

Hepatitis-B Vaccine in National Programme

Some Issues

Independent analysis shows that introducing the Hepatitis-B vaccine in the national immunisation programme will yield small gains at high cost.

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The central government is planning to introduce the hepatitis-B vaccine in its Expanded Programme of Immunisation (EPI). The Indian Academy of Paediatrics (IAP) has been recommending this step for many years and hence this new initiative has the backing of a reputed medical association. However, National Immunisation programme is too serious a matter to be left to clinicians and bureaucrats alone. Public health experts and health care management experts should also be involved in this decision-making. This is especially true for the Hepatitis-B vaccination programme, which would cost Rs 125 crore annually for the vaccine alone, even if only newborns are to be vaccinated and even if we assume that the vaccine cost per child would be half (Rs 50) of the current price. (the cost would go down in a mass programme). This amount is equal

to the central budget in 2001-02, for TB-control programme (Tuberculosis remains the number one killer disease in the adult population in India) and also more than the cost of all other six vaccines being given in the EPI, to the infants. Given this background, it is necessary to address the following issues: Where does Hepatitis-B rank in relation to other causes of morbidity and mortality in India? How effective will be the inclusion of hep-B vaccine in the EPI, in protecting the vulnerable population or controlling/eradicating this infection? What is the cost efficacy of this vaccine in terms of cost per life year saved due to vaccination and how does it compare with other vaccines currently used in EPI? What level of cost effectiveness should be acceptable to merit inclusion of any vaccine in the EPI?

It is necessary to address these questions in a developing country like India, where financial resources is always a constraint.

Secondly, in any case, modern health-care management should consider cost efficacy and effectiveness of any health care intervention paid through public money. Unfortunately, the above questions have not even been addressed by the IAP or by any other body. Yet these august bodies have been recommending this vaccine for inclusion the EPI?

Appropriate, adequate data are not available in India to conduct a rigorous exercise about issues mentioned above. But some guesstimate has to be made. Otherwise the decision in this regard is based only on the basis of purely subjective opinions.

We have attempted to estimate the cost-efficacy of hep-B vaccine in India. We have also estimated the cost-efficacy of measles vaccine, which is one of the vaccines given to infants under the EPI. Assuming that the hepatitis-B vaccination programme gives 100 per cent protection to all those who have been vaccinated, the cost-efficacy was worked out in terms of cost in rupees per year of life saved due to prevention of premature deaths and of illness episodes. The methodology, empirical assumptions and the results of our exercise have been detailed in a separate paper being sent for publication to a reputed medical journal. In this exercise we found that the cost-efficiency of hep-B vaccine for the 0-1 year age group is Rs 1,319 per life year saved, compared to Rs 42 per life year saved for measles vaccination in infants. The cost-efficiency of hep-B vaccine for other age groups ranges from Rs 1,045 to Rs 7,064 per life year saved.

A programme may be very cost-effective but may not be effective enough. In case of universal hepatitis-B vaccination programme, it fails on both counts. The universal hep-B vaccination programme means vaccinating every newborn with hep-B vaccine. Even if we assume that all infants would receive this vaccine, only a small proportion of these vaccinated children would be protected from the more dangerous, important type of hep-B infection. Hepatitis-B infection is of two types and is revealed by the presence of two different antigens Hepatitis-B surface antigen (HBsAg) and Hepatitis-B envelope antigen (HBeAg) in blood. The HBeAg infection is far more infectious to others and also far more dangerous to the infected persons than the HBsAg infection. Hence, we are primarily concerned with the HBeAg infection. In India, the most important source of this type of infection is from the

HBeAg positive mother to her baby during delivery or after it. To prevent this 'at birth' infection, the hepatitis-B vaccine has to be given within 24 to 48 hours of birth. (In India, we cannot even think of giving ready-made antibodies in the form of immunoglobulins to all such children, as this is too costly.) In India, in the foreseeable future, it is impossible to give any injection within 24-48 hours at birth to all the newborns, as today, 55 years after independence, 77 per cent of babies are born at home. In the EPI Hep-B vaccine will generally be given along with the first shot of triple vaccine, six weeks after birth. Such hep-B vaccination is useless to prevent the most important route of the far more dangerous type of hepatitis B infection. Hence the efficacy of this programme, from the view of public health, would be very minimal.

Given the comparatively costly nature of hep-B vaccine, its unacceptable cost-efficacy and its very low effectiveness in the India EPI, it is necessary that the plans to include this vaccine in the EPI be abandoned. The concerned drug companies have been pushing this vaccine vigorously. But public health should take

precedence over their sales. More funds are required for more pressing problem like TB control. After fulfilling such needs we can think of better strategies of hep-B vaccination. The universal strategy is unacceptable.

A similar exercise will be necessary for other vaccines. As newer and newer vaccines like meningococcal vaccine, chicken pox vaccine, etc, are being made available in India, there will be pressure from the concerned drug companies to include them in the EPI. Professional associations clinicians, partly due to lack of concern and adequate expertise in Public Health matters and partly due to the undue influence of the drug companies, may uncritically recommend inclusion of new vaccines in the EPI, as has happened in the case of hep-B vaccine. Public health experts need to formulate criteria and parameters to judge the suitability of any new vaccine for inclusion in EPI. There is a need to lobby for a scientific approach towards this issue of vaccination under the EPI. The Indian public health system cannot afford to spend resources on interventions, which have low efficacy or unacceptably cost-efficacy. **EPW**

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