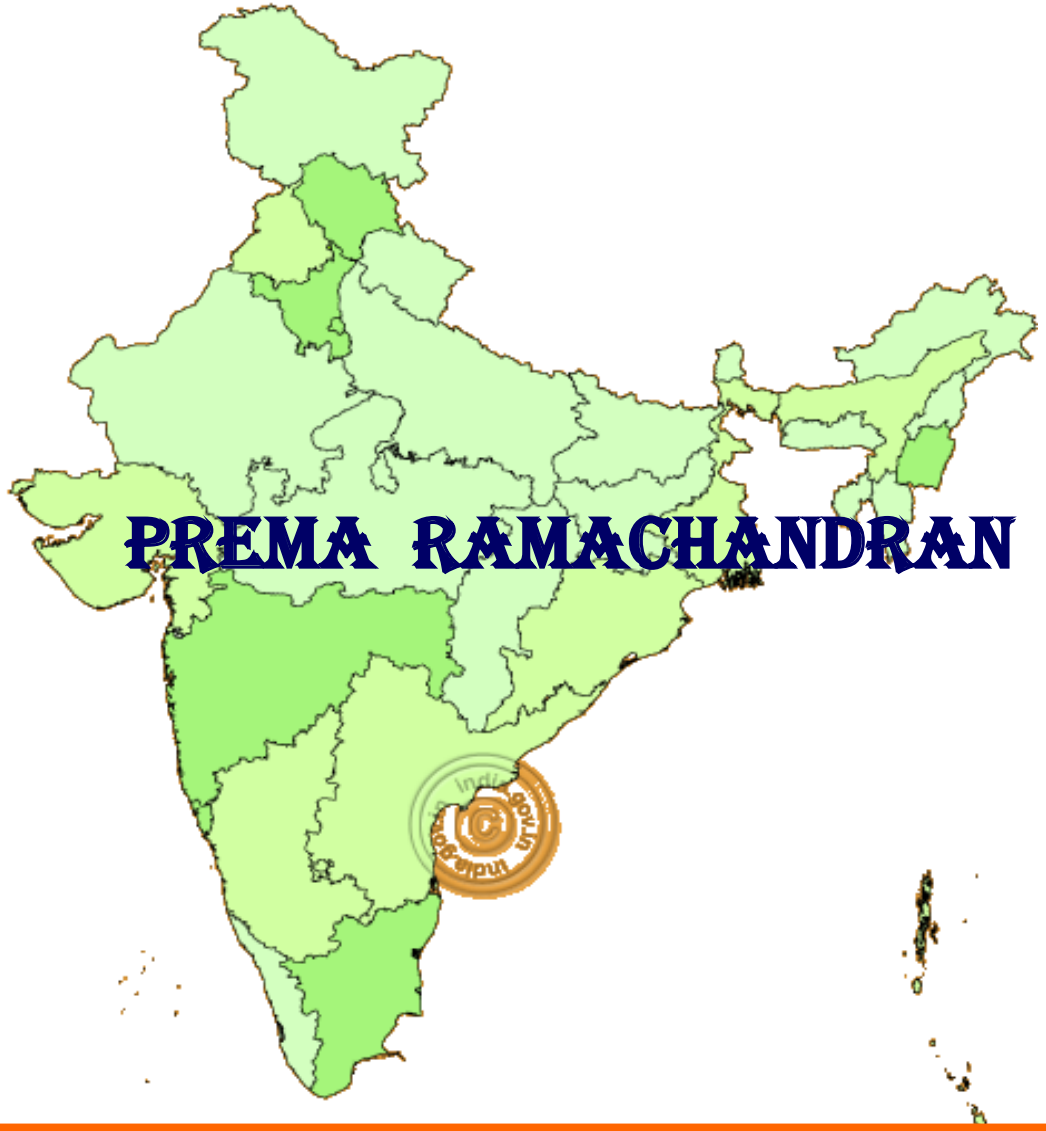
PUBLIC HEALTH APPROACH TO FOOD FORTIFICATION



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NAMS NFI SYMPOSIUM 29.11.2017

COMBATING MICRO-NUTRIENT DEFICIENCIES

Micro-nutrient deficiencies are major public health problems and affect all segments of population both in developed and developing countries

Global and Indian experience showed that:

Long term measures for the prevention and control of micro-nutrient deficiencies should be based on diet diversification and consumer education so that "all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life".

COMBATING MICRONUTRIENT DEFICIENCIES

Medium term measures for combating micro-nutrient deficiencies are:

- nutrition education for dietary diversification
- food fortification and
- nutrient supplementation.

Dietary diversification cannot occur at medium term and may be the least in the poorer segments of population.

Global evidence indicates that it is difficult to sustain long term nutrient supplementation programmes for large population groups.

In the short term context food fortification is an effective, inexpensive and sustainable method of combating widespread micro-nutrient deficiencies especially among developing countries.

Definition of food fortification

Micronutrient deficiencies identified as public health problems - global and in India

Conceptual basis of fortification

Fortification for priority nutrients in India

Mandatory fortification

Voluntary fortification

Way forward

DEFINITIONS

FOOD FORTIFICATION

Food fortification is "the practice of deliberately increasing the content of an essential micro-nutrient (vitamins and minerals) in a food stuff so as to improve the nutritional quality of the food supply and to provide a public health benefit with minimal risk to health".

Food enrichment is "synonymous with fortification and refers to the addition of micro-nutrients to a food which are lost during processing" eg vit A from milk during preparation of low fat milk.

Fortified foods reach large segments of population who may continue to take the fortified food (sometimes without even the knowledge that it is fortified) for long period of time without any monitoring, supervision or evaluation.

Therefore food stuff used for fortification and amount of the nutrient used for fortification should be chosen with care.

TYPES OF FOOD FORTIFICATION

PUBLIC HEALTH INTERVENTION: MASS FORTIFICATION

Undertaken as public health intervention in nutrient deficiencies characterised by:

- Low nutrient intake in large segments of population,
- High prevalence of deficiency signs and
- Well documented adverse health consequences of nutrient deficiency

Food fortification aims at bridging the gap between intake and requirement without any dietary modification by fortifying an identified commonly consumed food stuff.

This type of fortification will be focus of discussion in this presentation.

TARGETED FORTIFICATION

Fortification aimed at specific target groups with low nutrient intake such as:

- infants receiving complementary feeds with low dietary diversity
- population exposed to severe food insecurity eg refugees, natural disasters.

MARKET DRIVEN FORTIFICATION

Food manufacturers add micro-nutrients to their products not just to increase their nutritional value but also to increase their appeal to the health conscious consumer. The nutritional rationale and health benefit may not be well defined.

FOOD FORTIFICATION AS A PUBLIC HEALTH INTERVENTION

Food fortification can be a major public health intervention to combat micro-nutrient deficiency by shifting the intake of the nutrient to the right

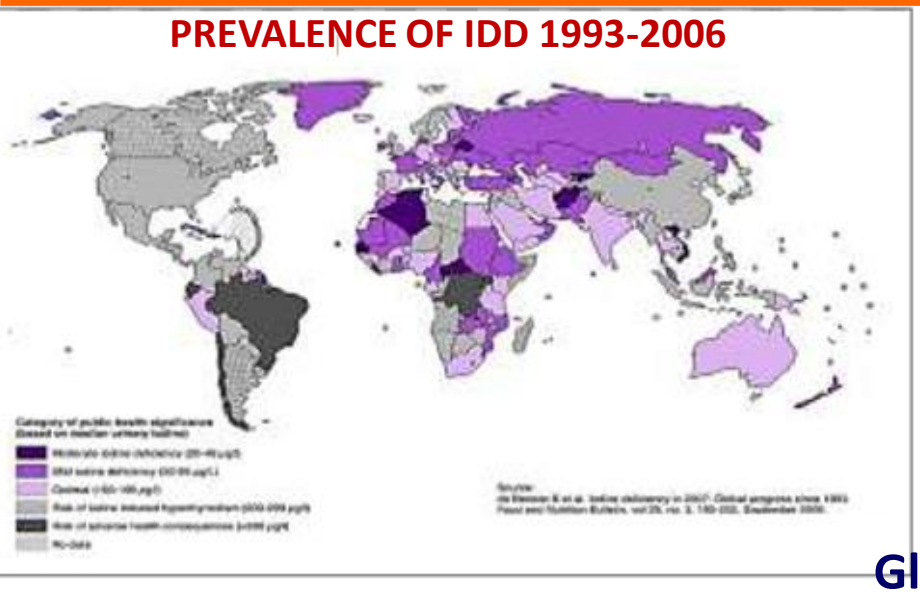
In designing public health food fortification programmes the following four major steps have to be followed:

1. Identify those nutritional deficiencies of public health importance
2. Obtain data on the adequate intakes of each nutrient in specific population groups. Identify the proportion of the population in whom intake is inadequate
3. Identify most commonly consumed food stuff in the population and the amount of the food stuff consumed daily
4. Compute the amount of nutrient to be used for fortifying the food stuff which would reduce the prevalence of inadequate intakes (i.e. the proportion below the EAR) and minimise the risk of excessive intakes (i.e. the proportion above the UL) that would be expected to occur in those groups who were consuming adequate nutrient.

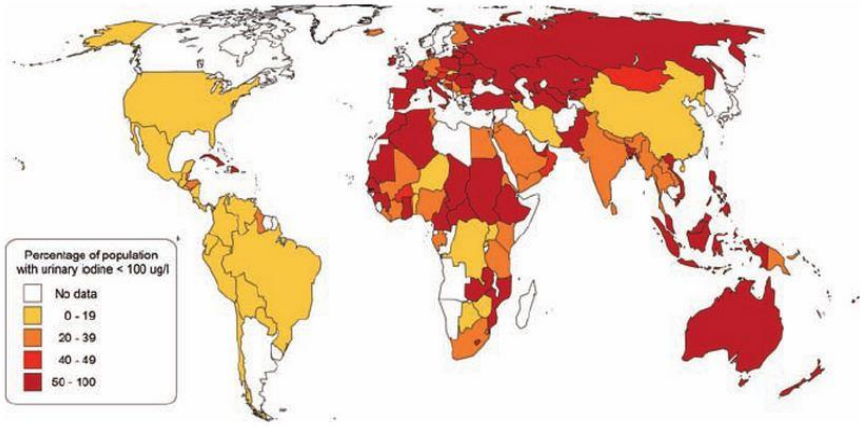
MICRO-NUTRIENT DEFICIENCIES IDENTIFIED AS PUBLIC HEALTH PROBLEMS - GLOBAL AND INDIAN

PREVALENCE OF MICRO-NUTRIENT DEFICIENCIES

PREVALENCE OF IDD 1993-2006

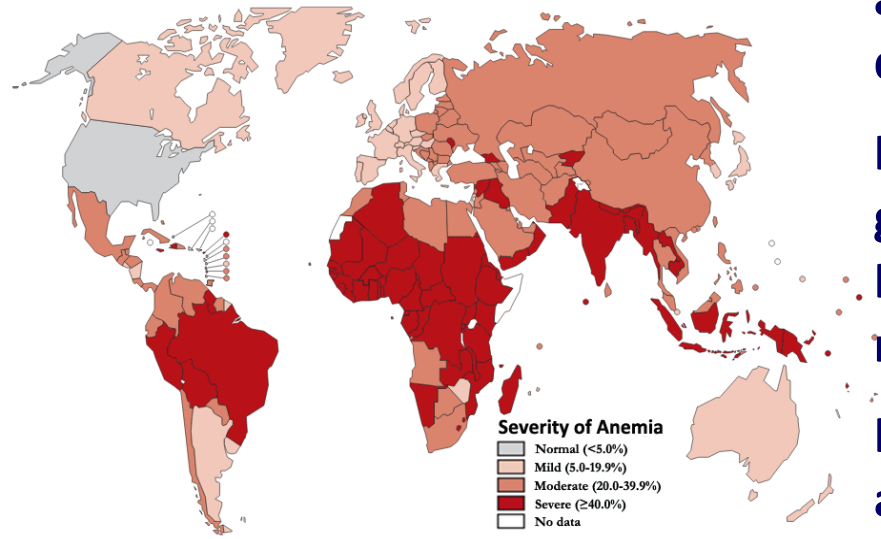


PREVALENCE OF VITAMIN A DEFICIENCY (WHO 2011)



Map 4.2. Iodine deficiency.

Worldwide Prevalence of Anemia, by severity

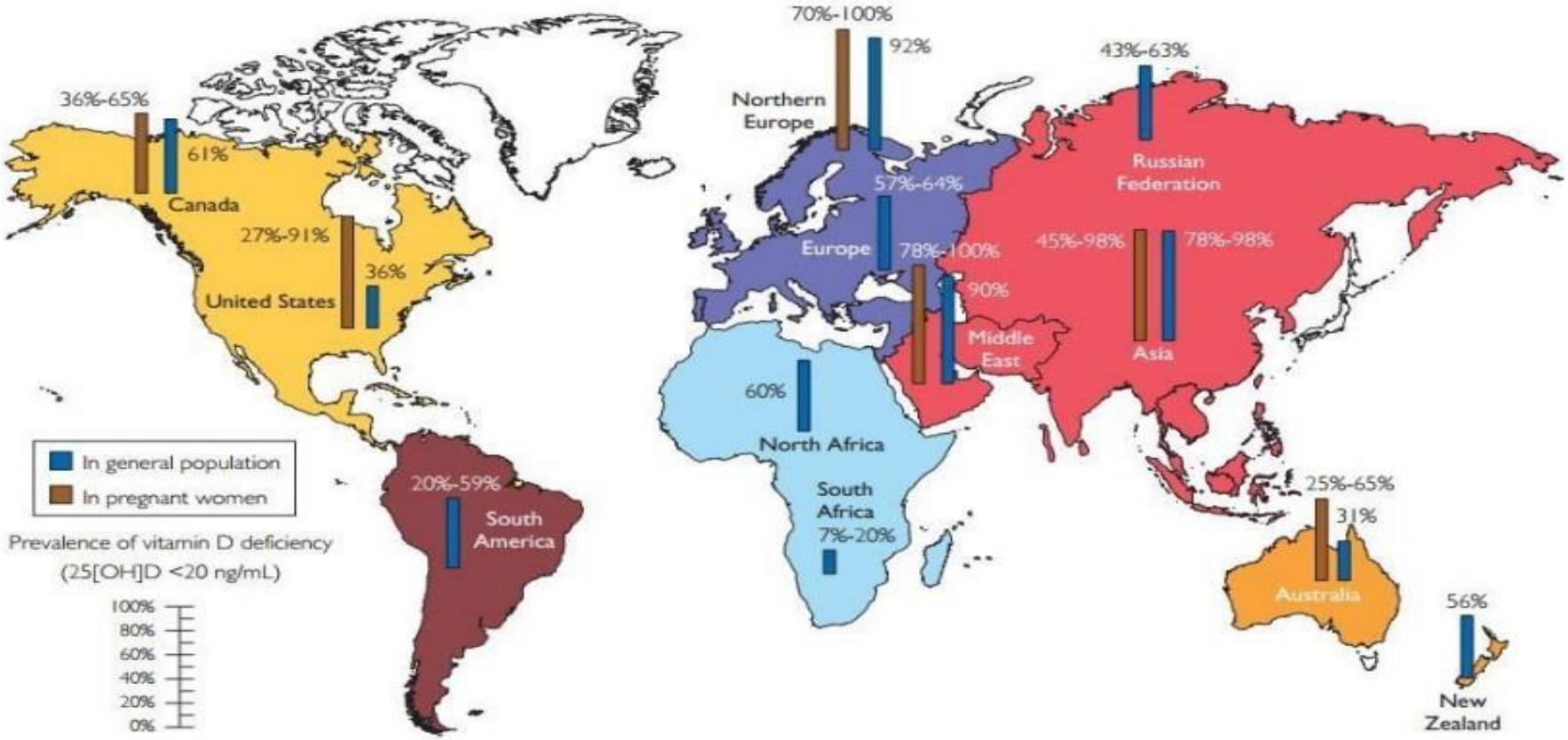


Globally and in India, micro-nutrient deficiencies - referred to as hidden hunger - are the most common type of nutritional deficiencies.

It is estimated that over 2 billion persons globally and majority of the 1.3 billion Indians, suffer from one or more of the micronutrient deficiencies.

Iodine deficiency, Vitamin A deficiency, and anaemia due to iron and folic acid deficiencies are major public health problems.

PREVALENCE OF VITAMIN D DEFICIENCY



Holick, Mayo Clinic Proceedings, 2013

Vit D 3 assays are now widely available

Prevalence of vitamin D deficiency, as assessed by vit D3 levels, is high across developed and developing countries

INDIAN SCENARIO

Soon after independence India recognised that there are three major micro-nutrient deficiency related public health problems in the country:

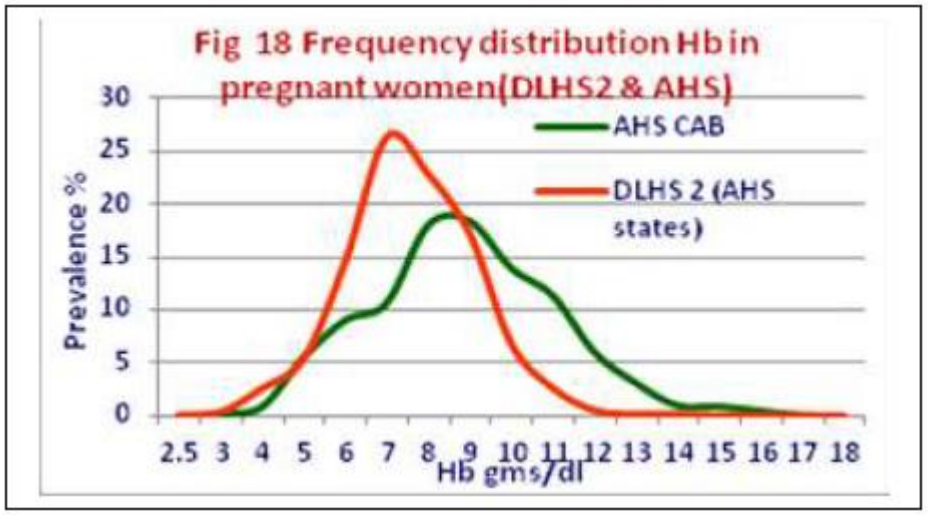
- Iodine deficiency resulting in goitre and cretinism
- Vitamin A deficiency associated with keratomalacia and blindness in young children, and
- Iron and folic acid deficiency leading to anaemia and its adverse consequences especially in children and pregnant women

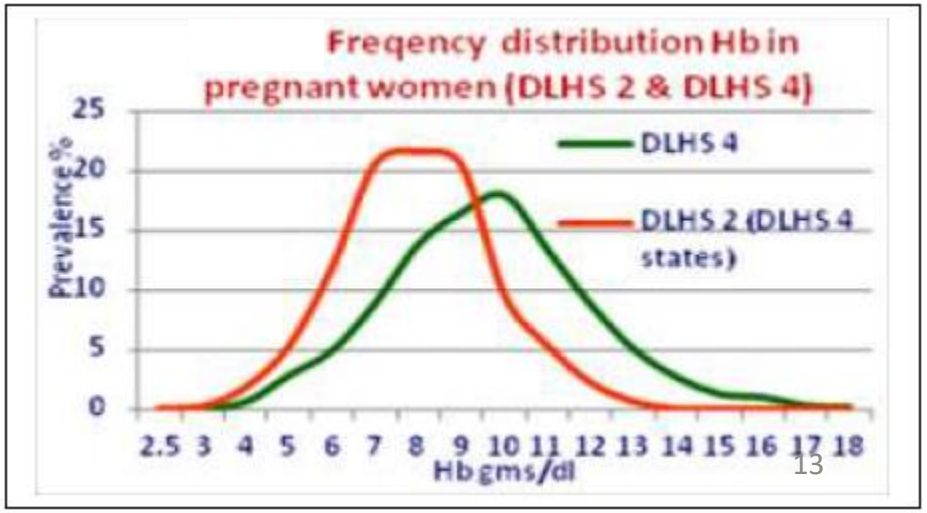
Govt of India initiated interventions to combat these micronutrient deficiencies:

National Goitre control programme to improve access to iodised salt (1962),
National Prophylaxis Programme Against Nutritional Blindness (massive dose vitamin A supplementation programme 1970)
National Anaemia Prophylaxis Programme (IFA supplementation 1970)

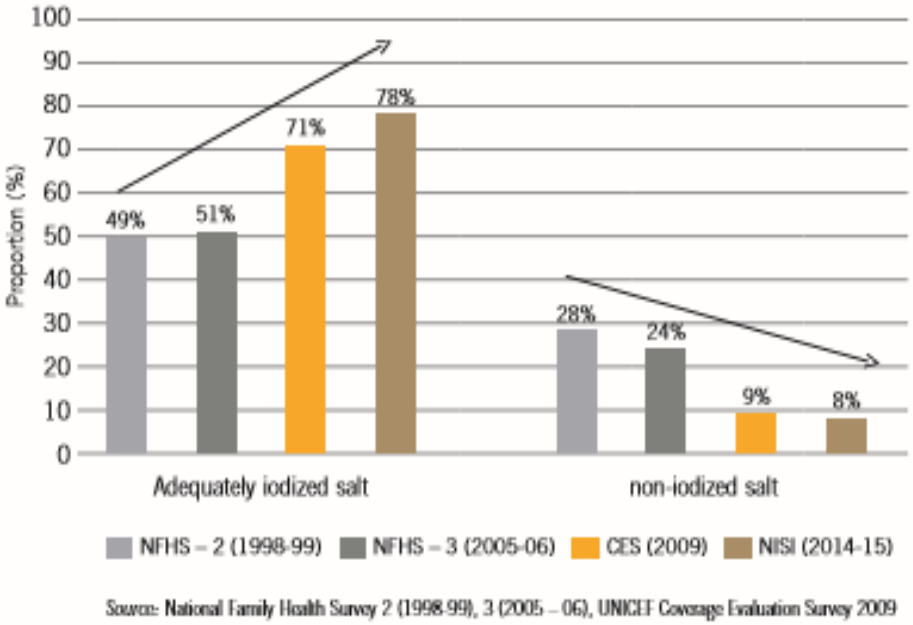
Review of the situation four decades later, showed that

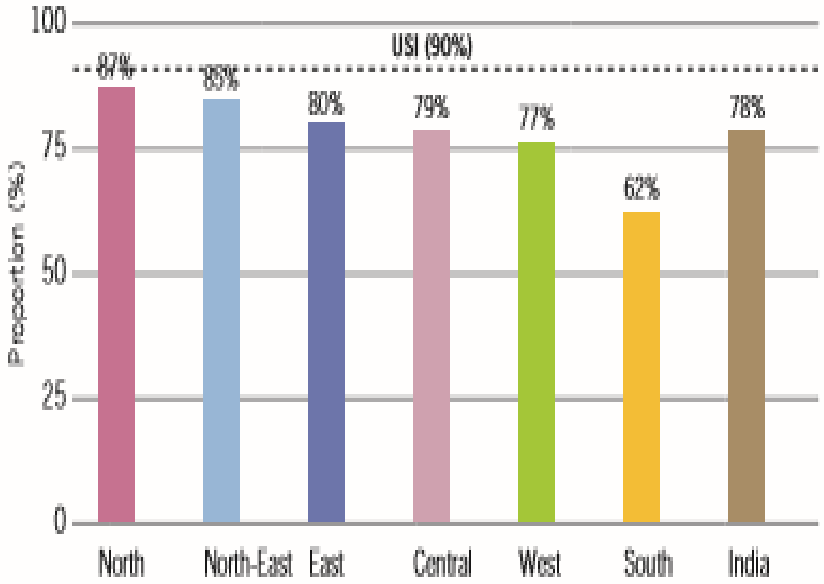
- **the country is nearing the goal of universal household access to iodized salt**
- **Keratomalacia due to severe vitamin A deficiency had been eliminated two decades ago. Prevalence of night blindness and Bitot spots are low except in pockets, but subclinical biochemical vitamin A deficiency is reported to be common.**
- **There has been some decline in the prevalence and severity of anaemia but anaemia and adverse health consequences associated with it continue to be major public health problems in the country.**





Experience in implementing the supplementation programmes for combating vitamin A deficiency and anaemia in the last four decades showed that it is difficult to achieve and sustain near universal coverage in supplementation programmes.





- The success of IDD control programme through mandatory iodine fortification of salt has given an impetus to efforts to use similar strategy to combat widespread micro-nutrient deficiencies such as iron deficiency anaemia.
- Centralised production, transport and distribution under the existing programme of iodisation of salt, offers a ready platform to launch and rapidly scale up the iron fortified iodised salt programme to combat both IDD and anaemia.

PREVALENCE OF VITAMIN D DEFICIENCY

	Cut off point	Prevalence of deficiency %
Goswami, Delhi, 2001	< 20 ng/ml	>90%
Javaid, Pregnancy Lancet, 2006	< 20 ng/ml	84%
Pregnancy, NIN study, 2008	< 20 ng/ml	87.8%
Cord blood, NIN, 2008	< 20 ng/ml	91%
Alok Sachan et al (Lucknow) pregnancy	< 10 ng/ml	42.5%
Seema Puri et al (Delhi) Adolescent girls	< 20 ng/ml	90.8%
Harinarayan et al Tirupati, children	< 20 ng/ml	75%

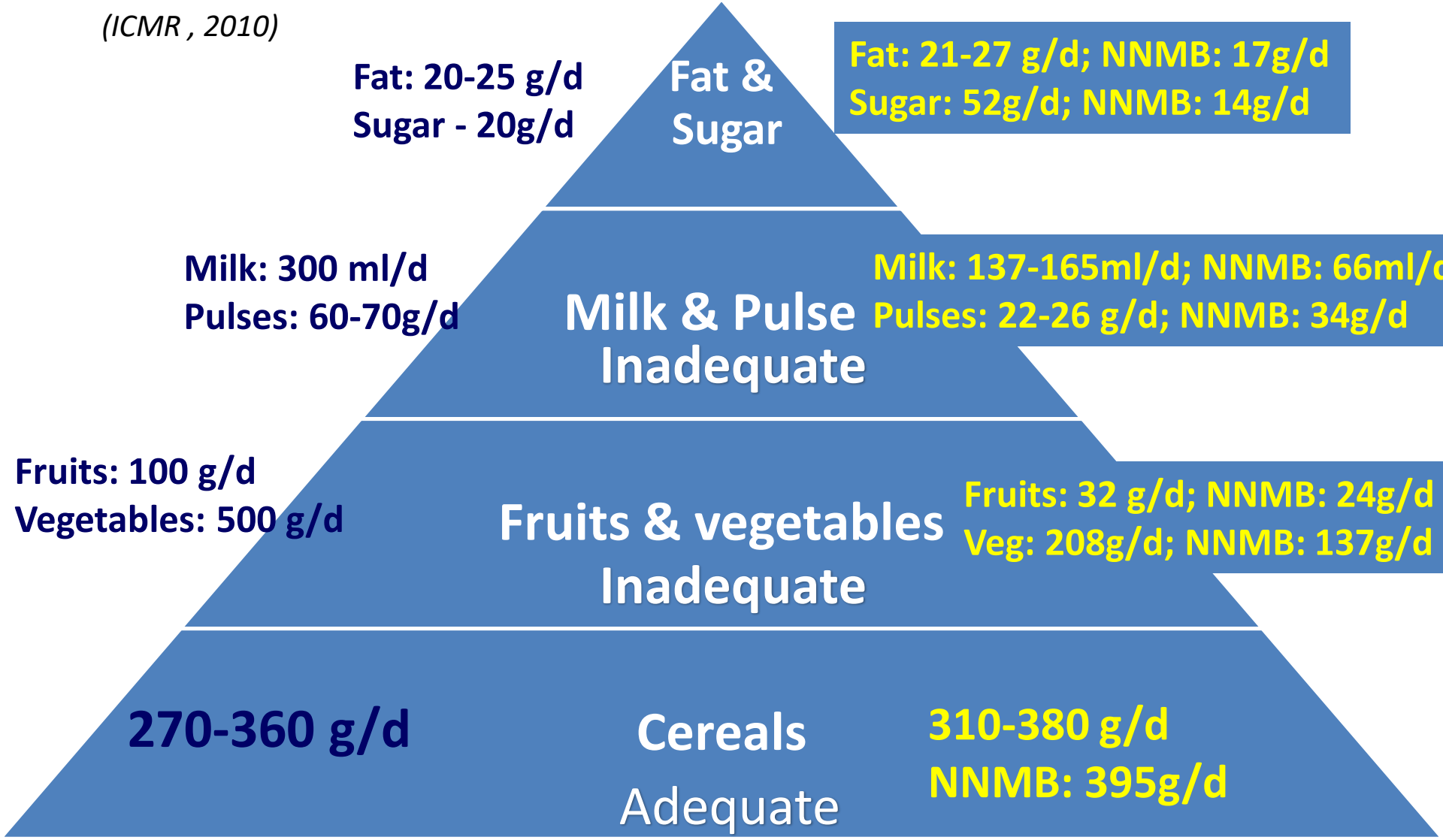
Prevalence of Vitamin D deficiency (as assessed by vitamin D3 estimation in blood) is very high in all age groups in all regions of India

DIETARY INTAKE OF SELECTED MICRO-NUTRIENTS

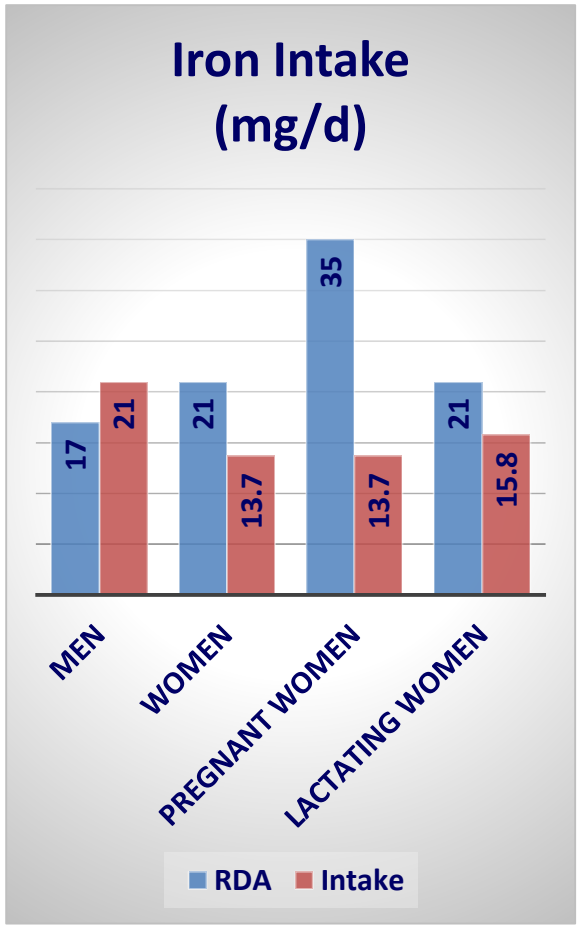
RECOMMENDED DIETARY ALLOWANCES

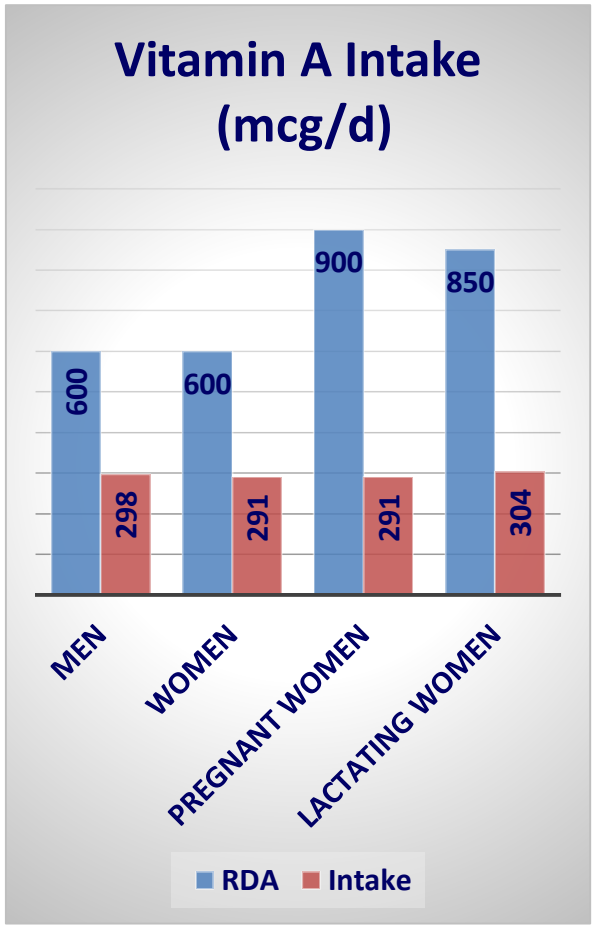
(ICMR , 2010)

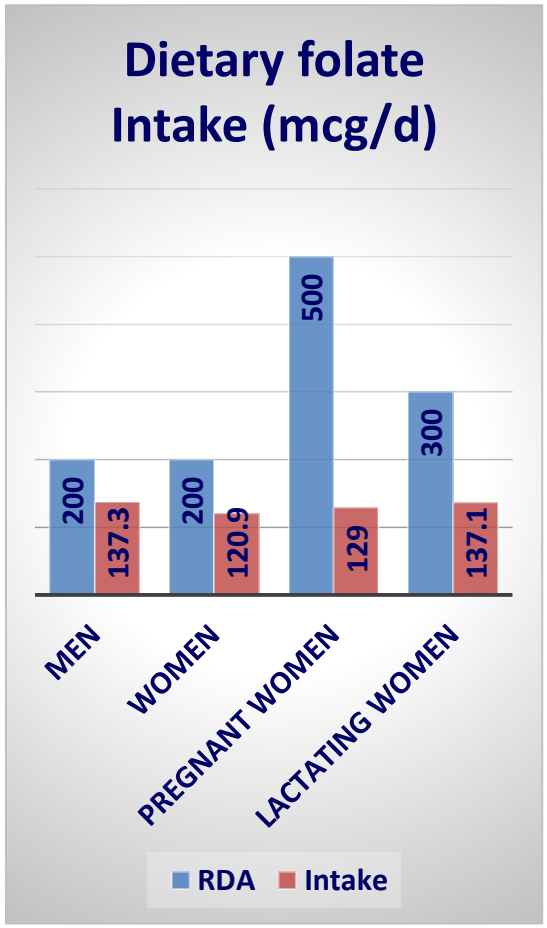
ACTUAL INTAKE



DIETARY INTAKE OF MICRONUTRIENTS FALLS SHORT OF RECOMMENDED ALLOWANCES







Source: RDA: ICMR, 2010; Intake: NNMB, 2012

On the basis of these data, priority nutrients for fortification for improving nutrient intake in India are:

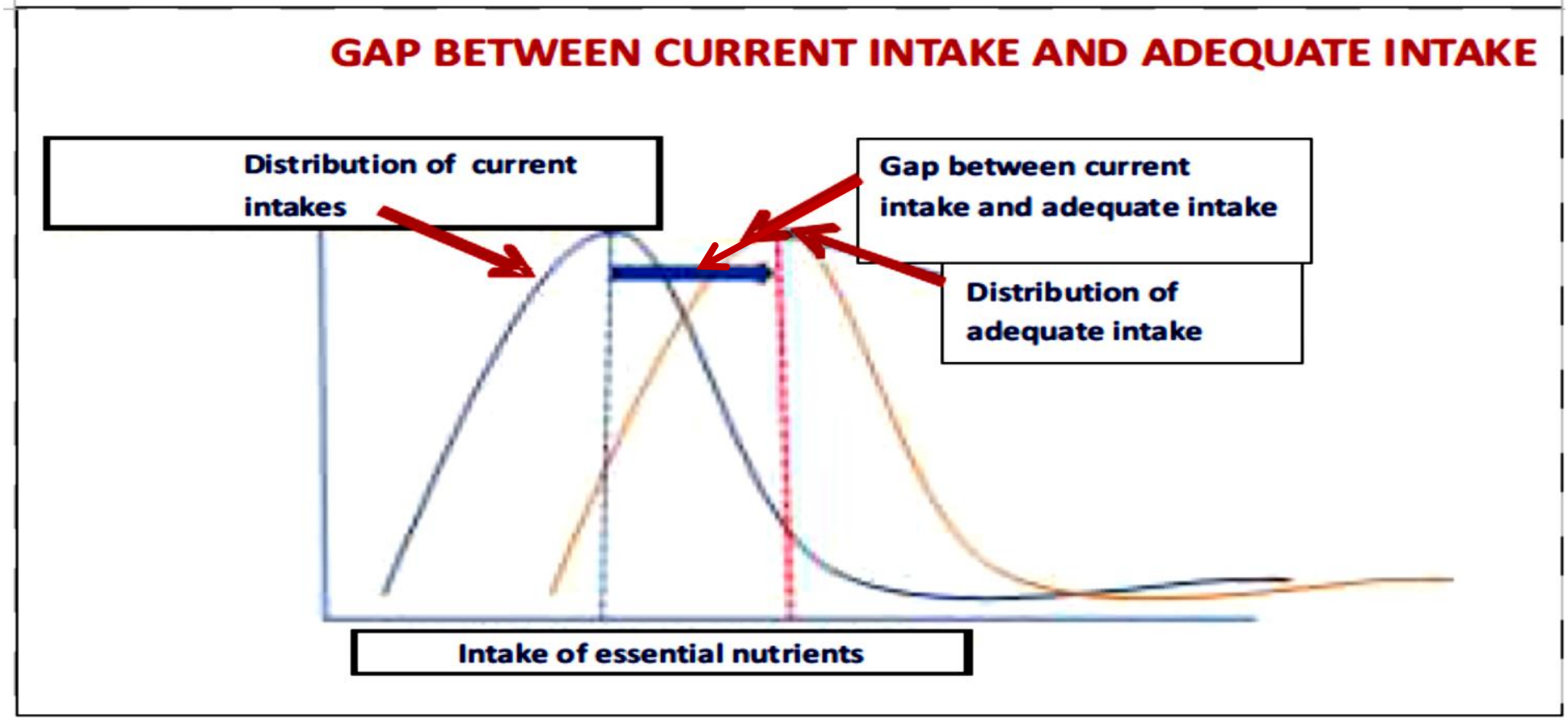
- **Iodine (for IDD)**
- **Iron and folic acid (for anemia)**
- **Vitamin A and D**

CONCEPTUAL FRAME WORK FOR FOOD FORTIFICATION

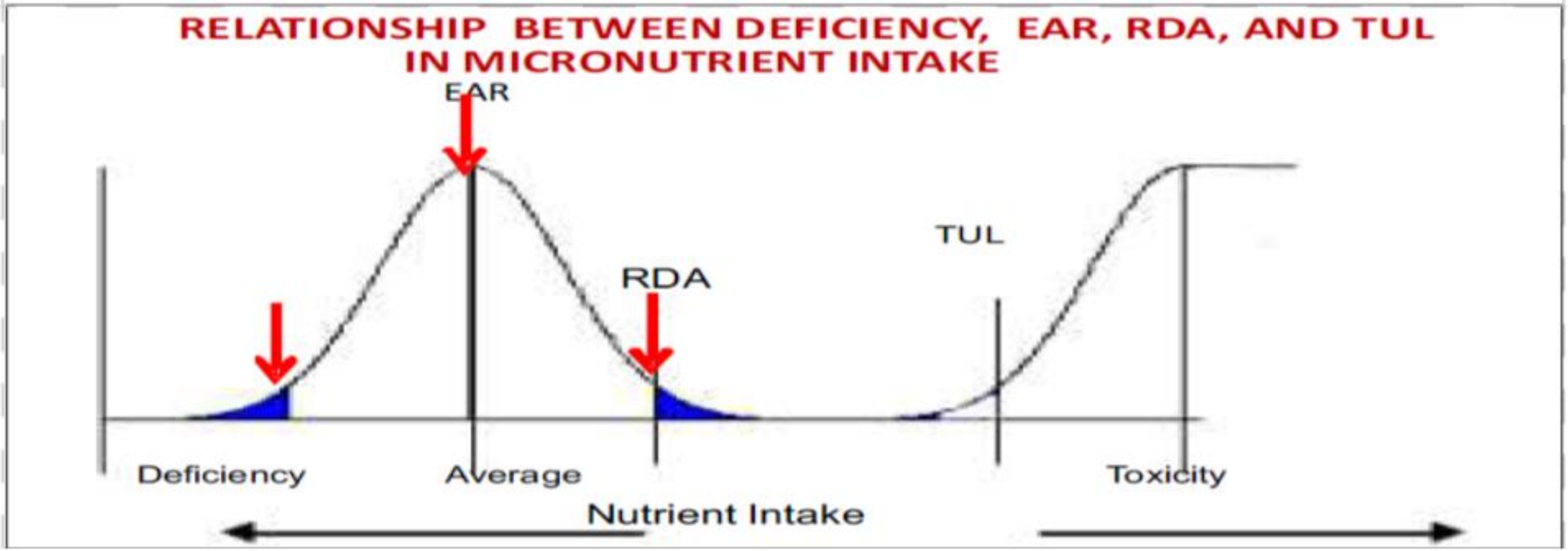
PUBLIC HEALTH NUTRITION TERMS REGARDING NUTRIENT INTAKE

Average Nutrient Requirement (ANR) Estimated Average Requirement (EAR)	Average daily nutrient intake level estimated to meet the requirements of half of the healthy individuals. It is used primarily to evaluate nutrient intake in populations or segments of population.
Adequate Intake (AI) Safe Intake	The Safe intake or Adequate intake is the average daily intake level by a group of apparently healthy people living without any economic or social constraints in accessing adequate food.
Recommended Nutrient Intake (RNI) Recommended Dietary Allowance (RDA)	Daily dietary nutrient intake level that is sufficient to meet the nutrient requirements of nearly all (97–98%) healthy individuals. This is ANR (or EAR) +2 SD. The indicator is used to primarily evaluate individual diets. The RDA is inappropriate for dietary assessment of groups as it is the intake level that exceeds the requirement of a large proportion of individuals within the group.
Upper Nutrient Level (UNL) or Tolerable Upper Level (TUL)	Highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population.

GENESIS OF NUTRIENT DEFICIENCIES



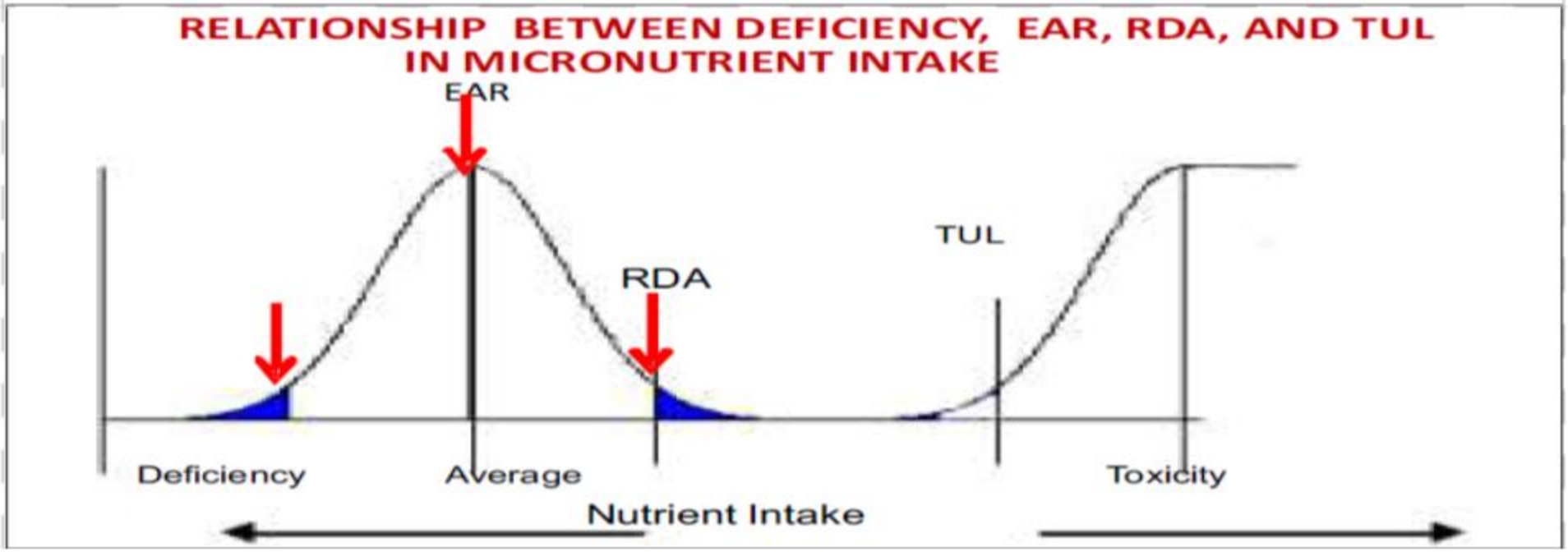
Nutrient deficiencies arise because of the gap between current nutrient intake and the nutrient requirement for a healthy active life. Food fortification aims to bridge the gap between intake and requirement without any dietary modification, through fortification of commonly consumed food stuff with the nutrient.



The amount of nutrient added to the food stuff for fortification is determined by:

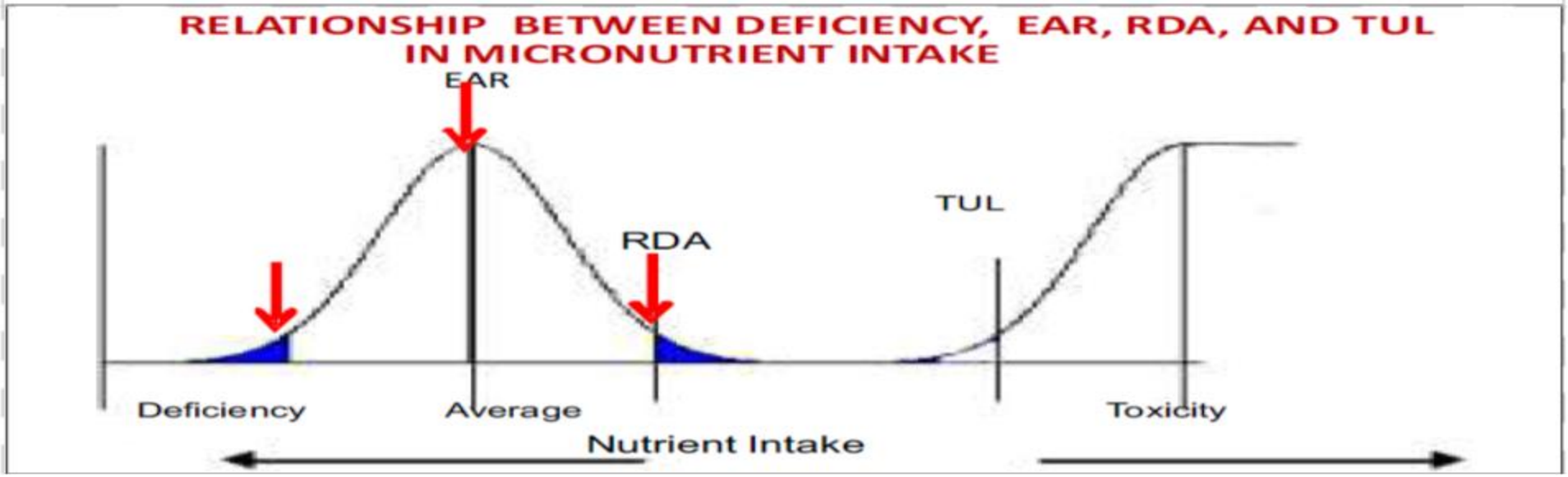
- **the magnitude of the gap in nutrient intake in the at risk population (with high levels of nutrient deficiency) and the amount of nutrient required to bridge the gap between requirement and intake in this group.**
- **the current consumption levels of the highest consumption group and the gap between total intake (food + fortification) in this group and TUL.**

Ideally the fortification should be at a level where consumption of the nutrient in food + fortification meets the requirement of nutrient in those with low intake but not much higher than RDA and far lower than TUL in the group with adequate intake from food alone.



It is relatively easy to determine the level of nutrient fortification for nutrients in situations where the fortification is done in only one food stuff, level of nutrient required to bridge the gap in the low intake group is small, and the difference between the total intake of nutrient from food and fortification and TUL is large.

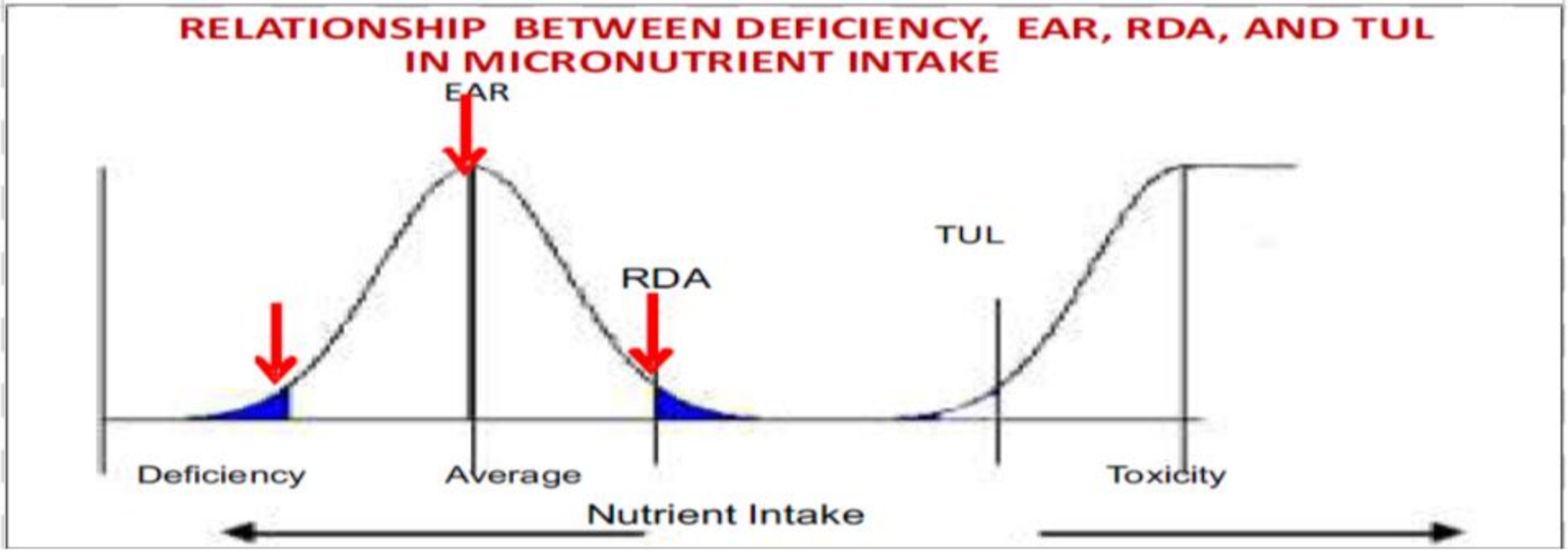
This was the advantage that we had with salt fortification with iodine to combat IDD



It is relatively easy to determine the level of fortification for nutrients in any one food stuff - the amount is usually between 30% and 50% of RDA

It is difficult to embark on fortification when the gap between nutrient requirement, RDA and TUL are close eg iron

If multiple food stuffs are fortified with the nutrient (as with iron), some segments of the population may consume more than one fortified food product, the total intake of nutrient from food and multiple fortified foods may cross the TUL even though fortification of any one food stuff was only about 30% of the RDA.



It is possible that even though the amount of nutrient used for fortification is adequate to bridge the nutrient gap if recommended quantity of food stuff is consumed, the gap could not bridged because:

- **it is not possible to fortify all of the food item consumed with the nutrient or**
- **The food stuff consumed is low in some segments of population**

Vit A and D fortification of milk falls under this category.

SALT FORTIFICATION WITH IODINE

Iodine fortification of salt was the first global and Indian effort to combat iodine deficiency using food fortification

A single nutrient was added to a universally consumed food item; excessive consumption of salt is unlikely

The requirement was small; there was a wide gap between level of fortification 30 ppm and TUL 1100 ppm

Technology is readily available

The cost of fortification was quite low

Main investment was to ensure quality and to ensure that the fortified salt reaches the consumer without any loss preferably by packing salt in poly packs

OPERATIONALISING IODINE FORTIFICATION OF SALT

National Goitre control programme was initiated in 1962

1990

- **Country had capacity to produce adequate salt**
- **Created efficient transport of iodised salt across the country**
- **Generated public awareness on importance of using iodised salt**
- **Majority of states had banned the sale of non-iodised salt for human consumption**

2000

- **In spite of unanimous technical advice that the ban on non-iodized salt should not be removed, the central government lifted the ban on sale of non-iodized salt for human consumption in October 2000 because "matters of public health should be left to informed choice and not enforced".**
- **This led to a dip in the use of iodised salt**

2007

- **National level ban on sale of non-iodised salt for human consumption was introduced**
- **Subsequently there has been substantial improvement in household use of iodised salt and the country is likely to achieve universal access to iodised salt soon**

MANDATORY FORTIFICATION

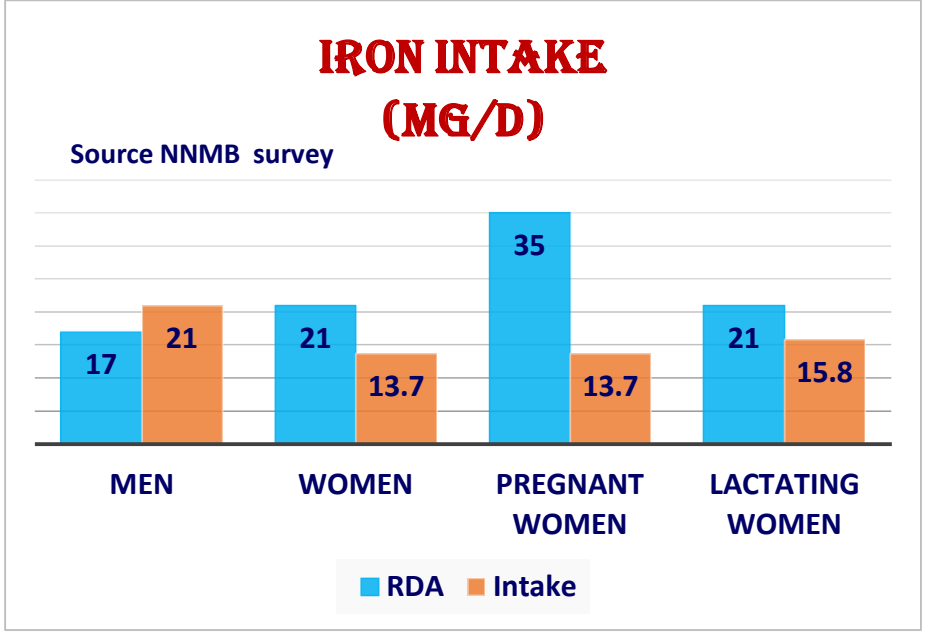
Mandatory fortification is considered only in those rare occasions when there is a major public health problem due to micro-nutrient deficiency, across all segments of the population, which cannot be tackled through food-based approach.

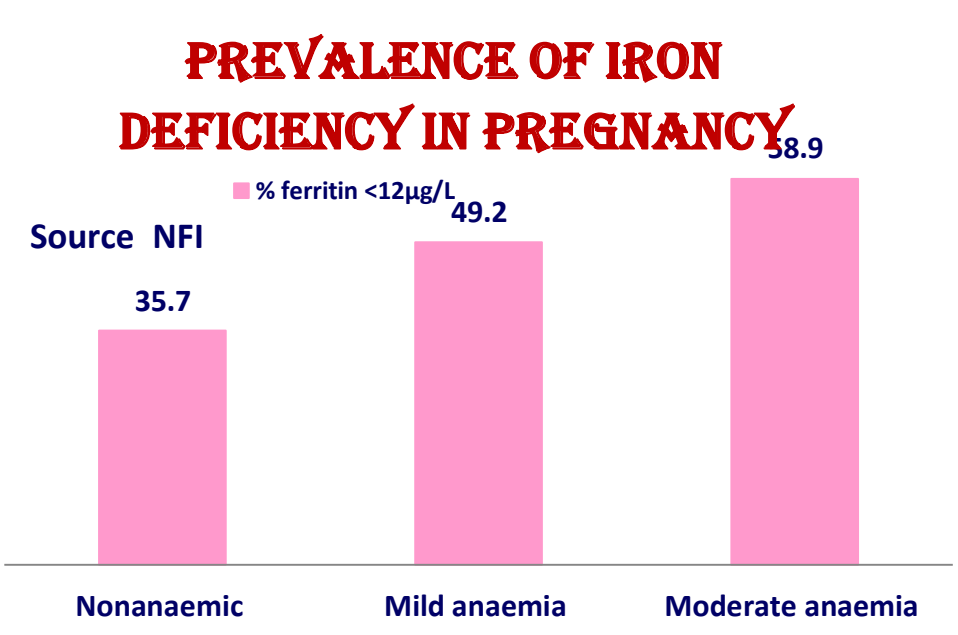
In the Indian context iodine and iron qualify under these stringent criteria.

Adequate production, transport and marketing should be ensured before considering mandatory fortification.

Over four decades elapsed between initiation of the goitre control programme (1962) and mandatory fortification of salt with iodine (2007). Mandatory iodine fortification of salt has been in vogue for the last ten years.

FORTIFICATION TO IMPROVE IRON INTAKE





- Estimated average intake of iron from Indian diets ranges from 10-20 mg/day; this is not far lower than the iron intake in developed countries.
- But the bioavailability of iron from phytate and fibre rich Indian diets is only 5-8% (which is less than 1/5th of bioavailability of iron from diets rich in animal foods).
- As a result majority of Indians irrespective of their age and physiological status are iron deficient and anaemic

SALT FORTIFICATION WITH IRON AND IODINE

- Over time there has been some increase in the vegetable intake in Indian population
- But it is very difficult to produce, procure, cook and consume the large quantities of micro-nutrient rich vegetables needed to meet the RDA especially in children and pregnant women.
- Iron fortified iodised salt represents the most feasible, economical and sustainable method of increasing iron intake by an average of 10mg/day (without any major dietary change) and reduce the prevalence of iron deficiency.

IRON FORTIFIED IODISED SALT

- Iron fortified salt was developed and tested by NIN in 1970
- Realising that universal use of iodised salt is likely to happen soon, NIN embarked on development and testing of iron fortified iodised salt

In 2000-2003 the iron fortified iodised salt was being:

- Manufactured on industrial scale,
- Provided through PDS in Chhattisgarh,
- Through ICDS in Uttarakhand.

- In 2011 Dept of Health and DWCD sent guidelines on use of DFS in hot cooked meal in ICDS and MDM. This could not be operationalised across the country because many states were unable to procure continuous supply of DFS
- Industry which expanded capacity to produce DFS faced loss due to non-utilisation of the capacity.

IRON FORTIFIED IODISED SALT

The technology for iron fortification of iodised salt, developed by NIN, has been transferred to the industry. Currently two technologies for producing DFS have been approved by FSSAI.

Voluntary fortification of salt using these technologies is under way

Guidelines for mandatory use of DFS in hot cooked food in MDM and ICDS have recently been re-issued

Implementation of these guidelines will ensure:

- **the installed production capacity is fully utilised and**
- **awareness, acceptance and use of DFS is built up.**

Centralised production and pre-existing programmes for salt fortification with iodine offer a very ready platform to launch iron-fortified iodised salt.

The process for legislating for mandatory fortification can begin only after ensuring adequate

- **capacity for production**
- **supply through PDS and open market**
- **offtake through Government programmes and home consumption.**

FORTIFICATION OF CEREALS

In view of the widespread nature of iron deficiency, and low production and limited access to iron fortified iodised salt, there has been advocacy for fortifying multiple foodstuffs with iron.

As folic acid and B12 deficiencies also contribute to anaemia, there have been efforts to voluntarily fortify rice and atta with iron, folate and B12.

The FSSAI has provided standards for rice and atta fortification with iron, folate and B12.

The tolerable upper limit of iron is estimated to be about 45 mg/day.

As and when access to iron fortified iodised salt becomes near universal, iron may have to be removed from the fortification mixture for cereals in order to prevent total intake of iron beyond TUL.

LONG TERM HEALTH IMPLICATION OF CONSUMPTION OF NUTRIENTS AT HIGHER THAN RDA LEVEL

Almost all the data on TUL are derived from therapeutic supplementation of the nutrient alone or in combination, for relatively short period of time under medical supervision.

In mass food fortification there is no provision for careful follow-up of individuals consuming the fortified food

It has been assumed that in fortification with water soluble vitamins such as folic acid with large gap between RDA and TUL there will be no problem if some segments of population consume more than RDA amounts of the nutrient through mandatory fortification

The US experience of mandatory fortification of wheat flour with folic acid has shown that this assumption may not be correct.

US EXPERIENCE: MANDATORY FOLIC ACID FORTIFICATION OF WHEAT FLOUR FOR NTD PREVENTION

Neural tube defect is a major congenital anomaly associated with a number of genetic polymorphisms affecting folate metabolism

Peri-conceptional therapeutic supplementation with folic acid (400µg daily) reduces risk of repeat NTD in women who had previously delivered infants with NTD and to a lesser extent reduces risk of NTD in general population.

US introduced mandatory folic acid fortification of wheat flour with 400 µg of folic acid (4 times RDA) to reduce incidence of NTD.

This resulted in 19 to 32% reduction in the incidence of NTD.

US EXPERIENCE: MANDATORY FOLIC ACID FORTIFICATION OF WHEAT

Mandatory folic acid fortification of wheat resulted in entire population in the country receiving higher than RDA level of folic acid for years.

Initially it was assumed that the excess of folic acid would be excreted in the urine and is therefore unlikely to lead to any adverse health consequences.

Ongoing monitoring of the mandatory folic acid fortification programme showed that this resulted in masking of B12-deficiency anaemia and delaying the diagnosis of B12 deficiency.

Some studies have reported that folic acid supplementation may enhance the development and progression of already existing, undiagnosed pre-malignant and malignant lesions or increase the risk of cardiovascular diseases. Data is insufficient to draw conclusions about the increase in risk of adverse health consequences in the general population.

US EXPERIENCE: MANDATORY FOLIC ACID FORTIFICATION OF WHEAT FLOUR

This experience demonstrates the need for:

- **caution while arriving at the nutrient level of fortification so that no group receives more than RDA of the nutrient through mass fortification**

- **monitoring ongoing fortification programmes for beneficial and potential adverse health consequences.**

- **In India in the ongoing voluntary fortification of rice and wheat flour, iron, folic acid and B12 are incorporated at one third RDA level.**

- **As folic acid as well as B12 are used together there is no risk of masking vitamin B12 deficiency**

LESSONS LEARNT AND WAY FORWARD

LESSONS LEARNT AND WAY FORWARD

The aim of fortification is to bridge the gap between intake and requirement of micro-nutrients when this cannot be achieved through dietary diversification.

Mass fortification results in fortified foods reaching large segments of population who may continue to take the fortified food (some times without even the knowledge that it is fortified) for a long period of time without any monitoring, supervision or evaluation.

Therefore food stuff used for fortification and amount of the nutrient used for fortification should be chosen with care.

LESSONS LEARNT AND WAY FORWARD

We can learn from the experiences of developed countries.

Excessive intake of one nutrient through fortification can lead to health hazards due to excessive intake or imbalance of nutrients.

Multiple nutrient fortification in multiple food stuffs may not have the intended benefit of reducing multiple micro-nutrient deficiencies but can have adverse health consequences.

So use fortification only to address micro-nutrient deficiencies which are:

- major public health problems across all segments of the population,
- which cannot be tackled solely through food-based approach.

Monitoring and review of the programme using process and impact indicators by experts should be an essential component of every mass food fortification programme.


Thank You