

Vitamin A supplementation in Indian children

Shally Awasthi and colleagues' DEVTA investigation (published online March 14)¹ purports to have studied 1–2 million children in Uttar Pradesh, India, from 1999 to 2004, half in villages in which vitamin A supplementation reached 86% of the children every 6 months for 5 years and half in which coverage was assumed to be low. About 25 000 deaths were reported; no difference in child mortality was found between the vitamin A group and the control group.

But this was neither a rigorously conducted nor acceptably executed efficacy trial: children were not enumerated, consented, formally enrolled, or carefully followed up for vital events, which is the reason there is no CONSORT diagram. Coverage was ascertained from logbooks of overworked government community workers (anganwadi workers), and verified by a small number of supervisors who periodically visited randomly selected anganwadi workers to question and examine children who these workers gathered for them. Both anganwadi worker self-reports, and the validation procedures, are fraught with potential bias that would inflate the actual coverage.

To achieve 96% coverage in Uttar Pradesh in children found in the anganwadi workers' registries would have been an astonishing feat; covering 72% of children *not* found in the anganwadi workers' registries seems even more improbable. In 2005–06, shortly after DEVTA ended, only 6.1% of children aged 6–59 months in Uttar Pradesh were reported to have received a vitamin A supplement in the previous 6 months according to results from the National Family Health Survey,² a national household survey representative at national and state levels. The level of contact

between anganwadi workers and children has historically been very low. Although 76% of children aged 0–71 months in 2005–06 lived in areas covered by an anganwadi worker, only 22% of children received any service from the anganwadi worker. Thus, it is hard to understand how DEVTA ramped up coverage to extremely high levels (and if it did, why so little of this effort was sustained). DEVTA provided the anganwadi workers with less than half a day's training and minimal if any incentive.³ Each of their 18 study monitors was responsible for overseeing the work of 463 anganwadi workers and the status of 55 000 children. Their alleged coverage reached or exceeded that of intensive efficacy trials, yet the researchers spent substantially less than US\$1 million.³ That comes to \$0.02 in field research costs per child per year (\$1 million per 1 million children per 5 years)—roughly a thousandth what a rigorously done field efficacy trial costs.⁴ Although an expensive trial does not guarantee quality, a trial that does not spend adequately raises serious questions about its validity.

We are also concerned that Awasthi and colleagues included the results from this study, which is really a programme evaluation, in a meta-analysis in which all of the positive studies were rigorously designed and conducted efficacy trials and thus represented a much higher level of evidence. Compounding the problem, Awasthi and colleagues used a fixed-effects analytical model, which dramatically overweights the results of their negative findings from a single population setting. The size of a study says nothing about the quality of its data or the generalisability of its findings.

At best, DEVTA is but one unorthodox study, done in one remote population of one country. If, for argument's sake, the DEVTA results were wrong, and Awasthi and colleagues had studied 4 million children instead of 1 million, their meta-analytical

approach would have virtually nullified, erroneously, all six previous rigorous trials, from four different countries, that showed significant reductions in mortality of 19–54%.⁴

We declare that we have no conflicts of interest.

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- 1 Aswasthi S, Peto R, Read S, Clark S, Pandale V, Bundy D, and the DEVTA (Deworming and Enhanced Vitamin A) team. Vitamin A supplementation every 6 months with retinol in 1 million pre-school children in north India: DEVTA, a cluster-randomised trial. *Lancet* 2013; published online March 14. [http://dx.doi.org/10.1016/S1040-6736\(12\)62125-4](http://dx.doi.org/10.1016/S1040-6736(12)62125-4).
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- 4 Sommer A, West KP Jr. Vitamin A deficiency: health, survival and vision. Oxford: Oxford University Press, 1996: 19–61.



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