EDITORIAL

Implementation of Double Fortified Salt in India is based on Low Scientific Evidence

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Micronutrient malnutrition (MNM) can affect all age groups, but young children and women of reproductive age are most at risk of developing micronutrient deficiencies. Iodine Deficiency Disorders (IDD) and Iron Deficiency Anaemia (IDA) are two important Public Health problems. Out of 342 districts surveyed, so far IDD is a major public health problem in 286 districts. No state in India is free from iodine deficiency (1). Iron Deficiency Anaemia is reported in about 70% of the population across all age groups (2). The magnitude of Vitamin B12 deficiency is documented to be about 73.5% in the adolescents (3) and Zinc deficiency is reported in about 49.4% amongst children (4). In addition, there are deficiencies of other micronutrients and minerals like Folic Acid, Vitamin D which are of public health concern.

Fortification of food is one of three primary strategies to combat micronutrient deficiencies. Fortification is defined by the World Health Organization (WHO) and Food and Agricultural Organization (FAO) as "the practice of deliberately increasing the content of an essential micronutrient, i.e. Vitamins and minerals (including trace elements) in a food irrespective of whether the nutrients were originally present in the food before processing or not, so as to improve the nutritional quality of the food supply and to provide a public health benefit with minimal risk to health". Food fortification is one of the most cost effective ways to make up for the deficient vitamins and minerals in low quality diets. The edible salt is the most widely used food vehicle for fortification with micronutrients (5).

Fortification of salt with iodine, to prevent IDD, under the National Iodine Deficiency Disorders Control Programme, is in operation since 1962 (1). This intervention has led to significant prevention and control of IDD (6). Recently, the technology has been developed for fortification of salt with iron and iodine commonly known as DFS, to simultaneously combat IDD and IDA (7-9).

Fortification of Salt with Iron

In 1980s, National Institute of Nutrition (NIN), Hyderabad developed Iron Fortified Salt (IFS). The efficacy cum effectiveness trials of IFS were conducted in five regions of the country. It was found that IFS intervention led to an increase in Hemoglobin (Hb) levels (10). However, in 1986, Universal Salt Iodization (USI) policy was adopted in the country. Under this policy, all edible salt was to be iodised. MOHFW, Government of India decided that two types of salt i.e. IFS and Iodized Salt (IS) in a population would create operational difficulties in monitoring of iodine content of salt and hence IFS was given low priority.

Salt Fortified with Iron and Iodine

The National Institute of Nutrition continued its efforts in the field of fortification of Salt with micronutrients and developed Double Fortified Salt (DFS) in 1986 to address dual problem of iron and iodine deficiency simultaneously (7).

Generation of Scientific Evidence on NIN-DFS

1. Study in Tribal Population

A community based effectiveness study was conducted in tribal area of East Godavari District in Andhra Pradesh. This study was initiated in 1989 and

concluded in 1992. A population of about 5000 was included. The prevalence of Goitre decreased significantly; however, there was no significant impact of DFS on the prevalence of Anaemia (11).

2. Study in Residential Schools

In 1996, a Randomized Double Blind study was carried out for a period of two years among children belonging to backward communities in four residential schools in and around Hyderabad. Hemoglobin status, urinary iodine excretion and calcium-phosphorus homeostasis of the beneficiaries were evaluated. The children were followed up after 6 months, 1 year and 2 years after commencement of the study. Out of about 500 children, only 107 were available at the end of 2 years. A defaulter rate of about 80% was observed. This study also did not show improvement in the Hemoglobin levels of the children receiving DFS. The results obtained from this study raised the concerns about stability of iodine in the DFS (12). The studies were recommended to assess the stability of iodine in NIN-DFS.

Stability of Iodine in DFS: Study 1

In 1999, a multicentric study was initiated in 6 centers to assess the stability of iodine in NIN-DFS. The DFS was produced and sent to six different regions of the country. The DFS was stored under the programmatic condition as IS was routinely stored. After 12 months of storage, it was found that iodine was not stable in the DFS (13).

Stability of Iodine in DFS: Study 2

In 2004, the stability of iodine in the NIN-DFS was investigated again. This study was undertaken only in two centers (Delhi and Hyderabad). The iodine content in DFS was assessed after 3 months of storage of NIN-DFS in room conditions. It was found that iodine was stable in the DFS. The iodine content in DFS was however done by modified Standard Iodometric Titration Method, in which sulfuric acid was replaced by Ortho-phosphoric acid (14).

Formulation of Guidelines by MOHFW on NIN- DFS

In 2005, vide letter no: Z 28020/16/2005-CH/PH, Ministry of Health constituted a Committee under the Chairmanship of Prof. M. K. Bhan, Secretary, Department of Biotechnology, Government of India, New Delhi, to formulate Guidelines for use of DFS as a measure to reduce prevalence of anaemia.

In 2006, based on the findings of the residential school study (12) and stability of iodine in NIN-DFS after storage in room condition for three months (14), Dr. Bhan Committee recommended that NIN-DFS can be utilized as a measure to reduce prevalence of anemia (15).

In 2010, Indian National Science Academy published a technical report which mentioned that the efficacy of NIN-DFS has been tested in small scales studies. Systematic programme for scaling up is needed to examine the effectiveness of DFS in preventing iron and iodine deficiency and replacing IS with iron fortified iodised salt. Evaluation of DFS should be done by an independent agency rather than ICMR (17).

In 2011, Prime Minister's National Nutrition Council Meeting was held. In this meeting, it was recommended that NIN-DFS should be utilized for controlling anemia and IDD. A Notification was issued immediately by the Ministry of Women and Child Development vide letter no- 5-4/2011 ND/Tech in 2011 for use of NIN-DFS in ICDS Programme. Similarly, Ministry of Human Resource Development also issued an order for using NIN-DFS in Mid Day Meal Programme for school children (16).

Do we have Strong Scientific Evidence on Efficacy or Effectiveness of NIN-DFS?

We have poor scientific evidence on impact of NIN-DFS in improving Hb levels and preventing IDD. Also existing evidence is based only on one single study, in which dropout rate was more than 80%. Also, no evidence of increase in Hemoglobin levels was observed in the DFS intervention group (12).

The way forward

Presently, there are more than 10 salt producers who are producing NIN-DFS. These manufacturers are supplying DFS to more than 15 states in the country. The NIN-DFS is distributed under public distribution system to the population (18). We do not have adequate scientific evidence on efficacy and effectiveness of NIN-DFS. Hence, there is an urgent need to generate scientific evidence by undertaking efficacy and effectiveness studies of NIN-DFS in different regions of the country. The independent agencies should undertake the efficacy and effectiveness studies to avoid conflict of interest. Simultaneously, the stability of iodine in

DFS needs to be assessed after storage in programmatic conditions. The iodine deficient population should not be deprived of iodine due to lack of stability of iodine in NIN-DFS.

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