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*Responses: WN October commentary*

**Vitamin A saves lives.**

**Sound science, sound policy**

In May we published Michael Latham's commentary 'The great vitamin A fiasco'. In June we published a series of short communications and letters, in response. With one exception these were of two types. Some supported Michael Latham's critical view that the current universal programme using megadoses of vitamin A administered to small children between 6 months and 5 years, should be scrapped. Others supported his positive view that the best approach to actual or potential undernutrition includes de-worming, vaccination, breastfeeding, and use of scarce human and material resources to protect and promote nutritious local food systems. These included responses from an executive and senior staff at the Food and Agriculture Organization of the United Nations (FAO), and from a former Chief of Nutrition at the UN Children's Fund (UNICEF).

The one letter critical of Michael Latham's position came from Keith West and Alfred Sommer of the Johns Hopkins Bloomberg School of Public Health. For many years they and colleagues have championed the universal vitamin A capsule approach, and have done much to set out the evidence-based case for its efficacy and to ensure that it is put into practice. This they have done through the International Vitamin A Consultative Group, then the Micronutrient Forum, and in partnership with donor organisations, the US Agency for International Development (USAID), the World Health Organization (WHO), and UNICEF.

We invited Keith West and Alfred Sommer to state their case, which they did, together with their colleague Rolf Klemm, in their commentary 'Vitamin A saves

lives. Sound science, sound policy', in last month's *WN*. As reported last month, Michael Latham and Keith West also debated the issue of the universal vitamin A capsule programme, at the Second World Congress on Public Health Nutrition held in Porto in September.

Below, in this issue, we publish two further short communications and one letter. These respond to the commentary written by the Johns Hopkins authors. They are from Michael Krawinkel of the Justus-Liebig University, Giessen, Germany; Ted Greiner of Hanyang University, Seoul, South Korea; and Umesh Kapil and HPS Sachdev, respectively of the All-India Institute of Medical Sciences, and the Sitaram Bhartia Institute of Science and Research, New Delhi, India. They are all concerned about the scale and scope of the vitamin A capsule programme and the claims made for it. They are also concerned about its impact on food-based programmes which, when properly funded and supported as the front-line approach, and when effective, are indefinitely sustainable and also protect national and local food systems, economic livelihoods and social autonomy.

So far, the position taken by Drs West, Klemm and Sommer has not been wholeheartedly supported in any communications received for publication in *WN*. This is not for want of trying. We have invited relevant executives from the WHO, from UNICEF, and from USAID, to write short communications or letters outlining the reasons why they are partners in and support the current universal vitamin A capsule programme. At the time of writing, all have declined to do so. Given the concern expressed about the programme, including from distinguished correspondents from many countries, in our June issue, and now this issue, and given the importance of the issue, we think this is troublesome. This silence also seems to us to be a discourtesy to the Johns Hopkins group and the case they make, and a disservice to policy-makers in countries with large populations of small children who are actually or potentially undernourished. Not to mention the children themselves, and their families and communities.

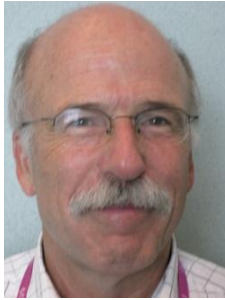
We continue to invite short communications or letters designed to justify the current universal vitamin A capsule programme, and to amplify the points made by Drs West, Klemm and Sommer. Next month we will publish further comments, and a *WN* editorial whose purpose will be to summarise some of the scientific, practical, ethical, social and other issues, and to come to judgement on this extremely important issue of – world nutrition.

***The editors***

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*Short communication: WN October commentary*  
**Broader vision is needed**



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The debate about vitamin A supplementation initiated by Michael Latham in this journal (1) needs to be seen with a broad vision. The issue is not just one of a nutrient, its needs and availability, and its specific meaning for child survival. To *treat* people suffering from vitamin A deficiency with the nutrient is clearly essential. This therapeutic approach is beyond debate, if only for ethical reasons.

But *prevention* of vitamin A deficiency is another matter. This is more than an extension of the therapeutic approach to children at risk. Supplementation as one means for preventing micronutrient deficiencies has its inherent challenges and problems, and limited potential. In emergency situations it may be the only alternative, as long as vitamin A-fortified foods are not available. In an urban slum, fortification is much more appropriate and effective in reaching the population at risk.

The principal weakness of any supplementation strategy for the prevention of vitamin A deficiency, is that in most cases inadequate diets are not short of or deficient in one nutrient only (2). Much child mortality is not caused just by vitamin A deficiency. It follows that various dietary approaches to nutritional problems are needed.

The potential and benefits from the distribution of vitamin A capsules have been demonstrated in many studies over a long time. But all these success stories and achievements cannot be related only to the reduction of vitamin A deficiency by supplementation. For examples, more extensive immunisation and improved basic primary health care provision have also contributed.

Also, are resources used for supplementation programmes optimally used, and could more have been achieved? It's hard to say. In most cases no well designed baseline surveys, nor post-intervention surveys, have been done. If they had been, they might have helped the proponents of supplementation programmes a lot. But this was not part of the plan.

### ***Supplements do not reach children in greatest need***

One inherent weakness of supplement provision is that it is generally restricted to areas easy to reach by plane, ship, train and vehicle. Children outside such areas generally cannot benefit. The costs of distribution in remote areas need to be taken into account. Effective medicines have no impact on disease in patients having no access to them (3). Also, studying vitamin A deficiency is more readily done in areas that are easy to reach. How far have investigators gone to investigate or even to identify those in greatest need ?

The colleagues who have designed and implemented the supplementation programmes have done vital work. Originally, with the challenge of the observed and assumed single nutrient deficiency, supplementation was probably an approach without any real alternative. Now though, considerations of driving forces, and the development of the market for artificial nutrient providers, are of real concern. How free are organisations like the Global Alliance for Improved Nutrition (GAIN) and the Micronutrient Initiative, from the companies that manufacture synthetic vitamin A?

### ***Supplementation suppresses food-based approaches***

As my predecessor in my post at the university Claus Leitzmann has pointed out: 'Constipation does not indicate a lack of laxatives'. Vitamin A deficiency needs to be prevented by dietary means. In this way, complex deficiencies can be addressed, local resources can be developed and used, and local food systems can be strengthened.

Because many children with the greatest dietary needs have multiple nutrient and also energy deficiencies, there is no fully rational alternative to dietary approaches, while accepting fortification as an intermediate stage, but always aiming at balanced wholesome food systems and supplies and thus diets. This 'developmental approach' to the prevention of vitamin A deficiency is surely more appropriate than any narrowly focused approach. Supplementation programmes have weakened the 'Alma Ata' primary health care philosophy, and do not contribute to the development of stable food systems.

Yes, supplementation is effective in reducing vitamin A deficiency. But why are the Millennium Development Goals far from being reached in most African countries? Do these countries not receive enough supplements? Or do they need research into and development of functioning local and regional food systems? And do we need to pay more attention to unexpected effects of the provision of antioxidants on a population basis? (4).

### **Conclusion**

The nutrition policy-making and scientific community would be wise not to focus on single nutrient approaches, but instead on people's dietary needs (5). The main problem of serious research on the potential of diverse diets still is scientific neglect and severe underfunding. Who protects the funding needs of food-based policies and programmes? Most funding agencies want quick results that seem to show the success of narrowly focussed interventions. Rational nutrition policies are still to be developed. These need to be interdisciplinary and used to identify the need for sustainable preventive nutrition interventions; which is to say, for the nutritional, societal and other development of those in greatest need (6).

Since 2008, WHO has refocused on primary health care. The nutrition community is well advised to adopt the developmental approach to food systems, nutrition and diets, and to leave single nutrient focussed interventions to nutrition therapists. First steps in this direction are already being made (7).

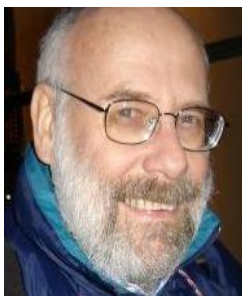
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*Short communication: WN October commentary*  
**The case for universal  
supplementation is not well made**



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I will begin by expressing my pleasure with some of the points made by Professor West *et al*, in their October *WN* commentary (1), and in particular their call for movement on the important and neglected food-based approaches to undernutrition. Evidently they, like me, believe these deserve equal attention to the other approach they advocate, (originally called an ‘emergency’ approach in the early 1970s when WHO missions began advocating to South Asian governments) of universal semi-annual supplementation of young children with large-dose vitamin A capsules.

Cite as: Vitamin A saves lives. Sound Science, sound policy. [Responses]  
*World Nutrition*, November 2010; **1**, 6: 270-285

I also agree that vitamin A deficiency is still a serious public health problem in many areas, including in much of India. I believe Professor Latham's point, in his May *WTN* commentary (2), was rather that, from the trend data available from a few countries, the prevalence of serious clinical deficiency tended to decline substantially before national vitamin A capsule programmes with high coverage rates could plausibly 'take credit' for such a change.

Prevalence rates have continued declining since the late 1990s, when vitamin A capsule distribution programmes reached the kinds of coverage levels required before any such impact could be expected. But the rate of improvement appears to have been more rapid before than in Bangladesh, one of the few countries where enough national surveys have been conducted to allow an estimate of such a difference.

***Exclusive focus on universal vitamin A supplementation has harmed nutrition programme and policy development***

West *et al* mention only low vitamin A capsule coverage rates as a likely explanation for the world not having done better in reducing vitamin A deficiency. I suggest that a larger contribution is made by the fact that such programmes only cover children during part of the year, and often fail to reach the worst affected populations. The children who least need supplementation, are likely to be the ones who first receive it. For example, in India, the 20 per cent who recently received it had less malnutrition and came from families with lower mortality rates in young children. This is a possible cause of spurious attribution of lower mortality to receipt of the capsules until coverage rates achieve very high levels (3). Another likely reason is that donors have listened only to proponents of the capsule programme as the sole approach. The Micronutrient Initiative, for example, has been required by a major donor not to spend more than 15 per cent of its budget on food-based approaches. And of course supplementation does not reach a majority of the population.

Like Michael Latham, I am convinced that the widespread implementation of vitamin A capsule programmes has also had the effect of reducing government and donor interest and motivation in implementing basic approaches to improve diets. Executives and other professionals working for governments and donors have told me as much. In the case of vitamin A fortification, I have been told by policy makers in several countries that it cannot even be considered, as this would make things even more precarious for the young children routinely being given huge doses. Others have told me they have heard the same thing. No, there are no clinical trials to back up these statements. But in my experience, valuable as clinical trials may often be for policy-making, limiting oneself to peer-reviewed published trials is likely to make policy-making appear to be a mystical activity. Of the 21 factors listed as causes of nutrition policy change in lower-income countries by a World Bank/UNICEF review (4), only two related to such evidence.

As stated (2), at the 1993 International Vitamin A Consultative Group meeting, when it was clear that the findings from the mortality trials was likely to raise interest among donors, I called for an integrated response—as West *et al* now seem to do. I suggested donors say ‘yes’ to requests for support to the short-term approach, while asking countries at the same time to present proposals for an equal amount of funds for longer-term, more sustainable and self-reliant approaches and for a simple system of monitoring that would allow them to know when universal capsule distribution was no longer needed. Given that semi-annual capsule distribution would improve serum retinol for only a few months a year, I agree with West *et al* that serum monitoring during the other months would be better than the dietary approach I suggested, though the use of retinol-binding protein would be just about as effective, and much cheaper, than serum retinol (5).

However, no balanced response emerged. Michael Latham and I, as well as many of the others who have commented on his initial article in *WN*, find this highly questionable. We believe governments and funding agencies should be held accountable for this serious policy failure..

### ***Measles may be confounding the trial results***

One major point Michael Latham makes has been expressed similarly in a paper co-authored by a colleague of West *et al* (6): ‘It was reasonable to expect, given the large reductions in mortality, that vitamin A would modify the incidence and severity of the principal causes of child mortality—that is, lower respiratory tract infections, diarrhoea, and malaria.’

But something doesn’t add up, since the majority of studies that have looked for such effects have failed to find them. Latham went on to hypothesise that measles may hold the key to understanding this anomaly. There is no doubt about the impact of vitamin A on measles, and measles commonly kills children in low income settings. At the time when the original trials were done, measles vaccination coverage was likely to have been low in the areas studied, while it might have been higher years later when the huge DEVTA trial, which showed no mortality impact of vitamin A supplementation, was done.

West *et al* say that, contrary to what Latham said, measles was not identified as the cause of most of the mortality prevented in the trials they refer to. But how children died in those studies was not determined by a physician at the child's bedside, nor by a real autopsy. Cause of death was rather simply assumed, based on asking a series of questions, weeks or months later, to a parent. While useful for some purposes, such a ‘verbal autopsy’ is completely unable to discriminate deaths caused by measles from deaths caused by a range of other causes, because measles can and often does cause similar symptoms. Certainly it often causes diarrhoea and typically a few days of fever



before the rash appears. These may kill a seriously vitamin A deficient child. Such a death may be reasonably attributed to diarrhoea/dehydration, even though investigators cannot know how often measles was the actual cause of the diarrhoea. By analogy, 'verbal autopsies' often attribute to malaria, deaths occurring while a child is suffering from fever, which certainly cannot be considered to be more than a reasonable guess.

West *et al* agree that vitamin A has no impact on morbidity in general, but quote a few findings that suggest it may attenuate diseases or help the body cope better with severe disease. Perhaps this is so important that vitamin A supplementation would reduce mortality even in well-vaccinated populations. Let's hope such research will be forthcoming. But for the moment we cannot rule out the possibility that achieving high coverage of measles vaccination will largely remove the impact of vitamin A supplementation on young child mortality.

Further adding to the plausibility of Latham's hypothesis is the fact that measles tends to occur in local epidemics or in waves, with very few cases showing up in between. If indeed the well-documented link between measles and vitamin A *was* responsible for much if not most of the mortality that vitamin A supplementation prevented in most of the trials, then that would explain why two of the published trials found no impact. West *et al* cite data from a total of 165,000 children, but the DEVTA trial failed to find any impact among a million children in a low-income state in India – where West *et al* make a specific point that vitamin A deficiency is still a problem. What surely is most likely, is that measles happened to be relatively quiescent in those populations during the study periods. Alternatively, measles vaccination coverage may have been greater, or vaccinations done more effectively, than in the other study areas.

If diarrhoea *not* associated with measles had been responsible for much of the seemingly substantial mortality-protective effect of vitamin A supplementation, then why was this effect not operating in two of the study sites? One might expect some variation, but if vitamin A really eliminated 20-30 per cent or even more of mortality, wouldn't those studies, and the huge DEVTA trial, have shown at least say a 10-15 per cent impact? Plenty (though far from all) well-conducted studies have shown no impact of vitamin A on diarrhoea morbidity; whereas few if any well-conducted studies have failed to find a link between measles morbidity and vitamin A.

Vitamin A supplementation may often assist in fighting infection, among children deficient in vitamin A. But so do many other nutrients, many of which are commonly provided in food-based interventions but obviously not in vitamin A capsules. And if vitamin A alone has such a huge impact on mortality, via non-measles mechanisms, virtually all studies should also show that it also has an impact on morbidity as well, as it does for measles.

### ***The soft underbelly of vitamin A supplementation: morbidity***

West *et al* do not dispute that vitamin A supplementation has failed to be shown to have a beneficial impact on the other major causes of morbidity and mortality in low-income countries. They do say that ‘vitamin A prophylaxis and treatment can reduce the severity and fatality from measles and diarrhoea, among other less-well defined infections. No peer reviewed, published data has emerged in recent years to contradict these findings.’ Research on the issue is of course hardly a hot topic any longer, except for neonatal supplementation which, regarding diarrhoea, is certainly failing to live up to expectations (7.8).

Nevertheless, contrary to what West *et al* say, some trials with older infants and young children have in recent years failed to find any impact of vitamin A on diarrhoea (9). As cited by Latham, a recent meta-analysis of 8 trials found no effect. Half suggested a positive impact and half were negative (10). The impact is variable even in children exposed to HIV (11). And some recent studies suggest that other nutrients like zinc may have a much more powerful impact on diarrhoea than vitamin A (12). Again, food-based approaches could certainly provide zinc. Vitamin A capsules do not.

Contrary to what the *West et al* commentary would lead readers to believe, the capsule programme is associated with more than minor temporary side effects. It often appears to do harm, particularly in children who are not deficient (13). Of the 8 studies in the recent meta-analysis (10), 6 found adverse effects. None found statistically significant positive effects. The meta-analysis resulted in an overall significant finding of adverse respiratory outcomes.

### **Why no proper evaluations?**

West *et al* emphasise that universal vitamin A capsule programmes cost \$US 1-2 per child per year. But the food-based programme supported by the Swedish International Development Cooperation Agency and others in Bangladesh, in which I was involved, achieved substantial increases in household production and consumption of green leafy vegetables by children under 5 on a huge scale, at a cost of \$US 0.13 per child per year, while providing at the same time numerous other benefits (14).

It’s odd, to say the least, that after spending hundreds of millions of dollars over a 15-year period, donors who normally call for impact evaluations have apparently not funded any in this case – at least not any that have been published.

West *et al* cite what they describe as ‘program evaluations’ that provide evidence of impact. The first is a comparison of national surveys in Nepal, which might indicate that vitamin A coverage at 85 per cent was effective in reducing mortality rates, but

of course many other relevant changes have occurred there. Such findings in a majority of the dozens of countries involved would be needed to make a strong case using such data. Next they cite a study from 1984 finding that vitamin A supplementation reduces xerophthalmia. This refers neither to a programme nor to mortality. Next is a US CDC study estimating overall impact and cost based on 'assumed mortality reduction.' Next is a study done in one slum of India, comparing data with another randomly selected slum that did not receive supplements. This quasi-experiment involved monthly visits to homes, which hopefully resulted in sick children receiving attention, making impact somewhat distant from that likely to be seen in real life supplementation programmes. There were no significant differences in morbidity but a decrease in mortality. The next examined the case fatality effect of vitamin A supplementation on hospitalised children, again hardly relevant. The final citation is of an estimate of the burden of disease attributable to vitamin A deficiency in South Africa. Again, it assumed mortality impact, it did not measure it.

Thus, in contrast to what West *et al* would have the reader believe, none of these were actually programme evaluations. In contrast to what they correctly say about the status of publication of the original clinical trials, most of these studies were published in low-impact national journals.

As West *et al* point out, such evaluations are extremely challenging to do. But large scale interventions with comparable costs, like oral rehydration therapy, breastfeeding promotion, and folic acid fortification, have been accompanied by evaluations that have done a much better job. Any objective reviewer of this situation must be left wondering whether they – or the programme donors – actually want any real impartial impact evaluation to be done.

### ***Food-based programmes are the way forward***

Food-based programmes designed to reduce under-nutrition are often criticised for doing a patchy job. So what? Leafy green vegetables, and most of the other foods promoted in food-based programmes, are extremely nutrient-dense foods. They provide a wide range of nutrients, more even than Sprinkles, and many of the other currently popular multi-micronutrient supplementation approaches.

Helping poor people eat more nutritious food does not require justification by proofs that this totally solves deficiencies of one nutrient for one group in the population. Justification for spending hundreds of millions of dollars in ways that distract from food-based programmes, certainly does require strong proof. Without such justification, such programmes should be phased out. Where the vitamin A capsule programme is demonstrably acting as a barrier and impeding fortification or other food-based programmes, then the phasing out process may need to be rapid.

*Editor's note. Professor Greiner has been a colleague of Professor Latham for many years, and supported him as he prepared his May WN commentary.*

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### *Letter. WN October commentary*

## **No good evidence that supplementation actually saves many lives**

Sir: West *et al.* (1) have again claimed, based on studies conducted in the 1980s, that vitamin A supplementation reduces under-5 mortality rate in children in the range of 23-34 per cent in undernourished settings. They also state that 'No peer reviewed, published data have emerged in recent years to contradict this finding'. However, the most recent and a robust trial conducted on 1 million children in deprived settings in India (the DEVTA trial), documented no impact of vitamin A supplementation on under-5 mortality (2). It remains a mystery as to why even after completion of the trial in 2006, it has yet not been published or apparently even submitted for publication. Probably forces other than science are at work.

The trends in routinely collected under-5 mortality data from lower-income countries (3) with more than a 90 per cent mega-dose vitamin A supplementation coverage also do not support a child survival effect of vitamin A. The table shown here illustrates under-5 mortality rates in 24 countries for three time points (1960, 1990 and 2002).

There is no evidence of a roughly 30 per cent decline rate after vitamin A supplementation was introduced. What these figures do show, is a consistent and sometimes impressive decline in the period 1960-1990. This was before introduction of the mega-dose vitamin A supplementation programme. In the

period 1990-2002, after the vitamin A capsule programme was instituted, there were practically no changes in mortality in 9 countries, a reduction in 11 countries, and in 4 countries an increase in mortality. Such results can have a number of causes. They do not support the claims made by advocates of the vitamin A capsule programme.

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Trend of under 5 mortality among children in countries with  
90% or more coverage with vitamin A supplementation in 2001

Countries and territories	Vitamin A supplementation coverage rate (6-59 months, 2001)	Under-5 mortality rate		
		1960	1990	2002
Burkina Faso	97	315	210	207
Burundi	95	250	190	190
Cameroon	100	255	139	166
Central African Republic	90	327	180	180
Congo	100	220	110	108
Côte d'Ivoire	97	290	155	176
Djibouti	91	289	175	143
Gambia	91	364	154	126
Ghana	100	215	126	100
Guinea	93	380	240	169
Guinea-Bissau	100	-	253	211
Kenya	90	205	97	122
Korea	99 t	120	55	55
Liberia	100	288	235	235
Mauritania	98	310	183	183
Mongolia	93	-	104	71
Myanmar	97	252	130	109
Nepal	98 t	315	145	91
Pakistan	100	227	130	107
Rwanda	94	206	178	183
Sierra Leone	91	390	302	284
Sudan	92	208	120	94

Tanzania,	93	241	163	165
Yemen	100	340	142	107

t indicates countries that have achieved a second round of vitamin A supplementation within any one year.

Source: UNICEF. *The State of the World's Children 2004*. Obtainable at <http://www.unicef.org/sowc04/>. Accessed 5 October 2010.

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Countries with limited financial resources and competing health priorities cannot afford the luxury of initiating interventions to raise serum biochemistry alone. Unambiguous demonstration of prevention of health consequences below a serum retinol cut-off is imperative to consider vitamin A supplementation, based on these considerations. Extrapolations based on simple cross-sectional correlations have no value in this context.

In addition, the magnitude of vitamin A deficiency is grossly inflated by the serum retinol cut-offs proposed by West *et al.* (1). The authors provide no convincing evidence of benefit of supplementation below these cut-offs. Further, in the Indian context, these levels have not been corrected for simultaneous C-reactive protein levels.

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