National Study of Adverse Reactions after Vaccination with Bacille Calmette-Guérin

F. M. Turnbull,[1] P. B. McIntyre,[1] H. M. Achat,[2] H. Wang,[1] R. Stapledon,[3] M. Gold,[4] and M. A. Burgess[1]

[1]National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases, Royal Alexandra Hospital for Children and the University of Sydney, and [2]Centre for Epidemiology, Indicators, Research and Evaluation, Western Sydney Area Public Health Unit, Sydney, [3]South Australian Tuberculosis Services, Royal Adelaide Hospital, and [4]Department of Paediatrics, Women's and Children's Hospital, South Australian Immunisation Coordination Unit, Department of Human Services, Adelaide, Australia

Few large prospective studies of adverse reactions after bacille Calmette-Guérin (BCG) vaccination are available. In a prospective national study of such adverse reactions among 918 subjects (aged 1 day to 54 years) over a 14-month period, 45 vaccinees (5%) reported 53 adverse reactions (23 injection-site abscesses, 14 severe local reactions, 10 cases of lymphadenitis, and 6 other reactions). Only 1% of vaccinees required medical attention. Reactions, particularly lymphadenitis, were significantly less common in infants <6 months old (but not in subjects aged ⩾6 months) vaccinated by trained (vs. untrained) providers (relative risk [RR], 0.24; 95% confidence interval [CI], 0.09–0.68). Injection-site abscesses (RR, 2.96; 95% CI, 1.11–7.90) and severe local reactions (RR, 4.93; 95% CI, 1.11–21.90) were significantly more common in older vaccinees. Local reactions were more frequently reported by adult females than by adult males (RR, 7.18; 95% CI, 1.59–32.45). Adverse reactions were not significantly associated with any currently available vaccine batch, previous receipt of BCG vaccine, or concomitant administration of other vaccines.

BCG vaccine has been used for routine vaccination against tuberculosis for nearly 80 years. Despite its modest efficacy [1, 2], the vaccine has been used in >80% of the world's population [3]. In Australia, childhood BCG vaccination was discontinued in the 1980s, and vaccination is currently recommended only for those individuals at high risk of exposure to tuberculosis, including Aboriginal or Torres Strait Islander neonates living in regions of high incidence; children aged <5 years who will be traveling to live in countries with a high tuberculosis prevalence or who live in households with migrants or visitors from countries with a high incidence of the disease; health care workers in certain occupational areas; and travelers aged >5 years

who will spend prolonged periods in countries with a high prevalence of tuberculosis [4].

Serious adverse reactions after BCG vaccination are rare, occurring in association with <1 in 1 million doses [5]. Although local and regional adverse reactions occur most frequently, the majority are self-limiting. Variations in the frequency of adverse reactions have been reported and are attributed to a number of factors, including dose and strain of vaccine, age and immune status of the vaccinee, and technique of vaccine administration [5].

In Australia, an increase in adverse reactions to BCG [6] was reported from one region after there was a change in the national supply of BCG vaccine in mid-July 1996. At this time, the BCG vaccine produced by CSL Vaccines (derived from the New York strain; $7–15 \times 10^5$ cfu per 0.1 mL, with lactose stabilizer) was replaced by a Connaught vaccine derived from the Montreal strain ($8–32 \times 10^5$ cfu/mL with monosodium glutamate stabilizer). In response to the regional report, national active surveillance was established from November 1998 through April 2000 to determine the in-

cidence and nature of BCG reactions in a consecutive sample of vaccine recipients.

METHODS

Study population. Administering BCG vaccinations on a frequent basis centers in all Australian states or territories were invited to participate in the study. The geographic distribution of vaccine recipients in the study sample was related to the distribution of BCG providers rather than to regional population size. Providers were asked to enroll consecutive BCG vaccinees and to record information at the time of vaccination, including the patient's age, sex, and ethnicity, previous receipt of a tuberculin skin test, the clinic setting, the BCG vaccine dose administered, vaccine batch, and the training of the provider. Standard data collection forms were used. Providers were also asked to record whether they had been specifically trained to administer the vaccine. Deidentified data for all enrolled vaccinees were forwarded for entry and analysis. Where possible, investigators confirmed the written reports of adverse reactions and their management by discussion with the provider who reported them.

Vaccine and administration. The vaccine used during the study was the Connaught (Montreal strain) freeze-dried, live BCG vaccine. When reconstituted with PBS, each 0.1 mL of vaccine contains $8–32 \times 10^5$ cfu and monosodium glutamate 1.5% as a stabilizer. The vaccine is recommended to be given via intradermal injection (Connaught product information, distributed by CSL, Melbourne, Australia).

Case identification. Adverse reactions were detected by active case patient–finding by health care providers (by telephone or in a face-to-face interview) at 2–4 weeks and again at 16–18 weeks after vaccination. Vaccinees were also encouraged to report any adverse reactions to their provider during this time.

Adverse reactions. Adverse reactions were classified, according to World Health Organization definitions [7], as injection-site abscess, lymphadenitis, severe local reaction, and "other" (including disseminated BCG infection).

Statistical analysis and ethics approval. The incidence of adverse reactions was calculated as the number of people who reported reactions divided by the total number of vaccinees for whom follow-up information was available. Vaccinees were stratified by age into 2 groups for analysis: those aged <6 months and those aged ⩾6 months. These age groups were selected because both age and dose (0.05 mL for infants <6 months and 0.1 mL for older people) are known to influence the rate of adverse reactions [5, 8, 9]. In this study, "adult vaccinees" were defined as all vaccinees aged ⩾15 years.

A sample size of 900 vaccinees was calculated to be necessary to achieve a precision of ±2.5% around an expected adverse reaction incidence of 3% with 95% confidence. Statistical analysis was performed with SAS version 6.12 (SAS) and Epi Info version 6 (Centers for Disease Control and Prevention). The cumulative incidence of adverse reactions for the 2 age groups was calculated. To compare the groups, RRs and their 95% CIs were determined for each reaction type, and Fisher's exact test was used to ascertain whether the relative risks were significant and to identify factors associated with an increased risk of adverse reactions. Continuous variables were analyzed by analysis of variance.

The study was approved by the Communicable Diseases Network of Australia and New Zealand and by the Australian Defence Medical Ethics Committee. Only vaccinees from the Australian Defence Force were required to give written consent to participate in the study.

RESULTS

Study population. Vaccinees were enrolled by BCG providers from all Australian regions except the state of Queensland. During November 1998–December 1999, 1246 vaccinees were enrolled in the study; 918 patients (74%) completed followup. The remaining 328 vaccinees could not be contacted for follow-up. The majority of these vaccinees, particularly the members of the Defence Force, were traveling overseas for extended periods. One infant died of sudden infant death syndrome within 5 weeks of vaccination; because of communication difficulties and the remote location of the infant, no other information was available. Although the proportion of eligible vaccinees was unknown, patients lost to follow-up were not significantly different from those who completed the study in terms of age ($P = .9$), sex ($P = .2$), or ethnicity ($P = .1$). Most vaccinations (63%) were administered in hospital-based or Defence Force clinics (which are listed in the Acknowledgments). The remaining vaccinations were given in community health clinics (19%); student health centers (10%); and in general practice, council, or travelers' vaccination clinics (8%). The numbers of vaccinees from each region were as follows: New South Wales, 122; Victoria, 109; Western Australia, 98; South Australia, 113; Australian Capital Territory, 241; Northern Territory, 185; and Tasmania, 50.

Vaccinees ranged in age from 1 day to 54 years. Among the 414 infants aged <6 months, 74% were neonates (⩽28 days old), and 90% were Aboriginal or Asian (table 1). Of the 504 vaccinees aged ⩾6 months, 91% were adults (⩾15 years). That the majority (80%) of vaccinated adults were of European descent and were aged 15–24 years reflects the large proportion of vaccinations given to Defence Force personnel and to students training in health care–related occupations. Although the overall male:female ratio for adult vaccinees was 1.7:1 (table 1), for Defence Force personnel, the ratio was 3:1. Conversely,

Table 1. Demographic characteristics of 918 vaccinees who received BCG.

| | No. of vaccinees, by age group[a] | | | | | | | | | |
| | <6 Months (n = 414) | | | ≥6 Months (n = 504) | | | | | | |
Characteristic	Total	<4 weeks	4 weeks–5 months	Total	6 months–4 years	5–14 years	15–19 years	20–24 years	25–29 years	≥30 years
Sex										
Male	188	138	50	296	24	3	199	49	14	7
Female	222	169	53	206	14	2	135	40	10	5
Country of birth										
Australia	414	310	104	464	37	5	310	78	23	11
Other	0	0	0	40	1	0	26	11	1	1
Ethnicity										
European	20	13	7	421	13	4	292	78	22	12
Aboriginal	250	238	12	3	1	0	2	0	0	0
Asian	121	44	77	45	14	0	22	7	2	0
Other	20	13	7	17	8	1	6	2	0	0
Indication for BCG										
ADF										
Male	—	—	—	198	—	—	156	35	6	1
Female	—	—	—	65	—	—	61	4	0	0
HCW or student										
Male	—	—	—	34	—	—	30	3	1	0
Female	—	—	—	52	—	—	40	11	0	1
Other[b]										
Male	188	138	50	64	24	3	13	11	7	6
Female	222	169	53	89	14	2	34	25	10	4

NOTE. ADF, Australian Defense Force; HCW, health care worker.

[a] Demographic data not available for all age categories.

[b] Indication for BCG vaccination includes living in a region with a high incidence of tuberculosis or travel to country of high prevalence.

among those training in areas of health care, women outnumbered men (female:male ratio 1.5:1).

Of the 504 vaccinees for whom a tuberculin test was indicated (individuals aged ≥6 months), 489 (97%) were tested before vaccination. None was recorded as having a positive test result (≥5 mm). Only 13 (1.4%) of 918 had received a previous BCG vaccination, from 9 to 28 years before their current vaccination. No vaccinee was known to be immunocompromised.

Concomitant vaccinations (those given within 4 weeks before BCG vaccination) were administered to 292 vaccinees (32%). Of these, 234 were infants receiving routine childhood immunizations (predominantly hepatitis B vaccine [94%] but, also, diphtheria-tetanus-pertussis and oral polio vaccine). With the exception of oral polio vaccine, all infant vaccinations were administered intramuscularly in the vastus lateralis muscle of the leg.

Of the infants, 99% received the recommended BCG vaccine dose of 0.05 mL (dose was not recorded for the remaining 1%). Of the 503 adults for whom a vaccine dose was recorded, 96% received 0.1 mL; the remainder received either 0.05 mL or 0.075 mL.

Vaccine batch was documented for 99.6% of subjects. Vaccinees received 1 of 4 vaccine batches: 2612-12 (26 vaccinees), 2614-12 (69 vaccinees), 2615-13 (807 vaccinees), and 2616-14 (13 vaccinees). Connaught batch 2615-13 accounted for 90% of the BCG vaccine distributed in Australia in 1998. The vaccine batch associated with the earlier regional cluster of adverse events [6] was not distributed during the study.

In 86% of instances, BCG vaccine was given by a provider trained in BCG vaccination. A greater proportion (95%) of providers who vaccinated older individuals were trained, compared with those who vaccinated infants <6 months of age (76%). All vaccinations were given in the deltoid region of the arm. Information about injection technique (e.g., whether the vaccine was inadvertently administered subcutaneously rather than intradermally) was not recorded.

Adverse reactions. A total of 53 adverse reactions were reported by 45 (5%) of 916 vaccinees. Most adverse reactions were mild and self-limiting. There were no reports of disseminated BCG infection. Eleven vaccinees (1%) required attention from a health care practitioner (table 2).

Injection-site abscesses accounted for 23 (43%) of 53 reac-

Table 2. Cumulative incidence (%) of adverse reactions after BCG vaccination, by age group and type of reaction.

| Condition | No. (%) of vaccinees, by age group | | | RR (95% CI)[a] | P |
	<6 Months (n = 414)	≥6 Months (n = 504)	All ages (n = 918)		
Abscess	5 (1.2)	18 (3.6)	23 (2.5)	2.96 (1.11–7.90)	.02
Lymphadenitis	6 (1.4)	4 (0.8)	10 (1.0)	0.55 (0.16–1.93)	.3
Severe local reaction	2 (0.5)	12 (2.4)	14 (1.5)	4.93 (1.11–21.90)	.02
Other	2 (0.5)	4 (0.8)	6 (0.7)	1.64 (0.30–8.93)	.6
Any reaction[b]	14 (3.4)	31 (6.2)	45 (4.9)	1.82 (0.98–3.37)	.05

[a] Cumulative incidence of adverse reactions in vaccinees aged ≥6 months compared with those aged <6 months.
[b] Eight vaccinees reported >1 reaction.

tions. The median time to onset was 30 days (range, 4–65 days). Of the 23 abscesses, 7 required treatment (surgical excision, 2; antibiotics, 3; and symptomatic treatment, 2). All 16 remaining abscesses resolved spontaneously.

Lymphadenitis, which was reported by 10 vaccinees (1%) and involved axillary nodes in 9 vaccinees and cervical nodes in 1 vaccinee. The onset of lymphadenitis occurred at a median of 63 days after vaccination (range, 16–87 days). Lymph node, diameter was 15–30 mm. Most episodes resolved without intervention; however, one infant (aged 3 months) was treated with antituberculosis therapy (isoniazid and rifampicin).

Severe local reactions comprising pain, redness, or swelling that lasted >3 days were reported by 14 vaccinees (1.5%) and accounted for 14 (26%) of 53 reported reactions. No reaction caused swelling beyond the nearest joint or resulted in hospitalization. Three vaccinees received antibiotic treatment for severe local reactions.

Another 6 problems categorized as "other" were reported: pronounced scars (n = 3), marked redness at the site of injection within 24 h of vaccination (n = 2), and fever for 2 days after vaccination (n = 1). None required treatment.

Eight vaccinees reported having > 1 complication. Types of reactions reported were as follows: local and other (n = 3), abscess and local (n = 4), and abscess and other (n = 1).

The overall incidence of adverse reactions was higher for older subjects (6.2%) than for infants (3.4%) (table 2). This difference was attributable to a higher reported rate of injection-site abscesses (RR, 2.96; 95% CI, 1.11–7.90) and severe local reactions (RR, 4.93; 95% CI, 1.11–21.90). In vaccinees aged <6 months, lymphadenitis was more common (1.4%) than in vaccinees aged ≥6 months (0.8%) (RR, 1.82; 95% CI, 0.52–6.41), but this difference was not statistically significant.

Factors associated with the development of adverse reactions and their management. Adverse reactions were less common among older subjects when a previous tuberculin skin test had been performed (RR, 0.27; 95% CI, 0.09–0.77). Al-

though there was no difference in the overall incidence of reactions according to sex, (10 [83%]) of 12 older vaccinees who reported local reactions were women (RR, 7.18; 95% CI, 1.59–32.45). Older individuals were more likely to receive treatment for their reactions (RR, 4.11; 95% CI, 0.90–18.64; table 3).

Adverse reactions among infants were less likely when the vaccination was given by trained staff (RR, 0.24; 95% CI, 0.09–0.68). Neither age at vaccination (P = .61) nor birth weight (P = .54) were significant factors. Among the 310 neonates (aged 0–28 days), all adverse reactions occurred in Aboriginal infants (11 [5%] of 238).

The development of an adverse reaction was not significantly associated with concomitant administration of other vaccines, previous BCG vaccination, or vaccine batch (table 3). However, the power of this analysis was limited by small numbers of prior BCG recipients and receipt of the same vaccine batch in 85% of infants and 90% of older individuals.

DISCUSSION

The incidence of reactions (5%) in this national prospective study was within the range (0.1%–19%) reported elsewhere [3, 5, 10–14], but differences in the methods used to detect and define cases make direct comparisons difficult. In particular, an earlier regional study's suggestion of a significant increase (from 0.7% to 3%) in adverse reactions after introduction of the Connaught vaccine could not be examined because the previous (CSL) vaccine was no longer in use [6] . Also, the cases in the earlier study were detected by retrospective review of patient records with probable incomplete ascertainment. In the current study, adverse reactions were identified by active surveillance that used standard case definitions [12]. Although some complications have been reported to occur up to 2 years after vaccination, the majority occur within the first 20 weeks [5].

Table 3. Factors examined for an association with the development of adverse reactions after BCG vaccination, by age group.

Factor	No. of vaccinees aged <6 months			No. of vaccinees aged ≥6 months		
	Total	With any reaction	RR (95% CI)	Total	With any reaction	RR (95% CI)
Country of birth			—			0.58 (0.21–1.58)
Australia	414	14		464	27	
Other	0	0		40	4	
Ethnicity			2.4 (0.68–8.47)			—
Aboriginal	250	11		3	0	
Other	164	3		501	31	
Sex			0.85 (0.30–2.37)			1.74 (0.88–3.46)
Female	222	7		206	17	
Male	188	7		296	14	
Local reaction (by sex)			—			7.18 (1.59–32.45)[a]
Female	222	2		206	10	
Male	188	0		296	2	
Trained provider			0.24 (0.09–0.68)[a]			1.70 (0.24–12.0)
Yes	313	6		477	30	
No	101	8		27	1	
Concomitant vaccine			1.27 (0.43–3.72)			1.38 (0.50–3.77)
Yes	243	9		49	4	
No	171	5		455	27	
Previous skin test			—			0.27 (0.09.0.77)[a]
Yes	13	0		490	28	
No	410	14		14	3	
Previous BCG vaccination			—			1.37 (0.20–9.17)
Yes	1	0		12	1	
No	413	14		492	30	
Batch			0.46 (0.15–1.41)			0.60 (0.25–1.89)
Common (2615-13)	350	10		457	27	
Other	64	4		47	4	

[a] $P<.05.$

Because we followed the vaccinees for 18 weeks, it is unlikely that adverse reactions were underestimated; however, several factors may have led to the overestimation of reactions. These include the method of case ascertainment, publicity concerning the vaccine, and loss to follow-up of nearly one-quarter of enrolled vaccinees, assumed that those lost to follow-up experienced fewer adverse reactions, because it is unlikely that these vaccinees would fail to report serious adverse reactions to their provider.

Adverse reaction rates were higher overall for older people compared with infants. This was in part due to the predominance (>80%) of young adult women who reported local reactions. Similar findings have been reported elsewhere [15]; however, the reason for this sex difference remains unknown. The smaller size of the study and the higher vaccine dose, relative to weight, for most female subjects may be important;

some studies have suggested that female vaccinees find the local reaction to BCG cosmetically unacceptable [16]. It is unclear why older people experienced a higher incidence of injection site abscesses; however, failure to perform standard Mantoux testing before vaccination may have been a contributing factor. These local complications after BCG vaccination highlight the need for careful consideration of the indication for vaccination (including interpretation of tuberculin skin test results) and clear explanation of possible side effects [17].

Vaccination by health care workers untrained in administering BCG vaccine is likely to have contributed to the development of reactions in vaccinees of all ages [18]. However, this was most pronounced in infants aged <6 months, 24% of whom were vaccinated by untrained staff.

Although current Australian guidelines recommend that vaccination be done by a trained provider, there is no universal

training standard. Therefore, it is possible that certain vaccination centers operating without such standards may have been responsible for the majority of reactions. This analysis was limited by the overall small overall number of reactions and by the fact that, for the most part, individual centers vaccinated homogeneous populations (for example, young adults in the Defence Force or Aboriginal children).

Providers' lack of experience in administration of the vaccine may also have contributed to an increased incidence of reactions. A recent survey [19] in the Australian state of Victoria found that, because of an increase in the number of registered vaccinators, 69% of BCG providers vaccinated <25 individuals per year. Vaccination skills are more likely to be maintained when the vaccine is given on a regular basis. This is particularly important for neonatal vaccination, for which there is an increased risk of inadvertent subcutaneous injection. For this reason, multipuncture percutaneous administration of the vaccine has been advocated because the technique is easier to learn and is associated with a lower incidence of reactions [20].

Certain characteristics of the recently introduced BCG (Connaught) vaccine may have accounted for a proportion of adverse reactions. Some strains are known to be more potent (reactogenic) than others [10, 12]. In particular, BCG vaccines with lower numbers of culturable particles (and therefore lower ratios of live to killed bacilli), including Connaught, have been associated with an increased incidence of adenitis. In 1982 in Saint Lucia, the incidence of adenitis increased from 4.3% to 9.8% when the supplied vaccine changed from the Glaxo to the Connaught preparation [21]. After reintroduction of the Glaxo vaccine, the rate returned to previous levels. Similar findings have been reported in other countries [13]. Other vaccine properties, such as the composition of vaccine stabilizers, have been implicated. For instance, monosodium glutamate, used as the stabilizer in the Connaught preparation, may make reconstitution more difficult, leading to an increase in reactogenicity [12]. Although batch-to-batch variation is known to occur [6], a relationship between adverse reactions and a specific batch could not be determined in this study because almost all subjects received vaccine from the same batch.

The current passive Australian surveillance system for adverse events (Adverse Drug Reactions Advisory Committee, or ADRAC) identified only 20 BCG adverse reactions during the period of our study (ADRAC, unpublished data). Underreporting and lack of accurate denominator data limit the usefulness of passive systems in determining vaccine safety. Active surveillance of adverse events after vaccination is not conducted routinely in Australia but has been previously conducted in specific instances, such as the 1998 Measles Control Campaign [22]. Although there are limitations associated with prospective studies of adverse events, such as the long delay before results become known and the loss to follow-up (for example, people vaccinated before traveling overseas, as in the present study), prospective studies remain valuable public health tools. In Australia, where claims (based on a case report [23]) of significant problems after BCG vaccination, attracted considerable media attention, data from our study were able to put such claims into perspective.

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