Risks and Benefits of Mandatory Folic acid Fortification

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Introduction

• Folate and health (conventional role)
  – One C substrate in nucleic acid and amino acid metabolism
  – Homocysteine → methionine

• Folate RDAs (US)
  – Adults = 400 µg DFEs
  – Pregnancy = 600 µg DFEs
  – Lactation = 500 µg DFEs

• Dietary sources
  – Green leafy vegetables
  – Legumes
  – Citrus fruits and juices
Introduction

• Folic acid and health (new nutrition paradigm)
  – Reduces the risk of NTDs (spina bifida, anencephaly)

• Folic acid reference values
  – Women of child-bearing age = an additional 400µg folic acid/day during the periconceptional period
  – All adults = UL of 1000µg folic acid/day

• Dietary sources
  – Folic acid supplements
  – Folic acid fortified foods
Folic acid evidence → Policy

“Adding a biologically active ingredient to the food supply of 300 million people is a very weighty issue. You can’t experiment on the American people”

[Personal communication, 26 July 2012, Professor David Kessler, former Commissioner of the US Food and Drug Administration].
Complexity + controversy

• NTD Severity
  – Tragic abnormalities
  – Significant emotional, social and financial cost

• Prevalence
  – Varies across the world (0.5 – 6/1000 births)
  – Apparent long term reduction since 1970s
  – Variable intervention effectiveness (mean ~48%)
Complicating factors

• Cause(s) of NTDs is unknown
  - Cannot identify at-risk individuals
  - Women with C677T polymorphism of gene encoding MTHF reductase at increased risk of an NTD-affected pregnancy.

• Folic acid’s protective mechanism is unknown
  - Optimal dose unknown

• Neural tube closed by ~28th day post-conception
  - Small window of opportunity for protection

• Unplanned pregnancies
  - The ‘window of opportunity’ may have closed by the time a woman is aware that she is pregnant
Risks, benefits and ethical considerations of policy interventions

1. Mandatory folic acid fortification
2. Voluntary folic acid fortification
3. Promotion of folic acid supplements to target group
4. Nutrition education of target group (and population)
5. Status quo
Mandatory folic acid fortification

Large number of potential risks and benefits because of folate’s role in critical metabolic pathways, eg DNA synthesis and repair.

“But folate being involved in so many of life’s fundamental processes not only leads to its possibilities as a panacea but also to the prospect that ‘messing around with folate’ could do extensive harm” (Smith, 2004)
Risks

Risks throughout the lifecycle have been identified:

• **Pregnancy:** Risk of multiple births (Haggarty et al, 2006).
• **Newborns:** Risk of atopic dermatitis (Kiefte-de Jong et al, 2012)
• **Childhood:** Risk of asthma (Whitrow et al, 2009)
• **Mid-life:** Lingering concerns about promoting the progression of colorectal cancer (Mason, 2011).
• **Older adults:** Risk of cognitive decline (Morrrris et al, 2007)
• **Older adults:** Masking the clinical symptoms of vitamin B12 deficiency and subsequent risk of irreversible nerve damage (Israels and Wilkinson, 1949)
• **Lifespan:** Long term consequences of raised levels of unmetabolised serum folic acid?
Benefits

- Mostly effective in reducing NTD prevalence
- Mixed cost-effectiveness (many assumptions)
- Equitable
- Practical advantages:
  - Passive exposure
  - Govt has greater control over public health intervention
- Other health benefits:
  - In those countries with population-wide folate deficiency it will increase folic acid intake to protect public health
  - May protect against cognitive decline (Walker et al, 2012)
Ethical considerations

• Not proportional
  – a non-discriminating approach of high benefit for at-risk individuals, but also exposing the population for little benefit and possible risk

• Highly coercive

• Not highly necessary (other interventions available)

• Low public justification
Voluntary folic acid fortification

Expanding the regulatory provisions to enable a greater number of food products to be fortified with folic acid.
Risks

• Low-moderate risk of excessive intake for the population and the target group
  • In Ireland it has been reported that voluntary folic acid fortification practice may be resulting in excessive exposure in certain population groups (Boilson, 2012)

• The food industry is responsible for implementation so it is difficult to control the timing, level and extent of fortification
Benefits

• Variable effectiveness

• Limited evidence of cost-effectiveness
Ethical considerations

As for mandatory fortification though less effective and less coercive—more free choice for individuals
Folic acid supplementation

http://healthsupplementstore.co.uk/
Risks

- No risk for the population as a whole

- Low risk of excessive intake for the target group (depending on behaviour)
Benefits

• Variable effectiveness
  – Dependent on behaviour change and ongoing compliance

• Some evidence of cost-effectiveness

• Low–moderate equity

• Advantage of delivering directly to target group

• Can deliver a precise minimum dose
Ethical considerations

• High proportionality—high benefit for target group and low risk for population
• Low infringement on the population and maintains individuals’ free choice
• Necessary
• Publicly justified
Nutrition education

Risks
• Requires a significant change in current dietary behaviours to achieve folic acid intake recommendations
• Low effectiveness
• Low equity

Benefits
• Secondary benefits in promoting a healthy diet

Ethical considerations
• Maintains individuals’ free choice
• Necessary in that it complements alternative policy options
Status quo

Risks
• Not effective, cost-effective or equitable
• NTD prevalence will return to pre-intervention levels if an effective policy option is stopped

Benefits
• Has the practical advantage of providing a policy-maker with time to obtain more evidence

Ethical considerations
• Maintains population’s free choice
• Not proportional as there exists convincing evidence
Mandatory folic acid fortification around the world

- Despite having access to the same epidemiological evidence, policy-makers around the world are recommending different policy interventions to increase target group’s folic acid intake.

- 66 countries recommend mandatory folic acid fortification (2012)

- WHO guidelines on levels of folic acid fortification for wheat and maize flour = 1.0 - 5.0 ppm, depending on a country’s wheat flour consumption per capita
Alternative policy interventions around the world

• Voluntary folic acid fortification
  – Three countries initially did recommend mandatory folic acid fortification but then reversed their decision in favour of voluntary fortification

• Limited investment in sustained policy activities to promote folic acid supplementation and nutrition education
Considerations for Asian countries into the future

• Baseline folate intake
  – Dietary patterns throughout Asia

• Baseline folate status

• Baseline NTD prevalence
  – EG: Northern China (4.8/1000 pregnancies → 1.0/1000 pregnancies) versus Southern China (1.0/1000 pregnancies → 0.6/1000 pregnancies) (Berry et al, 1999)
Considerations for Asian countries into the future

- Ethnic differences in the frequency of the C677T polymorphism, ranging from 0% in African American women to 3.8%, 7.2% and 18.1% in Asian, white and Mexican women respectively
  - Indicates ethnic variations in folate requirements (Botto, Yang, 2000).

- Proportion of pregnancies that are planned – increases likely effectiveness of supplements, eg premarital examination in China (Berry and Yang, 1999).

- Political will for policy alternatives
Monitoring and evaluation

- Process
  - Compliance
  - Quality control (overage)

- Dietary intake
  - Sufficient
  - Safe (natural + fortified + supplements = ?)

- Health outcome
  - NTD prevalence
  - How measure what we don’t know?
Concluding comments

- Mandatory food fortification can be a powerful public health policy tool
- Yet, mandatory folic acid fortification is controversial
- As a policy response it does not efficiently address the underlying cause of the policy problem
- Many risks, benefits and ethical considerations
- A combination of alternative policy interventions may be preferable
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