

## Recent Issues in Vitamin-A supplementation in India and Strategies for their Prevention and Control

### Umesh Kapil

Prof Public Health Nutrition, Department of Gastroenterology and Human Nutrition, All India Institute of Medical Sciences, New Delhi, India, 110029.

### Neha Sareen

Research scientist, Department of Gastroenterology and Human Nutrition, All India Institute of Medical Sciences, New Delhi, India, 110029.

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#### Abstract

Vitamin-A Deficiency (VAD) was a public health problem in 1960s. For prevention and control of VAD, a National Prophylaxis Programme against Nutritional Blindness due to vitamin-A deficiency was initiated in 1970. There has been a steady decline in the prevalence of VAD during last 40 years. The nutritional blindness due to VAD is no more documented; however the programme of universal Vitamin-A Supplementation (VAS) is being continued in the country. Presently, the VAS is possibly being done for reduction in under 5 mortality. The current evidence of VAS on under 5 mortality is poor. In the year 2000, Universal VAS was done in campaign mode by Assam government in collaboration with UNICEF. The deaths were reported amongst children which led to poor credibility of the state government for all community based programmes. Judicial enquiry of VA related deaths in Assam convicted state government and UNICEF for negligence and ordered them to pay compensation to the families of children who died due to VAS in campaign mode. Thus, areas with VAD should be identified and the VA prophylaxis and treatment for VAD should be undertaken. What the poor children need is more "FOOD" – not pills, tablets or sprays. Make food intake adequate enough to provide basic energy needs, needs of VA and other nutrients would be met. The sustainable solution of prevention and control of VAD is through promotion of the intake of green leafy vegetables and local available foods.

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Deficiency of vitamin-A has long been known to be the largest preventable cause of blindness among children. But only recently the important role of vitamin-A in ensuring protection against infections and maintaining normal body functions in many systems, especially body immunity, became evident. Mortality in childhood and infancy as well as even intrauterine fetal loss has been associated with vitamin-A deficiency.

The integrity of epithelial barriers and the immune system are compromised before the visual system is impaired. This leads to increased severity of some

infections and risk of death, especially among children. When vitamin-A depletion is sufficient to affect the visual system, night blindness occurs as inability to see in dim light. This stage, on deterioration, leads to xerophthalmia which affects both conjunctiva and cornea. If unattended, corneal ulceration results and may lead to partial or total blindness (keratomalacia).

In severe VAD like keratomalacia, mortality is as high as 60%. Lowered resistance to infections due to VAD has been observed in children even before eye symptoms appear. Vitamin-A intervention to deficient children has shown to restore cell-mediated immune response and enhance antibody response as well as macrophage functions, suggesting an immunopotential effect of vitamin-A.

Vitamin-A deficiency disorders (VADD) is a major public health problem in many developing countries, the severe forms of this deficiency lead to corneal blindness in children under 5 years.

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**Corresponding Author:** Umesh Kapil, Prof Public Health Nutrition, Department of Gastroenterology and Human Nutrition, All India Institute of Medical Sciences, New Delhi, India, 110029.

E-mail: [umeshkapil@gmail.com](mailto:umeshkapil@gmail.com)

It is estimated that it afflicts about 7% of all children below 5 years of age and countless other children suffer from sub-clinical forms of vitamin-A depletion, a condition associated with decreased resistance to infectious diseases and increased mortality.

In 2013, WHO estimated that VAD was endemic in 39 countries. It is now estimated that VAD, including clinical and sub-clinical forms of severe and moderate degrees of public health significance, exists in 60 countries and it is likely to be a problem in at least an additional 13 countries. An estimated 2.8 million pre-school children are clinically affected by VAD. At least 251 million children aged 0-4 years are "at risk" in terms of their health and survival.

### **Situation in India**

Surveys carried out in different parts of the country in early seventies showed that 5-7% of all Indian children suffer from varying degrees of eye disorders associated with VAD. The prevalence rates were higher in school age children than in young age groups, but severe forms of the deficiency resulting in blindness are confined to children below 3 years. The surveys of National Nutrition Monitoring Bureau (NNMB) in 10 Indian states showed a reduction in the prevalence of bitot's spots from 2% in 1979 to about 0.7% in 1990. Although the national averages show a declined trend, there is a wide variation in the prevalence between the states and within the states [1-3].

### **Vitamin A supplementation in India**

In India in the 1950s and 1960s, vitamin-A deficiency was a major cause of blindness in children below 5 years of age. A five-year long field trial demonstrated that massive dose vitamin-A (200,000 IU) administration to preschool children reduced the incidence of xerophthalmia significantly [4]. The National Prophylaxis Programme against Nutritional Blindness due to vitamin-A deficiency was initiated in 1970 as an urgent remedial measure to counter the unacceptably high magnitude of xerophthalmic blindness [5]. Under this centrally sponsored scheme, all 1-5 year old children were to be administered 200,000 IU of Vitamin-A orally once in six months. This programme has been implemented in all the states and union territories during the last 40 years.

During the early 1990s the age group of intended beneficiaries was changed to 9 months until 3 years [6] because prevalence of clinical deficiency was

greatest between 6 months and 3 years of age. However, in the year 2006 the age range was again increased to from 6 months until 5 years. This was after reconsidering the recommendations of WHO, UNICEF, and Ministry of Women and Child Development (Order no. Z.28020/30/2003-CH dated 2 November 2006, Government of India Ministry of Health and Family Welfare, Department of Family Welfare, Child Health Division). The stated objective of the universal vitamin-A supplementation program remains unaltered. However, the current rationale for intensification, and increase in age range, primarily pertains to child survival benefit.

### **No need for supplementation of Vitamin A**

Clinical VAD has declined drastically since 1950s and 1960s. There has been virtual disappearance of keratomalacia, and a sharp decline in the prevalence of Bitot spots [7-8]. The predominant decline antedated a functioning vitamin A supplementation program [7]. Conversely, an increase in coverage with universal vitamin-A supplementation in recent years has not been associated with disappearance or substantial decline of clinical deficiency. Recent surveys indicate that the prevalence of Bitot spots is  $\geq 0.5\%$  (conventional cut-off to define public health problem) in few geographical pockets, which are socio-economically backward with poor health infrastructure [6-8]. Obviously, now there is no justification for continuing universal Vitamin-A supplementation program for eliminating nutritional blindness.

### **Poor evidence for child mortality**

The basis for the of-cited mortality benefits are systematic reviews of global trials conducted almost two decades ago, when the prevalence of clinical vitamin-A deficiency was much higher. A more recent systematic review assessing the impact of vitamin-A supplementation on mortality concluded that 'vitamin-A trials are not consistent, and there is no evidence as yet in favour or against substantive benefit of universal vitamin-A supplementation to children in India' [9].

The recent DEVTA trial conducted on one million children above 6 months of age in underprivileged rural areas of Uttar Pradesh, India, with relatively higher prevalence of clinical vitamin-A deficiency, confirmed that there was no survival benefit of this intervention [10]. The sample size of this trial is greater

than all earlier studies pooled in the meta-analyses. It is speculated that intense pressure by the 'vitamin-A lobby' has prevented submission of results for publication even six years after the trial was completed. One million Indian children have participated in this 'experiment'. Is it ethical if their collective experience does not formally feed national policy through publication? It is evident that universal vitamin-A supplementation will have no child survival benefit even in underprivileged areas of India.

#### *Problems with supplementation*

An intervention that was intended to be an interim 'fire fighting' exercise to control xerophthalmic blindness is now a permanent 'quick fix', for several reasons outlined in Dr Latham's commentary. Intensification and permanency of such 'quick fixes' is an important barrier to sustainable solutions, development process and self sufficiency in India, which is struggling to prioritise competing interventions within the available financial resources.

The Indian Academy of Pediatrics has warned against adverse consequences of linking vitamin-A to the pulse polio program [11]. Notwithstanding this warning, overzealous efforts at intensification of vitamin-A supplementation through 'campaign mode' were associated with deaths of over 30 children in Assam, probably due to micronutrient over-dosage [12]. To add insult to injury, for a nation mourning this tragedy, leaders of the 'vitamin-A lobby' labelled this unfortunate episode as mass hysteria [13]. It would be imprudent to ignore the potential for serious adverse effects with 'campaign' approaches for vitamin-A supplementation.

The following potentially important adverse effects have either been conveniently ignored or under-explored [14]. An increased risk of developing acute respiratory infection [15], which violates the basic public health principle of causing no harm [16]. Possible long term effects on mental development of an increased risk of bulging fontanelle in infancy (RR 1.53, 95% CI 1.03 to 2.27, P=0.034; HPS Sachdev, unpublished observations from meta-analysis) [17]. The effect of multiple high doses of vitamin-A on bone resorption in young undernourished children subsisting on low calcium intakes is as yet unknown.

The aforementioned potential negative consequences alone provide enough rationale for the discontinuation of universal vitamin-A supplementation.

On the basis of current evidence, universal vitamin-A supplementation cannot be justified as a priority public health intervention for prevention of

xerophthalmic blindness or childhood mortality in India. We recommend an immediate phasing out of this intervention, with a simultaneous shift of focus and efforts towards sustainable solutions, including dietary diversification and agricultural production, sanitation, immunisation, and prevention and treatment of childhood infections.

There may be an extremely limited and interim role of vitamin-A supplementation in certain deprived geographical pockets with very high prevalence of clinical deficiency. India is steadily marching ahead on the economic and development fronts.

#### **Recommendation on Eligibility of Children for Vitamin-A Supplementation Programme IAP Subspecialty Chapter on Nutrition**

There have been recent newspaper reports of children of Class V falling sick with vomiting, immediately after ingestion of Vitamin-A syrup, administered as a part of an ongoing health check up campaign in Ladhuwala village in Rajasthan [18]. Concerned with the routine administration of mega-dose of Vitamin-A in children over three years of age, the Central IAP Office requested the Indian Academy of Pediatrics Subspecialty Chapter on Nutrition, to examine the issue and make relevant recommendations. An expert group meeting on this subject .The group examined the evidence and the recent recommendations on Vitamin-A supplementation by the Indian Council of Medical Research [19] and the Ministry of Health and Family Welfare Expert Committee constituted for Vitamin-A and Iron/Folic Acid Supplementation in Reproductive and Child Health Programme-II. It was agreed that:

- (i) There is no compelling epidemiological data to indicate an increase in clinical Vitamin-A deficiency specifically in children above three years of age. Thus scientific evidence does not support the need for mega-dose supplementation in this age group.
- (ii) The recent recommendations from the above groups/committees for selecting the eligible children for Vitamin-A supplementation were unanimously endorsed. These recommendations state: (i) Under the Vitamin-A supplementation programme, children between 9 months to 36 months of age are to be provided Vitamin-A solution every six months starting with 100,000 IU at 9 months age with measles vaccination, and subsequently 200,000 IU every six months till 36

months of age. (ii) Children with a clinical diagnosis of severe protein energy malnutrition (visible severe wasting or edema both feet) should be given an additional dose of 100,000 IU Vitamin A solution at the time of diagnosis, if the child has not received a mega dose of Vitamin-A in the preceding four weeks. (iii) In severely malnourished children (weight for age below -3 SD) above 3 years of age, a single dose of Vitamin A (200,000 IU) is to be given at the time of diagnosis by a physician, if the child has *not* received a mega dose of Vitamin-A in the preceding four weeks. (iv) Children with measles should be given an additional dose of Vitamin-A at the time of contact as per their age and nutritional status if she/he has not received it during the previous one month as outlined above.

- (iii) The State Branches of the Indian Academy of Pediatrics should be requested to reinforce to their respective nodal State Ministries to restrict the Vitamin-A supplementation program to only the eligible children as defined above.

#### VA Related Deaths in Assam, India during 2001

In spite of the GOI recommendation that VAS should be done in children in the age group of 6 – 36 months and should be distributed as part of the routine primary health care. The campaign mode should not be utilized for VA distribution. In Assam state, India, on a single day, 11 November 2001, health workers administered VA to 3.2 million children. The mass administration of syrup was part of UNICEF's vitamin A campaign, to reduce VAD among children. On the same day, about 1,000 children who were administered the syrup fell ill, showing symptoms of vitamin-A toxicity, including vomiting, nausea and headache. Children in the more remote villages were unable to access medical care in time. There were deaths of children. According to the GOI report, 15 of these were in the age groups of 1-3 years. Significantly, two cases were outside the target group - seven-month-old infant and a five-and-a-half year old child [20-24].

#### VAD situation in Assam

The state level data is not available, however, the Indian Council of Medical Research, GOI in 1999, conducted a survey in two districts of namely: Dibrugarh and Nagaon and found that VAD was not public health problem. Only 0.3% of children had Bitot's spot, a marker of vitamin-A deficiency.

#### Deviations made during VA supplementation campaign in Assam

- (i) In 2000, the GOI made specific recommendation that the VA should be administered to children (9 to 36 months) as a part of the routine health care services and campaign mode should not be adopted.

In Assam State, the VA supplementation was done in a campaign mode and to all children in age group of 6 - 60 months as if there was an epidemic of VAD in the state.

The campaign approach for distribution of vitamin A is not recommended as it creates the culture of perpetual dependence on the health infrastructure for receipt of vitamin-A for control of VAD. Also, all the efforts of the health functionaries are more on delivery of vitamin-A doses to achieve the targets allotted to them rather than giving health and nutritional education to mothers of the beneficiaries for consumption of vitamin A rich foods [25].

- (ii) All types of village level functionaries (trained/untrained) participate in the campaign approach for administration of VA. In a mass campaign where the object is to "capture" as many children (and to push in as much vitamin-A) as possible, the common precautions cannot be adhered to. Also, in a campaign approach of administration of VA, the routine health care activities of the workers get disrupted, and the mothers are not usually counseled for improving the dietary intake of vitamin A in their children, which is the 'main stay' of the National Program.

A study conducted in Orissa State, India earlier documented that where VA was linked with pulse polio immunization, with large resources and inputs from an International organization, more than 52% of the mothers did not know that the solution administered to their children was vitamin-A, indicating poor health education activities undertaken in a campaign mode. The same study reported that despite a well-organized campaign approach, about 21.4% infants who were "not" the eligible beneficiaries, received vitamin-A.

- (iii) UNICEF replaced the traditional 2 ml spoons with 5 ml cups to pour out vitamin-A for the campaign. The 2 ml spoon was being used by the health workers for last 30 years in the program. This 5 ml cup was introduced by IA (UNICEF) without concurrence of the GOI. The workers were not

trained about the use of 5 ml cup. This theoretically allowed delivery of up to 500, 000 IU (275 mg retinyl palmitate) of vitamin-A in a single dose, to a child (if the 5-ml cup was filled and administered to the children). This constituted administration of largest a single dose of vitamin-A to children unprecedented in the annals of human health-care [26].

### **The Judicial Enquiry of VA related deaths**

The deaths of children in Assam related to VA in 2001 were referred to the judiciary. The Guwahati High Court of Assam, India, ruled that both the United Nations Children's Fund (UNICEF) and the government of Assam are to be blamed for the death of >20 children who were given vitamin A in the state. A 2-judge bench of the High Court pronounced its verdict in a public interest case filed by 2 Assam residents against the state government and UNICEF. The court ordered the state government to pay compensation to the families of the children who died, at the rate of 20,000 rupees (US\$400) in addition to the paltry 5000 rupees (US\$100) that each family had already been paid. Chief Justice PP Navlekar and Justice AH Saikia said in their judgment that UNICEF had introduced stronger doses of vitamin A by replacing the traditional 2 ml dosing spoon with 5 ml medicine cups. The justices stated that the health workers involved were not properly trained and briefed and had administered greater doses than many of the sick children could tolerate. In the judgment mentioned that there was an element of negligence in the way the Assam health department had administered the vitamin A, and that negligence led to the death of many children [27].

### **Investigation of the Assam Human Right commission (AHRC)**

The Assam Human Right commission (AHRC) (28) investigated the VA related deaths in Assam, India and considered two questions. One was whether the deaths were coincident with the vitamin A administration, and not due to vitamin A - a view expressed by some experts, given the high under five mortality rate (U5MR) in Assam. The second question was whether there was any violation of human rights by any public servant, and if so what steps should be taken by the government.

In order to substantiate the theory of coincidence, in his submission to the Commission the Director of

Health Services of Assam had provided a statement detailing the cases of 31 children who died in the first post-week of the campaign. Of these eight had not received vitamin A. After considering the causes of death from a medico-legal perspective, the Commission rejected this premise on the grounds that the signs and symptoms preceding the deaths of several children were attributable to vitamin A toxicity or allergy, and distinct from other causes of common poisoning.

Further, a forensic examination of the viscera (stomach, kidney and liver) of two cases (of two years and three years respectively) was positive for vitamin A poisoning. The Commission also said that the opinions of experts were too theoretical and could not be accepted in the context of the case. Based on these considerations, the Commission's Report argued that there exists a strong prima facie case that some of the children died owing to vitamin A administration.

The Commission's conclusion with regard to the second question pointed out that the pamphlet (in Assamese) distributed to the health workers as part of the training did not contain any warning to the workers and the parents or guardians of the children about the possible side effects of high dose vitamin A administration. Also, the training did not give any consideration to the health status of the child and the pamphlet did not caution workers against giving vitamin A to sick or ailing children. Nor did it indicate whether vitamin A should be administered to a child suffering from chronic vitamin A toxicity, as even 2 ml may be a mega dose in such a case. Vitamin A may have precipitated the death of children already suffering from gastroenteritis, viral fever and other childhood diseases, the report has said.

AHRC pointed out that, significantly, the leaflet also did not warn the workers against exceeding the 2 ml limit while measuring out with a 5 ml cup. The supervision provided, in the form of one doctor for 10 booths, was also not sufficient to ensure safe administration.

One of the suspected causes for the deaths was the unilateral switch by UNICEF to the use of a 5 ml dispenser. The Government of India's stated norm is a 2 ml dose. The dispensing health workers were reportedly not warned of this or trained adequately. The Report, took cognisance of the fact that a change in methods of dispensing in some areas might have resulted in the administration of a higher dose and that some children may have suffered side effects due to the plastic cup measuring out a mega dose.

### Aftermath of Assam Episode

The deaths of children after administration of VA in Assam raised many concerns in delivery of public health services in the country.

- (i) The episode VA related deaths in Assam led to an erosion of public confidence in government healthcare program and caused a serious setback to the pulse poliomyelitis campaign for 2-3 years. The parents refused the OPV immunization during the PPI campaigns due to fear of adverse effect.
- (ii) The years following the Assam episode, all the public health care activities in the country were curtailed.
- (iii) The health functionaries stopped administering the VA doses in the country.
- (iv) UNICEF withdrew the 5 ml cup for distribution of VA from the states where the UNICEF's sponsored supply of VA were made. The 5 ml cup was introduced first in Assam for campaign mode.

### Lesson Learnt from VA Supplementation Related Death in Assam

The era of gross and rampant vitamin A deficiency leading to blindness is past in India. We should resist the soft option of resorting to supplementation of mega dose of VA in order to escape the responsibilities of improving the diets of young children. The children in poor communities need more "food rather than pills / tablets/sprays. The supplementation of mega dose of VA creates the culture of perpetual dependence on the health infrastructure. The difference between the food-based approach and the synthetic VA supplement based approach is somewhat like the difference between teaching a man to catch the fish that he needs from his own local pond, on the one hand, or giving him instead (not a fish but) a 'fish substitute' as a dole. The former is 'time consuming' while the latter may be 'immediate', but the 'beneficiary' will have to be probably dependant on the substitutes, even assuming that the 'substitute' is in fact as good as food itself.

Most projects seeking to change diets, however, ends with people returning to their old ways. If we wait for a food-based approach alone to work, we will not solve the problem. The magnitude of the problem is such that we can't wait (The implication here appears to be that diversification of diets in

households 'can wait' but the business of synthetic micronutrient supplementation cannot wait but must be intensified).

The states of Bihar, Rajasthan, Arunachal Pradesh, Uttar Pradesh, Madhya Pradesh in India where there is poor intake of food, which provides all the micronutrients, may be given high priority and simultaneously the states from where no cases of VAD have been reported and immunization status and food intake is high, the vitamin A administration may be continued as a part of routine health care to have most cost effective utilization of limited resources available in the health sector.

At present the VAS program is exclusively aiming only at universal synthetic vitamin A supplementation in all states without consideration of prevalence / achievements of the state with respect to prevalence of VAD, severe PEM, immunization status, under five mortality and Infant mortality rates, dietary intake of vitamin A and prevalence of clinical VAD etc. Epidemiological characteristics of VAD and its prevalence in the states should be kept in mind before universal VA supplementation is carried out. For example, presently the state of Kerala has same policy of Vitamin A supplementation as in Uttar Pradesh although the child health and Nutrition parameters mentioned Kerala differs widely.

The sustainable solution of prevention and control of VAD is through promotion of the intake of green leafy vegetables (GLV) and local available foods. The intake of GLV can be answer to more than the problem of VAD. GLV are good sources of carotenes, folic acid, vitamin C, iron and calcium and can therefore contribute improvement of the overall nutritional status of children. The micronutrient deficiencies are often the result of lack of enough habitual food in the household rather than to the poor quality of such foods. When overall food intake becomes adequate enough to provide basic energy needs, needs of other nutrients would be met to a considerable extent even with the current diets. The food-based approach to combat VAD in non-clinically deficient areas is the sustainable and cost effective solution. We should look to our farms not pharmacies, for the nutritional improvement of our children. Solutions to the problem of VAD must be 'food-based' – not 'drug-based' [29-30].

In India, for cost effective utilization of limited resources available to the health sector, the 'Triple A' approach for prevention and control of a disease i.e. Assessment, Analysis, Action' should be adopted i.e. first assess the problem of VAD and then undertake the detail analysis of causes of VAD and then decide the combination of approaches which should be

adopted for prevention and control of VAD in the community.

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