For discussion

BCG vaccination of schoolchildren in England and Wales

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Information on which an assessment of the scheme for BCG vaccination of schoolchildren in England and Wales can be based has now been collected and published.[1–3] The main relevant conclusions from these papers are summarised below as an introduction to a discussion of the present and future usefulness of the scheme.

The estimates that follow relate intentionally to the white population only. The scheme for BCG vaccination of 13 year old schoolchildren introduced in 1953 was an appropriate method for the control of tuberculosis in the population of England and Wales, which was then almost entirely white. The usefulness of the scheme should consequently be considered primarily from the same standpoint. Although the high risk ethnic groups now resident in England and Wales benefit from the scheme they need BCG vaccination at a much younger age. This service is provided in many areas and its continuation and expansion will rapidly diminish the value of vaccination at an older age in these communities, whether the national scheme is continued or not.

BCG vaccine given to children at about the age of 13 years has shown a high and consistent level of protection against tuberculosis, of about 75%, throughout more than 30 years' use in England and Wales.[1] There has been a continuous steep decrease in tuberculosis notification rates in young white adults over a rather longer period, most of which is attributable to causes other than BCG vaccination of schoolchildren.[2] In the decade before 1983 the annual rate of decline in both unvaccinated and vaccinated subjects was about 9%. Because of this decrease and the maintained efficacy of BCG, the numbers of tuberculosis notifications prevented by the schools BCG scheme are also decreasing steeply—indeed, as rapidly as the notification rate.

Assuming that the BCG in schools scheme is continued with its present coverage (75%) and efficacy, and that notification rates for young white adults continue their recent rate of decline, estimates have been made of the numbers of tuberculosis notifications of white adults aged 15–29 years expected during the next 25 years,[3] and of the numbers of notifications that would be prevented by the scheme.

The consequences of discontinuing the scheme at various dates have also been estimated.[3] The primary effect would be some additional notifications in those left unvaccinated, arising from the existing sources of infection; these would increase to a maximum 10–15 years after vaccination ceased (as the proportion of unvaccinated young adults gradually increased from 25% to 100%) and would then decline, because of the continued decline in the sources of infection. There would be a smaller number of secondary additional notifications arising from the added sources of infection among the primary additional cases; these would gradually increase to a maximum about 15–20 years after vaccination ceased and then decline. The total epidemiological consequences, whenever the scheme was stopped, were summarised as a substantial slowing of the rate of decline of the numbers of tuberculosis notifications in young white adults, confined almost entirely to the 15–29 year age group for about 15 years, after which a steeper rate of decline would be resumed.

Since preparing that report[3] we have realised that it is epidemiologically more relevant to summarise the effect of stopping the scheme in terms of the rate of decline in the numbers of *sources of tuberculous infection* instead of the trend in the numbers of *tuberculosis notifications*. These two rates of decline are virtually the same while the scheme continues, and have been taken as 9% annually. If the scheme is stopped they will differ because the primary additional notifications all arise (by definition) from the *existing* sources of infection, and only the smaller number of secondary additional notifications arise from the *new* sources of infection. The trend in sources of infection would therefore be less affected by stopping the scheme than the trend in notifications, and would be modified by factors that depend on the relative numbers of secondary additional notifications and all other notifications. Using these factors, which are given in reference 3, we have estimated that whenever the scheme was stopped the rate of decline of the numbers of sources of infection for the age group 15–29 years would be reduced from 9% to about 6% annually for about 15 years. Thereafter a steeper rate of decline would be resumed in this age group, the rates of decline in sources of infection in other age groups having been

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Table 1 Estimated risk of developing notified tuberculosis between the age of 15 and the age of 30 years for an individual white adult in England and Wales if the BCG scheme continues, or stops in certain years

	Tuberculin negative at age 13 years			
	If BCG scheme continues		*If BCG scheme stops*	
Cohort reaching age 13 years in	*BCG vaccinated*	*Not vaccinated*	*At end of*	*Not vaccinated*
1984 (1982–86)	1 : 6500	1 : 1700	—	—
1989 (1987–91)	1 : 10 000	1 : 2700	1986	1 : 2200
1994 (1992–96)	1 : 17 000	1 : 4300	1991	1 : 3400
1999 (1997–2001)	1 : 26 000	1 : 6900	1996	1 : 5400

almost unaffected throughout. It is therefore clear that epidemiologically the cessation of the scheme would not be disastrous for young adults, and other age groups would be only slightly affected.

These estimates are based on data collected up to the end of 1983, and depend on the continuation of an annual decrease of 9% in notification rates at ages 15–29 years. The Medical Research Council Cardiothoracic Epidemiology Group made a national survey of tuberculosis notifications in England and Wales in 1988,[4] on the same lines as the two previous surveys.[5,6] One of the main reasons for this survey was to assess the secular trends in tuberculosis incidence in the various ethnic groups since 1983. The results of the survey, not yet available, will indicate whether the estimates of notifications prevented by the scheme, if it continues, and of the additional notifications if it is discontinued, should both be regarded as too large or both as too small. No radical alteration in the pattern of effects of continuing or stopping the scheme, however, is to be expected.

Relative merits of continuing or stopping the schools BCG scheme

There are several different ways of presenting the above results. Table 1, based on reference 3, summarises the chances that a tuberculin negative white child aged 13 years will have (notified) tuberculosis between the ages of 15 and 30 years in various circumstances, given continuance of existing trends. Table 2, also from reference 3, shows the notifications expected at ages 15–29 years if the scheme continues, and the annual numbers of additional notifications if BCG vaccination is stopped at various dates, on the same assumptions. These findings are now considered in more detail as they concern the individual about to be vaccinated, the epidemiologist, and the administrator.

THE CHOICE FOR THE INDIVIDUAL

Benefits of vaccination

As table 1 shows, the current risk that an unvaccinated tuberculin negative young white adult will develop tuberculosis during a 15 year period has become very small, at 1 in 2700, and vaccination renders it very small indeed, at 1 in 10 000. (At the time of the Medical Research Council trial,[7] which started in 1950, the corresponding risks were 1 in 52 for the unvaccinated and 1 in 238 for the vaccinated.)

If the scheme is stopped, the risk to a tuberculin negative white child who is not vaccinated at age 13 years will be increased, because of the added risk of developing tuberculosis from the new sources of infection among the primary additional notified cases. Table 1 shows that if the scheme stopped at the end of 1991 the risk of having (notified) tuberculosis between ages 15 and 30 years, for the first five year cohort of tuberculin negative 13 year olds left unvaccinated, would be 1 in 3400, instead of 1 in 4300 if the scheme continued. The risk for the second five year cohort (age 13 years in 1997–2001) after stopping at the end of 1991 would be about 1 in 5000 (not tabulated), and for subsequent cohorts less still. Thus stopping the scheme would not greatly increase the already small risk of developing tuberculosis. It would therefore be reasonable to stop the scheme when the individual risk of developing tuberculosis in the absence of vaccination is judged to have fallen to an acceptably low level.

Individual judgment on this point will be influenced by the availability and efficacy of treatment. For a cooperative patient a diagnosis of tuberculosis now requires only a short period off work, if any, and regular daily medication for six months, with an excellent prognosis thereafter. Prevention is still better than treatment, but a diagnosis of tuberculosis now means much less disruption for the patient and his family than it did 30 years ago. The availability of effective and acceptable treatment has thus diminished the importance to the individual of acquiring the protection offered by BCG vaccination.

Table 2 Primary and secondary effects of stopping the schools BCG scheme in certain years: estimated numbers of tuberculosis notifications occurring at ages 15–29 years among white adults resident in England and Wales at age 13 years

		1983	*1988*	*1993*	*1998*	*2003*	*2008*	*2013*
Total notifications occurring if scheme continues		446	288	165	90	52	33	21
Primary additional notifications resulting from stopping scheme at end of:	1986		0	47	71	69	44	27
	1991		0	0	31	45	44	27
	1996		0	0	0	19	28	27
Secondary additional notifications* resulting from stopping scheme at end of:	1986		0	14	47	60	51	32
	1991		0	0	9	31	38	32
	1996		0	0	0	6	19	24
Total notifications occurring, including primary and secondary effects of stopping at end of:	1986		288	226	208	181	128	80
	1991		288	165	130	128	115	80
	1996		288	165	90	77	80	72

*Some of the secondary additional notifications will be outside the age range 15–29 years.

Disadvantages of vaccination

At the present low levels of risk of developing tuberculosis other considerations become important to the individual contemplating vaccination. These range from the very low risk of severe adverse reactions to the possibility of early or late local complications, and even to the perceived discomforts and inconvenience of the vaccination procedure itself.

Severe complications due to dissemination remain very rare indeed after BCG vaccination of schoolchildren.[8] Little information on the frequency of early local complications of vaccination is available for England and Wales. Complications at the vaccination site or in regional lymph nodes sometimes occur, and there have been a few outbreaks where their number and scale have been sufficient to cause local concern.[9] These, on investigation, have been attributed to faulty vaccination technique. The higher rates of later keloid formation quoted in the recent worldwide review of complications by Lotte *et al*[8] have all occurred in racial groups known to be prone to keloid formation, and have shown associations with dosage and technique. A recent study in England and Wales (J A Lunn, personal communication) has shown keloid formation in more than 2% of BCG scars at the recommended site for vaccination (the insertion of the deltoid muscle) at ages 18–25 years. The percentage of keloid scars was greater for vaccination sites over the deltoid muscle, and especially large for sites near the acromioclavicular joint, as has been emphasised previously by a plastic surgeon.[10] The importance of good technique, including vaccination at the correct site, is again apparent.

THE EPIDEMIOLOGICAL POSITION

As indicated in the introduction, and more fully in reference 3, whenever the scheme is stopped the adverse consequences would be limited in time, and would not be epidemiologically disastrous. Unless this were the case, it would not be realistic to consider stopping the scheme at all. However, the epidemiological disadvantage of stopping the scheme (the total number of additional notifications) will always equal the epidemiological advantage of continuing (the total number of notifications prevented). Thus the disadvantage of stopping *relative* to the advantage of continuing does not change with time, but in terms of their *absolute* level the disadvantage and the advantage would both decrease by 9% annually. A decision to stop the scheme would therefore be reasonable on epidemiological grounds when the absolute number of additional notifications expected to arise annually throughout England and Wales after the end of the scheme falls to or below a level that would be regarded as an acceptable addition to the national case load (the then current efficacy of tuberculosis treatment regimens being taken into account). Summation of corresponding items in the second and third sections of table 2 shows that stopping the scheme at the end of 1991 would give rise to a maximum of about 80 additional notifications each year in the first few years of the twenty first century, with a subsequent decline. Stopping at the end of 1996 would give rise to a maximum annual number of additional notifications of about 50.

Because of the availability of effective chemotherapy BCG vaccination is not the major method of control of tuberculosis in England and Wales.[2] In this respect tuberculosis differs completely from other infectious diseases, for which immunisation or vaccination procedures are used on a community basis and for which these procedures are the only effective methods of control. In numerical terms, between 1953 and 1983 the average annual decrease in tuberculosis notification rate in the white ethnic group aged 15–24 years was 12·2%; the part of this decrease that was attributable to the introduction and expansion of the BCG in schools scheme was about 4%. Between 1978–9 and 1983 the annual decrease in notification rate was 11·1%; the contribution of the BCG scheme to this was 1·2%.[2]

FINANCIAL CONSIDERATIONS

The financial cost of the schools BCG scheme in relation to its monetary benefits was assessed by Stilwell in the early 1970s.[11] He concluded that the cost of the BCG scheme had become greater than its benefits by the end of 1975, possibly by a factor of 2. Since then the cost of the scheme in real terms has increased because of the recommendation to use a separate syringe for vaccinating each child,[12] but the financial benefits are becoming progressively less as the absolute number of cases prevented declines and as courses of effective treatment become shorter, with shorter durations of hospital stay and time off work. The financial costs of the BCG scheme now may substantially exceed the resulting monetary benefits.

Preventing a case of tuberculosis, however, is preferable to allowing it to develop, even though highly effective treatment is available. There are also disadvantages in developing tuberculosis to which it is not possible to assign a financial value. A financial cost-benefit ratio greater than 1, even substantially greater than 1, cannot be regarded by itself as an adequate criterion for stopping the scheme.

Tuberculosis and the acquired immunodeficiency syndrome

Those infected with the human immunodeficiency virus (HIV) have an increased risk of developing tuberculosis.[13] There is understandable concern that the expected increase in the numbers of AIDS patients in England and Wales will also lead to increased numbers of tuberculosis notifications, and that this may seriously disturb the current downward trend of the disease.

The effects on the incidence of tuberculosis of an increase in the proportion of the population with HIV infection are analogous to the consequences of an increase in the proportion of the population left unvaccinated if the BCG scheme is stopped. The primary effect would be additional cases of tuberculosis as part of the AIDS syndrome among those whose im-

munocompetence was impaired by HIV infection. Some of these would represent new sources of tuberculosis infection in the general population, and would give rise to secondary additional cases of tuberculosis. These secondary additional cases would increase the estimates of the future risks that an individual not infected with HIV would develop tuberculosis in all three of the circumstances envisaged in table 1. As explained below, the magnitude of these increases cannot yet be estimated, but the effect will not necessarily be large.

Among those infected with HIV tuberculosis arises principally from a substantial risk of endogenous reactivation of past tuberculous infection and to a much smaller extent from current exogenous infection.[14] There is evidence that at least 30% of young adults with longstanding tuberculous infection still harbour living bacilli capable of causing clinically active tuberculosis after infection with HIV.[15] In the young white adult population of England and Wales, however, the current prevalence of past tuberculous infection is small and so, despite the high reactivation rate, the proportion (and the number) of patients with AIDS who are expected to develop tuberculosis will also be small. Further, because of the underlying downward trend in tuberculosis, the number of secondary additional cases of tuberculosis in the general population not infected with HIV is expected to be smaller than the number of primary additional cases among the patients with AIDS. Thus tuberculosis associated with HIV infection is not currently a major problem in England and Wales, though no precise estimate can be made.

Its future trend will depend on the balance between the rate of increase of new cases of AIDS and the rate of decrease of the proportion of young adults harbouring viable tubercle bacilli as a result of a past tuberculous infection. Hence the number of cases of tuberculosis associated with HIV infection will decrease only if the rate of increase of the number of new cases of AIDS is less than the 9% annual decline in the proportion of young adults with past tuberculous infection (and presumably also in the proportion harbouring tubercle bacilli). The total numbers of new cases of AIDS, however, in the United Kingdom reported to the Communicable Disease Centre in the first nine months of 1987, 1988, and 1989 were 494, 575, and 669, suggesting a current annual increase of more than 16%.[16]

Experience of stopping BCG schemes in other countries

The value of mass BCG vaccination in a low prevalence country and the question of its discontinuation were first considered by Wallgren in 1955.[17] He concluded that the sudden discontinuation of mass BCG vaccination in Sweden would be most unlikely to lead to any increase in tuberculosis mortality. Rouillon and Waaler[18] assessed the advantages and disadvantages of BCG vaccination in various epidemiological circumstances, but were unable to produce a definitive answer to the question of when to stop routine BCG vaccination in a community.

The only full assessments of the effects of a change in BCG policy are from Sweden.[19–21] Routine vaccination of the newborn was stopped in 1975 because of the complication of osteitis. It was estimated that if 100 000 children born in 1975 were to be left unvaccinated, they would produce about 17 cases of tuberculosis before they were 15 years of age, which is less than the 25/100 000 cases of BCG induced osteitis found in 1972–4.[20] After routine vaccination had stopped, the number of cases of tuberculosis that occurred by the end of 1981 was well within the predicted range; in particular, up to five cases of tuberculous meningitis had been regarded as possible, and two were observed.[20] In view of the declining incidence of tuberculosis, routine tuberculin testing and revaccination of non-reactors were abandoned for 7 year old children in 1965, for military conscripts in 1976, and for 14 year old children in 1986. BCG vaccination schemes continued for children with a family history of tuberculosis, children born (in Sweden or elsewhere) to immigrants from high prevalence countries, and children travelling to such countries.[21]

The first results of a planned discontinuation of BCG vaccination of the newborn from April 1986 in an area of Czechoslovakia with a population of 2 million have been reported.[22] So far the estimates of the risks of tuberculous infection and of breakdown to tuberculosis, based on 15 infections and two cases, are within expected limits.

In West Germany BCG vaccination of the newborn was suspended during the period June 1975 to July 1977, because of complications of vaccination.[23] A retrospective hospital study showed that the number of cases of tuberculosis in the first year of life from September 1975 to August 1976 was 79, compared with 33 in 1973 and 35 in 1974 in the same hospitals. A later reference[24] to the same episode, covering a longer period of observation, gives the number of cases in children born during the period of suspension as 1198, including 53 cases of tuberculous meningitis, but gives no comparative figures for a period when BCG was in use, so that these figures are impossible to interpret. Clearly BCG vaccination should not be suspended or stopped without a careful assessment of the probable effects of the change of policy.

In Norway[25] and Finland (A S Härö, personal communication) BCG vaccination policy has been reviewed, with decisions to continue routine vaccination. In Denmark BCG policy has been reviewed[26] and a recommendation made that compulsory vaccination at age 7 years should be ended, because only 27 new cases of active tuberculosis were likely to be prevented between the ages of 7 and 22 years among the 900 000 children eligible for vaccination in the period 1980–94. Routine vaccination of schoolchildren has, however, continued in most areas (A Kok-Jensen, personal communication).

Finally, developed countries that have used and not used BCG vaccination on a community basis have achieved similarly rapid declines in tuberculosis.[27 28]

Discussion

The purpose of this paper is to bring together information relevant to the use of BCG vaccination at about age 13 years in England and Wales so that the reader can form a fair judgment on the usefulness of the scheme, and particularly on whether the scheme should be continued for several years more, or be terminated in its present form within a year or two. We make no formal recommendations ourselves.

The main conclusion is that if the scheme for BCG vaccination of schoolchildren is stopped at any time it will give rise not to an increase in tuberculosis but to a slowing in the annual rate of decline of the risk of tuberculous infection in young adults from about 9% to 6% for a period of about 15 years, after which a steeper rate of decline would be resumed. In this respect BCG vaccination differs from all other immunisation and vaccination procedures currently in use. Tuberculosis has been declining steeply in England and Wales for many years for reasons unconnected with the use or efficacy of BCG vaccination, and this decline would be continued if BCG vaccination stopped. For other infectious diseases, with their different epidemiological background, cessation of the appropriate immunisation or vaccination procedure would be followed sooner or later by a return to the epidemiological pattern of the era before the introduction of the protective procedure.

The important question is therefore not whether but when the scheme for BCG vaccination of schoolchildren in England and Wales should be stopped. Because of the continuing decline in tuberculosis of about 9% a year, the absolute benefits of the scheme are declining as fast as the notification rate, while the disadvantages, including the inconvenience and complications of vaccination, continue at an unchanging level. For a tuberculin negative individual aged 13 years in the early 1990s the risk of developing tuberculosis before the age of 30 years if the scheme continues is 1:4300 if he or she is unvaccinated and 1:17 000 if vaccinated. If the scheme were stopped at the end of 1991 the risk would be 1:3400; if the scheme were stopped five years later the risk would be 1:5400. In the assessment of what level of risk is small enough to justify stopping the scheme the efficacy of tuberculosis treatment is relevant.

Another way of looking at the question is in terms of the absolute numbers of additional notifications that would be expected. If the scheme were discontinued some cases would occur that could have been prevented and these would give rise to further cases. If the scheme stopped at the end of 1991 the total number of additional notifications would gradually increase to a maximum of about 80 a year for 10 years around the end of the century, after which the number would decline. If it were stopped five years later, the additional notifications would increase to a maximum of about 50 per year, and then decline.

In the last few years the possibility has arisen of a separate source of additional tuberculosis notifications—namely, in patients with impaired immunity from HIV infection and in those whom they infect. The present indications are that in England and Wales these additional notifications are few, but they may be increasing. Nevertheless, their eventual influence on the general decrease in sources of tuberculous infection in the population will not necessarily become large.

The conditional recommendation by the Department of Health to stop the routine BCG vaccination of schoolchildren before 1990[29] appears reasonable, but it depends on a continuing decline of 9% a year in the notification rates of young white adults. The results presented in this and related papers[1-3] are all derived from data obtained up to the end of 1983. The results of the 1988 notification survey[4] and the possible future impact of tuberculosis associated with HIV infection will need to be taken into account before that conditional recommendation is accepted. The other condition attached to that recommendation, that a suitable organisation is in place to continue BCG vaccination of groups at risk, retains its importance whenever the school BCG vaccination scheme is stopped.

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