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Selective Versus Universal Hepatitis-B Vaccination in India

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ABSTRACT: (318 words)

This paper compares the cost–efficiency of Selective and Universal hepatitis-B vaccination of newborns in India. **Part-I** critically examines this comparison made by Aggarwal and Naik (the only such comparison in India). It argues that firstly Aggarwal-Naik have measured cost-efficacy in terms reduction in HBsAg-pool and not in terms of reduction in the highly infectious and highly pathogenic HBeAg pool. Secondly in their cost-calculations, they have made biased, unrealistic assumptions about cost of the Selective Vaccination programme, which renders their exercise invalid. Thirdly, the data they have used, itself shows that Selective Vaccination of newborns of HBsAg positive mothers would reduce the HBeAg pool by 40% by immunizing just about 4 % of the newborns; epidemiologically a very attractive option.

Part-II compares the cost efficacy of Selective versus Universal hepatitis-B vaccination strategies in India. The Selective vaccination strategy that we propose consists of in year I, identifying all the HBsAg positive mothers through antenatal screening and vaccinating their newborns within 24 hours of birth. This would protect about 40% of the newborns from the risk of HBeAg positivity by vaccinating only the 3% of the newborns, and the programme would cost one fourth of the programme of Universal Vaccination of all the newborns. Logistically also it would be a far better strategy. From year II onwards, only the HBsAg positive primis would be detected and their newborns will be vaccinated, along with vaccinating subsequent newborns of the cohort of HBsAg positive mothers, identified in year I. This subsequent annual screening of only the primis would, without reducing its efficacy, reduce the annual cost of the Selective Vaccination Programme from year II onwards, to only 8% of the annual cost of Universal Vaccination. In our epidemiological and socioeconomic situation, eradication of hepatitis–B is neither warranted nor possible in the next 50 years even with Universal Vaccination. This fact strengthens the case for this highly Selective Vaccination strategy .

Key – words – Universal hepatitis-B vaccination, Selective hepatitis-B vaccination, HBeAg, HBsAg, cost-efficacy, primi gravida.

Part I Critique of Universal Strategy

Introduction

Vaccination is one of the important measures to prevent Hepatitis-B infection. As a public health measure, in the vaccination strategy, there are two options-

- i) Universal Vaccination (U.V.) which involves vaccinating all members of a particular subset of population i.e. all newborns, or all adolescents etc.
- ii) Selective Vaccination (S.V.) -Vaccinating all the members of a high risk group; for example, medical personnel or newborns of HBsAg positive mothers etc.

Universal Vaccination is a bit of a misnomer as it also involves vaccination of only a subset of the total population i.e. all the newborns in India and not vaccination of the whole of the population from infants to octogenarians. The Indian Academy of Pediatrics (IAP) has recommended ‘Universal’ vaccination of all the newborns in India ¹. To implement this recommendation, it would cost Rs. 1250/- million annually for the vaccine alone, at the rate of Rs. 50 per new born for the 25 million annual births in India. Compare this with the budget in the year 2000 -2001, of Rs. 1250 million for TB-control ², when TB remains the number one killer of Indian adults. When a recommendation which involves such huge expenses is made, its cost-efficacy, compared with that for vaccination against other diseases or with other option like Selective vaccination needs to be assessed. The final decision should depend upon our health-care priorities, funds required and comparative cost-efficacy of different options. To our knowledge, the IAP has not done this exercise. However, Aggarwal –Naik have compared the efficacy of Universal Versus Selective Hep-B vaccination and have concluded that cost per carrier prevented would be five times in the Selective Vaccination strategy compared to the Universal Vaccination strategy ⁴. Their estimation thus supports the recommendation of the

IAP. We critically examine below, the core of Aggarwal-Naik's exercise to assess whether their methodology and results are valid.

Critique of Aggarwal – Naik’s paper

We would like to point out first that the WHO has recommended Universal and Selective Vaccination for countries with a carrier rate of above and below 2%, respectively ⁽⁵⁾. Selective Vaccination is in use in low prevalence countries like Japan, U.K. Netherlands ^(6,7,8). In India, the Universal Vaccination has been proposed under the assumption that the carrier rate in India is above 2%. This assumption is based mainly upon the estimation by Thyagarajan et al that the carrier rate in India is 4.7% ⁽⁹⁾. We have pointed out elsewhere, that this estimation is erroneous because the author has made an elementary error in arriving at a proper average of the hepatitis-B positivity rates in different studies and has mistakenly equated positivity rate with carrier rate. Using the same data scientifically, we arrived at a carrier rate of around 1.5 % (*Phadke Anant, Kale Ashok, Some Critical Issues in the Epidemiology of Hepatitis – B in India. Indian Journal of Gastroenterology, 2000, Vol. 19 (Suppl. 3) December, C76-C77.*) Thus on the grounds of low carrier rate alone, it is clear that the Universal Strategy is invalid in India. Yet, we would discuss the comparative cost-efficacy of these two strategies so that the issue is discussed comprehensively in a scientific manner.

Aggarwal-Naik have used data from a study of 8575 infants born in two large hospitals in Delhi ¹⁰. This study found that 322 (3.7%) of the 8575 pregnant women were HBsAg positive. The follow-up of the infants born to these mothers is given in Table No I ¹¹.

Table I
Incidence of Serum HBsAg Positivity in Infants According to Mother’s Serum HBsAg Status

Mother’s Serum HBsAg status	Infant age in Months			
	3-5	5-7	7-10	10-14
A. Positive	21/188(11.2%)	10/118(8.5%)	0/85	3/43(6.9%)
B. Negative	5/328(1.5%)	4/245(1.6%)	6/163(3%)	4/59(6.8%)

Aggarwal-Naik have applied the data from this study to a hypothetical cohort of 10,000 newborns to compare the cost-efficacy of Universal and Selective HB vaccination in terms of cost per HBsAg carrier prevented. Their extrapolation of the ‘Delhi study’ data about HBsAg positively, to this cohort is summarized in table II.

Table II¹²
Hepatitis-B Carrier Rate in Babies Borne to 10,000 Pregnant Women.

	Sub-Cohort of HBsAg positives	Sub-Cohort of HBsAg negatives	Total
Number of mothers	370	9630	10,000
Vertical transmission rate	18.6%	3%	
Risk of chronicity	75%	50%	
No. of HBsAg carrier children by one year	$370 \times .186 \times .75 = 52$	$9630 \times .03 \times .5 = 144$	196 (100%)
Proportion of HBsAg carriers in sub- cohorts	$52/196 = 26.5\%$	$144/196 = 73.5\%$	100%
Number of HBeAg positives at one year	22 (42% of 52)	32 (22% of 144)	54
Proportion of HBeAg carriers in sub-cohorts	$22/54 = 40\%$	$32/54 = 60\%$	100%

"Assuming an epidemiological equilibrium", Aggarwal-Naik estimate that a further 174 babies will become HBsAg positive, subsequently by adulthood by horizontal transmission so that a prevalence of 370 (190 + 174) HBsAg positives per ten thousand would be maintained. They distribute these 174 'subsequent HBsAg positives' proportionately, amongst the cohorts of newborns borne to HBsAg positive and negative mothers respectively. They then estimate the efficacy and cost efficacy of Hep-B vaccination by Selective and Universal Strategy. For this estimation, they make some assumptions about vaccine efficacy, the cost of screening maternal serum for HBsAg, the cost of the vaccine and its administration. Here we would consider only their cost-efficacy exercise, (cost per carrier prevented) leaving their exercise of comparing the efficacy of Selective and Universal vaccination, for a future debate. Here we would point out only one problem of their efficacy exercise -- To protect newborns from the perinatal Hep-B infection from HBsAg positive mothers, the newborns have to be given the first dose of the HB-vaccine within 12 hours of birth. In near foreseeable future, it is impossible that in India, all the newborns will be vaccinated within 12 hours of birth with any vaccine since 77% of deliveries take place at home¹³ The assumed efficacy of 75 to 95% Universal Vaccination at birth, would in practice, be only on paper.

Turning to their cost-efficacy exercise, it suffers from two other crucial weaknesses -

1. Inappropriate Parameters

The cost-efficacy of HB Vaccination should be measured in terms of cost per highly infectious carrier (HBeAg positive) prevented and not merely HBsAg positive carriers prevented. This is because HBeAg positive carriers are far more dangerous to public health, as they are far more infectious¹⁴. Secondly, they are far more likely to develop serious chronic liver disease later on than mere HBsAg positives¹⁵. In the 'Delhi study' used by Aggarwal-Naik, the data for HBeAg positivity were available. But Aggarwal-Naik chose not to use these data for their cost-efficacy estimation.

Infants born to HBsAg positive mothers are far more likely to be positive for HBeAg. For example, in this 'Delhi-study' it was found that out of the 31 HBsAg positive infants born to the carrier mothers, 13 (42%) were HBeAg positive, by the age 6 months; whereas only 2 (22%) out of the 9 HBsAg positive infants born to HBsAg- negative mothers turned HBeAg positive by the age of 6 months¹⁶. Thus in a cohort of 10,000 newborns, out of the 52 HBsAg carriers born to HBsAg carrier mothers, 22 (42%) would be HBeAg positive. Compared to this, out of the 144 HBsAg carrier-babies of the HBsAg negative mothers, only 32 (22%) would be HBeAg positive. Universal Vaccination would protect all the 54 children from the risk of perinatal acquisition of HBeAg positivity by immunizing 10,000 infants, whereas Selective Vaccination would protect 22 (41%) infants from this risk by immunizing just 370 (3.7%) children!

2. Biased Cost Calculations

Aggarwal-Naik have estimated the cost of Selective and Universal HBV Vaccination¹⁷. In this exercise, they report that some drug-manufacturers have offered prices "as low as U.S. 0.55 dollars, provided the order-size was large". They have therefore assumed the cost of each vaccine dose to be 0.75 US dollars, 2.25 US dollars for 3 doses. In case of Selective Vaccination however, they have assumed that "price of the vaccine is likely to be higher since economies of scale are not possible. It may be safely assumed to be double than that for Universal Vaccination i.e. US dollars 4.50 per infant". This assumption is arbitrary. For Selective Vaccination of infants, going by their own assumption of prevalence of HBV carrier rate to be 3.7%, 0.93 million newborns would be immunized annually requiring 2.79 million doses annually. This is a huge order and it is wrong to assume that "economies of scale are not possible". Economies of scale do not operate beyond a limit in many cases..

Aggarwal-Naik have also assumed the cost of administration of the vaccine to be double in case of Selective Vaccination compared to Universal Vaccination, "since the newborns of HBsAg positive mothers will have to be specifically located and immunized". This assumption is again arbitrary and biased. In the Selective Vaccination programme, HBsAg positive mother would be identified during routine antenatal check-

employed to locate these mothers. Compared to the efforts required in the Universal Vaccination strategy to reach all newborns immediately after birth for HB vaccination, in the Selective Strategy, only the newborns of the HBsAg positive mothers (4%) will have to be reached for giving the first dose within 12 hours of birth.

Thirdly, the unit cost of the material for HBsAg screening in Selective Vaccination programme has been taken as 2 US dollars. No consideration has been given to the fact that annually millions of women would undergo HBsAg screening and hence the cost of this screening would drastically go down. The cost of the batch Elisa kit for HBsAg screening was around Rs. 20/- (about 0.5 dollar) per test in September 2001. With an order running into millions of kits, this cost would come down substantially.

To conclude, Aggarwal-Naik's cost efficacy comparison of Selective versus Universal HB-vaccination is seriously flawed and hence invalid. There is a need to do this comparison by using reduction in the highly infectious and damaging HBeAg positive pool as the parameter to measure cost-efficacy and by avoiding biased assumptions. We have done this exercise in Part II below.

Part II

Selective Hep-B Vaccination: A Cost-effective Strategy

Prevention of perinatal (vertical) transmission from Hepatitis-B positive mothers requires that the newborns be given the first dose of the vaccine during first 12 hours of birth. However, in India, as pointed out earlier, since 77% births take place at home, this condition can not be met in majority of the cases. The first dose of Hep-B vaccine would be given in the Indian National Immunization Programme at the earliest, with the BCG vaccination visit and generally with the DPT-vaccination visit at 6 weeks after birth (In many places BCG vaccine is also given during the DPT vaccination visit!). Even if it is given a little earlier, inability to give it in the first 12 hours after birth means that at least in 77% of births, the newborns will not be protected. It is well known that newborns who get infection at birth, have the highest (90%) risk of carrier rate and have the highest proportion of HBeAg positives amongst infants.¹⁸ This most vulnerable group, is precisely the one that would remain uncovered by Universal Vaccination in India. The WHO, the American Academy of Pediatrics and almost all other health agencies have recommended that the first dose of HBV must be given as early as possible and in any case not later than 48 hours after birth.¹⁹

Hence, there is a need to look for alternatives, especially in view of the relatively high cost of the vaccine. Selective Vaccination of high-risk newborns offers a better and more cost-effective alternative which focuses on the most vulnerable group of newborns of hepatitis-B positive mothers.

The Selective Vaccination Strategy

This S. V. strategy involves screening of all pregnant women for HBsAg and giving the first dose of the vaccine within 24 hours of birth, to the newborns of only the Hepatitis-B positive mothers detected during this antenatal screening.

This strategy can further be made more Selective. This Highly Selective Vaccination (HSV) strategy would involve the following -

1. In year-I, screening all pregnant women for HBsAg positivity. From year II, to conduct this screening every year only for the primigravida.
2. To give the first dose of the vaccine immediately after birth, to all the newborns of the HBsAg positive mothers in year I and also to the subsequent newborns of cohort of all these HBsAg positive mothers.,
3. From year II, at birth to vaccinate also the newborns of every additional batch of HBsAg

Apart from the cost-efficacy advantage described below of this Highly Selective Vaccination Strategy, it would automatically provide data for monitoring of the prevalence of HBsAg positivity rate amongst child bearing women. Secondly this strategy is logistically much more practical than the U.V. strategy. We get 6-7 months to screen the pregnant women for HBsAg during antenatal check-ups. Secondly only about 3% of the newborns will have to be vaccinated within 24 hours of birth. The mothers of these babies would have been detected well in advance and it would be much easier for the ANM to track down and vaccinate within 24 hours five (3%) of the 150 births that would occur in one year in the 5000 population she is to serve.

The cost-efficacy details of this strategy are given in table III, and the results are seen in row 5, 7, 12 and row 13 of this table.

Comparison with Universal Vaccination

It is seen from row 7 of table No. III that the cost - Rs. 9260 per infant protected from HBeAg positivity - by Universal Vaccination Strategy is more than the cost in case of Selective Vaccination (Rs.5227). Secondly, to cover all the pregnant women and their newborns in a year, the total annual cost of the programme for Universal and Selective vaccination for a cohort of 10,000 would be Rs.5,00,000 and Rs.1,15,000 respectively. In a country like India, where funds are very limited, an option, which costs less than one-fourth to protect 40% of the infants from the risk of perinatal acquisition of HBeAg positivity, is obviously preferable. (Subsequently it will also reduce horizontal transmission considerably, but this can not be quantified easily). In the above estimation, we have not accounted for factors like efficacy of giving only the vaccine to the newborn without giving hyperimmune globulin or the cost of human power, as these factors apply equally to Selective and Universal vaccination

This cost can be further reduced considerably, if we screen only the primigravida pregnant women from year II onwards, and continue to vaccinate infants subsequently borne to the cohort of the HBsAg positive mothers detected earlier. As seen from row 13 of table III, the total annual cost of such a Selective Vaccination would be a mere Rs.101 million, i.e. 8 % of the annual cost of Universal Vaccination.

The rationale for focussing on the primigravida, from year II of the programme, is as follows – It was found in a large study involving 8445 women by Nayak Panda et al, that the HBsAg positivity rate in women for age-groups 15 to 20 years and 20 to 30 years was 3.3% and 3.6% respectively, and that this difference was not statistically significant²⁰ The prevalence of HBsAg positivity was found to be significantly more after 30 years of age. In India, most women complete their childbearing before the age of 30 years. Hence if initially all the pregnant women in India are screened for HBsAg positivity, and the pool of HBsAg-positives is identified, it is unlikely that this pool would expand during their remaining childbearing period. It would suffice to screen every year only the primigravida from year II, as only they would add to the pool of HBsAg-positive child bearing women in India.

As seen from row 7 and 5 in table II, going by the data of the 'Delhi-Study' by Nayak-Panda et al, Selective Vaccination would directly prevent only 40% and 26.5% of the HBeAg-positive and HBsAg positive newborn carriers respectively, whereas Universal Immunization would prevent all newborn carriers. If we are able to control 40% of vertical transmission of the highly infectious and pathogenic HBeAg positivity, at less than 10% of the annual cost of Universal Vaccination, this is an excellent bargain. This bargain is to be seen in the context of the fact that in India, it is not appropriate to spend Rs.1250 million annually on Hep-B vaccination, when our budget for TB-control is Rs.1250 million, and the budget for all other vaccines together is less than the budget-requirement of Universal HB-vaccination alone!

Table III
Comparative Cost Efficacy of Universal and Selective Hep-B Vaccination in a Cohort of 10,000 Pregnant Women and Their Newborns

		Selective Strategy	Universal strategy
1	Cost of HBsAg screening for 10,000 antenatal cases (@ Rs 10) ^(A)	Rs. 1,00,000	
2.	HBsAg Positivity Rate	3% ^(B)	
3.	Number of HBsAg Positive mothers	300	
4.	Vaccine cost of the vaccination of the newborns of positive mothers @ 50 per child for 3 doses ^(C)	Rs. 15,000	Rs. 5,00,000
5	Cost of screening and vaccination (row 1 + row 4)	115,000	5,00,000
6	Number of HBeAg carrier children prevented ^(D)	22	54
7.	Cost of preventing one HBeAg carrier (row 5 /row 6)	Rs. 5227	Rs. 9260
8.	No. of primi gravida to be screened from year II onwards, annually ^(E)	3000	
9	Annual cost of screening additional batch of primigravida and vaccinating babies of HBsAg positive primiparous women (30% for row 5)	Rs. 34,500	
10	Cost of vaccinating 600 babies that would be borne to the cohort of 300 HBsAg positive mothers in say next 5 years	Rs. 30,000	
11	Annual cost of this vaccination if spread over 5 years	Rs. 6,000	
12	Total annual cost of the programme (row 9 + row 11)	Rs. 40,500	
13	Total annual cost of this programme if all the 25 million pregnant women in India are to be included in this programme (40,500 x 25 millions/10,000)	Rs. 101 million	Rs. 1250 million (25 million x Rs 50)
14	Total cost of this programme in year I, if all the 25 million pregnant women in India are to be included in this programme (115,000 x 25 millions/10,000)	Rs.287.5 million	Rs. 1250 million(25 million x Rs 50)

NOTES –

A) The kit cost per test during September 2001 was around Rs.20 per test, (with some price variation with different manufacturers). We assume that in the mass screening, this cost would come down to Rs.10/- per test,
 B) Kant Lalit, Arora Narendra; Transmission of Hepatitis B Virus in Children : Indian Scenario; in Hepatitis-B in India. Sarin S.K., Singal A.K., (editors) CBS Publishers and Distributors, 1996, Table-2. (We have rounded off this figure in table II)

C) The cost of the vaccine during September 2001 was Rs.100/- per child for 3 doses. We have assumed that this would come down to Rs.50/- per child in a mass-vaccination programme.

D) Row 6 from table II

E) With around a 3-child norm in India, we assume that 30% of all the pregnant women would be primigravida.

F) Assuming the 3 child-norm, each of these 300 HBsAg positive mothers would on an average, give birth to two more children in the subsequent, say five years.

It may be pointed out that in India, HBV infection is not a priority issue. Indians have a lifetime risk of less than 0.1% of dying due to consequences of HBV infection. (*Phadke Anant, Kale Ashok, Some Critical Issues in the Epidemiology of Hepatitis – B in India. Indian Journal of Gastroenterology, 2000, Vol. 19 (Suppl. 3) December, C76-C77.*). We therefore need not aim at eradicating HBV-infection but should aim at drastically reducing the HBeAg pool.

Secondly, even the Universal HB Vaccination programme will not eradicate HBV in foreseeable future. If all newborns are successfully protected by vaccination since birth, even then it will take the U.V. Programme

population) would have been protected, free of hepatitis-B infection and hence vertical transmission would stop completely. Horizontal transmission amongst 'below 40 year' age-group would also stop after 40 years of this programme. To stop horizontal transmission amongst above 40 year population also, it will take further 25 years of U.V., because average life- expectancy at birth in India is 65 years and it will take these many years before every Indian would be protected by this vaccination programme for infants. During these coming 65 years, the life-expectancy would further increase, with the resultant consequences for this programme.

The vaccine cost for Universal Vaccination of only the newborns would be Rs.1250 million @ Rs.50/- per child (3 doses). If all children up to the age of two years (up to which EPI programme covers children) are also included as part of the routine Vaccination, the vaccine-cost would be Rs. 3750 million in year I of the programme. Compared to this, as seen in row 14 of table III, the vaccine cost of Highly Selective Vaccination would be only Rs.287.5 million in the first-year and Rs.101 million per year thereafter.

In the Highly Selective Programme outlined above, some women would be left out of the screening-those who were not pregnant during year I of the programme and become pregnant for their second or third baby after the first year of the programme. To reach out to them, the programme can be modified to also include from year II, all multigravida also who have not been screened so far. We can not estimate the number of such women. But with this modification, this 'missed pool of HBsAg positive pregnant women' would be covered in say about 5 years. From year VII onwards, only primis would need to be screened to detect the addition to the pool of HBsAg positive pregnant women. Till then, i.e. for the first 5 years or so the programme-cost would be, at the most, Rs. 288 million annually. Thereafter, as seen from row 13 of table III, it would be Rs. 101 million annually; i.e. less than 10% of the cost of the Universal Strategy. (As mentioned above, in this comparison, we have excluded the human power and other cost).

This modification would also help to include all those who should have been covered in the screening in the previous years, but were left out due to inadequate reach of the programme.

To conclude, epidemiologically, financially, logistically the Selective strategy is far more fruitful and prudent compared to the UV strategy, in controlling the spread of HBV-infection in India.

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Key Messages

- Before recommending any additional vaccine in the EPI, the decision should depend upon our health-care priorities, funds required and comparative cost-efficacy of different options.
- The cost-efficacy of HB Vaccination should be measured in terms of cost per highly infectious carrier (HBeAg positive) prevented and not merely HBsAg positive carriers prevented.
- In our epidemiological and socioeconomic situation, eradication of hepatitis-B is not warranted nor is it possible in the next 50 years even with Universal Vaccination.
- A Selective Hep-B Vaccination Programme of identifying of HBsAg positive mothers by antenatal screening and vaccinating their newborns within 24 hours of birth would reduce the HBeAg pool by 40% by immunizing just about 3% of the newborns and would cost only 10% to 25 % of the cost of Universal Vaccination

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