

Opinion n°92

**Opinion on screening for tuberculosis and BCG
vaccination**

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Professor Didier Houssin, Director General for Health, referred to CCNE on January 11th, 2006 concerning issues connected to changes in tuberculosis (TB) control policies:

- BCG vaccination for children no longer mandatory. To be used only for populations at risk.
- Certain schoolchildren targeted for TB screening using the intradermal tuberculin skin test.
- Newly hired personnel whose work puts them in contact with children undergoing the above vaccination and screening procedures, to be systematically screened for TB using x-rays and intradermal tuberculin skin test.

Although the targeting concept is designed to benefit at-risk sectors of the population, it raises many ethical issues which are by no means confined to the purely scientific and medical concerns involved. The onset of TB is facilitated by precarious living conditions and migration from a country where the disease is endemic. Its appearance can therefore also reveal a social context.

Medical recommendations aiming specifically to help highly vulnerable people may have societal consequences that militate in favour of ensuring that an active screening policy and the vaccination policy with which it must be connected are coherent.

I Epidemiology

The revised policy is justified by surveillance data which shows that since 1997, incidence of the disease in all sectors of French society has stabilised at close to 10 new cases per 100,000 inhabitants per year. Tuberculosis, a disease which is caused by the infective agent *mycobacterium tuberculosis*, also called Koch's bacillus, has been a notifiable disease since 1964. In 2003, 6,350 people were infected, of which 6,234 in Metropolitan France and 116 in French overseas territories. In 2004, there were 5,512 cases with a global incidence in France of 9 per 100,000.

Among the most severe forms of the disease in 2003, 114 cases of tuberculous meningitis (theoretically prevented by BCG vaccination) were observed, of which 2 children under the age of 5 years (one of whom had undergone BCG vaccination; the other child's vaccination status was unknown). However incidence varies with country of origin; in Metropolitan France in 2003, the average was 5.7 cases per 100,000* French nationals and 74.2 cases per 100,000 foreign nationals (114.3 in the Ile de France (greater Paris area) as regards the latter).

* The International Union Against Tuberculosis and Lung Diseases consider that BCG vaccination may cease when the rate is below 5 per 100,000.

The risk of contamination therefore most certainly exists for populations living in precarious conditions, particularly children living below the poverty line, be they French nationals or originating from highly endemic countries.

Essential epidemiological considerations include both the contamination to which such populations may be exposed and also the real risk that they may represent for the rest of the population. In other words, there is a need to differentiate between the risk to themselves and the risk to others. Although epidemiological figures lack precision (it is often difficult to identify the source of infection) it is probable that the risk is mainly to populations living in precarious conditions.

This question of individual and collective risk is not specific to tuberculosis. Any vaccination policy will aim to include both protection of the individual concerned and protection of society.

II Screening

Although a few procedures persist, the systematic screening policy is being phased out. Little more is being done than the micro x-rays that some companies require for new employees and those included in prison admission procedures.

Screening is particularly complicated in France by the fact that the tuberculin skin test cannot distinguish between BCG-vaccinated and TB-infected persons¹.

Although it is legitimate to believe that screening is more likely to be positive — and therefore beneficial — to vulnerable populations, to propose it purely on the basis of social and economic or geopolitical conditions, which are more or less associated with the disease, raises ethical issues. The medical profession is being asked to identify a pathological situation which is the expression of a precarious lifestyle. If screening were to be generalised, in conditions that remain to be defined, it would become a neutral procedure whose profitability would vary with prevailing situations.

The absence of two components is much to be regretted: the almost total disappearance of school-based healthcare and the lack of public health-related training for physicians. Another point is that for a long time, screening for TB was inevitably associated with access to employment in the French civil service, so that screening has taken on an excessively administrative character.

¹ Cell-mediated immune response tests to distinguish BCG-vaccinated and TB-infected persons are now being evaluated.

Finally, there is the essential issue of access to screening and its implementation. The paradox is that those who would most need it, i.e. people who are excluded from the system, have less access than those who are a well-integrated part of the system and need it least. Any strategy where medical and social structures are circumvented, for whatever reason, is in full contradiction with any real prevention policy.

III BCG vaccination

BCG vaccination against TB is mandatory in France. It is recommended in the first month of the life of neonates at risk and is required for other children when they enter into any community infrastructure (crèche) and in any case before 6 years of age. The programme is well performed and supported. It aims to avoid the most severe forms of the disease.

BCG, the Calmette-Guérin bacillus, is a live bacterial vaccine derived from a strain of *Mycobacterium bovis*, cultured for 13 years starting in 1908, by Calmette and Guérin.

In France, vaccinal coverage rate up till now was 84% at 24 months and 95% at 6 years, which is excellent.

The only available strain so far in France was the “Mérieux”. It was replaced in 2005 by a more immunogenic Danish strain, called “Copenhagen” (Danish 1331) from the Statens Serum Institute (SSI).

The “Mérieux” strain’s elimination is accompanied by the phasing out of the multipuncture Monovax® ring vaccination device which was in frequent use in France, in particular for infants.

The Copenhagen strain will now be the only vaccination option, but it is done by intradermal injection which requires more technical skill than is needed with the multipuncture device. Some practising physicians, in particular paediatricians, were not trained in intradermal injection techniques. Furthermore, among the adverse effects frequently encountered with either of the strains, are subcutaneous suppuration on the vaccination site and adenitis in the territory adjoining the site of vaccination. Although these complications always clear up in patients who are not immunodepressed or suffering from any generalised disease, which would be contraindications for this vaccination, they can lead to irreversible and unattractive scarring. Some rare forms involving undiscovered immunodepressed patients can be lethal.

“BCGitis”² is most frequently observed in children vaccinated before six months or even one year of age. It is all the more frequent when the vaccination technique was faulty.

² Suppuration on the vaccination site and in the lymph node drainage territory.

However, the BCG vaccine only has proven efficacy in the more severe forms of the disease, in particular in children, for miliary TB and tuberculous meningitis. 100 million doses annually could prevent 30,000 cases of tuberculous meningitis and 11,000 cases of miliary TB, meaning that 2,500 vaccines prevent 1 case of tuberculous meningitis in 1 child. BCG's efficacy is considered to be rather variable (50%) for the other usual forms of tuberculosis³. For this reason most industrialised countries have stopped its generalisation and in fact refer to the intradermal tuberculin skin test to treat infected patients and stop the dissemination of the bacillus*. The microbe is disseminated by aerosol from cough and sputum so that tuberculosis is still a highly contagious disease. Furthermore there are growing numbers of multidrug-resistant (antibiotic-resistant) strains.

A combination of factors: incidence of TB which is still high in vulnerable populations, the end of use of Monovax®, the mandatory use of intradermal skin testing, the excessive burden of "BCGitis" and insufficient protection provided by this vaccine against the usual forms of the disease, led to an enquiry followed by a recommendation to drop the systematic use of this form of vaccination. The *Conseil Supérieur d'Hygiène Publique de France* and the *Académie Nationale de Médecine* approved the plan to adopt a vaccination policy targeting only at-risk sections of the population.

And yet France depends on generalised prevention using BCG. Screening is less and less frequently used and is replaced by this vaccination. This attitude is in contradiction with that of a large number of countries, which do not use the BCG or limit its use to certain people, but have adopted a very active screening policy.

This strategy should be kept in mind before proposing major changes in the BCG vaccination technique. If we stop using generalised vaccination but keep screening at its present level, there is a serious risk of TB recurrence. Targeted vaccination will have limited efficacy if it does not go hand in hand with a generalised screening policy. BCG vaccination is no replacement for screening. Paradoxically, it can hamper screening by not allowing the intradermal test to discriminate.

IV Public health, precariousness, economic and social fragility

³ B. Bourdin Trunz, P.E.M. Fine, C. Dye, *Effect of BCG vaccination on childhood tuberculous meningitis and miliary tuberculosis worldwide : a meta-analysis and assessment of cost-effectiveness*, The Lancet, 2006, vol 367, pp. 1173-1180

* BCG is not used in the Netherlands, Germany and North America. It is only administered to at-risk « groups » in the U.K., Switzerland and Sweden (where an upsurge of cases has been noted)

Even without a clear definition of precariousness, the connection is clear, for this disease particularly, between social, economic and geographic conditions and the risk of contracting TB. The difficulty lies in defining the role of the public health system. Should its mission be to take on medical issues alone without reference to conditions of onset? If their task is limited to pathology, there may be criticism that the sources of the pathology are not being considered. But if they are taken into consideration, the system may well be overwhelmed by societal problems it is not equipped to handle.

In addition to the above, the public health authorities are concerned about the existence of a dual-track individual or community policy. A priori, and this is another paradox, public health is directly concerned with group health at a time when individualised management of disease is in demand. Society is trying to protect the group but individuals wish to protect themselves while ignoring the potential contradiction between the two postulates.

Protecting the group necessarily means limiting the freedom of individuals. Even though it may appear obvious that a person with tuberculosis needs treatment, society is still aware of the risk that person represents. This has already been addressed in a referral regarding treating for TB with the risk of microbial dissemination by homeless people rejecting the very notion of treatment. CCNE had expressed an opinion which can be summed up as saying that society's debt to those persons gives them more rights over society through their disease than society has over them.

V Ethical issues

The Committee appreciates the gap which may exist between a decision that is a sensible one in medical terms, to cease using a vaccine that seems to *no longer be useful to the greater majority* of people, and the ethical and social implications of that decision. There is a risk that only the “at-risk” sector of the population will be the target of a public healthcare operation which could seem discriminatory or stigmatising and furthermore difficult to implement.

The Committee is also aware of the dubious connotations that may be attached to the verb “targeting”, which is not a neutral word. We must keep in mind that an expression such as “targeting a population” strikes an insidiously aggressive note so that it should be used sparingly unless a more suitable form of words can be found.

1) Vaccination

- **1.1** Is ceasing to practise systematic vaccination and replacing it with targeted vaccination likely to protect vulnerable children or reduce the risk they represent for others? Although obviously the first of the two justifications is preferable, both are ethically acceptable. Even if targeting is designed to improve the sanitary conditions in which targeted populations are living, the main objective should not be to protect society from them. It need hardly be said that the reduction of the incidence of tuberculosis in vulnerable sections of society is bound to reduce the risk for the population as a whole. But reducing that risk should not be the prime objective.

- **1.2** To target a population, its characteristics must first be defined. Will ethnic origin be the criterion, or where the population concerned lives, or the family's income, or how comfortable are the homes they live in? This lack of precision which administrative services are left to deal with could result in the BCG becoming a social label. Even in the event that administrative services were not involved as such, and the responsibility taken on by the medical profession, the list of situations motivating a recommendation to vaccinate can only lead to confusion because of its very imprecision. Instructions can turn into forceful recommendations. It would be unacceptable to move from a generalised and systematic procedure to a targeted "systematic" situation. The risk of stigmatisation becomes very serious and could mean that people who are seen to be dangerous if they are not vaccinated become scapegoats to be blamed if endemic situations persist.

- **1.3** If vaccination becomes *de facto* discriminating, even if the discrimination is said to be "positive", would there not be a risk that people would try to evade the measure or be obliged by administrative services to submit in a situation that becomes coercive? There could be, for instance, in a school where pupils come from various kinds of population, the difficulty of choosing who would or would not be vaccinated and the stigmatising consequences of that selection.

- **1.4** Would it be possible to vaccinate consistently only the targeted population without this objective becoming in fact more of a segregation than a protection? If vaccination were one day considered to be effective, would it not be generalised immediately?

2) Screening

- **2.1** Could at-risk persons be more difficult to screen because they are vaccinated? In other words, if protection is considered to be poorly effective, people who are less exposed will in the end be more easy to screen by intradermal tuberculin skin tests than more vulnerable people, since there can be confusion between a positive intradermal reaction connected to BCG and an intradermal reaction connected to latent TB infection or tuberculosis. This situation could change if cell-mediated immune response tests now being validated turn out to be discriminating.
- **2.2** Tuberculosis is a disease which is very closely correlated with social and economic inequalities and disparities.

This is justification enough for society to be duty-bound to seek out more vulnerable persons within the population, but not hunt them down. The healthcare provisions for screening should be as welcoming and as wide open as possible and sited where such persons are to be found. Conditions in which screening is organised should include a reinforcement of the institutions capable of implementing the operation (school-based healthcare, prisons, national borders, etc.) and also specific training for medical and paramedical staff concerned.

Welcoming vulnerable persons cannot be limited to a screening process accompanied by deterrents in the form of identity checks. Priority in this respect should be given to the creation of anonymous, free of charge screening centres following the model of the anonymous free screening centres for HIV contamination, and should provide for the individual's personal consent. If this were the case, people being screened would be favourably disposed to receiving healthcare, assistance and vaccination. The central object of the operation is above all to help those who are the most vulnerable.

The major condition of an effective healthcare policy is that there should be access without fear to healthcare structures. The major risk of targeted vaccination is that it could be cancelled out by an avoidance strategy. In this respect, the positive action of associations should be encouraged.

These comments are similar to those already formulated by CCNE as regards the ineffective and even counterproductive character of mandatory or oriented screening for potentially HIV-positive persons.

As regards the monitoring of the younger and more vulnerable members of the population, there are several causes for concern: the sparse resources made available to school-based healthcare, the failings of so-called proximity healthcare (free clinics, NGOs, associations), and finally the serious consequences owed to the conditions outlined in the circular dated February 21st, 2006, giving the police force the authority to intervene in certain “hospital facilities”...

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Recommendations

CCNE recommendations are the following:

1. Even though the Committee does not wish to take a stand in the debate concerning the cost-to-benefits ratio of this kind of vaccination, although it considers that, taking into account the recently published epidemiological studies carried out in countries who have conducted an effective screening, prevention and evaluation programme, the elimination at some future point of the mandatory features which now prevail could be reviewed, it recommends the most extreme caution in processing plans to suppress the generalised BCG vaccination, because the ex abrupto cessation of this systematic vaccination, without prior implementation of well-organised screening on a national scale, would inevitably lead to an increase of the risk of tuberculosis, in particular in its severe forms.
2. The Committee therefore recommends that any change in the BCG vaccination policy should be preceded by a reinforcement of generalised screening practices, particularly for schoolchildren (school-based healthcare should be a primary concern), in geographic areas which are particularly exposed (the greater Paris area (Ile de France) and large conurbations in particular) and for persons judged to be at risk because they come from countries where TB is highly endemic or they are living with contaminated persons.
3. Since the existence of people who are particularly exposed to risk is indisputable, the Committee recommends that specific attention paid to such persons both as regards screening and vaccination does not become a policy applicable in particular to any given population. Targeting based on purely social, economic and geographic criteria could be seen as a form of discrimination or serve as an alibi for discrimination in disguise.

4. The Committee recommends that this vaccination, if it is to be reserved for certain persons, should only be practised in the case of infants and children for strictly medical reasons, evaluated by the physician exclusively (in schools, centres for healthcare to mothers and children, by paediatricians and general practitioners) who would need of course to take into account specific social situations, to the exclusion of any negative discriminating procedure.
5. CCNE recommends that anyone professionally exposed to a risk of contamination be able to apply for screening, without necessarily targeting persons whose work puts them in contact with socially vulnerable children or from particularly exposed countries. Furthermore, only physicians, assisted by social workers and nursing staff, will be allowed to evaluate the specific conditions of a high-risk situation.
6. CCNE would hope that on this occasion when thoughts turn to public health matters, that some consideration could be given to reinforcing the resources available for school-based healthcare, occupational medicine and training general practitioners for assistance to vulnerable persons, rather than to make such persons bear the blame for an ever present risk.
7. The Committee would like to awaken more interest in the usefulness of intradermal tuberculin skin test screening generalised for all schoolchildren and not just limited to children described as targets. CCNE recommends that the intradermal injection technique should be encouraged and revived and that nursing staff should be trained in this technique, which is necessary, according to present international recommendations, for BCG vaccinations and verifying cutaneous reactions to tuberculin.
8. It recommends that screening for tuberculosis should reach out to people by facilitating access to “anonymous and free” healthcare structures, managed by social institutions (“street medicine”) to avoid the fears that some people may have that their health status could lead to negative consequences for their social reinsertion.
9. CCNE recommends that cost benefit evaluation of generalised screening be carried out and renewed at intervals for a certain period of time, given that such screening would represent an essential preamble to eliminating generalised vaccination.

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