

## **IRON FOLIC ACID SUPPLEMENTATION IN SCHOOL CHILDREN – A BIGGEST CHALLENGE IN FRONT OF G.O.I. AND HEALTH COMMUNITY**

**Pravin R Joshi<sup>1\*</sup>, Yogesh Jirankalgikar M<sup>2</sup>**

1. Dept. of Dravyaguna, Gangadharshastri Gune Ayurveda Mahavidyalaya, Ahmednagar, Maharashtra, India.
2. Ayurveda Consultant, Jath, Sangli, Maharashtra, India.

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### **Abstract**

Recently recurrent incidents regarding side effects and even serious casualties after intake of IFA supplements distributed freely by GOI under the aegis of NRHM to combat anaemia in school going children are reported. These events have put some serious questions and challenges in front of medical fraternity which need to be answered. A list of such events with their venues and other details are hereby enlisted along with its possible causes. Opinions of various stalwarts in this field in general and in particular to this case are also included. Some serious questions regarding safety and efficacy of these tablets along with its post market surveillance (Phase IV) in this regards are also dealt and at last solutions which are cost effective and with minimal side effects with added benefits of usage and easy administration as food adjuvant from the age old science of life Ayurveda are also suggested.

**Key words:** Iron Folic Acid; GOI; NRHM; Ayurveda.

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### **\*Address for correspondence:**

Vd. Pravin R Joshi M.D., Ph.D. (Ayu)  
Dept. of Dravyaguna,  
Gangadharshastri Gune Ayurveda Mahavidyalaya,  
Ahmednagar, Maharashtra, India – 414 001.  
E. mail: [ayurpravin@yahoo.co.in](mailto:ayurpravin@yahoo.co.in)

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## INTRODUCTION

India is still among the top four that account for 50 per cent of global under-five mortality. In this context, India co-convened the June 2012 Global Call to Action on child survival along with Ethiopia and United States of America.<sup>[1]</sup>

Reports suggested by scientific evidence that all over the globe 5 – 15% adverse effects after consumption of iron folic tablets, including black stools, vomiting and nausea associated with a feeling of discomfort, constipation and diarrhoea as well. The Hindu reported the statement of Anuradha Gupta, Mission Director, National Rural Health Mission (NRHM), that “The side effects of IFA tablets are less than one per cent in India which is acceptable”.<sup>[1]</sup>

There were so many instances of side effects reported of IFA in various national news papers, some of them are encountered as in Guwahati 50 students (Times of India, Aug 14, 2012 & May 25, 2012) Parabhani (Aundha nagnath, Jawala bazaar) 90 students (Lokmat times, 29-06-2013). Solapur (Malkavatha) 115 students (Maharashtra times, Jul 19, 2013), Chandigarh 100 students (The Indian Express, Jul 25, 2013) were affected.

In spite of these short comings a sort of adamant is shown by GOI (Government of India) to push ahead this program which is contrary to current medical ethics. On contrary it will appropriate to once again have a through exercise to establish safety and efficacy of these tablets with special emphasis on stage three clinical trials i.e. post market surveillance.

Collection and analyses of the data can be done, as all the beneficiaries are students which can be easily accessed and evaluated for above said purpose.

## WHO SAID WHAT?

### **Opinion of A.K. Susheela, Director of Flourosis Research and Rural Development Foundation, New Delhi**

She pointed out a survey by the Indian Council of Medical Research (ICMR) in 1986 found no change in the prevalence of anaemia and so, from 1992, the dose of iron was increased from 60 mg to 100 mg’. She emphasised on reducing fluoride intake rather than IFA tablets.<sup>[3]</sup>

### **Doubts raised on expenses of NRHM scheme by A.K. Susheela**

Considering the huge cost involved in purchase and distribution of the IFA tablets, she hoped the proposed scheme to be implemented by the National Rural Health Mission (NRHM) does not become another scandal.

### **Solutions given by A. K. Susheela to combat anaemia**

A.K. Susheela’s foundation has successfully demonstrated a simpler strategy to tackle anaemia in school children as well as in pregnant women. ‘Her strategy imparts on withdrawal of fluoride consumption and a nutritive diet (with essential and micronutrients) through vegetables, fruits and dairy products,’

### **Side effects produced by IFA tablets:**

Students showed symptoms of dizziness, diarrhoea, headache and vomiting after consuming these tablets. There are lots of thoughts were carried out as consumption of the tablet on empty stomach and panicked reaction etc.

## **Various aspects regarding Iron and Folic acid** <sup>[3][4][5][6]</sup>

### **Interactions for Folic Acid**

Administration of phenytoin, primidone, barbiturates, methotrexate, nitrofurantoin, alcohol, or pyrimethamine may result in folate deficiency.

### **Contraindications**

Folic Acid (in United States Pharmacopeia) is contraindicated in patients who have shown previous intolerance to the drug.

### **Adverse Reactions**

Allergic sensitization has been reported following both oral and parenteral administration of Folic Acid.

Folic Acid is relatively non-toxic in man. Rare instances of allergic responses to Folic Acid preparations have been reported and have included erythema, skin rash, itching, general malaise, and respiratory difficulty due to bronchospasm. One patient experienced symptoms suggesting anaphylaxis following injection of the drug.

Gastrointestinal side effects, including anorexia, nausea, abdominal distension, flatulence, and a bitter or bad taste, have been reported in patients receiving 15 mg Folic Acid daily for 1 month. Other side effects reported in patients receiving 15 mg daily include altered sleep patterns, difficulty in concentrating, irritability, over activity, excitement, mental depression, confusion, and impaired judgement. Decreased vitamin B serum levels may occur in patients receiving prolonged Folic Acid therapy. In an uncontrolled study, orally administered Folic Acid was reported to increase the incidence of seizures in some epileptic patients receiving Phenobarbital, primidone, or diphenylhydantoin.

Another investigator reported decreased diphenylhydantoin serum levels in folate-deficient patients receiving diphenylhydantoin who were treated with 5 mg or 15 mg of Folic Acid daily. <sup>[5][6]</sup>

## **DISCUSSION**

### **Statistics Vis a Vis Health**

In relation to statistics this is not mere a problem significance of t or p value but when alteration in dose is suggested after this much vast use certainly creates doubts on the double blind studies as well as post market surveillance. Once the drug comes in market there are certain guidelines for using in children, these medicines are not rejuvenators or anything else. This is a mere supplement and it seems that it is having potential side effects.

It is ruthless question that lakhs of students were given IFA tablets and very few were affected. Statistics with relation to side effect has shown a lack of proper approach in coordination of scientific community and GOI. Once the side effects are noted the evaluation of the drug in complete prospect is required. The synergistic action of IFA tablets with other medicines must be reviewed again.

Whatever the suggestions and recommendations by researchers in western world are there, once the side effects are noted a thorough reevaluation in all aspects regarding the drug should be carried out by independent agency governed by GOI. These medicines should be legalised by considering the aspects of environment and suitability in each country. There is no question of standardization in medicine but medicine itself is problematic. So this is high time that GOI should think over Iron and folic acid supplementation to children in India.

In the American Journal of Clinical Nutrition the authors suggested that the consideration of

supplementation of young children with low doses of oral iron as well as evaluation of the balance of risks and benefits should be integral to the decision-making process. With the available data the authors suggested that the current recommendations regarding preventive iron supplementation should be re-examined.<sup>[7]</sup>

### **Thinking Beyond Iron and folic acid**

Administration of Iron is not only a health supplement but also a drug well known to Ayurveda since last three thousand years.

Many references and a cluster of formulations which are practised since almost thousand years effectively in management of anaemia exist in Ayurveda pharmacy industry.

More so ever the same has been proved and confirmed by many recent researches that elemental iron from herbal sources is more easily accepted in body and easily metabolised. Keeping this in mind various herbo – mineral formulations are formulated in Ayurveda which are in various forms such as tablets, syrups as well as linctus which can be readily accepted by school going children by its increased palatability (sweet taste). More over including different formulations based on co morbidities such as helminthiasis can be achieved in a single drug as such formulation are already practiced in Ayurveda.

NRHM in its motto quoted that it aims at increasing the participation of Indian medicine system which is traditionally the original health system of India.

Keeping these points in mind such effort for establishing an alternative to IFA tablets and its usage can help our country in many ways. Some pilot projects about usage of Ayurveda iron supplements during pregnancy are already carried out under aegis of NRHM one among them is Dhatri loha in pregnancy administered

in Karnataka has provided encouraging results.

With the broad view of thoughts it is time to move on alternative therapies like Ayurveda which give probable safe and effective aspects of treatment to serve a better policy to save the nation. Drug is having various aspects and the quacks in India with various sorts of conditions should be avoided. A much needed transparent policies are needed to stop a hostile or quacks like healers, Vaidus, sisters-brothers as a doctor and so much on. An ethical team work is much need of hour to build up a nation health policy first and its children first.

The extracts of the herbal medicines can be tried after ethical trials. Reversely with the reverse pharmacology aspects of beside to bench the Ayurvedic drugs looks more suitable to Indian culture. These drugs will cover total aspect as body, mind etc. as per the treatment concerns. Rather than using unprocessed iron the suddha iron (Processed iron) as indicated in Ayurvedic texts may be much more beneficial.

Diet-based approaches may help properly as an alternative prevention and control strategies. The affected population groups served with proper food preferred one can avoid the adverse effects associated with supplementation. (The American Journal of Clinical Nutrition)

Reviewing Anaemia and Iron Folic Acid Supplementation Program in Bangladesh - A Special Article-Bangladesh Medical Journal 2010 Vol. 39 No. 3 has been noticed that there is no marked improvement in case of Anaemia. The authors reported that Despite IFA supplementation being in place for many years, the magnitude of anaemia is still high. Further they recommended that to have a fresh look at the problem of iron/folic acid deficiency anaemia prevailing in Bangladesh and the perspective of the supplementation program.<sup>[8]</sup>

## CONCLUSION

The holistic approach should be adopted to fight against Anaemia and to Control the circumstance; certain health programmes can be adopted to eradicate such circumstances. A thorough aspect should be taken into consideration to strengthen the national health policies. A review of each programme should be done every year on ground level i.e. 0 level and not mere on the basis of statistics.

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