

1 **The impact of Bacille Calmette-Guérin shortage on immunisation practice and**  
2 **policies in Europe – A ptbnet survey**

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55 **Abbreviations:**

56 AE - adverse event

57 BCG - BacilleCalmette-Guérin

58 ECDC - European Centre for Disease Prevention and Control (the)

59 TB – tuberculosis

60 MDR - multidrug-resistance

61 ptbnet - Paediatric Tuberculosis Network European Trials group (the)

62 SSI - StatensSerumInstitut (the)

63 UNICEF - United Nations Children's Emergency Fund (the)

64 WHO - World Health Organization (the)

65 XDR - extensive drug resistance

## **Abstract**

### Background

Universal or selective Bacille Calmette-Guérin (BCG) immunisation is part of tuberculosis prevention in most European countries. Recent reports indicate an ongoing BCG shortage that may influence immunisation practice. This study aimed to determine current availability of BCG vaccine across Europe, and describe the implications on immunisation practices and policies in Europe.

### Methods

Web-based survey among Paediatric Tuberculosis Network European Trials Group (ptbnet) members, conducted between May and October 2015.

### Results

Twenty individuals from 13 European countries participated. BCG was routinely used in 11 countries, comprising BCG-Denmark SSI 1331 (10/11;91%) and BCG-Russia Bulbio Sofia (1/11;9%). BCG was imported (10/11; 91%) or produced nationally (1/11, 9%). The main reported distributors were government agencies or departments of health (5/7; 71%); and in two countries private companies. Ongoing BCG shortages were reported in eight countries (8/11, 73%). Additionally, one country reported a previous shortage that resolved in 2014. As a consequence of the shortage, BCG was not given as completely unavailable in some countries (2/8, 25%), was given only whenever available (1/8, 13%), or only in certain regions of the country (1/8, 13%). Strategies reported to reduce loss of immunisation were administration to selected high-risk individuals (2/8, 25%), or cohorting vaccinees on specific days to maximise the use of multi-dose vials (3/8, 38%). Authorities in two countries each were considering a change of manufacturer/supplier (2/8, 25%) and were stockpiling BCG vaccine (2/8, 25%).

### Conclusions

In this European survey BCG vaccine shortage was reported in eight countries in 2015. In the affected countries the shortage has led to adapted immunisation practices. The proportion of infants and children eligible for immunisation at risk of not receiving BCG is significant. To ensure necessary BCG immunisations, collaboration between national health agencies and vaccine manufacturers is crucial.

## Introduction

Globally, tuberculosis (TB) is one of the most important infectious diseases and children are especially vulnerable [1,2]. Compared to adults, children infected with *Mycobacterium tuberculosis* are more likely to develop active TB disease within a short period of time. In 2014, an estimated 1 million new TB cases and 140.000 TB deaths occurred globally among children below 15 years of age [1]. Although the overall TB incidence in Europe is decreasing, TB remains a major public health concern [3]. The World Health Organization (WHO) estimates that there were 31.000 new TB cases among children in the European Region in 2014, of which only 32% were reported [1]. In many countries, the majority of TB cases are foreign-origin, and with the current migration in Europe this will affect epidemiology in low incidence TB countries [3,4]. Furthermore, with the emergence of multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB, treatment is becoming increasingly challenging, placing further emphasis on the importance of prevention [3].

Infant Bacille Calmette-Guérin (BCG) immunisation prevents severe and disseminated TB in children, and may also protect against latent TB infection [5,6]. The protective efficacy of BCG against drug-susceptible and MDR TB is likely similar and, therefore, BCG immunisation has been suggested as a preventative measure for individuals exposed to MDR-TB [7]. BCG is one of the most commonly used vaccines globally, with approximately 90% of children covered world-wide and over 120 million individuals vaccinated annually [8,9]. In high TB incidence countries, BCG immunisation is a cost-effective intervention and an essential part of TB control and prevention strategies [5].

Currently, three BCG vaccine strains are in large-scale production: BCG Denmark, BCG Russia and BCG Japan [10]. In Europe, BCG Denmark has been the most commonly used BCG vaccine strain in the last decade [11,12].

BCG supply and demand has been influenced by a decrease in manufacturers worldwide together with an increased global demand, likely as a result of rising birth rates and improved immunisation coverage. In 2014, the demand increased by more than 20 million doses, and it is estimated to increase further by an annual 10 million doses [8]. In addition to this, since 2013, a reduced production capacity of two manufacturers, the Statens Serum Institut (SSI) in Denmark and the Serum Institute of India, further affects annual global BCG availability [13]. Although some manufacturers were able to increase their production, the overall BCG availability fell by 6 million doses [8]. In fact, the United Nations Children's Emergency Fund (UNICEF) estimated that in 2014 the global BCG production fell short by over 20 million doses, and that in 2015 the unmet demand carry-over together with growing demand and continuing production shortage may result in a deficit of over 70 million doses [8].

This shortage is likely to affect BCG immunisation practices and coverage in Europe, as universal or selective immunisation is a part of TB prevention in at least 27 European countries [11]. We therefore conducted a survey to determine current availability of BCG vaccine across Europe, and describe the implications on immunisation practices and policies.

## **Methods**

We conducted a web-based survey among Paediatric Tuberculosis Network European Trials Group (ptbnet) members between May 2015 and October 2015. Ptbnet comprises clinicians, microbiologists, epidemiologists and researches with a special interest in paediatric TB [14,15]. At the time of the survey, ptbnet had a total of 117 members in 25 European countries. Members were invited by e-mail to participate in the survey, which included 16 questions on the participant's demographics, use of BCG vaccine, BCG availability, and consequences of possible shortage. Answers were collected through Google Docs software (Google Inc., Mountain View, CA, US) and/or Word questionnaire (Microsoft Corporation, Redmond, WA, US). Participants were allowed to reply to all or only some of the questions. The full questionnaire and the response rates to each question are shown in the supplementary data. Two reminders were sent: to all members in September 2015, and only to the designated ptbnet representative of member countries in October 2015. In instances where responses were unclear or conflicting, these were clarified through email until January 2016. The final data were collated into and analysed using Excel (Version 2011, Microsoft Corporation, Redmond, WA, US).

## **Results**

Twenty individuals (20/117; 17%) from 13 European countries (13/25; 52%) participated (Table 1). Respondents were based in Austria, Belgium, Bulgaria, Croatia, Finland, Germany, Greece, Italy, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Respondents from eleven countries reported using BCG as part of their national immunisation programme (11/13, 85%). The most commonly reported vaccine strain used

was BCG Denmark SSI 1331 (10/11, 91%). In addition, BCG Russia Bulbio Sofia was used in Bulgaria (1/11, 9%). BCG was reported to be imported in most countries (10/11, 91%), with the exception of Bulgaria, where it was reported to be produced nationally (1/11, 9%). Respondents reported that BCG was distributed by government agencies or departments of health in most countries (5/7, 71%); in two countries, private companies were reported to be national distributors - Econophar (Kortenberg, Belgium) and Pro Farma AG (Baar, Switzerland). Data regarding the total number of doses imported in 2014 were only available from two countries and therefore not further analysed.

Specific national BCG immunization policies that were reported included selective newborn immunization (5/11, 45%), selective immunisation at a later age (3/11, 27%), or both (1/11, 9%), and universal newborn immunisation (2/11;18%). BCG immunisations were reported to take place in maternity hospitals (3/11, 27%), community health centre in primary care (3/11, 27%), primary school (1/11, 9%), or all of these / multiple places (4/11, 36%).

A current BCG shortage was reported by respondents from eight countries (8/11, 73%). In addition, a respondent from Croatia reported a recent shortage that lasted less than a month; the respondent stated that unmet carry-over immunisations took place when the shortage had resolved. All affected countries were using BCG Denmark. Responses concerning the onset of the shortage varied and were sometimes conflicting; most respondents reported that the shortage had started at some point in 2013.

Changes in BCG immunisation practices or policies were reported by respondents from seven countries (7/8, 86%) (Table 2). Members from Belgium and Italy reported a

discontinuation of immunisations as a result of BCG being entirely unavailable; in Greece, BCG was reported to be given whenever available. In Spain, BCG was reported to be available only in certain regions of the country and, due to the shortage, given only to selected high-risk individuals. Members from Finland, Sweden and the United Kingdom reported cohorting vaccinees on specific days to use as many doses from multi-dose vials as possible. One respondent from the United Kingdom also reported that due to the shortage BCG was only given to selected high-risk individuals. Switching manufacturer and BCG strain were reported to be under consideration in Belgium and Finland. A respondent from Sweden reported that national data about the BCG shortage was being collected. Out of the eight countries in which a BCG shortage was reported, five reported that national BCG stockpiling was not taking place (5/8;63%) and two reported that stockpiling was done (2/8;25%). Public national information about the BCG shortage was reported to be available in five countries (5/8;63%), and unavailable in three countries (3/8;38%).

Shortage of BCG for bladder cancer treatment was reported by respondents from two countries (2/11, 18%) and nine respondents had no personal knowledge on this matter.

## **Discussion**

Our results show that the ongoing global BCG vaccine shortage has significant consequences on immunisation practice in Europe. The survey identified BCG shortages in eight European countries, all of which were using BCG Denmark produced by SSI. A survey conducted in 2013 showed that 24 out of 31 countries in the European Region were using BCG Denmark, and that at least 3 out of the 18 high priority countries in the fight against TB, as defined by the European Centre for Disease Prevention and Control



(ECDC), were using BCG Denmark [3,11]. Therefore, it is likely that the limited supply of BCG Denmark affects also further countries not captured in our survey. Among the countries captured in our survey, only Bulgaria is classified as a high priority country in the fight against TB [3]. Bulgaria uses a nationally produced BCG vaccine, and no shortage was reported from this country.

Our results also highlight that in many European countries on-going BCG shortages have resulted in changes in immunisation practices and policies. One approach is optimising the use of multidose BCG vaccine vials by centralising and cohorting BCG immunisations to reduce vaccine loss, and there is some data to support that this may be effective. Unpublished data from Finland suggest that centralising immunisations and giving BCG only on specific dates using multidose vials resulted in halved vaccine consumption (personal communication from Pertti Sormunen, Director of Pharmaceutical Wholesale, National Institute for Health and Welfare, Finland, April 19, 2016). However, a report from Australia where a similar approach was used, estimated vaccine wastage to be around 75% [16].

Another option to address the ongoing shortage is changing the BCG vaccine manufacturer. In our survey, authorities in two countries (Belgium and Finland) were reported to be considering an alternative manufacturer. As of April 2016, two countries captured in the survey (Finland and Sweden) have changed the manufacturer and are now using BCG-Japan (personal communication from Pertti Sormunen, Director of Pharmaceutical Wholesale, National Institute for Health and Welfare, Finland, April 19, 2016) [17]. Furthermore, other countries, including France and Australia, have temporarily replaced BCG Denmark with BCG Brazil manufactured by Biomed Lublin in Poland

[18,19]. Considering the ongoing BCG Denmark vaccine delivery delays, it appears likely that further countries in Europe and globally will change to another BCG manufacturer, resulting in a change of the BCG vaccine strain used in their national immunisation programmes.

Importantly, changes in the BCG vaccine strains may have significant consequences. Different BCG vaccine strains have been shown to influence the immune response and protection against TB [9,10,20]. However, it currently remains unclear which BCG vaccine strain offers the best protective efficacy, and consequently any change might affect protection on a population level. In addition, previous reports have shown that changes in the BCG vaccine strain can be associated with an increased incidence of BCG-associated adverse events (AEs). For instance, in 2002 Finland changed from BCG Glaxo to BCG Denmark, as the production of the former was discontinued. In the subsequent two years the incidence of BCG-associated AEs increased considerably, which, in combination with a decreasing TB incidence, ultimately led to discontinuation of universal BCG immunisation in Finland in 2006 [21,22]. Similarly, a change from BCG Connaught to BCG Denmark in Australia in 2012 led to, when administered doses were taken into account, an estimated increase incidence of BCG-induced abscesses and lymphadenitis [16]. AEs related to immunisations cause concern in both healthcare professionals and the general public, potentially impacting the general attitude on vaccinations and thereby influencing immunisation coverage rates. Thus, monitoring protective efficacy and AEs after a BCG vaccine strain change is important.

It appears obvious that the problems related to the ongoing BCG vaccine shortages cannot be solved by changing the vaccine manufacturer, as this approach simply shifts the

demand to another manufacturer. It is therefore important that supranational health organisations, such as UNICEF, WHO and ECDC, engage with vaccine manufacturers to jointly devise mechanisms that ensure a stable BCG vaccine supply that meets global demand. Notably, in December 2015 UNICEF reported having increased orders with three manufacturers amounting to an additional 38.3 million BCG doses in 2015, which still left an estimated deficit of 16.5 million doses that year [23]. In addition, the communication between manufacturers, national public health agencies and end users of the BCG vaccine requires improvements so that the immunisation services can adapt timely in the event of future shortages.

**Conflicts of interest**

None.

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**Table 1.** Demographic details of participants and summary of BCG use and shortage

	n	%
<b>Participants working at</b>	20	100
Paediatric hospital	16	80
General hospital	3	15
Outpatient Tb specialised clinic	1	5
<b>Countries</b>	13	100
Not routinely using BCG(Austria, Germany)	2	10
No current shortage (Bulgaria, Slovenia, Croatia*)	3	15
Currentshortage (Belgium, Finland, Greece, Italy, Spain, Sweden, Switzerland, United Kingdom)	8	75

\* reported a recent shortage prior to the survey being conducted

**Table 2.** Details of BCG shortage and reported consequences for immunisation practice and policy

Reported current BCG shortage	Country	TB incidence / 100,000 in 2014 [1]	BCG coverage in 2014 [24]	BCG strain used	BCG immunisation policy ***					BCG shortage consequences				BCG stockpiling			
					Universal newborn	Selective newborn	Selective at older-age	No BCG given	BCG given only to selected high-risk individuals	Other (reported in comment section)				NS	Yes, national	No	NS
										Cohorting vaccinees	Considering manufacturer and strain change	Available only in some regions	Used whenever available				
No	Bulgaria	27	97%	R	x												x
	Croatia*	12	98%	D	x												x
	Slovenia	7.7	NS	D		x											x
Yes	Belgium	9	NS	D			x	x			x						x
	Finland	5.6	NS	D		x				x		x				x	
	Greece	4.8	NS	D			x					x				x	
	Italy	6	NS	D		x		x									x
	Spain	12	NS	D		x	x		x								x
	Sweden	7.5	26%	D			x			x							x
	Switzerland	6.3	NS	D		x							x				x
	UK	12**	NS	D		x			x								x

\* reported a recent shortage prior to the survey being conducted  
\*\* incidence in United Kingdom of Great Britain and Northern Ireland (the)  
\*\*\* as reported by participants of the survey  
NS – not specified  
UK – United Kingdom  
R – BCG-Russia/Bulbio Sofia  
D – BCG-Denmark SSI 133

## Supplementary data. Survey questionnaire and response rates.

Questionnaire section	Question	Answer option	Drop-down options	Response rate
Responder details	Name	Freetext		100% (20/20)
	Contact e-mail	Freetext		100% (20/20)
	Country	Drop-down	List of countries	100% (20/20)
	Type of institution	Drop-down	Paediatric Hospital Pulmonary Specialized Hospital Tuberculosis Specialized Hospital General Hospital Outpatient TB Specialized Clinic Primary care Other	100% (20/20)
BCG general	Is BCG routinely given to all newborns?	Drop-down	Yes No, selective newborn immunization No, selective immunization at a later age No, BCG not used in my country	100% (20/20)
	Where is BCG given?	Drop-down	Maternity hospital Community health center Primary Care Private practice International vaccination specialised Centre All of these Somewhere else (where?)	94% (16/17)*
	BCG strain used	Drop-down	BCG Denmark SSI 1331 BCG Russia Bulbio Sofia BCG Russia other manufacturer BCG Japan Tokyo 172 Locally produced BCG Other imported BCG (specify)	94% (16/17)*
	How does your country import BCG?	Drop-down	Produced nationally Imported by a single distributor Imported by several distributors Imported by the government agency/department of health Other (pls specify)	94% (16/17)*
	Specify distributor (if known)	Freetext		41% (7/17)*
	No of doses imported in 2014	Freetext		24% (4/17)*
BCG shortage	BCG shortage present		Yes No Don't know	100% (17/17)*
	Month/Years since start of shortage	Freetext		59% (10/17)*
	Consequences of shortage	Drop-down	No BCG given BCG given only to selected individuals Change in BCG vaccine Other Not applicable	71% (12/17)*
	Form of stockpiling BCG	Drop-down	No Yes, locally Yes, regionally Yes, national Yes, combination of above	65% (11/17)*
	Has there been a national/local information about BCG shortage?	Drop-down	Yes No Not applicable	100% (17/17)*
	Shortage of BCG for bladder cancer treatment?	Drop-down	Yes No Don't know	100% (17/17)*
Comments		Freetext		53% (9/17)*

\* out of 17 participants from countries with either universal or selective BCG immunisation