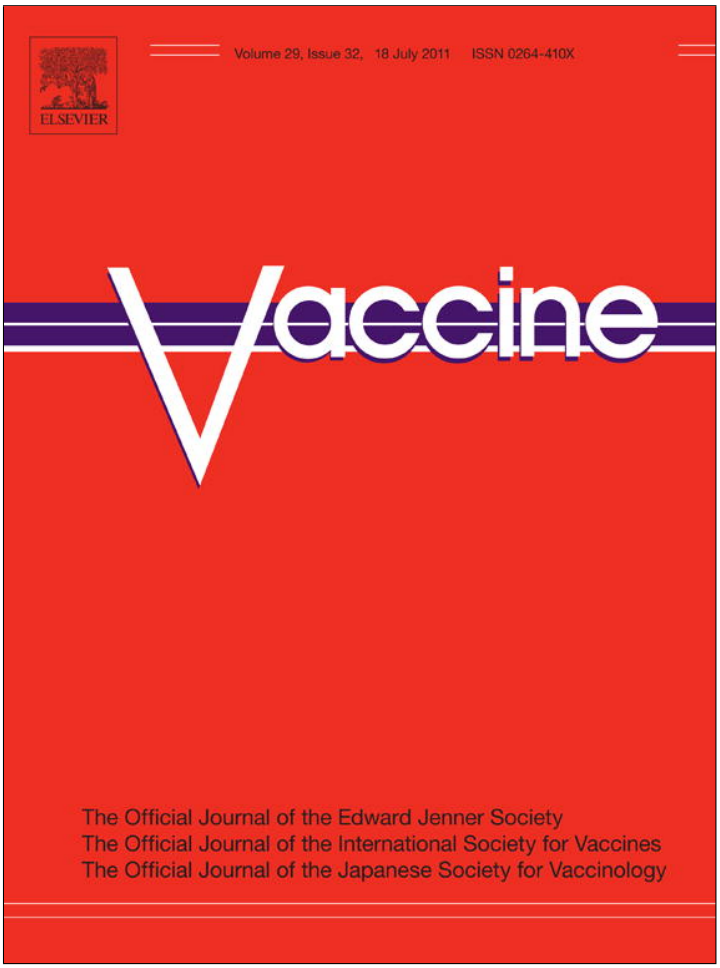

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Barriers to implementation of the new targeted BCG vaccination in France: A cross sectional study

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ABSTRACT

The aim of the study was to assess factors influencing BCG vaccination among targeted children after the end of universal and mandatory BCG vaccination in France. A cross-sectional study was conducted in 2009 among general practitioners (GPs) of the French Sentinel Network. With the participation of 358 physician-investigators, 920 children were included. Of the 261 children (31%) identified to be at risk of tuberculosis, only 113 (44%) were vaccinated. The median number of French criteria for BCG vaccination correctly cited by the GPs was 3 of the existing 6. Of the 10 proposed, a median number of 5 regions in the world according to their level of tuberculosis risk were correctly classified by GPs. After adjustment using an alternating logistic model, 7 variables were found to be associated with the immunisation status of the target population. Six of these increased the probability of being vaccinated: children older than 6 months (OR = 3.4 (CI 95% [1.4–8.6])), residents in central Paris or its suburbs (OR = 14.7 [4.4–49.5]), children expected to travel to highly endemic regions (OR = 3.5 [1.4–8.6]), those living in unfavourable conditions (OR = 19.9 [6.2–63.9]), the GP's good knowledge of vaccination guidelines (OR = 1.4 [1.1–1.9]) and the GP's perception of tuberculosis as a common disease (OR = 2.2 [1.1–4.5]). Surprisingly, GPs with university training on infectious diseases tended to be more reluctant to follow vaccination guidelines (OR = 0.14 [0.1–0.4]). Actions targeted at these factors could contribute to improving BCG immunisation coverage.

1. Introduction

Incidence of tuberculosis gradually decreased in France from 60.3 to 9 cases per 100,000 between 1972 and 2008 [1]. The epidemiology of tuberculosis in France, together with increasing concerns about the adverse effects of Bacille Calmette-Guérin (BCG) vaccination as well as the replacement of the multipuncture device by the intradermal BCG in January 2006 [2–4], led to the suspension of universal mandatory BCG vaccination in 2006. Based on studies estimating the effects of discontinuing or changing the BCG vaccination strategy [5–9], the French Health authorities recommended targeting children considered to be at risk of tuberculosis [10,11], i.e., those (i) living in the region of Paris or French Guyana, (ii) born in a country with a high incidence of tuberculosis, (iii) with at least one parent born in such a country, (iv) planning to stay at least one month in such a country, (v) with a history of tuberculosis in his/her close family, or (vi) any other situation considered to be at risk of exposure to tuberculosis by the physician.

In 2005, Infuso et al. led a survey on BCG vaccination in children in all 25 EU countries, as well as Andorra, Bulgaria, Norway, Romania and Switzerland [12]. 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. There were a wide variation among BCG recommendations in Europe, and nearly half the countries surveyed were considering revisions, at a

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Table 1
Characteristics of 358 French general practitioners (GPs) who participated in the study, *N* (%).

	GPs who participated in the survey, *N* (%), *N* = 358	French metropolitan GPs, *N* (%), *N* = 61,347[a]
Gender (7 missing values): male	284 (81)	39,598 (73)
Age, mean (SD), year (8 missing values)	53.0 (7.7)	51
Region Ile-de-France (Paris and its suburbs)	52 (15)	10,073 (16)
Individual and occupational characteristics		
Part-time activity		
In some specific children's service (8 missing values)	32 (9)	
In hospitals (9 missing values)	50 (14)	
In medical school (8 missing values)	108 (31)	
Academic degree in the field of		
Infectious disease	21 (6)	
Paediatrics	23 (6)	
Alternative medicine	18 (5)	

[a] Data from National Health Insurance on 31st December 2008.

time when the European Centre for Disease Prevention and Control were advocating for harmonised vaccine strategies. Two first experiences of discontinuing BCG vaccination in children gave major data. In April 1975, the Swedish authorities replaced the mass vaccination of newborn against tuberculosis by selective vaccination of groups at risk [13–15]. It caused a decrease in BCG coverage of the risk group recommended for vaccination, resulting in an increased incidence of tuberculosis and other mycobacterial diseases in children. After the end of mass BCG vaccination in a selected area of the Czech Republic in 1986, benefit analysis proved that the advantages and disadvantages of BCG vaccination were in balance [16,17]. The number of nonvaccinated children developing tuberculosis was so small that mass application of BCG has been found to be redundant. In 2005, United Kingdom replaced BCG vaccination by selective vaccination of newborn in group at risk [18]. They have described difficulties in the implementation of the new policy. Due to those difficulties and the risk of increased incidence of tuberculosis, changing BCG vaccination has to be associated with strengthening tuberculosis control, surveillance, and information to health care provider.

Since the withdrawal of the BCG multipuncture device and the end of compulsory vaccination 18 months later in France, several health indicators have shown a decrease in the immunization coverage among the target population [19,20].

This study aimed to: (i) assess factors influencing rate of BCG vaccination in the target population, (ii) describe French general practitioners' (GPs) practices regarding BCG vaccination and (iii) quantify the immunisation coverage of children born after the end of compulsory vaccination.

2. Materials and methods

2.1. Study population and data collection

Between June and September 2009, we led a cross sectional study among GPs of the French Sentinel Network. The Sentinel Network is a computerised system comprising 1298 volunteer GPs located throughout France and participating in the ongoing surveillance of 10 health indicators and in epidemiological studies [21]. GPs of the Sentinel Network are considered to be similar to the population of French GPs regarding regional distribution, proportion of GPs working in rural practices and age [22].

All GPs of the French Sentinel Network were contacted by mail and asked to complete a questionnaire on the last three children they had seen at their practice who were born after the end of compulsory vaccination (July 2007). To be included into this study, children had to be regularly followed by the GP. The questionnaire was split into two parts: the first concerned the GP (demography, practice, questions on knowledge and perceptions about tuberculosis and BCG vaccination guidelines) and the second collected data on the 3 children included (sociodemographic characteristics, immunisation status with dates of vaccination and reasons for not being vaccinated, according to the GP's opinion). Data were retrospectively collected during 3 1/2 months and GPs were allowed to consult their medical files to fill in the questionnaire. Five reminders were regularly sent if there were no answers.

2.2. Sample size

Sample size calculation was based on minimal OR that we wished to detect. Considering that 30% of children were eligible for vaccination [19] and that 50% of eligible children were actually vaccinated, we calculated that 822 children were needed to detect determinants with OR ≥ 2 (when 50% of eligible children not vaccinated are exposed to these determinants [19]). Based on our previous experience, we expected about 300 GPs to participate. It was therefore decided that each GP would be asked to include three children.

2.3. Statistical analysis

Qualitative variables were expressed as *N* (%) and compared using Fisher's exact tests. Quantitative variables were expressed as mean (standard deviation) and compared using Wilcoxon tests. All tests were two-sided at significance level of 0.05. The main outcome variable was the BCG immunisation status of the target children (vaccinated or not vaccinated). To take into account correlation between children under the care of the same GP, an alternating logistic regression (ALR) model was used [23,24]. The ALR algorithm models the association between pairs of responses with log OR. Analyses were conducted first using a log OR constant for all clusters and pairs, and then using a model with two different log ORs: one for clusters whose GPs practised in Paris and its suburbs, the only region in mainland France where all children remain targeted for BCG vaccination, and one for clusters of other GPs. Univariate associations between BCG immunisation status and other variables were tested using ALR, as well as for multivariate analysis.

Variable selection was conducted as follows. First, all variables collected, which concerned GPs or children, were tested in the univariate analysis and those achieving a p-value < 0.05 (score test) were included in the multivariate analysis. A backward stepwise variable selection procedure was then used to remove factors with p-value > 0.05. Second, variables that achieved a p-value $0.05 \leq p \leq 0.20$ in the univariate analysis were subsequently introduced into the ALR model and a forward multivariate selection was applied. Adjusted odds ratios and 95% confidence intervals (CIs) were calculated for determinants that remained in the final model. Missing values were indicated and excluded in ALR algorithm. Data were collected with EPI-Data and analysed with R 2.11.1 statistical package (R Development Core Team; R Foundation for Statistical

Table 2
BCG vaccine and tuberculosis perception of French general practitioners (GPs) participating in the survey ($N = 358$).

	All GPs $N = 358$, N (%)	GPs in IdF $N = 52$, N (%)	GPs out IdF $N = 306$, N (%)	p value[b]
Perception of GPs on tuberculosis and the BCG vaccine				
Tuberculosis is a common disease (1 mv.)	68 (19)	27 (52)	41 (13)	<0.001
BCG SSI® is a useful vaccine (7 mv.)	222 (63)	38 (75)	184 (61)	0.08
BCG SSI® is a dangerous vaccine (7 mv.)	71 (20)	4 (8)	67 (22)	0.02
BCG SSI® is an expensive vaccine (21 mv.)	63 (19)	5 (11)	58 (20)	0.16
BCG SSI® is technically difficult to perform (1 mv.)	268 (75)	37 (71)	231 (76)	0.49
Criteria for each eligible group of the French recommendations cited by GPs				
Resident in a region with high incidence (IdF)	105 (29)	32 (62)	73 (24)	<0.001
Born in tuberculosis endemic countries	213 (60)	18 (35)	195 (64)	<0.001
Parents born in tuberculosis endemic countries	192 (54)	19 (37)	173 (57)	0.001
Expected to travel to a highly endemic country	103 (29)	9 (17)	94 (31)	0.049
Family history of tuberculosis	86 (24)	6 (12)	80 (26)	0.022
Unfavourable living conditions	268 (75)	31 (60)	237 (77)	0.009
Areas correctly classified, according to their level of tuberculosis risk				
North America[a]	352 (98)	51 (98)	301 (98)	1
Africa	332 (93)	45 (87)	287 (94)	0.08
Oceania[a]	330 (92)	47 (90)	283 (92)	0.58
Eastern Europe	258 (72)	31 (60)	227 (74)	0.044
Asia	171 (48)	27 (52)	144 (47)	0.55
Middle East	126 (35)	19 (37)	107 (35)	0.88
South America	113 (32)	16 (31)	97 (32)	1
Central America	96 (27)	11 (21)	85 (28)	0.4
Central Europe	78 (22)	8 (15)	70 (23)	0.28
Some countries of Western Europe	44 (12)	4 (8)	40 (13)	0.36

mv., missing value. IdF, Ile de France (Paris and its suburbs), identified as a high risk area.
[a] Countries not targeted by the French recommendations.
[b] p value of the Fisher test.

Computing, Vienna, Austria [http://www.R-project.org]) and SAS 9.2 (SAS Institute, Cary, NC).

3. Results

Overall, 358 GPs participated in the survey (i.e., 119% of the expected). Individual and occupational characteristics of the GPs are detailed in Table 1. More than half (59%) reported not having seen tuberculosis patient in consultation since 2006. GPs' perception of tuberculosis incidence and BCG vaccination are detailed in Table 2. The median number of French criteria for BCG vaccination correctly cited by the GPs was 3 of the existing 6; details of each criterion are presented in Table 2 and proportion of GPs cited 0–6 criteria are presented in Fig. 2. Of the 10 proposed, a median number of 5 regions according to their level of tuberculosis risk were correctly classified by GPs; details of each geographical area are provided in Table 2. There were statistical differences between GPs working in high risk area (Paris and suburbs) and the other GPs. For GPs working in Paris and suburbs, knowledge of criteria for BGG vaccination was lower and more of them perceived tuberculosis as a common disease.

Fig. 1 shows the flow chart according to the inclusion of patients, their BCG vaccination eligibility and their immunisation status. Of the 974 children selected by the participating GPs, 920 were included. The mean age was 11.6 months (standard deviation = 6.5), with 53% male (479/907). The eligibility for BCG vaccination was determined for 92% of the children included (843/920), and 261 of them were eligible (31%, CI [28–34%]). For each criterion of eligibility, the proportion of children was 17% (153/920) for "parents born in tuberculosis endemic countries", 13% (120/920) for "resident in a region with high incidence (Paris and its suburbs)", 10% (88/920) for "unfavourable living conditions", 8% (72/920) for "expected to travel to a highly endemic country", 1% (11/9220) for "family history of tuberculosis", and 1% (6/920) for "born in a country with a high incidence of tuberculosis". Of the 261 eligible children, only 113 (44%, CI [38–50%]) were vaccinated. BCG immunisation coverage was 59% [50–68%] in Paris and its suburbs (Ile de France region), and 32% [24–40%] outside this area.

The median age at time of BCG immunisation was 2 months, and it was performed by their usual GP for 58% (66/113) of the children. The other vaccination places were mainly maternal and child health clinics (20%, 23/113), paediatricians (13%, 15/113) and maternity units (3%, 3/113).

After adjustment, seven variables were significantly associated with the immunisation status of the target children (Table 3). Vaccination had been administered more often to children older than 6 months (OR = 3.4 (CI 95% [1.4–8.6])), living in a region with high incidence (Paris and its suburbs) (OR = 14.7 [4.4–49.5]), planning to travel to tuberculosis endemic regions (OR = 3.5 [1.4–8.6]) or being at higher risk of tuberculosis according to their GP's opinion (OR = 19.9 [6.2–63.9]). Similarly, good knowledge of vaccination guidelines (OR = 1.4 [1.1–1.9]) and perception by the GP of tuberculosis as a common disease (OR = 2.2 [1.1–4.5]) were factors associated with a higher rate of BCG immunisation, while GPs with an academic degree in the field of infectious diseases had lower vaccination rates (OR = 0.14 [0.1–0.4]). No difference was identified when using a model with the two different log ORs (depending on occupational area of the GP).

Of the 142 children eligible but not vaccinated (56%), the two main reasons for not being immunised with the BCG vaccine were the GP's inability to identify the child as belonging to the target group (33%, 47/142 children) and parental refusal (11%, 16/142 children). This is based on data reporting by physicians. No differences have been shown depending on being in a high risk area (Paris and suburbs).

4. Discussion

The aims of this study were to assess the factors associated with the BCG immunisation status of children born after the suspension of universal mandatory BCG vaccination in France and targeted by BCG, and to describe French GP practices about BCG vaccination.

The seven factors associated with the immunisation status of target children can be grouped into two main points of discussion: GP's knowledge of recommendations, and perceived risk of infection and vaccination. These factors may partly explain the practice

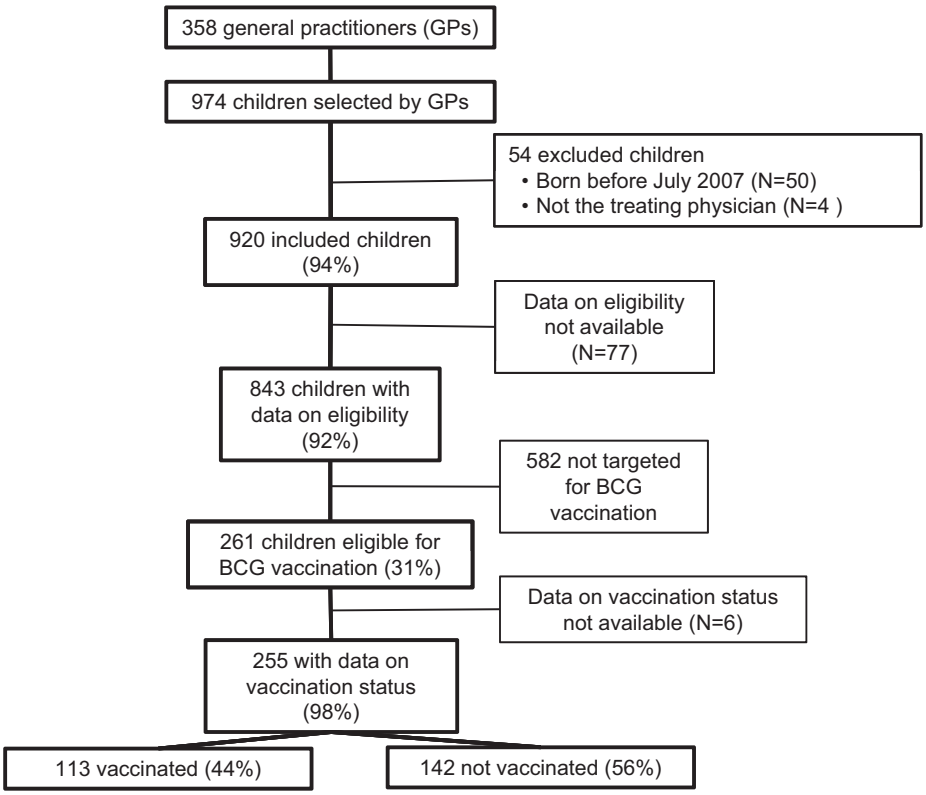

Fig. 1. Flow chart.

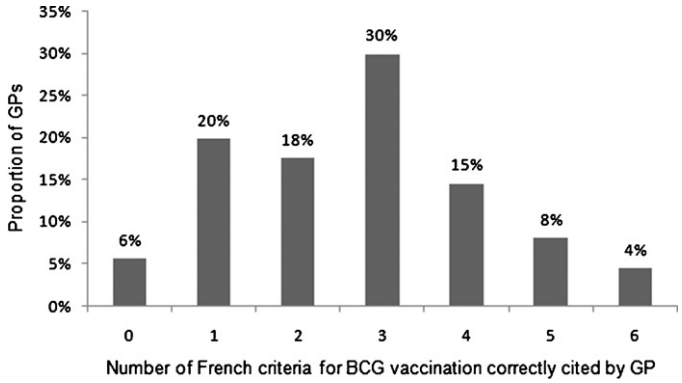

Fig. 2. Proportion of general practioners (GPs) based on number of cited criteria for BCG vaccination in France.

of physicians and insufficient BCG immunisation coverage (44%, CI [38–50%]) of the eligible children. A third of children, aged 2 years and less, seen by GP were eligible for BCG vaccination (31%, CI [28–34%]). Immunization coverage was similar as found by Guthmann et al. in 2008 for children seen by GP and paediatricians (with 33% of target children and 58% of them vaccinated) [19]. Even if immunization coverage was higher for children followed in maternal and child health clinics (73%) [20], low immunization coverage of children eligible for BCG vaccination in general practice (44%) alert to the risk of recurrence of severe forms of tuberculosis in children. GPs have a central place in the vaccination policy. It helps identify and vaccinate or refer the children at risk.

Knowledge of the recommendations appeared as a factor associated with BCG vaccination: the probability of being vaccinated increased with the number of recommendations cited correctly by the GP. Indeed, the three recommendations listed by at least half of the GPs (country of birth, country of origin of parents and unfavourable living conditions at risk of tuberculosis) cover 70%

Table 3
Factors associated with BCG immunisation among eligible children ($N = 255$).

Variables	Vaccinated children $N = 113$	Unvaccinated children $N = 142$	Unadjusted OR (IC 95%)	p value[a]	Adjusted OR (IC 95%)	p value[a]
Individual factors						
Resident in a region with high incidence (Paris and its suburbs)	68 (60)	48 (34)	2.9 (1.6–5.4)	<0.001	14.7 (4.4–49.5)	<0.0001
Child with unfavourable living conditions	62 (55)	24 (17)	7.1 (3.6–14.3)	<0.0001	19.9 (6.2–63.9)	<0.0001
Expected to travel to a highly endemic country	40 (35)	32 (23)	2.2 (1.2–4.0)	0.02	3.5 (1.4–8.6)	0.01
Age > 6 months (4 missing values)	87 (77)	93 (67)	1.6 (0.7–3.1)	0.12	3.4 (1.4–8.6)	<0.01
GP factors						
Knowledge of recommendations in linear (score/6) mean (SD)	2.8 (1.6)	2.2 (1.3)	1.3 (1.1–1.6)	0.02	1.4 (1.1–1.9)	0.01
Perception of tuberculosis as a common disease	45 (40)	23 (16)	3.1 (1.6–5.9)	<0.01	2.2 (1.1–4.5)	0.046
Academic degree in the field of infectious diseases	4 (4)	14 (10)	0.3 (0.1–0.8)	0.02	0.14 (0.1–0.4)	0.01

TB, tuberculosis; SD, standard deviation.
[a] p value of the score test.

of eligible children. Similarly, areas of high endemic tuberculosis known by more than half of the GPs were Africa and Eastern Europe. Based on official figures [25], these areas accounted for only 49% of immigrant families native from tuberculosis endemic countries. This lack of knowledge probably leads to difficulties in the identification of eligible children (in this study, the GP's inability to identify the child as being in the target group was the reason for not vaccinating in a third of the cases (33%)). Differences exist between Paris and its suburbs, and the other French regions. These differences may be due to the existence of two types of criteria in the French recommendations: one criterion targeted on the areas of residence and the other on individual factors [10–11]. In 2005, selective vaccination of newborns based on area or individual criteria also replaced the mandatory vaccination in United Kingdom. Following this change in vaccination policy, a study showed that two thirds of British parents and health professionals interviewed did not know the new recommendations. It was suggested that this may cause difficulties for the identification and vaccination of eligible children [18]. To date, there is no study on British immunisation coverage of children targeted by these recommendations.

Beyond knowledge of the recommendations, a lack of confidence in BCG vaccination exists and varies depending on the occupational area, by the perception of the risk of infection and vaccination.

This is the source of a controversy as old as epidemiology. In 1760, Bernoulli showed that a hypothetical cohort subject to smallpox vaccination would live 2.5 years longer than at present without smallpox vaccination. In response to Bernoulli's research, d'Alembert explained that the smallpox vaccination was more than a mathematical problem and opposed the individual and immediate risk of vaccination to its mass and more distant benefit [26]. Due to the differences in perception, target children did not have the same opportunity to be vaccinated as shown by the factors identified and, in particular, the criterion of residence (in central Paris or its suburbs), which was associated with a higher opportunity of being vaccinated (59% vs. 32%). Another factor that may be related to the perception of risk was having an academic degree in the field of infectious disease, which was associated with lower immunization coverage. Difficult to explain this determinant could be due to a different perception of the disease and vaccine efficacy. With a more visible risk of side effect than infection, GPs had difficulties vaccinating children with BCG. Even if the BCG vaccine had more technical difficulties and side effects than other vaccinations, "the psychology of risk perception puts the emotive evaluation of the risks associated with vaccination incorrectly into a high risk category" as shown by Spier [27].

About technical difficulties, Wattrelot et al. had shown a decrease of BCG vaccine after the withdrawal of multipuncture vaccine (Monovax®) and the end of universal mandatory vaccination in France [28]. They suggest that intradermal route constitutes an obstacle for BCG vaccination. "Perception of BCG vaccine as dangerous" and "side effects as barriers to vaccination" were not associated with the immunisation status of target children in our study.

These findings are the first numerical results demonstrating the reasons for the low immunisation coverage of BCG in France. The preliminary qualitative study allowed us to build a robust questionnaire, therefore, only a few responses were correlated. The information collected was of good quality because there were few missing data and participation exceeded expected goals.

Some limitations of our study should be acknowledged. First, it was retrospective, introducing a memory bias as the data collected were not in the patient's medical record. This bias was known at the outset and accepted in order not to influence the GP's practice if we had used a prospective study. Therefore, we collected information on those past acts. For similar reasons, the eligibility of children was not asked directly to the GP but recorded from sociodemographic questions. Second, it is important to note that the GPs included in this study participate in a health surveillance network. Thus, the findings highlighted in this study concerned children of 2 years and less who were followed by French GPs aware of epidemiological questions.

5. Conclusion

Two years after the end of universal and mandatory BCG vaccination, the targeted vaccination policy had some difficulties in its implementation in France. With less than half (44%) of the children eligible for BCG vaccination actually vaccinated, there is a risk of recurrence of severe forms of tuberculosis in children. Therefore, improving tuberculosis diagnosis, investigating cases as well as epidemiological surveillance are necessary, together with a better dissemination of vaccine recommendations. Moreover, factors associated with immunisation status, in particularly knowledge of the recommendations and perceived risk of infection and vaccination, may guide us to choose which health actions have to be conducted. Further studies are necessary to know the impact of these actions and to distinguish influences attributable to GP and to parents in childhood vaccination.

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