European survey of BCG vaccination policies and surveillance in children, 2005

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Abstract

In 2005, all 25 EU countries, as well as Andorra, Bulgaria, Norway, Romania and Switzerland, participated in a survey on BCG vaccination in children. BCG was recommended nationally for children under 12 months in 12 countries, in older children in five countries and in children at risk (from origin, contact or travel) in 10 countries. Seven countries did not use BCG systematically. Revaccination was practised in four countries. In countries with universal vaccination, BCG coverage was high (83.0% to 99.8%). TB cases commonly occurred in vaccinated children (at least 30%-98% in five countries using universal or high-risk approach). Disseminated infection due to BCG was rarely reported in recent years (0-1/100 000 vaccinated). There is a wide variation among BCG recommendations in Europe, and nearly half the countries surveyed were considering revisions, at a time when the European Centre for Disease Prevention and Control is advocating for harmonised vaccine strategies. Data on monitoring of BCG coverage in target groups is important but often lacking in Europe. Information on BCG status and eligibility should be collected routinely through TB case notification. The incidence of severe adverse effects of BCG in children should be monitored. Given lack of evidence to its efficacy, revaccination should be discontinued.

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Introduction

In most of the countries in the European Union (EU) and western Europe, tuberculosis (TB) notification rates are lower than 20 cases per 100 000 population [1]. In recent years, TB incidence has continued to decrease by around 4% yearly overall in the EU, to reach a mean notification rate of 13.8 per 100 000 in 2003. However most of the decrease has occurred among individuals originating from EU countries, while rates have remained stable, at much higher levels, in people of foreign origin, most of whom come from countries with high TB incidence. The proportion of cases of foreign origin has increased steadily to reach at least 31% of TB cases notified in 2003.

The decrease in overall incidence of TB, coupled with the increasing proportion of cases among patients originating from high incidence countries, has led to important modifications of BCG policies since the 1960s [2,3]. In a growing number of European countries, BCG vaccination has been discontinued or has been limited to children 'at risk', such as those born in or originating from countries with high prevalence. Additionally, BCG revaccination has been progressively abandoned.

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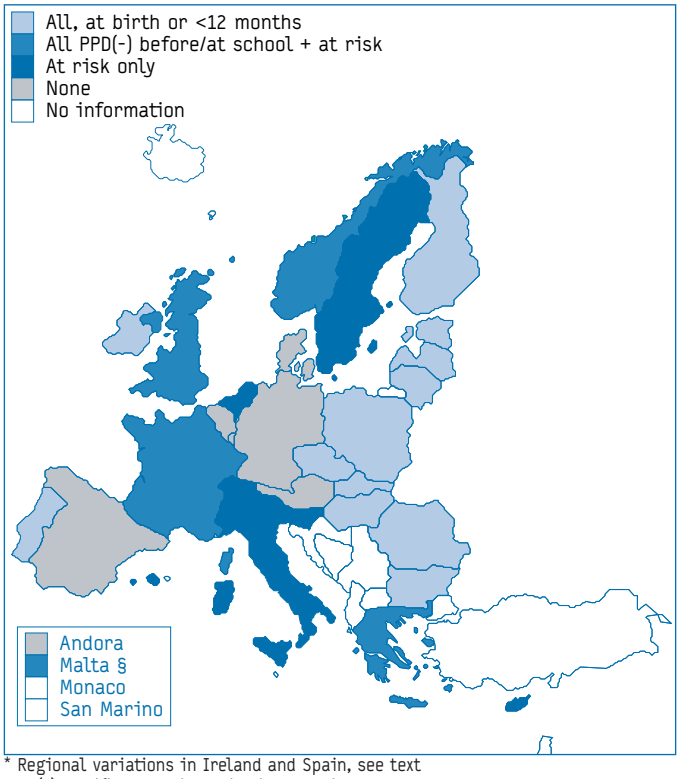
BCG vaccination has no sizeable impact on TB transmission dynamics as its effectiveness has been mainly demonstrated in childhood, when tuberculosis is rarely contagious. Studies in European countries have shown that discontinuing BCG vaccination in children or decreasing its coverage results in an increased incidence of TB [4-6] and other mycobacterial diseases in children [7,8]. In Sweden, when the BCG vaccination strategy was changed from one covering 95% or more of all newborns to one targeting only children at higher risk, there was a temporary increase in TB rates observed in Swedish-born under-5 year olds although rates remained very low since then [6,9]. The occurrence of serious TB since has been extremely low (0.2 per million person-years) but half the cases occurred in unvaccinated, at-risk individuals who might have benefited from BCG.

In 2005, EuroTB undertook a survey of BCG vaccination policies and vaccination-related surveillance in children in Europe. The aim of the survey was to update information useful for describing and comparing BCG policy and surveillance in Europe and to stimulate further European collaboration in this area.

Figure 1

Groups of children targeted for BCG in national recommendations*, Europe, 2005



* Regional variations in Ireland and Spain, see text
PPD (-): Purified protein derivative negative
§ Schoolchildren only

Methods

A questionnaire was developed, field tested by national EuroTB correspondents in three countries and distributed in March 2005 to national EuroTB correspondents in the 25 EU countries, seven other European countries with low TB incidence (Andorra, Iceland, Israel, Monaco, Norway, San Marino and Switzerland) and four EU applicant countries (Bulgaria, Croatia, Romania and Turkey). A reminder was sent one month later. All questionnaires received up to early July 2005 were validated through communication with responders. Countries defined children as individuals aged 0-14 years, except the Netherlands, where children were defined as being aged 0-12 years. Data on paediatric TB notification in 2003 were extracted from EuroTB databases. Responses were accepted up to September 2005.

Table 1

TB notification rates per 100 000 (2003), BCG recommendations in children (2005), and BCG coverage, Europe

	TB notification rates, 2003			Groups of children targeted for BCG vaccination, 2005							BCG coverage			Changes to BCG policy being considered?
Country	Overall	Children	Rate Ratio (adults: children)	All, at birth or <12 months	All, older age	Parents from / birth in high incidence areas	Travel to high incidence areas	Family history of / Contact with TB case	Other risk	No systematic use	%	Year		
Bulgaria	41.3	16.1	2.8	X*			-				n/a	-		No
Czech Republic	11.3	0.7	18.9	X*							98.8%	2003	*	Yes
Estonia	47.1	1.9	29.3	X							97.0%	2004		Yes
Finland	8.0	0.4	24.0	X							98.0%	2002		Yes
Hungary	27.8	0.6	55.0	X							99.8%	2003		No
Ireland	10.6	2.8	4.5	X	X (reg.)	X (reg.)	X (reg.)	X (reg.)			90.2%	2004	§	Yes
Latvia	74.8	30.3	2.7	X							99.7%	2004		No
Lithuania	81.9	20.5	4.7	X							98.9%	2004		No
Poland	26.2	1.5	20.9	X*							95.0%	2003	*	Yes
Portugal	41.1	5.0	8.0	X							83.0%	2003		No
Romania	141.6	43.5	3.7	X							98.6%	2003		Yes
Slovakia	18.2	2.1	10.3	X*							98.1%	2003	*	Yes
Malta	1.8	1.3	1.5		X						87.0%	2004		Yes
France	9.8	2.7	4.3		X				risk environment		95.0%	1997	†	Yes
Norway	7.5	2,0	4.4		X	X		X			>95.0%	2002	†	Yes
United Kingdom	12.3	3.4	4.2		X	X					75.0%	n/a	†	Yes
Greece	5.6	1.1	5.5		X			X			31.3%	2003	†	No
Sweden	4.6	1.1	4.9			X	X	X			88.0%	2004	‡	No
Netherlands	8.2	2.0	4.8			X	X				60-90%	2000-4	**	Yes
Slovenia	14.8	3.1	5.4			X			HIV+ mother		70-90%	2004	§§	No
Switzerland	8.7	2.1	4.7				X				n/a	-		No
Cyprus	4.4	0.0	-					X			n/a	-		No
Italy	7.9	2.2	3.9					X			n/a	-		No
Andorra	12.6	0.0	-							X	-	-		No
Austria	12.1	3.2	4.3							X	-	-		No
Belgium	10.9	4.0	3.1							X	-	-		No
Denmark	7.3	3.3	2.5							X	-	-		No
Germany	8.7	2.3	4.3							X	-	-		No
Luxembourg	11.9	1.2	12.0							X	-	-		No
Spain	18.2	8.2	2.4	X (reg.)						X	-	-		No

(reg.) = regional policy; n/a = not available; - = not applicable

* revaccination also recommended; BCG coverage only refers to newborns

§ coverage estimated in 4 regions + 1 unit

† coverage among older children

‡ coverage among all three target groups (at 2 years of age)

** coverage among children of parents from high incidence country (calculated for 4 areas)

§§ coverage among children of parents from high incidence country; 98% for children of mother with active TB or HIV

Results

Questionnaires were returned from 30 countries (all 25 EU countries, and Andorra, Bulgaria, Norway, Romania and Switzerland), a response rate of 83% [FIGURE].

National BCG recommendations and practices

BCG recommendations in children were applied nationwide in 28 countries but had notable regional variations in Ireland, where neonatal BCG was used in 6/8 regions, and in Spain, where national recommendations discourage routine BCG vaccination, while neonatal vaccination is only practised in one region. In this description of national policies, these two countries are classified according to their national recommendations [TABLE 1].

BCG vaccination was recommended nationally for:

- all children at birth or under 12 months of age in 12 countries;
- older children before starting kindergarten/school or at 6-14 years in five countries;
- selected groups of children at risk in 10 countries, including four of those where all older children were vaccinated.

In seven countries BCG was not used systematically in any group of children [TABLE 1]. In two of these countries, BCG was administered on an individual basis to children planning to have a long stay in a high TB incidence area (Denmark), or to live permanently in such an area (Belgium).

Revaccination of all or of PPD (purified protein derivative) negative older children was recommended in four of the countries where BCG was recommended at birth: Slovakia (PPD negative at 11-13 years), Czech Republic (PPD negative at 10 years), Poland (all at 7 years and PPD negative at 12 years) and Bulgaria (all at 7-10 months, 7 years, 11 years, 17 years).

Groups of children targeted for BCG vaccination

The definition of children at risk for whom BCG vaccination was recommended varied across countries [TABLE 1], and included one or more of the following reasons:

- born in, or with parents/family originating from, high incidence areas — 5 countries
- contact with or family history of active TB — 5 countries
- travel or planned residence in high incidence countries — 3 countries
- born to a HIV-infected mother — 1 country
- 'risk environment', not further specified — 1 country

Furthermore, the exact meaning of these groupings differed between countries. Likewise, the age range for vaccination and the recommended minimum age for PPD testing before BCG administration varied.

Date of issue or last update of recommendations and plans to change BCG recommendations

BCG recommendations were last updated before 2000 in 10 countries and in 2000 or later in 19 countries. In 12 countries there were ongoing discussions or plans to change or update national BCG recommendations, including 7 of the 21 countries that had already updated recommendations since 1999. Planned changes included:

- Shifting from universal vaccination to vaccination of children at risk — 4 countries
- Stopping school vaccination, strengthen vaccination of newborns at risk — 1 country
- Defining a policy for travellers — 1 country
- Defining a policy for children of HIV+ mother — 1 country
- Stopping vaccination of children at risk — 1 country
- Discontinuing neonatal BCG in selected areas — 1 country
- Stop revaccination — 1 country
- Decreasing number of revaccinations — 1 country
- Not specified — 1 country

Countries without systematic use of BCG were not currently considering changes to their policies.

BCG coverage

In 11 of 12 countries implementing universal BCG vaccination of newborns, BCG coverage ranged from 83.0% to 99.8% (no data for Bulgaria) [TABLE 1]. In countries where only older children were vaccinated, coverage of BCG vaccination was low in Greece (31%) and ranged from 75% to over 95% in the other four countries. Coverage data for children originating from a high TB incidence area was not available in the United Kingdom (UK); this data ranged from 60% in two rural areas to 90% in two urban areas in the Netherlands; coverage was estimated at between 70% and 90% in Slovenia and was considered to be 'high' in Norway. In Sweden, coverage was 88% overall for all three groups of children targeted for BCG vaccination.

No coverage information was reported for vaccination of children travelling to high TB incidence areas or contacts of TB cases. In Slovenia, coverage of the newly introduced recommendation to vaccinate newborns of HIV-infected mothers was estimated to be 98%.

Table 2

BCG eligibility and BCG status among paediatric tuberculosis cases*

Country	Criteria used to define BCG eligiblity	Childhood BCG coverage §	Paediatric tuberculosis cases							
			Years	Total notified	Eligible for BCG		Vaccinated with BCG		BCG status unknown	
					N	(%)	N	(%)	N	(%)
France	No information	80-95%	2003	311	n/a	-	193	(62.1)	64	(20.6)
Ireland (6/8 regions)	All newborns	90%	2000-2003	42	42	(100.0)	18	(42.9)	10	(23.8)
Latvia	All newborns	100%	2004	110	108	(98.2)	108	(98.2)	0	(0.0)
The Netherlands	Child / parent national of a high incidence country	60-90%	1993-2003	715	517	(72.3)	215	(30.1)	68	(9.5)
Sweden	Risk linked to origin, travel, or contact	88%	2000-2004	94	91	(96.8)	44	(46.8)	28	(29.8)
United Kingdom	Non-white child	75%	not stated	389	324	(83.3)	n/a	-	n/a	-

* 0-14 years, except The Netherlands (0-12 years)

§ among all children targeted (see also Table 1)

BCG coverage and eligibility among paediatric TB cases

Among children with tuberculosis, information on BCG status was collected through TB notifications in 15 of the 23 countries that used BCG systematically. At least five of 10 countries recommending BCG for children at risk collected information on whether paediatric TB cases had been eligible for BCG or not.

Data about the BCG vaccination status and/or eligibility for BCG among children with notified TB infections were provided by six countries [TABLE 2]. Information on BCG status was frequently incomplete. In Ireland and Latvia, where BCG was recommended for all newborns (coverage >90%), and in France (coverage >80% at 2 years and 95% at 6 years), the majority of notified paediatric TB cases for which information on BCG status was available occurred in vaccinated children.

Three of the countries with targeted BCG recommendations provided information on BCG eligibility for paediatric TB cases. The majority of paediatric TB cases reported were in children who had been eligible for BCG. In the UK, 83% of the cases were considered eligible when non-white ethnicity was taken as a proxy of origin from a high incidence country. In the Netherlands, 72% of cases notified between 1993 and 2003 were in children who had (or were born into a family with) foreign citizenship. In Sweden, 99% of the cases (2000-2004) belonged to one of the three groups targeted for BCG.

Among the four countries with information about both BCG status and eligibility, only Latvia reported 100% vaccination coverage among eligible cases, with the other three countries achieving less than 50% coverage.

Mycobacterial disease other than TB in children

The questionnaire addressed availability of data on the frequency of mycobacterial infections other than TB in children. Data on mycobacterial infections other than TB in children were available in eight countries. All mycobacterial isolates are notifiable by laboratories in Finland, Norway and Sweden. Data are available from the national reference laboratory in Denmark and from TB case notification in the Czech Republic and in Italy. Sentinel surveillance of these infections, based on hospitals and laboratories, exists in Germany and in certain parts of Spain. Specific studies are known to have been carried out in Spain [8], Sweden [7] and the UK [10].

Surveillance of disseminated BCGitis

A surveillance system or a source of data on disseminated infection due to BCG (BCGitis) was reported to exist in 13 countries, as part of surveillance of adverse effects following immunisation (AEFI) or of reporting systems for severe adverse effects of drugs and medical products [TABLE 3]. In Sweden a specific study has estimated the incidence of disseminated BCGitis at 4 per 100 000 infants born in Sweden and vaccinated at birth for the period 1979-1991 [11].

Discussion

While the response to this survey was high, information from six countries (Croatia, Iceland, Israel, Monaco, San Marino and Turkey) was not available. The interpretation of target groups differed between countries and the availability and the completeness of data requested also varied, rendering comparison problematic at times.

This survey confirms the wide variability and the continuing evolution of BCG recommendations in Europe that has been highlighted in previous surveys [2,3]. Nearly half the EU countries were considering changes to their policy. Universal vaccination of newborns remains recommended in all countries with higher notification rates (over 20 cases per 100 000). In countries with lower incidence, recommendations were very diverse, ranging from no systematic use of BCG in children in seven countries to universal use of BCG at birth in four countries with revaccination in older age groups in two of them. In five countries, all PPD negative children were vaccinated before starting or leaving school, including the UK, where the school vaccination programme has been discontinued since this survey was conducted.

Table 3

Data on disseminated BCG infections, Europe

Country	Data source	Years	Total vaccinated	Cases of disseminated BCG infections
Cyprus	TB case reporting	2001-2004	n/a	0
Denmark	Surveillance of AEFI*	-	-	-
Finland	Surveillance of AEFI, clinician reporting and laboratory reporting	2001-2004	220 860	4 (3 osteitis, 1 miliary)
Hungary	Routine reporting	1991-1994	n/a	0
Germany	Surveillance of AEFI	2000-2003	n/a	0
Ireland	Irish Medicine Board	1981-2004	n/a	0
Malta	Self report	-	23 843	0
Norway	Surveillance of AEFI	recent years	n/a	less than 1 case per year
Poland	Surveillance of AEFI	2000-2003	2 086 319	0
Portugal	Nat. Inst. of Pharmacy & Medicine	2000-2004	472 120	1
Slovakia	National reporting system	2001-2003	233 605	2
Sweden	Specific study#	1979-1991	101 000	4
	Medical Product Agency and laboratory reporting	1992-2004	n/a	0
United Kingdom	Not specified	-	-	-

* AEFI = Adverse events following immunisation

n/a = not available

Romanus et al [11]

Targeted vaccination of children considered to be at risk was the only policy recommended in six countries, two of which were considering changes to this policy, such as stopping BCG before travel and following cases with skin testing upon return. Four other countries were planning to shift to targeted vaccination. Children born in, or with family members from, a high TB incidence area were the most numerous and important risk group targeted for BCG, as they represented over 10% of birth cohorts in many countries. The data on eligibility available from TB notification show that most paediatric TB cases occurred in this group, indicating that it represented a suitable target in the current epidemiological situation in low incidence countries in Europe. However, data also indicate lower coverage in this group compared with coverage of universal neonatal BCG vaccination. Maintaining high coverage in this group may represent the most important challenge to render targeted BCG vaccination effective.

Among the other groups of children targeted for BCG, those travelling to areas with high TB incidence and those in contact with TB patients represented smaller groups, in which an individual risk assessment is often required before vaccination. Data on coverage in these groups were generally not available. Defining 'travellers at risk' presents difficulties linked to duration, destination and type of contact during the stay. Vaccination of children travelling from low incidence areas to high incidence areas is included in World Health Organization (WHO) recommendations for travellers [12]. Use of BCG in PPD negative children who are in prolonged contact with TB patients, or who have a family history of TB, was recommended in some countries, with indications being frequently very specific. The implementation of this policy could be monitored as part of routine feedback information on interventions following investigations of TB contacts.

In western Europe, an increasing proportion of HIV infections is diagnosed in persons from sub-Saharan Africa or from other high TB incidence countries. Many children originating from such regions are targeted in countries using a high risk approach to BCG. Vaccination of children born to HIV-infected mothers was recommended in only one country and is under consideration in another. In a number of low prevalence countries, including the Netherlands and the UK, HIV infection was a contra-indication to BCG vaccination [13,14]. Infants born to HIV-positive mothers may have their BCG vaccination withheld for a few months after birth until HIV infection can be excluded.

BCG at birth or in infancy significantly reduces the risk of TB by over one half [15]. Tuberculosis case surveillance would thus be expected to be useful in monitoring the efficacy of BCG policies. Unfortunately, it has several limitations. Laboratory confirmation of notified paediatric cases was not frequent in several countries. With the high BCG coverage achieved by many countries implementing universal BCG at birth, most TB cases occur in children who have been vaccinated. In countries with information on BCG status of paediatric TB cases, the proportion of vaccinated cases among paediatric TB cases was highly variable, reflecting mainly the wide range of BCG vaccination strategies and coverage in children. In certain countries using neonatal BCG, higher TB rates in adults compared to children [TABLE 1] may reflect the protective effect of BCG in childhood, although this may be compounded by other issues, such as the proportion of TB cases among recent immigrants.

Information on BCG status and eligibility of notified paediatric TB cases was available in a limited number of countries and is frequently incomplete. In countries with information on BCG eligibility, such as Sweden or the UK, the very high proportion of children eligible for BCG among paediatric TB cases suggests that children at risk are an appropriate target for BCG vaccination and such policies could be effective provided a high coverage is maintained in this group.

The utility of revaccination of children after a first dose in infancy is not confirmed [16]. Only four countries reported this practice, and two of the four were considering the elimination or restriction of revaccination.

Studies have already been undertaken in Europe to weigh the advantages and disadvantages of maintaining universal BCG vaccination against other alternatives [17,18]. One of the advantages of universal BCG is the reduction of disease due to mycobacteria other than *M.tuberculosis* complex. The European experience has shown a marked increase in the incidence of mycobacterial disease other than TB after stopping BCG or targeting BCG to children at risk [7]. However, the size of this effect is hard to quantify as these infections are rarely notifiable in Europe, because most are relatively benign. The frequency of severe adverse effects of BCG vaccination is also important to consider when evaluating the risks and benefits. Serious adverse effects of BCG are rare but may be very severe in immunocompromised children. In Sweden, the recommended age for vaccination was shifted from birth to 6 months following a study showing appreciable occurrence of BCGitis in neonates [11], and the policy was retained despite an increase in the occurrence of atypical mycobacterial disease thereafter [7]. In several European countries, information on disseminated BCGitis is not available, or not readily accessible to TB surveillance teams, while surveillance of adverse effects following immunisation is recommended by WHO.

Conclusions and recommendations

Our study uses surveillance data to describe health policies in the context of a changing epidemiological situation. We trust that our findings will enhance collaboration between European countries and complement the initiatives of the European Centre for Disease Prevention and Control (ECDC) to harmonise vaccine strategies and schedules.

In order to enable monitoring of the effects of any newly introduced policy, such as targeted BCG, surveillance of TB in children should first be strengthened. Monitoring BCG coverage in target groups is important and may necessitate new measures to capture the denominator for certain risk groups (such as travellers to high incidence regions or child contacts of open TB cases). Information on BCG status and eligibility should be routinely collected through TB case notification and regularly analysed.

Operational research, taking into account cost considerations, should be used to augment the knowledge base on the subject and to help decision making.

While HIV infection is a contra-indication to BCG vaccination in a number of low-prevalence countries, the decision to give BCG at birth to the asymptomatic child of a HIV-positive mother should be based on a careful assessment of benefits versus potential adverse effects in a setting at increased risk of tuberculosis transmission .

Given the lack of evidence to its efficacy, revaccination should be discouraged, regardless of TB incidence.

The incidence of severe adverse effects of BCG in children should be monitored as part of the surveillance of adverse events following immunisation and by introducing laboratory reporting. Data on isolates of *M. bovis* BCG or *Mycobacteria* other than *M. tuberculosis* complex in children could be obtained by introducing laboratory reporting of all human isolates of *Mycobacteria*, as already exists in Scandinavian countries.

† Andrea Infuso, EuroTB scientific coordinator, died suddenly on September 20, 2005. This Eurorounddup is a posthumous publication.

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ORIGINAL ARTICLES

Surveillance report

PROSPECTS FOR THE BCG VACCINATION PROGRAMME IN FRANCE

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Until recently, the French BCG vaccination programme consisted of a mandatory BCG vaccination before children started at daycare centres, and of re-vaccination of tuberculin-negative children. A re-assessment of this programme has been undertaken in recent years. It has led to the discontinuation of all revaccinations and post-vaccination tuberculin tests except those post-vaccination tuberculin tests performed as part of a diagnosis of tuberculosis infection or disease or of the follow-up of health or social workers for whom BCG vaccination remains mandatory. Based on an estimate of the epidemiological impact of either selective vaccination of high risk children or discontinuation of BCG vaccination, and taking into account the risk-benefit balance that can be made of the two options, the Conseil Supérieur d'Hygiène Publique de France (CSHPF, national high council of public hygiene) has recommended a change to selective vaccination. However, the committee has proposed the strengthening of other control measures aimed at decreasing the risk of infection for children, as a pre-requisite to the implementation of this strategy. This position is made more complex by the withdrawal of the multipuncture technique in early 2006, previously used in France in more than 90% of BCG primary vaccinations.

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