

UN sustainable development goals

The 2030 Agenda for Sustainable Development includes 17 Sustainable Development Goals (SDGs), and was adopted by all United Nations Member States in 2015. SDG 2 (Zero Hunger) and SDG 3 (Good Health and Well-being) are both intrinsically tied to improved nutrition.³ This includes SDG 2.2, which specifically aims to address the nutritional needs of adolescent girls, and pregnant and lactating women.³ Additionally, SDG 3.2 commits countries to ending preventable deaths of newborns and children under five, and SDG 3.8 includes improving access to quality essential reproductive, maternal, newborn and child health services. Inherent in improving health status is creating birth registries and legal identity for all by 2030 (SDG 16, target 16.9).³

While progress has been made since the adoption of the SDGs, there are still significant gaps in access to healthcare. Preventing NTDs by improving the folate status of WRA remains key in efforts to reduce neonatal and under-five mortality in LMIC.

UN Convention on the rights of persons with disabilities

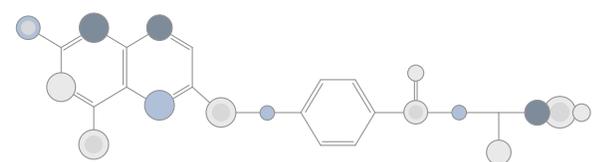
As NTDs cause birth defects that can result in lifelong disabilities, it is essential that the life and dignity of those affected are protected. It is also crucial to understand that those affected should be consulted when creating policies that will affect how they live their lives. The United Nations Convention on the Rights of Persons with Disabilities (UN CRPD)⁴ states that persons with disabilities should have the opportunity to be actively involved in decision-making processes about policies and programs, including those directly concerning them. Children with disabilities also have the right to express their views on all matters affecting them (Art. 7).

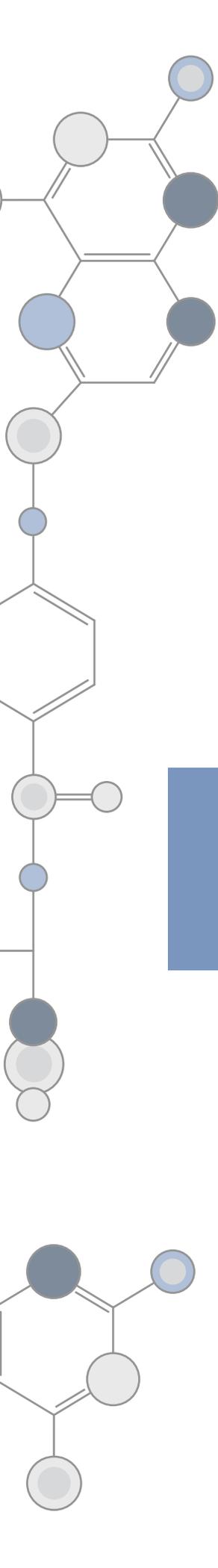


Subsequently, all policies and strategies for both NTD prevention and care should actively include organizations that represent persons living with these conditions in these processes, such as IF.

The UN CRPD also reaffirms the right to life (Art. 10), which is enshrined in the Universal Declaration of Human Rights. It proclaims that children with disabilities shall be registered immediately after birth and shall have the right from birth to a name, the right to acquire a nationality and, as far as possible, the right to know and be cared for by their parents (Art. 18.2).

The convention also states that parties shall recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability (Art. 25). Effective and appropriate measures—including through peer support—should be taken to enable persons with disabilities to attain and maintain maximum independence, full physical, mental, social and vocational ability, and full inclusion and participation in all aspects of life (Art. 26).





SUPPLEMENTATION

Legislation on supplementation

For women who plan to get pregnant, supplementation is an effective intervention to prevent NTDs. Periconceptual folic acid supplementation to prevent NTDs is listed in the WHO e-Library of Evidence for Nutrition Actions (eLENA).⁵

The WHO recommends a daily 400 mcg supplement of folic acid starting before conception and continuing during the first 12 weeks of pregnancy to reduce the risk of NTDs. For women at a higher risk of having a pregnancy affected by an NTD, WHO recommends a higher daily dose (5 mg).⁵ This includes women who have already experienced an NTD-affected pregnancy, couples who have spina bifida or who have a family history of NTDs, women with diabetes, women taking certain anti-seizure medications for epilepsy, women with coeliac disease or other conditions that affect intestinal absorption, and women that are very overweight/obese (BMI >30 kg/m²).

For recommendations in malaria endemic regions, please see important information regarding the use of the 5 mg dose in our knowledge brief “The importance of preventing neural tube defects in low- and middle-income countries” found at www.folatetaskteam.org.

Despite the WHO’s “Standards for Maternal and Neonatal Care for the Prevention of Neural Tube Defects”,⁶ which requires that “A national policy and locally adapted guidelines on folic acid supplementation are available and are correctly implemented” and that, “Folic acid is available and affordable to women”, few LMIC have a supplementation policy recommendations in place.

It is important to recognize that many women only begin to take supplements once they are pregnant, usually at 12 weeks gestation or later, when it is too late to reduce the risk of NTDs. Lack of supplementation policy and poor availability makes an effective fortification strategy even more important.

WHO standards for maternal and neonatal care

In 2006, the WHO published “Standards for Maternal and Neonatal Care - Prevention of Neural Tube Defects”⁶, which states that:

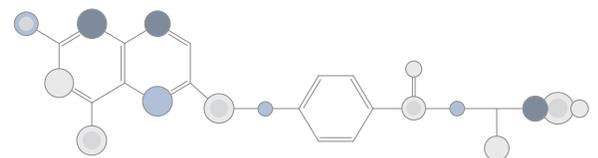
“All women, from the moment they begin trying to conceive (ideally starting two months before the planned pregnancy) until 12 weeks of gestation, should take a folic acid supplement. Women who have had a fetus diagnosed as affected by a neural tube defect (NTD) or have given birth to a baby with an NTD should receive information on the risk of recurrence, be advised on the protective effect of periconceptional (before pregnancy and during the first three months of pregnancy) folate supplementation and be offered high dose supplementation.”

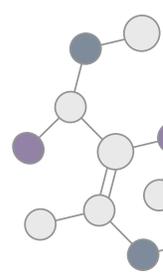
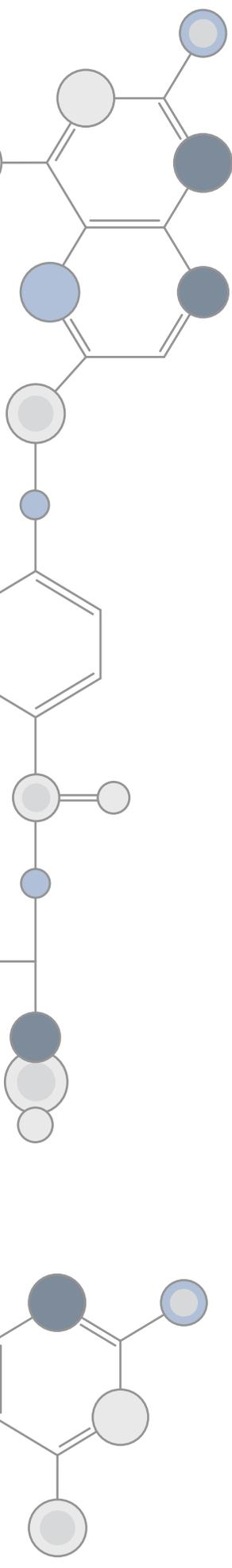
The standard also requires the following:

- National policy on supplementation available and correctly implemented,
- Health providers are equipped to provide correct preconception advice on timing and dosage of folic acid,
- Folic acid is available and affordable for women,
- NTD-affected pregnancies are recorded,
- Preventative treatments are recorded properly, and
- Health education and awareness-raising activities are conducted to explain the importance of preconceptional folic acid supplementation

WHA 63.17 Resolution on Birth Defects

In May 2010, the World Health Assembly (WHA) adopted Resolution WHA 63.17 on Birth Defects⁷ to reduce child mortality in all countries. The WHA urges its Member States to develop expertise and build capacity on the prevention of birth defects and care of children with birth defects, and to increase coverage of effective prevention measures, such as folic acid supplementation. Member States should also develop and strengthen registration and surveillance systems for birth defects within the framework of national health information systems to have accurate information available to make decisions on prevention and control of birth defects and to continue providing care and support to individuals affected by birth defects.





FORTIFICATION AS THE PRIMARY INTERVENTION TO PREVENT NTDs

Legislation on fortification

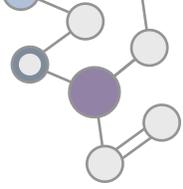
Mandatory flour fortification with folic acid for the prevention of NTDs is advocated by globally respected organizations, such as the WHO, NI, GAIN, the US Centers for Disease Control and Prevention, UNICEF, the Copenhagen Consensus Center and IF.

Over 80 countries, including LMICs, currently have a mandate to fortify at least one staple grain (wheat flour, maize, corn masa) with folic acid.⁸ However, even in those countries that have a mandate, the legislation is either not implemented or poorly enforced, particularly in LMICs. This is often due to lack of physical or technical capacity, lack of political will, lack of cooperation between government authorities, or lack of demand for fortified foods due to low levels of awareness among the population. Despite these factors, it should be noted that many LMICs are more advanced in their fortification efforts than those in Europe, where only Kosovo has a fortification mandate.

A meta-analysis conducted in 2010 using data from multiple countries indicated that mandatory flour fortification with folic acid could decrease the risk of NTD-affected pregnancies by an average of 46 percent.⁹ However, to be successful, fortification programs not only require legislation but also systems to enforce the legislation, regulatory frameworks, and quality control and assurance mechanisms.

Economic argument

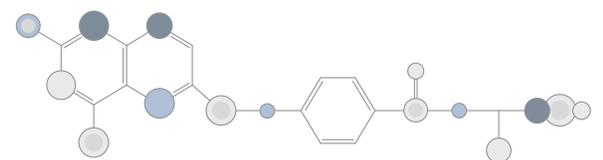
Research has shown that periconceptual folate/folic acid insufficiency increases the risk of NTDs. The fortification of staple foods is a cost-effective and well proven strategy to improve micronutrient deficiencies in many developing countries. An estimated two billion people suffer from

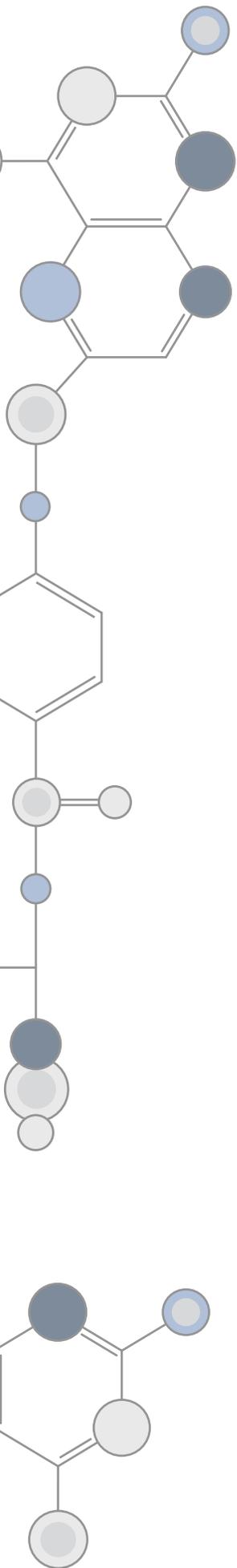


vitamin and mineral deficiencies. There is a strong economic argument for mandatory folic acid fortification. The direct costs (i.e. surgery and rehabilitation) and indirect costs (i.e. caregiver time off work) associated with treating individuals with NTDs are far greater than the comparative cost for flour fortification. The lifetime costs for an individual living with spina bifida can range between US \$100,000 and US \$700,000 depending on the country of residence and access to services including healthcare, education, and personal care assistance.¹⁰ The average cost per NTD death averted through food fortification has been estimated to an equivalent of US \$957, whereas the cost per death averted by the rotavirus vaccine is US \$3,015, and US \$2,770 per death averted by insecticide-treated bed nets and other malaria prevention interventions.¹⁰ In terms of the return on investment, taking South Africa as an example, every rand spent on fortification saved 30 rand in medical costs associated with NTDs, with a cost:benefit ratio of 46:1,¹¹ similar to the cost benefit ratio of 48:1 documented in the USA.¹²

WHO Fortification Consensus Statement

In 2008, the WHO published “Recommendations on Wheat and Maize Flour Fortification Meeting Report: Interim Consensus Statement”¹³ based on scientific reviews. The recommendations were aimed at “the food industry, scientists and governments involved in the design and implementation of flour fortification programs as public health interventions.” The advice and information contained within this document provides background knowledge critical for implementing a fortification program.





NI Position Statement on Fortification

Fortification of centrally processed staple foods like wheat/maize flour, cooking oil, rice and condiments like soya sauce are simple, affordable and effective approaches to reach large proportions of the population with iron, folic acid, zinc and other essential micronutrients. In fact, fortifying different food staples, oil and condiments with essential micronutrients is an intervention identified by WHO, the Copenhagen Consensus, and the Food and Agriculture Organization, as one of the top strategies for decreasing micronutrient malnutrition at the global level.¹⁴

IF Position Statement on Fortification

All representative organizations that are members of the International Federation for Spina Bifida and Hydrocephalus share the same mission: to **improve the quality of life** of people with spina bifida and hydrocephalus and their families, and to **reduce the incidence** of neural tube defects and hydrocephalus by primary prevention by raising awareness and through political advocacy, research, community building and human rights education.

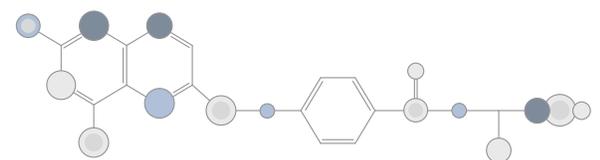
In 2005, IF and its members adopted the IF Position Paper on the prevention of NTDs and mandatory fortification to which they adhere to this day.¹⁵ They propose creating an international policy for mandatory food fortification to actively encourage all countries to adopt this measure.

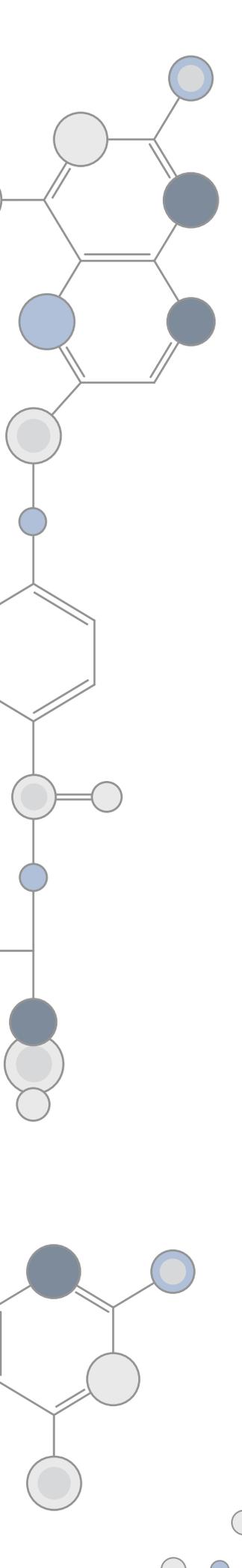


TAKE AWAY MESSAGES

FOR DECISION-MAKERS

- Active involvement of global, national and regional stakeholders—including representative organizations, industry and consumer organizations—is critical for creating a successful fortification program
- Development of effective NTD surveillance and monitoring systems is necessary to provide evidence on the burden of these conditions and to document the impact of fortification practices
- Improved education and awareness raising at national, regional and community levels around the topics of preconception health, birth spacing, nutrition, folic acid (availability/sources of fortified foods, sources of folate rich foods and supplementation with folic acid for all WRA, at the appropriate dose, before conception—including improved availability and access to supplements) is pivotal for the success of preventive programs
- A robust and comprehensive prevention strategy will include mandatory fortification, a supplementation policy and public health education
- Once mandates are in place, ongoing monitoring of fortified food and fortification processes will ensure application of standards and compliance (QA/QC)

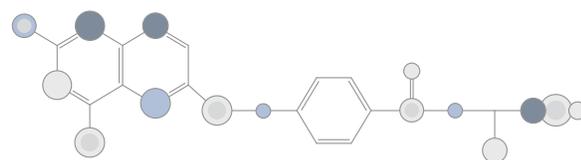




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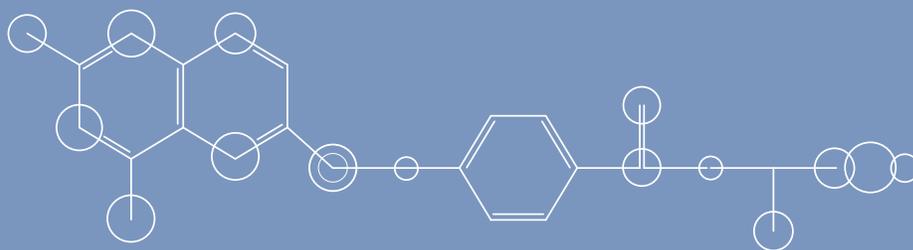




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