RECOMMENDATIONS

National Consultation-cum-Brain Storming Session on Fortification of Edible Salt with Micronutrients

Umesh Kapil[1], HPS Sachdeva[2]

[1]Professor, Human Nutrition Unit, All India Institute of Medical Sciences New Delhi, [2]Senior Consultant Pediatrics, Sitaram Bhartia Institute of Science and Research, New Delhi

Abstract | Introduction | Methodology | Results | Conclusion | References | Citation | Tables / Figures

Corresponding Author

Address for Correspondence: Dr Umesh Kapil, Human Nutrition Unit, All India Institute of Medical Sciences New Delhi.
E Mail ID: umeshkapil@gmail.com

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Abstract

Micronutrient malnutrition (MNM) can affect all age groups, but young children and women of reproductive age tend to be among those most at risk of developing micronutrient deficiencies. In India, Iodine Deficiency Disorders and Iron Deficiency Anaemia are important Public Health problems.No state in India is free from iodine deficiency. Out of 343 districts surveyed, 286 are reported have Iodine Deficiency Disorders. Iron Deficiency Anaemia is reported in about 60% population across all age groups. The magnitude of vitamin B12 Deficiency is reported to be about 47% in urban population of Delhi while Zinc Deficiency is reported in about 44% amongst Indian children. In addition, there are other micronutrients and minerals like folic acid 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 the Food and Agricultural Organization of the United Nations (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. Edible salt is the most widely used food vehicle for fortification with micronutrients.

Fortification of salt with iodine, under the National Iodine Deficiency Disorders (IDD) Control Programme, has been the strategy in operation in the entire country as a universal policy since 1962 to combat IDD. This has led to prevention and control of IDD in the country. In 1970s, an attempt was made to develop Iron fortified salt (IFS) or edible salt fortified with Iron. Efficacy trials and multi-centric effectiveness trials were conducted and documented positive results. However, with the policy focus on Universal Salt Iodization Programme in the country, IFS was not introduced in the country.

Subsequently in 1980s, the National Institute of Nutrition (NIN), India, Hyderabad developed edible salt fortified with Iron and Iodine, referred to as double fortified salt (DFS) or NIN-DFS. Efficacy studies were conducted with DFS with mixed results. Large scale effectiveness trials (under public health intervention conditions/programmatic conditions) have not been undertaken. In 1980s, another formula for production of DFS, using the encapsulation process for fortification of salt with iron and iodine, was developed by Micronutrient initiative (MI) - referred to as Micronutrient Initiative (MI) formula or MI-DFS. Both DFS-NIN and DFS-MI formulae are being used by Tamil Nadu State Government for ICDS and Mid-Day Meal Programme in the state. In 1990s, Sunder Chemicals also produced DFS using its own formula and undertook efficacy trials. The Human Nutrition Laboratory, Swiss Federal Institute of Technology, Switzerland also has a DFS formula, which has not been used or tried in India. However, findings from efficacy trials of this DFS are available in the peer review scientific journals.

To date, only one multi-micronutrient fortified edible salt (MMNS) has been produced in India. This was produced by Sundar Chemicals Pvt Ltd., a private sector undertaking, in 1990s.Edible Salt is fortified with 10 micronutrients, namely, Iron, Iodine, vitamin A, vitamins B1, B2, B6, B12, Folic Acid, Niacin and Calcium. The results of the efficacy trials have been published in peer reviewed scientific journals. A positive impact has been documented on the micronutrient status of the beneficiaries consuming such fortified salt.

The Ministry of Women and Child Development has adopted a policy that NIN-DFS is to be utilized for the feeding component of the ICDS programme. There are more than 10 salt producers who have been recognized by NIN as producers of double fortified salt using NIN-DFS formula and are supplying DFS to ICDS in selected states. In Tamil Nadu state, the mid- day meal programme in schools also use DFS, produced by Tamil Nadu Salt Corporation, using NIN or MI formulae.

Keywords

Double Fortified Salt; Anemia; Iodine Deficiency Disorders

Rationale of the Brain Storming Session (BSS)

In India, since last 50 years, we are successfully utilizing Iodized Salt. The results of the impact studies have shown significant reduction in Iodine Deficiency Disorders (IDD). In addition to IDD, iron deficiency anemia (IDA) is a major Public Health problem in the country. There is scientific evidence that edible salt can be fortified with iodine and iron. Various technologies and formulations have been developed for edible salt fortified with iron and iodine, or double fortified salt (DFS) to simultaneously combat IDD and IDA.

Data of large-scale effectiveness studies with DFS, developed by MI, NIN-Hyderabad, Sundar Chemicals Pvt Ltd. and Swiss Federal Institute of Technology is lacking. Switzerland. However, formulation and efficacy trials of DFS developed and tested by MI, NIN-Hyderabad, Sundar Chemicals Pvt Ltd. and Human Nutrition Laboratory, Swiss Federal Institute of Technology, Switzerland are available in the published literature. Recently, Central Salt and Marine Chemicals Research Institute (CSMCRI), Bhavnagar has also experimented with a new technique of producing DFS.

There is therefore a need to review the existing literatures on DFS efficacy findings and also explore any progress made to date on effectiveness trials. A one day "National Consultation-cum-Brain Storming Session on Fortification of Edible Salt with Micronutrients was therefore organized on 20th January,2015 at the All Institute of Medical Sciences, New Delhi with the following objectives and expected outcomes

Aims & Objectives

1. To review the current status of fortification of edible salt with various micronutrients.
2. To review the efficacy and effectiveness data pertaining to fortification of edible salt utilized using different formula.
3. To make recommendations for Government of India for combating the micronutrients malnutrition problem by adopting DFS.

Expected Outcomes

Evidence based scientific recommendations will be presented to prioritize the adoption of edible salt fortified with selected micronutrients in the country for combating deficiency of iron and iodine.

Recommendations

Following the presentation made by each of the four DFS formula developers and other scientists, a panel discussion was held. Following are the recommendations emerging on double fortified salt (DFS), which was the focus of discussions.

Technical issues regarding production of Double Fortified Salt (DFS)

1. The following two primary issues need to be resolved in the context of formulation and production of DFS: i) segregation and ii) reaction of nutrients and its implication on stability of iodine. Segregation and reaction is influenced by a number of factors such as particle size, moisture level and weight of salt. These factors need to be controlled and specified.
2. Production of DFS on a larger scale requires specific guidelines, including details regarding moisture content, purity and PH of salt to be used. Technologies need to ensure improved stability of iodine.
3. Convincing evidence is required on whether DFS produced using different types of salts have the same or nil influence on iodine retention and content.
4. Besides NIN, encapsulation formula of Toronto (referred as MI formula) and sunder Chemicals formula, a fourth formula of DFS developed by Central Salt and Marine Chemical Research Institute (CSMCRI) Bhavnagar is encouraging. However, bioavailability and efficacy trials remain to be undertaken.
5. The possibility of producing DFS using new low sodium salts, conforming to NCD guidelines, needs to be explored.

Gaps in Acceptability studies on DFS

1. Rolling out DFS in community settings (other than captive settings such as the MDM) requires an understanding of acceptability of consumers regarding cost, impact on colour of food when food item is consumed without cooking or when different methods of cooking or food preparations are used.
2. Cost of salt is influenced to a great extent by type of packaging required and used for large scale production and distribution as well as for retail packing and marketing. Implication on cost of product marketed to the consumer in open market and its acceptability needs to be studied.
3. The above factors which influence choice of salt for food items need to be systematically studied prior to considering DFS for replacing iodised salt in the open market.

Efficacy and Effectiveness studies

1. There is a need for information on benefits on use of DFS using both efficacy and effectiveness trials. Cost-benefit analysis should also take into consideration not only small controlled efficacy trials but effectiveness studies.
2. It was recognized that there are efficacy trials and findings reported for both three DFS formula but there are gaps in efficacy study design .It is therefore important that efficacy and effectiveness trials are rigorous and are undertaken keeping the following issues in mind by each of the DFS developers and promoters a) use of standardized protocols developed based on best practices b) mutually acceptable indicators used for measuring impact c)standardized acceptable methods used for measurements of iodine and iron levels d) quality control of the study and e) ensuring a mechanism is built for external quality control and data verification.
3. Efficacy study should measure loss and retention of nutrients used for fortification of salt when different methods of cooking are used.
4. The design of relevant efficacy studies should consider both the variety of salt used and the micronutrient formulations employed.
5. The above issues of efficacy and effectiveness trials would apply across all the four formulations of DFS i.e. NIN, MI, Sunder Chemicals and the newly developed CSMCRI - DFS.
6. For efficacy trials, bioavailability of nutrients should also be measured in vivo using acceptable standardized procedures. Outcome indicators should also be an integral part of the study. However, it was recommended that the impact study should not be limited to biochemical markers such as haemoglobin or iron status but to functional outcomes such as cognitive performance, morbidity etc. Iron stores should be measured to get an approximation of long-term bioavailability. Only standardized methods should be used.

7. Scientifically rigorous methodology needs to be used for efficacy and effectiveness trials even when such studies are planned at state level or by state governments. A group was recommended to be constituted, along with the participation of ICMR, to develop the required protocol.

Public Health

1. Effectiveness trials of DFS remain to be undertaken. In absence of such information, the implications of shifting the policy from universal iodised salt to use of DFS in public health programme needs to be considered on the basis of findings of effectiveness studies. Such information is crucial for rolling out DFS supply through the Public Distribution System (PDS) or Mid-Day Meal (MDM) programme or Integrated Child Development Services (ICDS) system. In case of the MDM or ICDS, use of DFS is limited to only one meal a day and this needs to be taken into consideration in the efficacy trials and policy issues pertaining to DFS.
2. Based on available information, a document needs to be prepared on the two formulations, NIN and MI, to facilitate the state governments in making a choice regarding when to introduce DFS and which DFS product to be used out of the two formulations i.e. NIN formulation or encapsulation formulation.
3. Documenting information regarding safety of DFS as well as of Multi-micronutrient salts is important. Implications of DFS in not causing any toxicity should be explicitly presented. Such an assessment and presentation should take into consideration safety of introduction of DFS programs even when population groups are regularly administered iron supplements for prevention of anemia.
4. Regulatory frameworks are required regarding production and supply of DFS in public health programme. Additionally, introduction of simple salt testing kits for checking presence of iron and iodine in salt needs to be tested and introduced for consumer level monitoring.
5. An oversight mechanism needs to be put in place for certifying quality of DFS to be procured and supplied by state governments through various programmes.

BRAIN STORMING SESSION ON DOUBLE FORTIFIED SALT (20TH JANUARY 2015)
LIST OF PARTICIPANTS

Name	Designation	Address	Attended (Yes/No)
Dr. M. K. Bhan	Former Secretary	Department of Biotechnology, New Delhi	Yes
Prof. R. K Srivastva	Former DGHS	MOHFW Consultant-USAID, National Institute of Health and Family Welfare, New Delhi	Yes
Dr. Rakesh Kumar	Joint Secretary	Department of Health and Family Welfare, New Delhi	No
Prof. HPS Sachdev	Senior Consultant	Sitaram Bhartia Institute of Science and Research, New Delhi	Yes
Dr. Rajesh Kumar	Scientist Group IV (I)	Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, New Delhi	Yes
Dr. Rajesh Kapur	Adviser	Department of Biotechnology, New Delhi	Yes
Dr Sila Deb	Deputy Commissioner (Child Health)	Ministry of Health & Family Welfare, New Delhi	No
Dr. VM Katoch	Secretary	Department of Health Research, New Delhi	No
Dr. G S Toteja	Sr. Deputy Director General / Scientist `G' and Head (Nutrition)	Indian Council of Medical Research, New Delhi	No
Prof. Panna Choudhury	Former President	Indian Academy of Pediatrics, New Delhi	Yes
Dr. Vamsi Krishna Addanki	Scientist	Food and Nutrition Division, Dept of Biotechnology, Ministry of Science and Technology, New Delhi	Yes
Dr. Neeta Bhandari	Director	Society of Applied Sciences, New Delhi	Yes
Dr. Sheila Vir	Public Health Nutrition Consultant, Director	Public Health Nutrition and Development Centre, New Delhi	Yes
Dr. Anju Sinha	Assistant Director General (Scientist F)	Division of RHN, Indian Council of Medical Research, New Delhi	Yes
Dr. Reeta Rasaily	Scientist F	Indian Council of Medical Research, New Delhi	Yes
Dr. Ravindra Mohan Pandey	Professor and Head	Department of Biostatistics, All India Institute of Medical Sciences, New Delhi	Yes
Prof. C. S. Pandav	Regional Coordinator-ICCIDD & Head	Centre for Community Medicine, All India Institute of Medical Sciences, New Delhi	Yes
Dr. Ravindra Goswami	Professor	Department of Endocrinology, All India Institute of Medical Sciences, New Delhi	No
Dr. Nikhil Tandon	Professor	Department of Endocrinology and Metabolism, All India Institute of Medical Sciences, New Delhi	Yes

Dr. Ramakrishnan Lakshmy	Professor	Cardiac Biochemistry, All India Institute of Medical Sciences, New Delhi	Yes
Dr. Kumud Khanna	Director	Institute of Home Economics, University of Delhi	Yes
Prof. Harish Cheelani	Head	Department of Pediatrics, Safdarjung Hospital	No
Dr. Dheeraj Shah	Professor	Department of Pediatrics, University College of Medical Sciences, New Delhi	No
Dr. Neena Raina	Regional Advisor	Child and Adolescent Health, World Health Organization, New Delhi	No
Dr. Padmini Angila de Silva	Consultant Nutrition Unit	World Health Organization, SEARO, New Delhi	Yes
Dr. John H McCullough	Regional Director, Asia	Micronutrient Initiative, New Delhi	Yes
Mr. Suvabrata Dey	National Program Manager	Micronutrient Initiative, New Delhi	Yes
Dr JK Raman	Scientist	New Delhi	Yes
Dr. Rajan Sankar	Regional Manager	Global Alliance for Improved Nutrition (GAIN), New Delhi	Yes
Dr. Jee Hyun Rah	Nutrition Specialist	UNICEF, New Delhi	Yes
Dr. Karanveer Singh	Nutrition Specialist	UNICEF, New Delhi	No
Dr. Narendra Arora	Executive Director	INCLEN Trust International and CHNRI, New Delhi	Yes
Dr. Raman Kumar Marwaha	Scientific Advisor and Senior consultant Endocrinology	International Life Sciences Institute and Former Additional Director and Head, Deptt of Endocrinology and Thyroid Research, INMAS, DRDO, MOD.New Delhi	Yes
Prof. Umesh Kapil	Professor	Department of Human Nutrition, All India Institute of Medical Sciences, New Delhi	Yes
Ms. Sarada Ali Khan	Joint Secretary	Department of Health and Family Welfare, New Delhi	No
Mr. HS Nanda	Dir. (FNB)	Shastri Bhawan, New Delhi	No
Ms. Manisha Prasad Panwar	Joint Secretary	Shastri Bhawan, New Delhi	No
Dr. Venkatesh Mannar	President Emeritus, Micronutrient Initiative, Adjunct Professor	Department of Chemical Engineering and Applied Chemistry, University of Toronto, 200 College Street, Toronto, ON M5S 3E5, Canada	Yes
Prof. Ram Rajasekharan	Director	CSIR- Central Food Technological Research Institute, Mysore-570 020, Karnataka	Yes
Dr. Anura Kurpad	Dean	St. John's Medical College & Research Institute, St. John's National Academy of Health Sciences, Bangalore 560 034, India	Yes
Dr. Sudha Venkatramanan	Scientist	Micronutrient Initiative	Yes
Dr. T.D Sundararaj	Consultant	Salt Fortifications, Madurai	Yes
Dr. Kalpagam Polasa	Director Incharge	National Institute of Nutrition, Jamai-Osmania, Hyderabad - 500 604, India	Yes
Dr. Madhavan Nair	Scientist - F	National Institute of Nutrition, Jamai-Osmania, Hyderabad - 500 604, India	Yes
Dr. M Raghunath	Scientist E	National Institute of Nutrition, Jamai-Osmania, Hyderabad - 500 604, India	Yes
Dr. Thiru.C.Kamaraj	IAS, Managing Director	Tamil Nadu Salt Corporation Limited, Mariyur - Valinokkam, Salt Complex, Sikkal, Kadaladi, Ramanathapuram, Tamilnadu	No
Dr. J.R Chunawala	Principal Scientist,	CSIR-CSMCRI, Bhavnagar	Yes
Mr. M.R Gandhi	Chief Scientist	CSIR-CSMCRI, Bhavnagar	Yes
Dr. Ulhas K Kharul	Senior Principal Scientist	CSIR-NCL, Pune	Yes
Dr. V. K. Srivastava	Prof. & Head	Department of PSM, Unique Medical College,Lucknow	Yes
Dr. Neelam Verma	Head	Department of Hematology, PGIMER, Chandigarh	Yes
Dr. Malavika Vinodkumar	Trustee	Sundar Serendipity Foundation,6-G, Century Plaza, Anna Salai, Teynampet, Chennai-600018	Yes
Mr. Lakshman Kumar Sethuraman	Senior Manager	Sir Dorabji Tata Trust and the Allied Trusts, Bombay House, 24, Homi Mody Street, Mumbai	Yes
Mr. Parag Gadre		Tata chemicals, Bombay House, 24, Homi Mody Street, Mumbai	Yes
Mr. Ganesh Iyer		Tata Trust, Bombay House, 24, Homi Mody Street, Mumbai	Yes
Ms. Aparna Ganesh	Senior Manager	Tata Trust, Bombay House, 24, Homi Mody Street, Mumbai	Yes
Dr. Pradeep Aggarwal	Associate Professor	Department of Community Medicine, Himalayan Institute of Medical Sciences, Jolly Grant, Dehrarun - 248140, Uttarakhand	Yes
Mr. M.A Ansari	Former Salt Commissioner	Government of India, Jaipur	No
Dr. B. Sesikeran	Former Director	National Institute of Nutrition, Jamai-Osmania, Hyderabad - 500 604, India	No
Dr. B. Sivakumar,	Scientist	National Institute of Nutrition, Jamai-Osmania, Hyderabad - 500 604, India	No
Dr. Jaya Prakash Muliyil	Consultant	Department of Gastrointestinal Sciences, Christian Medical College, Vellore	No
Dr. Meenakshi Singh	Scientist	Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, FDA Bhavan, Kotla Road, New Delhi – 110 002	Yes