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- 1 Hill P. Off license and off label prescribing in children: litigation fears for physicians. *Arch Dis Child* 2005;90:17-8.
- 2 Conroy S, Choonara I, Impicciatore P, Mohn A, Arnell H, Rane A, et al. Survey of unlicensed and off label drug use in paediatric wards in European countries. *BMJ* 2000;320:79-82.
- 3 McIntyre J, Conroy S, Avery A, Corns H, Choonara I. Unlicensed and off label prescribing of drugs in general practice. *Arch Dis Child* 2000;83:498-501.
- 4 Chalumeau M, Tréluyer JM, Salanave B, Assathiany R, Chéron G, Crocheton N, et al. Off label and unlicensed drug use among French office based paediatricians. *Arch Dis Child* 2000;83:502-5.
- 5 't Jong W, Eland IA, Sturkenboom MCJM, van den Anmer JN, Stricker BHCh. Unlicensed and off label prescription of drugs to children: population based cohort study. *BMJ* 2002;324:1313-4.
- 6 O'Donnell CP, Stone RJ, Morley CJ. Unlicensed and off-label drug use in an Australian neonatal intensive care unit. *Pediatrics* 2002;110:e52.
- 7 Neubert A, Dormann H, Weiss J, Egger T, Criegee-Rieck M, Rascher W, et al. The impact of unlicensed and off-label drug use on adverse drug reactions in paediatric patients. *Drug Safety* 2004;27:1059-67.
- 8 Medicines for children. European Commission proposal for regulation of the Council and of the Parliament on medicinal products for paediatric use, 29 September 2004. <http://pharmacos.eudra.org/F2/Paediatrics/index.htm> (accessed 30 Aug 2005).
- 9 European Medicines Agency. Guideline on conduct of pharmacovigilance for medicines used by the paediatric population. 27 July 2005. [www.emea.eu.int/pdfs/human/phwvp/23591005en.pdf](http://www.emea.eu.int/pdfs/human/phwvp/23591005en.pdf) (accessed 30 Aug 2005).
- 10 US Food and Drug Administration. Pediatric Research Equity Act of 2003. [www.fda.gov/opacom/laws/prea.html](http://www.fda.gov/opacom/laws/prea.html) (accessed 30 Aug 2005).
- 11 Costello I, ed. *BNF for Children*. London: Pharmaceutical Press, 2005.

## Stopping routine vaccination for tuberculosis in schools

*Brings the UK into line with much of the rest of the world*

From autumn 2005 the long running routine programme to vaccinate schoolchildren against tuberculosis with BCG vaccine will stop. This follows a decision by the chief medical, nursing, and pharmaceutical officers in July that there should be selective vaccination of high risk infants and other groups rather than routine vaccination of adolescents negative on tuberculin testing.<sup>1</sup> This decision comes after several years of discussion within the Joint Committee on Vaccination and Immunisation, and it closes an important chapter in the complex history of BCG vaccination. It comes as notifications of tuberculosis in England and Wales are at their highest level since 1983. The decision is well justified.

This BCG programme has been unique from its start in the mid-1950s, when a Danish vaccine (later produced by Glaxo) was introduced on the basis of efficacy shown in a trial carried out by the UK Medical Research Council.<sup>2</sup> The trial had been carried out in approximately 30 000 adolescents for pragmatic reasons—in order to recruit participants who were still tuberculin negative, but who were about to enter a period of high risk of disease. That trial remains the most rigorous trial of BCG vaccination carried out anywhere and is an important monument in the history of research in tuberculosis.

At the same time trials were carried out by the US Public Health Service (USPHS) in Georgia, Alabama, and Puerto Rico which found that the Tice BCG vaccines used there had little or no effect.<sup>3</sup> Faced with these results, each nation did the locally responsible thing—the USPHS decided not to introduce BCG vaccination because they had no evidence that it worked among their populations, whereas the UK authorities did introduce it, as they had good evidence of its value.

This touched off a controversy over the magnitude and determinants of the efficacy of BCG, which still continues. Many explanations have been proposed. Perhaps the most popular is that different populations are exposed to different environmental mycobacteria, which can provide as much immunity as BCG or otherwise interfere with it, and that the US trials happen to have been conducted in areas where such environmental exposure is highly prevalent.<sup>4</sup> Whatever

the explanation for those initial trial results, they determined the policy of vaccinating adolescents in the United Kingdom, and the efficacy of the vaccines so given has since been confirmed repeatedly in observational studies.<sup>4 5</sup>

The epidemiology of tuberculosis in the United Kingdom has changed greatly over the years since the BCG programme began. The annual risk of infection has declined from about 2% a year in 1950 to less than 1 per 1000 today, and the disease has become increasingly restricted to identifiable segments of the population, in particular immigrant communities: two thirds of cases in 2003 were in people born outside the United Kingdom.<sup>6</sup> Recent increases in the incidence of tuberculosis in the UK thus reflect patterns and trends in the movements of populations and in the epidemiology of tuberculosis worldwide.

That non-indigenous groups were at higher risk was first recognised in the 1960s and led to a national policy encouraging health authorities to consider supplementary BCG programmes for neonates or for people in contact with tuberculosis in these communities. The Joint Committee on Vaccination and Immunisation repeatedly examined the cost effectiveness of the routine programme in schools as an increasing proportion of the population at high risk received the vaccine in infancy and as the risk of disease in the general population fell. The number of cases in people born in the United Kingdom reached an all time low in 2003.<sup>6</sup>

Although the criteria set by the International Union against Tuberculosis and Lung Disease for moving away from routine BCG vaccination were achieved in the 1990s,<sup>7</sup> policy makers were reluctant to stop the programme in schools because of lingering concerns that increases in the prevalence of HIV and in tuberculosis internationally might increase the risk of tuberculosis in the UK general population. This has not occurred, and it is clear that the risk of tuberculosis among immigrant communities declines over time once they have settled in the United Kingdom and that the imported disease has not led to increases in the risk of disease for the indigenous population.

Under the new policy, BCG vaccination will be offered to infants in communities with an average incidence of tuberculosis of at least 40 per 100 000 and to unvaccinated individuals who come from, or whose parents or grandparents come from, countries where the incidence exceeds 40 per 100 000. Most people born in the United Kingdom will thus probably never receive BCG vaccination, and most will not be exposed to mycobacteria. This means that tuberculin testing will become increasingly efficient as a means of identifying people exposed to and latently infected with the tubercle bacillus, who may be given prophylaxis.

The change from routine to targeted vaccination is accompanied by technical changes. The Glaxo BCG vaccine has been replaced by one from the Danish Statens Seruminstitut and the multipuncture "Heaf" technique for tuberculin testing is being replaced by the intradermal injection "Mantoux" technique, which is the standard in the rest of the world. All of these changes bring the UK's approach to preventing infection with tuberculosis in line with policies and practice in many other countries.

BCG vaccination will continue to have an important role in protecting children in high risk populations from tuberculosis. Coupled with vigorous efforts to identify and appropriately treat cases, and to

ascertain and offer prophylaxis to people with latent infection, the new policy should allow more efficient control of tuberculosis in the entire UK population.

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Competing interests: PF is a member of the BCG Subcommittee of the Joint Committee on Vaccination and Immunisation and took part in discussions leading to this policy change.

- 1 Donaldson L, Beasley C, Smith J. Changes to the BCG vaccination programme. 6 July 2005. (CMO letter.) [www.immunisation.nhs.uk/files/CMO060705.pdf](http://www.immunisation.nhs.uk/files/CMO060705.pdf) (accessed 15 Sep 2005).
- 2 Hart PD'A, Sutherland I. BCG and vole bacillus vaccines in the prevention of tuberculosis in adolescents and early life. Final report to the Medical Research Council. *BMJ* 1977;ii:293-5.
- 3 Comstock GW, Palmer CE. Long term results of BCG vaccination in the southern United States. *Am Rev Respir Dis* 1966;93:171-83.
- 4 Fine PEM, Carneiro IAM, Milstein JB, Clements CJ. Issues relating to the use of BCG in immunization programmes: a discussion document. Geneva: World Health Organization, 1999. [www.who.int/vaccine\\_research/documents/en/bcg\\_vaccines.pdf](http://www.who.int/vaccine_research/documents/en/bcg_vaccines.pdf) (accessed 15 Sep 2005).
- 5 Sutherland I, Springett VH. Effectiveness of BCG vaccination in England and Wales in 1983. *Tubercle* 1987;68:81-92.
- 6 Health Protection Agency. Tuberculosis. [www.hpa.org.uk/infections/topics\\_az/tb/menu.htm](http://www.hpa.org.uk/infections/topics_az/tb/menu.htm) (accessed 15 Sep 2005).
- 7 International Union against Tuberculosis and Lung Disease. Criteria for discontinuation of vaccination programmes using Bacille Calmette Guerin (BCG) in countries with a low prevalence of tuberculosis. *Tubercle and Lung Dis* 1994;75:179-81.

## The Japanese healthcare system

*The issue is to solve the "tragedy of the commons" without making another*

The Japanese medical insurance system has a unique combination of characteristics that has led to the overuse of tests and drugs, unconstrained demand from patients, and an explosion of costs. Unless the system of medical insurance and reimbursement of healthcare providers changes, the combination of increasing technological advances, an ageing population, and unconstrained demand will produce a crisis in Japanese health care. Japan is only belatedly waking up to this crisis.

The Japanese medical insurance system has four characteristics that lie at the root of the problem. Firstly, Japanese citizens are covered comprehensively and exclusively by either national medical insurance (for the self employed) or social insurance (for employees). Beneficiaries have to make some co-payments, which are capped depending on income.<sup>1</sup> Secondly, mixed private and insurance payments are prohibited—that is, beneficiaries cannot pay privately for medical services that are covered by their medical insurance. Thirdly, beneficiaries have guaranteed access to any healthcare providers, from general practitioners to specialists, without being charged a premium fee. Finally, healthcare providers and institutions are reimbursed through fees for service.

Fuelled by economic growth after the second world war and facilitated by the healthcare system, Japan has become one of the most medically advanced nations in the world, especially in its service quantity. Compared with other developed countries in the Organisation for Economic Cooperation and Development (OECD),

Japan is the runaway leader in the number of magnetic resonance imaging and computed tomography scanners per head of population.<sup>2</sup> Because they are paid for each prescription or test rather than time spent with patients, healthcare providers, both private and public, are driven to prescribe more drugs and to order more imaging and tests.

Japanese patients visit outpatient clinics more often and stay in hospitals longer than patients in other OECD countries.<sup>2</sup> Profits gained from a "three-hour wait, three-minute contact" consultation (with an emphasis on ordering tests and prescribing drugs during the three minutes) primarily benefit pharmaceutical and medical equipment companies. Healthcare expenditures, both per head and as a percentage of gross domestic product, continue to increase despite the economic growth rate remaining low throughout the past 10 years. In Japan's ageing society, the economic burden rests with the insurers, who ultimately raise their funds from the working population and their employers.

Japanese health care is therefore a typical case of the "tragedy of the commons."<sup>3</sup> The name relates to grazing land: free access to common grazing land drives each herdsman to maximise his own take from the commons, even when it becomes overcrowded with grazing animals. Ultimately this behaviour ruins the common land, as well as those who depend on it for survival. In the Japanese system patients are the herdsmen, and specialists, medical resources, and health insurance coverage comprise the commons. A more

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