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Effect of vitamin A and β carotene supplementation on women's health

Evidence from Nepal suggests benefits—but raises further questions

Papers p 570

Much research has been devoted to child health in populations deficient in vitamin A[1 2] but much less to maternal health. On p 570 West et al present a report based on a large field trial in Nepal which examines the health benefits to women of supplementation with vitamin A or β carotene.[3] Vitamin A is found only in foods of animal origin, whereas β carotene is the main vitamin A precursor of plant origin. The authors used a hard endpoint—all-cause maternal mortality—in a strong design, and they found that both vitamin A and β carotene were effective. More work needs to be done, however, before supplementation is recommended for populations such as Nepal's.

Women of childbearing age were allocated according to area of residence, by cluster randomisation, to one of three dietary interventions: a single weekly oral supplement of either placebo, vitamin A, or β carotene. Female field workers gave participating women their assigned supplement and recorded health related information during weekly home visits.

Among the 44 646 participating women, 20 119 became pregnant once and 2070 twice. The main endpoint was maternal deaths from any cause during pregnancy or within 12 weeks of delivery. They occurred at rates of 704 per 100 000 pregnancies in the placebo group (51/7241), 426 in the vitamin A group (33/7747), and 361 in the β carotene group (26/7201). The corresponding preventive effects, expressed as relative risks, were 0.60 (95% confidence interval 0.37 to 0.97) for vitamin A and 0.51 (0.30 to 0.86) for β carotene.

What is the scientific strength of these findings? The researchers selected a strong design to test two hypotheses which, according to the protocol, had been defined a priori. They provided evidence that the doses given could affect serum retinoid concentrations, and they conducted a trial with a statistical power sufficient to study outcomes as rare as maternal mortality. This involved weekly personal contacts with over 44 000 women over three and a half years in a poor and uneducated population. The organisers should certainly be complimented for what they did accomplish.

Limitations of the study include the completeness by which numerators and denominators were assessed, the efficacy of masking, and some aspects of the analytic strategy. Among participating women in whom pregnancy had been identified all deaths during pregnancy were ascertained. However, 157 women were lost to follow up during the postpartum period (70 in the vitamin A group, 43 in the β carotene group, and 44 in the placebo group). If these women disappeared because they had died, this would spuriously decrease mortality in the vitamin A group compared with the placebo group. If, on the other hand, mortality among the 157 women was similar to that of the average population this differential loss would play no role.

The authors provide no data on ascertainment of deaths among participants with unidentified pregnancies (expected in around 10% of pregnancies), but it is unlikely to have been complete. This could have biased the results if there were differential ascertainment of such deaths across the three groups. Blinding should have avoided this problem, but there are some doubts about the blinding. The three types of capsules were identical in appearance, but opening them would reveal that the β carotene supplement had a different colour and consistency from the other supplements. What this meant for ascertainment of pregnancies and maternal deaths is difficult to know with certainty, unless it was addressed in a specific substudy.

Pregnancy related mortality, defined above, was selected as the primary endpoint, rather than conventional maternal mortality, which is limited to the first 42 days after delivery and excludes deaths due to injuries and accidents. This choice, made a priori, was justifiable because pregnancy-related mortality may occur later than 42 days and because of the difficulties of getting reliable information on causes of death. The authors did actually collect such information and, interestingly, injuries seemed to be the single group of causes which showed the greatest risk reduction when expressed in relative terms." However, these analyses had little statistical power, and conventional maternal mortality was in fact reduced by 40% ($P = 0.02$) in the combined treatment groups compared with placebo ($P = 0.08$ for vitamin A and $P = 0.04$ for β carotene).

What of the adverse effects of supplementation and endpoints other than deaths related to pregnancy? Vitamin A is a known teratogen, but the dose-response relations are debated.[4–7] One single observational study has suggested that daily amounts as low as 10 000-15 000 IU may be enough to cause malformations,[5] though other evidence suggests that these doses are safe.[4] The Nepal trial used doses of 23 310 IU (7000 :g) retinol, but on a weekly basis. High exposures in fetal life have also been hypothesised to cause schizophrenia.[8] Obtaining reliable information from the Nepal trial on malformations is likely to be difficult, let alone obtaining information on schizophrenia or its childhood prodromes. These other

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endpoints may be better addressed in prospective observational studies collecting dietary and other data in populations with possibilities for long term follow up through registries or selective follow up. β Carotene has no known teratogenic or neurotoxic properties,[4] and, using effect on maternal mortality as a yardstick, was at least as efficient as vitamin A. However, β carotene supplementation on a population basis may pose hazards in relation to other endpoints, such as cancer.[9–11]

Preventing vitamin A deficiency through natural dietary means is unrealistic in populations like that of Nepal. But before we move to implement widespread supplementation programmes several issues need clarifying. As well as evaluations of the practical and economic implications of supplementation, these should include further evaluation of the health benefits and possible hazards to women of childbearing age and their children.

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Countering poor training within the NHS

The BMJ tries to help

Training staff is vitally important in successful organisations. The British government recently identified poor training and staff development as one of the main reasons why British companies suffer from chronic low productivity compared with many foreign companies. As a result it introduced a scheme—"investors in people"—that allows organisations to be kitemarked if they achieve high performance in training and developing staff. Ironically, within the NHS—an organisation that is the responsibility of the government—there are glaring deficiencies with training, and the *BMJ* this week begins an attempt to address some of them.

The worst deficiency is that many posts for junior doctors are not approved for training. This means that the doctors who work in these posts do not make any progress in getting their certificate of completion of specialist training (CCST). The NHS Executive would prefer that all posts filled by junior doctors were approved for training but does not have the power to require it. The Junior Doctors Committee of the BMA has campaigned for years for the ending of such posts, but they persist. All posts clearly should be of such a standard that they can be approved for training.

A second deficiency is the proliferation of non-standard posts for doctors seeking permanent positions. Nationally agreed terms and conditions of service do not apply to these posts, so the doctors who fill them cannot be sure of receiving study leave and may be exploited financially. The NHS Executive thinks that there is no need for such posts, and the BMA's Central Consultants and Specialists Committee would like to see their abolition. Nevertheless, they persist. Although trusts and even the doctors filling the posts may obtain short term advantage through these posts, the long term interests of patients, the NHS, and the doctors means that they should disappear.

The *BMJ* cannot solve these longstanding problems, but we can help—through our classified advertising supplement—by increasing the likelihood that doctors who consider applying for these posts are aware of their deficiencies. From today we are beginning to draw attention to posts for junior doctors that are approved for training by emboldening the dean's statement of approval provided advertisers adopt the exact wording recommended by the NHS Executive.[1] If readers applying for these posts do not see an emboldened statement then they should ask the trust if the post is approved for training. We are also encouraging trusts advertising permanent positions to state that national terms and conditions of service apply. Such a statement will again be printed in bold. We have written to everybody who places these advertisements asking them to ensure that the relevant statements are included in their advertisements. In addition, we are including throughout the supplement notices reminding potential applicants to check whether posts are approved for training and are covered by national terms and conditions of service; we are publishing in the Important Notice ("black box") at the front of the supplement a warning to job applicants to discuss with the BMA any doubts over these posts.

It is in everybody's long term interest that such measures will not be needed because these deficient posts will cease to exist. We hope that our measures will be helpful, and we will be monitoring progress.

Richard Smith *Editor, BMJ*

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