Mycobacterium tuberculosis Infection in First Nations Preschool Children in Alberta

Implications for BCG (bacille Calmette-Guérin) Vaccine Withdrawal

Sandy Jacobs, BScN[1]
Andrea Warman, BScN[1]
Natalie Roehrig, BScN[1]
Wadieh Yacoub, MD[1]
Chandrani Wijayasinghe, MPVM[1]
Ruth Richardson, BScN[1]
Elaine Benjamin, RN[2]
Huey Chong, BSc[3]
Jure Manfreda, MD[4]
Richard Long, MD[2,3]

ABSTRACT

Background: On April 1, 2004, BCG (bacille Calmette-Guérin), a tuberculosis (TB) control vaccine, was discontinued in all but four high-risk communities in Alberta. To confirm the safety of vaccine withdrawal, and for future planning, the annual risk of infection (ARI) was determined in preschool First Nations children.

Methods: First Nations children born into reserve communities in Alberta between April 1, 1998 and March 31, 2004, and still living on reserve in 2004-2005, were identified. Health centre TB histories were validated by cross-referencing the birth cohort with the provincial TB Registry. Children that were not BCG vaccinated and not known to be tuberculin skin test (TST) positive underwent a TST. Birth cohort children were grouped as follows: (i) BCG vaccinated; (ii) BCG non-vaccinated, no TST; (iii) BCG non-vaccinated, TST; (iv) BCG vaccination status unknown. The ARI was calculated and the age and community characteristics of the groups were compared.

Results: There were 8,447 children in the 6-year birth cohort, 4,699 (55.6%) vaccinated, 2,696 (31.9%) non-vaccinated, and 1,052 (12.5%) whose vaccination status was unknown. Of the non-vaccinated children, 1,921 (71.3%) were tested and only 2 were TST positive. No other TST positive, BCG non-vaccinated children were identified in the TB Registry cross-match. The prevalence of infection in 2004-2005 was 0.1% and the ARI was 0.03%. The community risk of TB exposure was comparable in tuberculin-tested and non-tested BCG non-vaccinated children.

Conclusion: In low BCG-uptake First Nations communities in Alberta, the ARI is low and it is safe to withdraw BCG.

MeSH terms: BCG vaccine; mycobacterium infections

La traduction du résumé se trouve à la fin de l'article.

1. First Nations and Inuit Health Branch, Alberta Region
2. Alberta Health and Wellness
3. Tuberculosis Program Evaluation and Research Unit, University of Alberta, Edmonton, AB
4. Department of Medicine & Community Health Sciences, University of Manitoba, Winnipeg, MB

Correspondence and reprint requests: Dr. Richard Long, Tuberculosis Program Evaluation and Research Unit, Room 8325, Aberhart Centre 1, 11402 University Avenue, Edmonton, AB T6G 2J3, Tel: 780-407-1427, Fax: 780-407-1429, E-mail: richard.long@ualberta.ca

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Historically, Canada has had a longstanding interest in BCG (bacille Calmette-Guérin), a live, attenuated vaccine derived from *Mycobacterium bovis* and used to prevent or moderate tuberculosis (TB).[1] Beginning in 1926 in Quebec[2] and 1933 in Saskatchewan,[3] the National Research Council sponsored controlled trials of the safety and efficacy of BCG. Thereafter, BCG vaccination, either universal or selective, was promoted throughout Canada. Gradually, as anti-tuberculosis drugs became available and incidence rates fell, BCG was discontinued in most population groups. In recent years, its use has been limited to First Nations and Inuit peoples, a group in whom TB incidence rates remain relatively high and for whom there is a national TB elimination strategy.[4] However, in the wake of reports of disseminated BCG in Aboriginal children born with congenital immunodeficiencies,[5-7] and questions about its indication,[8,9] BCG is being discontinued in this group as well. BCG vaccine uptake has varied within and between the communities in which it has been offered (First Nations and Inuit Health Branch, Health Canada).

On April 1, 2004, BCG was discontinued in all but four First Nations communities in Alberta. In these four communities, there had been a high incidence of TB (≥15 smear-positive respiratory cases per 100,000 persons per year over the period 1993-2002) and a high acceptance of BCG (>60% of children born between 1998-2002 had been vaccinated). Coincident with the withdrawal of BCG, a survey was undertaken to determine the annual risk of infection (ARI) in First Nations preschoolers. Children who were BCG vaccinated were not eligible for tuberculin testing as the vaccine is known to influence the tuberculin response.[10]

METHODS

There are 3 Treaty areas with 44 reserve communities in Alberta; 23 in the north (Treaty 8), 14 in central (Treaty 6), and 7 in the south (Treaty 7). In the spring of 2004, each community was invited to participate in a survey of the tuberculin status of their BCG non-vaccinated preschool children. The survey was undertaken over a one-year period beginning April 1, 2004. First, a birth cohort consisting of all First

TABLE I

Age and Community Characteristics of the 1998-2004 Alberta First Nations On-reserve Birth Cohort by BCG Vaccination Status

Age and Community Characteristics	BCG Vaccination Status of Cohort			
	BCG Vaccinated (n = 4699)	BCG Non-vaccinated, no Tuberculin Test (n = 775)	BCG Non-vaccinated, Tuberculin Tested (n = 1921)	Unknown BCG Status (n = 1052)
Mean Age at Time of Survey* (SD)	3.45 (1.73)	3.38 (1.80)	3.53 (1.65)	3.20 (1.78)
Treaty Area of Community				
8 North	453 (9.6%)	322 (41.5%)	1018 (53.0%)	436 (41.4%)
6 Central	2578 (54.9%)	231 (29.8%)	649 (33.8%)	473 (45.0%)
7 South	1668 (35.5%)	222 (28.6%)	254 (13.2%)	143 (13.6%)
Community Population†				
Low	199 (4.2%)	138 (17.8%)	275 (14.3%)	84 (8.0%)
Medium	632 (13.4%)	258 (33.3%)	597 (31.1%)	285 (27.1%)
High	3868 (82.3%)	379 (48.9%)	1049 (54.6%)	683 (64.9%)
Community Isolation Type‡				
Not isolated	4555 (96.9%)	679 (87.6%)	1278 (66.5%)	942 (89.5%)
Isolated	144 (3.1%)	96 (12.4%)	643 (33.5%)	110 (10.5%)
Community BCG Coverage‡				
Low	113 (2.4%)	275 (35.5%)	1135 (59.1%)	380 (36.1%)
Medium	885 (18.8%)	138 (17.8%)	275 (14.3%)	412 (39.2%)
High	3701 (78.8%)	362 (46.7%)	511 (26.6%)	260 (24.7%)
Community Source Cases per 100,000 Person-years‡				
<1	2057 (43.8%)	460 (59.4%)	1103 (57.4%)	768 (73.0%)
≥1	2642 (56.2%)	315 (40.6%)	818 (42.6%)	284 (27.0%)

BCG non-vaccinated children were divided into those who were or were not tuberculin tested.
* The age of children who were not tested was taken at mid-year (September 30, 2004) of the survey year (April 1, 2004 to March 31, 2005).
† Communities were divided into three population groups using CWIS (Community Workload Increase System) data from 2001. For the 32 communities that were classified in the same manner for INAC (Indian and Northern Affairs Canada, 2001) and CWIS, the ratio of the INAC population number to the CWIS population number ranged from 0.73 to 1.13, with a mean value of 0.95.
‡ See text for definition of community isolation type, BCG coverage, and source case.

Nations children living on reserves and born between April 1, 1998 and March 31, 2004, was identified through individual Community Health Centre birth and immunization records. Next, a data abstraction form was completed for each child including the child's name, date of birth, gender, birth community, personal health care number and mother's name. The BCG vaccination status of each child was determined through review of the child's Health Centre record. The entire birth cohort was then systematically cross-referenced with the Alberta Health and Wellness TB Registry to identify possible cases of TB, contact investigations, or results of tuberculin testing. Preschool children are a vulnerable population. As such, they are given the highest priority in a contact tracing undertaking. According to Alberta Health and Wellness and the First Nations and Inuit Health Branch (FNIHB), Alberta Region, virtually 100% of preschool children identified as contacts are screened (personal information). BCG is not offered to First Nations children born into off-reserve communities.

Skin testing of BCG non-vaccinated children was performed by trained Community Health Centre nurses using 5 TU of PPD and the Mantoux method. Induration of 10 mm or more was considered positive. Children whose BCG vaccination status was not ascertainable were excluded from the tuberculin survey. BCG non-vaccinated children with a known positive tuberculin skin test (TST) – i.e., a TST of ≥5 mm induration if the child had been a contact, suspect or proven active case; a TST of ≥10 mm induration otherwise – were added to the tuberculin-tested group although they were not retested. BCG non-vaccinated children with a known negative TST were retested; if they were not available for retesting, the TST results in the TB Registry were used. TST results were added to the data abstraction form.

The birth cohort was divided into four groups: BCG vaccinated; BCG non-vaccinated, no TST; BCG non-vaccinated, TST; BCG vaccination status unknown. The age of a child was calculated at the date of TST; if the child was not tested, the age was taken at mid-point (September 30, 2004) of the survey year. Communities were grouped by Treaty area (North – Treaty 8; South – Treaty 7; Central –Treaty 6); population size [the range of Community populations, as reported by the Community Workload Increase System of FNIHB in 2001, was divided into three: high, medium and low]; isolation ["non-isolated": flights, good telephone service, <90 km to physician services; "isolated": all others][11]; and BCG coverage [low = 0-30%, medium = 31-60%, high = 61-100%]. Communities were also divided by their incidence rate of source cases (<1 or ≥1 person >14 years of age with notified, smear and culture positive respiratory TB per 100,000 person-years) from April 1, 1998 until March 31, 2005.

Statistical analysis

Groups were compared by age (mean [± SD]) and community characteristics. The ARI was derived from the prevalence of infection in BCG non-vaccinated children who had undergone tuberculin testing as part of the survey or whose TST results were already known. The ARI was estimated overall and by community characteristic.

The formula of Nyboe,[12-14] which assumes that risk did not change over calendar time, was used to calculate the ARI: $R = 1 - (1 - P)^{1/a}$ where "P" = the prevalence of infection and "a" is the mean age of children at the time of tuberculin testing.

Chi-square tests were used for comparisons of categorical variables and *t*-test was used to compare the difference in continuous variables (age of TST tested and not tested BCG non-vaccinated children). ANOVA followed by Tukey's test for mul-

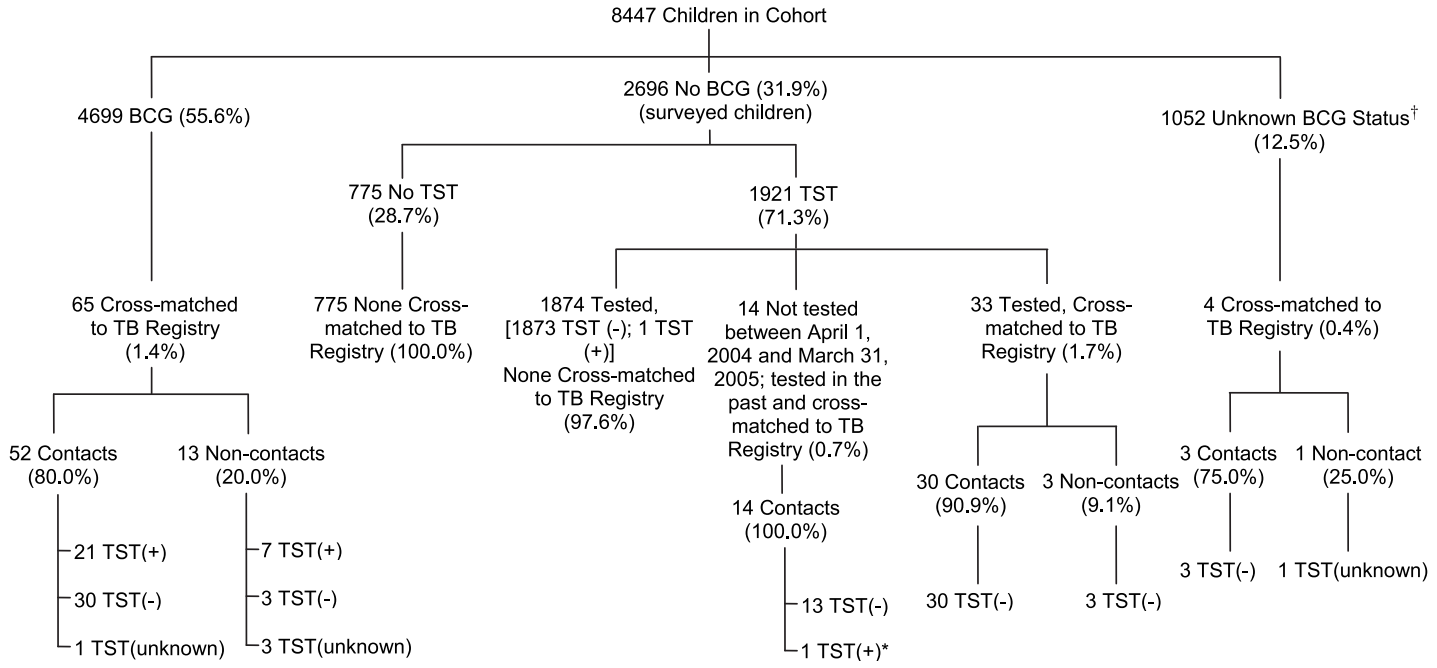

Figure 1. Alberta First Nations Pre-school Tuberculin Survey, 1998-2004

* This individual was diagnosed with active TB.

† BCG status was classified as "unknown" if the data abstraction form for a child was not completed and submitted to First Nations Inuit Health Branch (FNIHB) or if the BCG status data field was left blank in the submitted form.

TABLE II

ARI in BCG Non-vaccinated, Tuberculin-tested First Nations Preschoolers by Community Characteristic

Community Characteristic	ARI in Tuberculin-tested Children; Best-case and Worst-case Scenario	
	TST(+) = 2	TST(+) = 15
Treaty Area of Community		
8 North	0.0000% (0)	0.0564% (2)
6 Central	0.0434% (1)	0.3486% (8)
7 South	0.1072% (1)	0.5390% (5)
Community Population†		
Low	0.0000% (0)	0.1965% (2)
Medium	0.0494% (1)	0.2477% (5)
High	0.0267% (1)	0.2144% (8)
Community Isolation Type‡		
Not isolated	0.0440% (2)	0.2868% (13)
Isolated	0.0000% (0)	0.0895% (2)
Community BCG Coverage‡		
Low	0.0000% (0)	0.1027% (4)
Medium	0.0996% (1)	0.2994% (3)
High	0.0532% (1)	0.4279% (8)
Community Source Cases per 100,000 Person-years‡		
<1	0.0262%(1)	0.2097% (8)
≥1	0.0338% (1)	0.2370% (7)
Overall	0.0295% (2)	0.2216% (15)

* The age of children who were not tested was taken at mid-year (September 30, 2004) of the survey year (April 1, 2004 to March 31, 2005).

† Communities were divided into three population groups using CWIS (Community Workload Increase System) data from 2001. For the 32 communities that were classified in the same manner for INAC (Indian and Northern Affairs Canada, 2001) and CWIS, the ratio of the INAC population number to the CWIS population number ranged from 0.73 to 1.13, with a mean value of 0.95.

‡ See text for definition of community isolation type, BCG coverage, and source cases per 100,000 population.

tiple comparisons was used to test the differences in the mean ages of BCG vaccinated, non-vaccinated and unknown groups. P values <0.05 were considered as statistically significant.

RESULTS

Of those born into reserve communities in Alberta between April 1, 1998 and March 31, 2004, 8,447 were living in those communities in the survey year; 26.4% in Treaty 8, 46.5% in Treaty 6, and 27.1% in Treaty 7. The number of children varied considerably by reserve (from 11 to 1,693). We determined that 4,699 (55.6%) were BCG vaccinated and 2,696 (31.9%) were not, while the BCG status of 1,052 (12.5%) children could not be ascertained. The proportion of children known to be BCG vaccinated was significantly ($p<0.01$) smaller in the northernmost Treaty 8 area (20.3%) than in Treaty 6 (65.6%) or Treaty 7 (72.9%). Individual community BCG coverage ranged from 0.0% to 90.4%, with a median value of 42.4%.

In Table I, cohort children are grouped according to their BCG vaccination status and, if they had not been BCG vaccinated, whether they had undergone a TST. Compared to children whose BCG status was unknown, BCG vaccinated and BCG non-vaccinated children were slightly older ($p<0.01$). BCG vaccinated, non-vaccinated and unknown status children came from different Treaty areas, and communities with different populations and isolation types ($p<0.01$). BCG-vaccinated children were more likely than non-vaccinated children to come from a community with a source case ($p<0.01$). Compared to BCG non-vaccinated children who did not undergo a TST, those who did undergo a

TST were slightly older and more likely to come from different Treaty areas, communities with different populations, an isolated community, and communities with low BCG coverage ($p<0.05$).

Of the 2,696 BCG non-vaccinated children, 1,921 (71.3%) were tuberculin tested (Figure 1). This proportion was higher in Treaty areas 8 (76.0%), and 6 (73.8%) than in Treaty area 7 (53.4%) and did not differ by gender. Similarly there was no difference in the age distribution of those tested by Treaty area. Of the 1,921 children with TST available, 1,874 (and 33, see below) were tested during the survey year (April 1, 2004 to March 31, 2005). Among these, there was one child with a positive TST. This asymptomatic child had a healed primary (Ghon) complex on CT scan.[15] There were 14 non-tested children for whom the TST results were obtained from the TB Registry. Among these, one child was a TB contact with a positive TST and primary pulmonary TB in 2001. In addition, there were 33 children who were both tested during the survey year and had prior TST results in the TB Registry. These children were TST negative in both instances. In addition to the above two TST-positive children, 13 of the 1,874 BCG non-vaccinated children tested in the survey year had TSTs of 1 to 6 mm.

Table II shows the ARI overall and by community characteristic. With two TST positive children out of 1,921 BCG non-vaccinated, the prevalence of infection was 0.1%, the mean age of the surveyed children 3.53 years, and the ARI 0.0295%. While the ARI tended to be higher in the southern area (Treaty 7) and in communities with higher BCG coverage, it appeared relatively independent of community isolation and higher incidence of source cases. There were 13 children with TST induration between 1 and 6 mm. Assuming that they were positive (a worst-case scenario), the ARI was 0.2216 and varied between 0.0564 and 0.5390 by community characteristics.

The results of the TB Registry cross-matching are outlined in the Figure. In the entire cohort of children, 99 were determined to have been TB contacts; 52 BCG vaccinated, 44 BCG non-vaccinated and 3 whose BCG status was unknown. Contacts who had been BCG vaccinated were significantly more likely to be TST positive (40.4%) than contacts who had not been BCG vaccinated (2.3%), $p<0.01$.

DISCUSSION

At any particular time, the annual risk of tuberculosis infection or ARI reflects the current magnitude of the incidence and prevalence of infectious cases and the performance of the TB control program.[16,17] In low-prevalence countries, an ARI of less than 0.1% is a criterion for discontinuing BCG.[9] The only estimate of the ARI in prairie First Nations children was done by Ferguson and Simes in Saskatchewan in the 1940s. Among children born into reserve communities near the Fort Qu'Appelle Sanatorium, they found the annual infection rate to be 7.3% (range 4.5-12.2%).[3] The prevalence of infection was 68.7% in a cohort of children with an average age of 9 years. They published their ARI estimate and the results of their controlled trial of BCG vaccination in 1949,[3] just one year after the First International Congress on BCG in Paris in 1948.[1] Together, this Congress and their research influenced the BCG vaccination policy on the prairies for many years.[18] Serious adverse events were not reported, though they could have gone undetected, services and diagnostic capability being limited.[19] Two case-control studies, one in Alberta in 1975-79,[20] the other in Manitoba in 1979-83,[21] continued to show some benefit from BCG vaccination.

In recent years, the BCG vaccination policy of the First Nations and Inuit Health Branch (FNIHB) of Health Canada has come under review.[22] An unacceptably high risk/benefit ratio from BCG was found in certain communities, prompting a revision of the Canadian Immunization Guide.[5-7,23] FNIHB regions are now considering expanded programs of surveillance in lieu of BCG vaccination. However, the case for or against BCG on the basis of the ARI has not yet been made.

In this study, TB program partners in Alberta[24] undertook to determine the ARI in BCG non-vaccinated children born into reserve communities over a 6-year period, April 1, 1998 to March 31, 2004. Of 2,696 BCG non-vaccinated children, 71.3% were tuberculin tested and only two were determined to be TST positive. In a cross-match of the birth cohort with the TB Registry, a database of active cases, contacts and other referrals, no other BCG non-vaccinated, TST-positive children were identified. The estimated prevalence of infection in BCG non-vaccinated children was 0.1%. A similar low prevalence of infection was reported during school screening in British Columbia.[25]

The estimated ARI in BCG non-vaccinated children was 0.03%, well below the level considered safe for BCG discontinuation.[9] If we assume that the 13 non-vaccinated children with TST reactions of 1 to 6 mm had falsely negative reactions – a worst-case scenario – the re-calculated ARI is 0.22%, about twice the cut-off level of 0.1%. Our best-case ARI may be an underestimate because most of the tuberculin-tested children were from Treaty area 8 which had low BCG coverage and a low ARI. However, even in Treaty area 7, the ARI was not higher than 0.1. Assuming the worst-case scenario, the ARI is higher. If true, it may be too high to justify BCG withdrawal. But our worst-case scenario may be too extreme. If we allow that one half of the worst-case scenario is more reasonable, we arrive at an ARI that is not very different from 0.1.

Weaknesses of our study include: i) the inability to ascertain the vaccination status of the entire cohort, a result of the retrospective nature of the study, ii) the inability to tuberculin test all eligible children, iii) the administration of TSTs by multiple staff, iv) significant differences between BCG vaccinated, non-vaccinated, and unknown groups with respect to some characteristics, and v) significant differences between tuberculin-tested and non-tested BCG non-vaccinated children with respect to some characteristics. Strengths include the uniqueness of the study on the Canadian prairies and the comparable community risk of TB exposure in tuberculin-tested and non-tested BCG non-vaccinated children.

With respect to the program, it would appear to have been safe to withdraw BCG from communities that already had low BCG coverage, as the ARI was low in these communities. In the future, it may be difficult to maintain the BCG program in just a few communities. The current situation probably allows discontinuation every-

where. However, it should be replaced by increased vigilance for infectious cases and expanded surveillance for new infection.

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RÉSUMÉ

Contexte : Le 1er avril 2004, le vaccin BCG (bacille Calmette-Guérin) contre la tuberculose a été abandonné partout en Alberta sauf dans quatre communautés à risque élevé. Afin de confirmer que le retrait du vaccin ne posait aucun danger et de planifier les programmes futurs, nous avons calculé le risque annuel d'infection (RAI) chez les enfants d'âge préscolaire membres des Premières nations.

Méthode : Nous avons répertorié les enfants membres des Premières nations nés dans les réserves de l'Alberta entre le 1er avril 1998 et le 31 mars 2004 qui vivaient toujours dans des réserves en 2004-2005. Nous avons ensuite validé les dossiers sur la tuberculose des centres sanitaires en faisant des recoupements entre la cohorte de naissance et le registre provincial sur la tuberculose. Les enfants n'ayant pas reçu le BCG et n'ayant pas eu un résultat positif à un test de sensibilité cutané à la tuberculine (TST) ont été soumis à un TST. Les enfants de la cohorte de naissance ont été regroupés comme suit : i) vaccinés par le BCG; ii) non vaccinés par le BCG, sans TST; iii) non vaccinés par le BCG, avec TST; iv) statut vaccinal inconnu par rapport au BCG. Nous avons calculé le RAI, puis comparé l'âge et les caractéristiques communautaires des groupes.

Résultats : Sur les 8 447 enfants dans la cohorte de naissance de six ans, 4 699 (55,6 %) étaient vaccinés, et 2 696 (31,9 %) ne l'étaient pas; le statut vaccinal des autres (1 052, soit 12,5 %) était inconnu. Sur les enfants non vaccinés, 1 921 (71,3 %) avaient été testés, et 2 seulement étaient positifs pour le TST. Aucun autre enfant positif pour le TST et non vacciné par le BCG n'a été identifié par recoupement avec le registre de la tuberculose. La prévalence de l'infection en 2004-2005 était de 0,1 %, et le RAI était de 0,03 %. Le risque communautaire d'exposition à la tuberculose était comparable chez les enfants non vaccinés par le BCG, qu'ils aient subi ou non le test cutané à la tuberculine.

Conclusion : Dans les communautés des Premières nations de l'Alberta où les taux de vaccination par le BCG sont faibles, le risque annuel d'infection est faible également, et le retrait du BCG ne pose pas de danger.