The costs and benefits of a vaccination programme for *Haemophilus influenzae* type B disease

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Haemophilus influenzae type b (Hib) infection is a major cause of severe bacterial infection in young children in South Africa and world-wide. These diseases can be prevented by immunisation with conjugate Hib vaccines. In South Africa, unlike some developed countries, Hib vaccines are not part of the routine immunisation schedule. The objective of this study was to measure the expected net benefits from a hypothetical programme of vaccination of the 1992 Cape Town birth cohort (N = 46 537). Costs were calculated by summing the estimated direct medical care costs together with the indirect costs of Hib disease. The latter were calculated by valuing human life using alternative, and conservative human capital and willingness-to-pay measures. The difference between Hib disease costs (i.e. the benefits which would be gained from a successful vaccination programme) and the costs of the vaccination programme itself (HibTITER, Praxis Biologicals) defined the expected net benefits. In the absence of an immunisation programme, the estimated economic costs of Hib disease in the 1992 Cape Town cohort ranged from R10,7 million to R11,8 million. The costs of introducing the vaccine would have amounted to R8,3 million. Had the vaccine been administered to the 1992 birth cohort, benefits would have exceeded costs by between R2,4 million and R3,5 million.

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Before the introduction of vaccination in developed countries, invasive *Haemophilus influenzae* type b (Hib) disease was one of the leading causes of severe, sometimes fatal, bacterial disease in childhood.[1,2] After vaccination was introduced in the late 1980s[3] the incidence of Hib disease declined dramatically, and in some areas it has virtually been eliminated.[4,5]

A recent Cape Town study details the incidence, spectrum and impact of *Haemophilus influenzae* (Hi) disease in South

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Africa.[6] From 1 August 1991 to 31 July 1992, it is estimated that there were 310 cases of invasive Hi disease (type b and non-type b); meningitis and pneumonia accounted for most cases, while septicaemia, arthritis, mastoiditis and cellulitis were also recorded. Ninety-eight per cent of cases occurred in children aged under 5 years and 65% in children under 1 year. The mortality rates from meningitis, pneumonia and septicaemia were 4,7%, 14,3% and 40%, respectively. Forty per cent of meningitis patients had major complications on admission to hospital and 17,6% continued to show significant morbidity at discharge. Type b infection accounted for 88% of cases.[6]

In this paper, it will be assumed that the 1992 Cape Town metropolitan birth cohort will be subject to a similar cumulative disease pattern. Or, stated differently, the age spread of Hib cases observed will be presumed to resemble the expected disease course for the *de facto* unvaccinated 1992 cohort as it progresses to 5 years of age. Since the 1992 cohort is slightly larger than the four previous ones which together with 1992 births led to the observed cases, our assumed disease incidence rates may be slightly high. However, given that the incidence peaks before 12 months, this is a distortion of little consequence. Any exaggeration is also offset by our exclusion of cases occurring after age 60 months. This assumption enabled us to calculate the hypothetical net benefits of a vaccination programme against Hib disease in 1992. We assume that the 1992 birth cohort was 46 537.[7,8] We calculated a cumulative 5-year incidence for an annual birth cohort (the risk of disease over a 5-year period) of 666 Hi cases per 100 000 births.

Hib infection can be prevented by immunisation. Since most cases occur before the age of 1 year, the vaccine should be administered soon after birth. The US Food and Drug Administration (FDA) licensed the Lederle Laboratories product HibTITER, a Hib oligosaccharide-diphtheria CRM_{197} protein conjugate (HbOC), for use in infants from the age of 2 months. Vaccine efficacy is estimated to be 100% if 3 doses are administered.[9] When 2 doses are administered efficacy is unaffected but the statistical confidence decreases.[9] This paper compares the costs against the benefits of introducing such a vaccine in the Cape Town metropolitan area.

Methodology

General approach

The costs of Hib infection are the opportunity costs which would have been avoided if HibTITER had been applied retrospectively. These vaccine benefits (or opportunity costs) were compared with the hypothetical costs of vaccination. Net benefits are thus defined as the difference between the costs with and without the proposed vaccine programme. Disease costs include the indirect costs of illness relating to death and disability as well as the direct costs of medical treatment of and caring for patients with Hib disease. Indirect costs require assessment of the value of individual life and well-being. Direct costs necessitate analysis of Hib illnesses, incidence, and costs of care.

Direct costs

Direct costs consist of personal medical care and non-personal costs, such as research, prevention and testing.[10] The personal medical care costs of Hib disease were concentrated on (non-personal costs either constitute a very small fraction of total direct costs (e.g. prevention), or are already sunk (e.g. research into the development of vaccines), and so are amortised into the price of such vaccines and therefore explicitly accounted for later in this paper).

Indirect costs

Indirect costs embrace the value society places on death and poor health resulting from Hib disease. Since morbidity and mortality are not reflected through direct market transactions, these costs must be assessed separately. The three most common quantitative methods of estimating the value of life (the benefits of avoided death) are the implied value, the human capital, and the willingness-to-pay approaches. The second approach and a conservative variation of the third were adopted. The human capital approach values life in terms of an individual's productive output (equating output with earnings), discounted through time and adjusted to allow for labour force participation. It provides a floor evaluation since at least one objective of health care is to return people to productive employment. If there are other objectives, this floor must be a minimum.[11] The approach only captures a person's anticipated earnings and ignores other measurements of his or her value to family, friends and society. Furthermore, human capital evaluation leads to relatively modest results in developing countries such as South Africa because low average wages and high unemployment result in reduced estimates in relation to developed countries.

Willingness to pay overcomes these shortcomings by estimating how much people would be willing to spend to reduce their risk of death, regardless of their earning capabilities.[12] This approach typically provides a higher estimate of the value of life than either of the other methods. In our variation of willingness to pay, we developed a conservative 'hybrid' model which incorporated the floor human capital method during employment years (18 - 65), added to a willingness-to-pay component during non-employment years (1 - 18; 65 - 100). In the non-employment years, we conservatively used the minimum subsistence expenditures as a measurement of willingness to pay. Although Hib infection affects all income groups, in our models we valued life conservatively by using earnings and subsistence data only for the least well-off sector of society. Any net benefits we computed can then be regarded as minimum values, not likely or expected health care savings.

Vaccine administration costs

Since it is proposed that the HbOC vaccine be administered to infants concurrently with the diphtheria-tetanus-pertussis (DTP) vaccine at 3, 4, 5 and 6 months of age, vaccine administration costs would only involve the cost of the vaccine, the incremental time required to vaccinate infants,

syringes, and vaccine side-effects. We assumed the joint cost of a syringe and needle for HbOC vaccination to be R1,50 per infant, implying administration costs of R69 805,50 for the cohort. Although the time required to vaccinate an infant is probably negligible (say an extra 60 seconds per infant, on 3 occasions), we proxied this by including two nurses' salaries amounting to R72 466 in administration costs. This may be an overestimate given that DTP is administered simultaneously. If so, it again implies that the net benefit figure will be downward-biased. Finally, we assumed the price of a 3-vaccine dosage course at R175 per infant, or R8 143 975 for the cohort. We estimated this price from the 1988 US HbOC vaccine wholesale price of US$14,[13] adjusted it to 1992 dollars (using the medical care weight within the Consumer Price Index), and then converted to rands at the present exchange rate (US$1 = R3).

Disease pattern without a vaccination programme

Approximately 310 infants from the unvaccinated 1992 cohort will contract Hi disease. The clinical data indicate that 24,2% would contract meningitis, 70% pneumonia, 2,9% septicaemia, and 2,9% other Hi disease.

Vaccine efficacy and coverage

Although we assumed HbOC vaccine efficacy at 100%, 12% of Hi disease is non-type b (HibTITER will not prevent Hi cases which are non-type b). Also, infants will only have received the first 2 vaccine doses of a 3-dose course at the age of 4½ months. For this reason, the raw data imply that 43 cases of Hi disease would still occur even if a vaccine programme had been introduced. This figure includes cases occurring after 4 and before 5 months of age. Some of these cases would in fact have been prevented by a vaccine at 4,5 months. The exclusion of all 43 cases downward-biases our results. We assumed 95% vaccine coverage (i.e. 5% of infants are not taken for vaccination by their mothers). In the sensitivity analysis, the results were adjusted for coverage of 85% and 90%. The case data after excluding for the vaccination schedule, non-type b cases, incomplete vaccine coverage, and other factors are summarised in Table I.

Table I. Imperfect vaccine coverage and disease identity — avoided disease spectrum estimate for the 1992 cohort

Disease	No.
Meningitis	59,18
Pneumonia	150,61
Septicaemia	5,76
Other	5,76
Total	221,32

Mortality and morbidity

We defined morbidity as any health problems caused by the Hib infection. Long-term morbidity includes neurological sequelae or other physical or mental handicaps which extend throughout a patient's life. The observed data suggest that 17,6% of meningitis patients would suffer from long-term morbidity. Although lifetime institutional care is necessary for some fraction of such patients, we assumed that long-term morbidity would merely require monthly outpatient visits for a 24-month period after initial discharge. We estimated that meningitis patients suffering from sequelae would require care costing approximately R11 999,23 (R48 per outpatient visit x 24 months x 10,416 patients suffering sequelae).

We quantified the reduced labour productivity of patients suffering from long-term morbidity in both the human capital and willingness-to-pay approaches. We approximated the average severity of sequelae on a 10-point scale from 0 to 1 (1 being death) at 0,1. That is, after 24 months of outpatient care, we presumed that on average this small fraction of patients is unable to work, still requires care, or is subject to death. Since few data on distribution of the severity of sequelae experienced by meningitis patients exist in South Africa, we subjectively chose the most conservative 'sequelae index'. Next, we multiplied this by the number of expected meningitis patients with sequelae (10,416) to calculate 'long-term morality equivalents' at 1,04 (10,416 x 0,1). We added 1,04 to the total number of deaths expected in the 1992 cohort (26,625) to arrive at our 'total mortality equivalent' figure of 27,665. Mortality estimates for the unvaccinated 1992 population are summarised in Table II. The total mortality equivalent was employed in both models to estimate the indirect costs of both morbidity and mortality resulting from Hib disease.

Table II. Mortality data for unvaccinated 1992 cohort

Disease	Case fatality rate (%)	No. of expected deaths
Meningitis	4,7	2 781
Pneumonia	14,3	21 538
Septicaemia	40	2 306
Other	0	0
Total		26 625

Discount rate and economic growth

We discounted model cost and benefit estimates through time using an annual discount rate of 2% and assumed an average annual real economic growth rate of 1% for the economy.

Lifetime earnings — human capital approach

We adopted the average annual wage of the lowest income section of society in our models. The Central Statistical Office[14] calculates the March 1992 national average monthly wage rate for the RSA at R1 944, well above our annual figure of R14 916. This latter figure is conservative for two reasons. Firstly, it only relates to the most recently published employment and salary data for the 1st quarter of 1992.[14] Given monetary inflation, the quarter 2 or 3 salary estimates (which are presumably closer to the norm for the year) would probably be higher than the quarter 1 data. Secondly, we calculated the annual earnings using salary data for 'blacks', the group with the lowest estimated average income. We ignored average earnings data for the more highly renumerated 'whites, coloureds and Asians' categories. The average salary and wage per month (in rands) for the non-

primary sectors of the RSA are as follows: total — 2 003; whites — 3 543; coloureds — 1 489; Asians — 2 072; and blacks — 1 243.[14] We assumed unemployment at 20% after adjustment for informal sector activity.[15] The following formula (see Appendix A for derivation) enabled us to estimate the present value (in 1992) of the expected lifetime earnings of an infant born in the 1992 cohort:

$$PV = [Y/(r-g)]*[(1+g/1+r)^{17} - (1+g/1+r)^{65}]*L*e*(1+g)^{1/2},$$

where Y = annual wage rate (1992 prices) — R14 916; r = discount rate — 0,02; g = growth rate — 0,01; L = probability adjustment factor for actuarially computed expected (PAFACE) years of survival to age 65 given initial survival to age 17 — 0,94; PV = present value of an individual's expected lifetime earnings; and e = probability of employment — 0,8.

The term $(1 + g)^{1/2}$ explicitly introduces the assumption that all births occur on the first of January and that all income or earnings accrues to an individual during the middle of the year. An individual's expected lifetime earnings were multiplied by his probabilities of employment and PAFACE years of survival to age 65 given the probability of initial survival to age 17 (see Appendix A for explanation). This yields an estimate of the value of life and hence failure to survive to become an income-generating member of the population. It is the cost to society in foregone production of an infant's death. We then multiplied this estimate by our total mortality equivalent to calculate the expected indirect costs of Hib diseases for the 1992 Cape Town birth cohort. In this human capital approach, we calculated a floor value of individual life at R359 267,85.

Subsistence/human capital approach as a willingness-to-pay proxy

We created a second model which combined a subsistence/willingness-to-pay approach with the human capital method. The subsistence model was used during an individual's non-employment years (1 - 18 and 65 - 100) and the human capital approach during employment years (18 - 65). In our subsistence model, we assumed that the average annual subsistence level during the lifetime of an Hib-infected patient is R1 721. A previous study[16] reported that the September 1992 household subsistence level for a 6-person 'low-income' family in Cape Town was R860,50. We divided this by 6 and then multiplied the result by 12 to arrive at our annual subsistence level of R1 271. The subsistence approach conservatively assumes that minimum survival costs are all that people would be willing to pay to remain alive and in good health. The following formula was used in this combination model (see Appendix A for derivation):

$$PV(c) = \{[S/(r-g)]*[1-(1+g/1+r)^{18}]*L(a) + e*[Y/(r-g)][(1+g/1+r)^{17} - (1+g/1+r)^{65}]*L(b) [S/(r-g)]*[(1+g/1+r)^{84} - (1+g/1+r)^{100}]*L(c)\}*(1+g)^{1/2},$$

where PV(c) = present value of individual's expected lifetime earnings/subsistence costs; S = annual subsistence level (1992 prices) — R1 721; Y = annual wage rate (1992 prices) — R14 916; r = discount rate — 0,02; g = growth rate — 0,01; e = probability of employment — 0,8; L(a) = PAFACE years of survival to age 17 — 0,97; L(b) = PAFACE years of survival to age 65 given initial survival to age 17 — 0,94; and L(c) = PAFACE years of survival to death given initial survival to age 65 — 0,486.

We multiplied an individual's expected earnings/subsistence costs by our total mortality equivalent to create a second measure of the indirect costs of Hib disease incurred by the 1992 cohort. In the subsistence/human capital approach, we estimated a value of individual life of R399 892,17.

Hospitalisation costs

The Cape Town study led to the following hospitalisation estimates for Hib disease: meningitis, 14,6 days; pneumonia, 10,9 days; septicaemia, 7,6 days; other Cape Town Hib disease, 13,4 days. We assumed that hospitalisation in mid-1992 would cost approximately R300 per day (to the extent that this may be an underestimate, any net benefit we compute will again be downward-biased). Table III shows the expected avoidable hospitalisation costs for the 1992 Cape Town birth cohort suffering from Hib disease.

Table III. Hospitalisation costs (R) for unvaccinated 1992 cohort

	Meningitis	Pneumonia	Septicaemia	Other
Cases	59,18	150,612	5,764	5,764
Hospitalisation (d/patient)	14,6	10,9	7,6	13,4
Total cost (R)	259 208	492 501	13 142	23 171

Vaccine side-effects

After consulting one US study which assessed the safety of the Hib capsular polysaccharide vaccine, we estimated that approximately 1 in 58 000 vaccinated infants would experience severe side-effects due to vaccination against Hib disease. We adopted this figure from a US study which cited one anaphylactic reaction per 58 000 children vaccinated against Hib infection.[12] Treating such an anaphylactic reaction would increase the direct vaccination programme costs by approximately R3 600. We further assumed that the mild febrile reaction associated with the HbOC vaccine would lead to 1 out of 500 vaccinated infants seeking medical attention.[12] These medical visits would raise the direct programme cost by approximately R13 402,65. These estimates of the cost of vaccine side-effects are conservatively high, since it is very unlikely that someone who experiences side-effects will receive the full 3-dose schedule. Furthermore, a study restricted to the HbOC vaccine reported neither deaths nor hospitalisation associated with the HbOC vaccine.[17] Since we adopted the much higher estimates of Hay and Daum,[13] who studied the side-effects of a different conjugate vaccine, our model is again not unconservative.

Other Hib disease costs

We identified, but did not quantify, other costs (which are therefore vaccination benefits) associated with Hib disease. For example, our models do not account for the foregone earnings of parents caring for Hib-infected children, or for the spread of Hib illness to others through contact with Hib-infected infants. Our inability to quantify these costs further

stresses that our calculated net benefits of the vaccination programme are significantly underestimated.

Results

A vaccine programme would have prevented direct and indirect economic costs relating to 221,32 cases of Hib disease. Our projected avoidable costs of Hib disease to metropolitan Cape Town, including lost economic life, ranged from R10 739 166,23 to R11 863 038,23 (Table IV).

Table IV. Cost-benefit analysis in the human capital and subsistence/human capital models (costs in R)

	Human capital	Subsistence/ human capital
Value of life/infant	359 267,85	399 892,17
Mortality costs	9 939 145	11 063 017
Hospitalisation costs	788 022	788 022
Long-term morbidity costs	11 999,23	11 999,23
Total avoidable disease costs	10 739 166,23	11 863 038,23
Vaccine administration costs	8 303 249,16	8 303 249,16
Total net benefits	2 435 917,07	3 559 789,07
Net benefits/infant	52,34	76,49
Benefit/cost ratio	1,29	1,43

In the human capital model, we calculated total disease costs (potential vaccine benefits) at R10 739 166,23, or R230,77 per infant, using our base case assumptions. Indirect costs contributed R9 939 145,00 to total preventable disease costs and direct costs R800 021,23. Had the 1992 Cape Town birth cohort been vaccinated, the resulting total net benefits in our human capital model would have been R2 435 917,07, or R52,34 per infant (after deducting total vaccination administration costs of R8 303 249,16 or R178,42 per infant).

The subsistence/human capital method as a willingness-to-pay proxy led to higher preventable disease costs (vaccine benefits) than the human capital model. Our expected vaccination administration costs remained the same in both models. We estimated that Hib disease costs totalling R11 863 038,23 or R254,92 per infant, would have been avoided if the 1992 cohort had been vaccinated. Indirect costs amounted to R11 063 017 of total costs and direct costs to R800 021,23. Net benefits would thus be R3 559 789,07 and net benefits per infant R76,49. The results of our two models using base case assumptions are summarised in Table IV.

Sensitivity analysis

We performed sensitivity analysis to assess which base case assumptions had the greatest impact on model results. The effect of altering the value of life on our results is shown in Table V. Since we calculated reasonable values of life in our models (using the lowest average earnings data alone or in combination with bare subsistence expenditure estimates), it was helpful to recalculate model results using more realistic values of life. Net benefits, savings per cohort member, and benefit/cost ratios are shown for alternative life values in Table V.

Table V. Impact of value of life on model results (R cost estimates)

Value of life	Total net benefits	Net benefits/ infant	Benefit/ cost ratio
200 000,00	–1 970 227,93	–42,34	0,76
359 267,85*	2 435 917,07	52,34	1,29
399 892,12†	3 559 789,07	76,49	1,43
500 000,00	6 329 272,07	136,01	1,76
750 000,00	13 245 522,07	284,62	2,60
1 000 000,00	20 161 772,07	433,24	3,43
2 000 000,00	47 826 722,07	1 066,53	6,76

*Life value from human capital approach.
†Life value from subsistence/human capital method.

We also determined the sensitivity of results to parameter assumptions by calculating different benefit/cost ratios brought about by selected changes in important parameter variables. Our alternative values for the discount rate and expected economic growth rate had the largest impact on results in both models (note that our maximum assumed growth rate is 2,5% per annum contrasted with the Education Renewal Strategy assumption of 3 - 4%; in short we continue to choose conservative values). We summarise the results of the sensitivity analysis in Table VI.

Table VI. Sensitivity of model net benefit/infant results to selected changes in parameter values

Parameter	Base value	Alternative value(s)	Benefit/ cost ratio (HC)	Benefit/ cost ratio (SHC)
Base case			1,29	1,43
Discount rate (r)	0,02	0,015; 0,03	1,55; 0,92	1,72; 1,02
Growth rate (g)	0,01	0,025	2,27	2,52
Probability of employment (e)	0,8	0,7; 0,9	1,14; 1,44	1,28; 1,58
Average annual earnings (Y)	14 916	13 424,4 (–10%) 16 407,6 (+10%)	1,17; 1,41	1,31; 1,55
Average annual subsistence expenditure (S)	1 721	1 548,9 (–10%) 1 893,1 (+10%)	0; 0	1,42; 1,44
Vaccination coverage rate (V)	0,95	0,85; 0,9	1,02; 1,24	1,12; 1,37
Vaccine price (R)	175	157,5 (–10%) 192,5 (+10%)	1,43; 1,18	1,58; 1,30

HC = benefit/cost ratio in human capital model; SHC= benefit/cost ratio in subsistence/human capital model.

Discussion

Although we used the most conservative base values in both the human capital and the subsistence/human capital models, it is clear that the vaccination programme would have produced net benefits arising from avoided disease costs in metropolitan Cape Town ranging from R2 435 917,07 to R3 559 789,07. If we had been able to quantify other disease costs, such as the spread of Hib illness through contact with Hib infected infants or foregone parental earnings, the net benefits estimates would have been even higher.

Given the difficulty of predicting future economic events and the subjectivity inherent in attaching costs to morbidity and mortality, we chose 'floor' base values in our models. The promising results from our metropolitan Cape Town study suggest the urgency of conducing further Hib disease studies throughout South Africa.

Any net benefits would, of course, be much less in some rural areas, where the value of life — as measured by the utilitarian yardsticks of this study — would not only be less but perhaps be meaninglessly so. For such areas we would suggest that a more appropriate approach might be to extend this study and use the concepts of disability-adjusted life years and the related concept, the global burden of disease.[18] Public health policy makers would then have to assess comparative disease burdens for Hib and other diseases still not adequately provided for by primary health care. Priority ranking would then be made by comparing the annual rand cost per capita of alternative strategies against forecasts of respective reductions in disease burden to be obtained.

Nevertheless, infants could be vaccinated against Hib infection in conjunction with the DTP vaccination, and significant net lifetime indirect and direct disease costs could effectively be prevented, given our model's suggestion that a national vaccination programme against Hib disease could well produce substantial indirect and direct economic savings.

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Appendix A

Our basic formula for the present value of an individual's expected lifetime earnings between year k and year n is equation 1:

$PV = Y(1+g)^{k-1}/(1+r)^{k}+[Y(1+g)^{k}]/(1+r)^{k+1}+ \ldots [Y(1+g)^{n-1}]/(1+r)^{n}$,

where Y = annual wage rate; r = discount rate; and g = growth rate.

We multiplied both sides of equation 1 by the term (1+g)/(1+r) to arrive at equation 2:

$PV[(1+g)/(1+r)] = [Y(1+g)^{k}/(1+r)^{k+1}]+ \ldots +[Y(1+g) =^{n}]/(1+r)^{n+1}$.

We then subtracted equation 2 from equation 1 to arrive at equation 3:

$PV-PV[(1+g)/(1+r)] = Y(1+g)^{k-1}/(1+r)^{k}- \{[Y(1+g)^{n}]/(1+r)^{n+1}\}$.

After simplifying equation 3, we arrive at equation 4:

$PV = [Y/(r-g)]*[(1+g)/(1+r)]^{k-1}] - [(1+g)/(1+r)]^{n}$

Equation 4 is employed in the human capital, subsistence (substitution S = annual subsistence level for Y = annual wage rate), and subsistence/human capital models.

The term L, the probability adjustment for actuarially computed expected (PAFACE) years of survival to age n given initial survival to age k, was arrived at through obtaining two key actuarial statistics: P = the probability of living to year n given that a person was alive until an earlier year k; and E = the expected age of death given death varies under n and over k.

We used life expectancy data from English Life Tables Number 12, Life Contingencies, by Allister Neill. Although English actuaries generally estimate the terminal age at between 103 and 105 years, we adopt 100 years as an adequate approximation for South Africa. Our estimate is more conservative given that South African blacks have a lower life expectancy than English whites. The basic equation for L used in the human capital, subsistence, and subsistence/human capital approaches is:

$L = P + [(E - k)/(n - k)](1 - P)$.