

Complications of BCG Vaccinations in Rural Haiti

ABSTRACT

This study investigated an outbreak of axillary lymphadenitis and abscesses after Bacillus Calmette-Guérin vaccination among rural Haitian children treated at the Hospital Albert Schweitzer from January 1986 through March 1991. Seventy-seven cases of vaccine-related complications were identified, all among children immunized before the age of 1 year. The proportions of children with complications were 0.017% for 1986 through 1989, 0.91% for 1990, and 2.2% for January through March 1991. (*Am J Public Health*. 1993;83:583-585)

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Introduction

The World Health Organization recommends the use of Bacillus Calmette-Guérin (BCG) vaccine in developing countries where the incidence of tuberculosis is high, even though the vaccine's effectiveness is variable.¹⁻⁴

Lotte et al. point out that there are few data concerning complications related to the vaccine in developing countries; thus, estimating global rates of vaccine-induced complications remains problematic.⁵ Outbreaks of BCG vaccination complications such as lymphadenitis and abscesses are uncommon,³ although several outbreaks have been reported from various countries worldwide.⁶⁻⁸

The objectives of this study were to assess the risk of complications (lymphadenitis and/or abscesses) related to the vaccine among rural Haitian children and to evaluate whether this risk had increased between January 1986 and March 1991, as theorized by local clinicians.

Methods

The study was conducted at the Hospital Albert Schweitzer, located in the Artibonite Valley of rural Haiti. The hospital is the major provider of medical care to a district population of approximately 190 000 persons. The hospital's Community Health Department routinely vaccinates children within its district with BCG shortly after birth (or later if not vaccinated previously). Vaccination is performed by "vaccination teams" whose sole responsibility is the vaccination program. These teams travel throughout the district to bring the vaccination program to remote, rural populations. Hospital staff had observed an apparent increase in complications related to the vaccine beginning in early 1990.

All in-district children (birth through 5 years of age) who experienced complications related to BCG vaccination and who were treated at the Hospital Albert Schweitzer from January 1986 through March 1991 were identified by review of the hospital's discharge summary cards and patients' medical records. A case of complications related to the vaccine was

defined as any child who was immunized within the past 4 months and who presented with right axillary and/or supraclavicular lymphadenitis of at least 2 cm in diameter with or without an abscess.

The approximate proportion of children with BCG-related complications was estimated by relating the number of cases of vaccine-related complications identified within a specific time period to the number of children vaccinated during that time period. This approach was used because the available data did not allow follow-up of specific cohorts of vaccinated children. The number of children vaccinated per quarter remained relatively stable over the study period.

The BCG vaccine lot numbers for 1990 and 1991 were available from the Haitian government physician in charge of distributing vaccines. These lot numbers were Pasteur (Paris, France) R 5523 (for most of 1990) and E 5174 (for most of the first quarter of 1991).

Results

Seventy-seven cases of BCG-related complications were identified among in-district residents. Table 1 shows the number and percentage of children with vaccine-related complications by age at vaccination, age at diagnosis, and time period. The percentage of vaccinated children with BCG-related complications increased from 0.017% in 1986 to 0.91% in 1990 and 2.2% in January through March 1991. No vaccine-related complications were identified among the approximately 1400 immunized children aged 1 through 5 years.

For 1990, 20 of the identified cases were boys and 21 were girls. Eleven of the 41 cases were diagnosed in the first quar-

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TABLE 1—Number and Percentage of Children with Complications Related to the Bacillus Calmette-Guérin Vaccine: Hospital Albert Schweitzer, Haiti

Age at Vaccination	Age Diagnosed with Vaccine-Related Complications	1986–1989		1990		January–March 1991	
		No. of Cases	Complications, %	No. of Cases	Complications, %	No. of Cases	Complications, %
Fewer than 12 months		3	0.017	41	0.91	33	2.2
	1–4 months	3	...	33	...	23	...
	5–11 months	0	...	8	...	8	...
	12–14 months	0	...	0	...	2	...
12 months or older		0	0	0	0	0	0

Note. The number of vaccinations performed was available only for two age categories, fewer than 12 months and 12 months or older, although the hospital's policy is to vaccinate shortly after birth.

ter of 1990; the corresponding numbers for the second, third, and fourth quarters of 1990 were 18, 4, and 8. Nineteen infants (46%) presented with abscesses that either drained spontaneously or required surgical drainage.

From January through March 1991, 21 of the 33 identified cases were boys and 12 were girls. Twelve infants (36%) presented with abscesses.

All of the cases of complications related to the BCG vaccine were diagnosed between 8 days and 4 months after vaccination. Upon examination, large right axillary nodes were found, frequently associated with fever and/or abscesses that required drainage or that spontaneously drained. (The vaccine was given intradermally over the right deltoid.) Only a few of the abscesses were cultured; two were reported positive for *Mycobacterium bovis*. One child was diagnosed with supraclavicular nodes. As a rule, all affected infants received oral isoniazid for 3 to 6 months after diagnosis.

The relative proportion of children with BCG-related complications for 1990, as compared with the proportion for 1986 through 1989, was 54; the comparable relative proportion for January through March 1991 was 133.

Discussion

Improper vaccination technique, route of vaccination, and dosage and storage of the vaccines were unlikely causes of the increased risk of complications.^{5,9–11} The hospital follows the manufacturers' recommendations concerning vaccine refrigeration during storage and transport. Although the BCG vaccine is distributed by the Haitian government, UNICEF consultants oversee

storage and distribution. Disposable, single 1-mm syringes were used to prevent dosage errors. All immunization technicians had worked at Hospital Albert Schweitzer for at least 2 years prior to the start of the outbreak. In addition, the cases did not cluster at any immunization post. On the basis of the hospital records, complications at the vaccination site itself were reported for only one child between January 1990 and March 1991, attesting to the skills of the vaccination technicians. In rural Haiti, axillary and/or supraclavicular lymphadenitis is rare unless associated with vaccination, trauma, or extreme malnutrition (B. Bonnlander, written communication, August 1992).

One possible source of error warrants discussion. It is likely that the number of cases of BCG-related complications were underreported because the long travel distances to the Hospital Albert Schweitzer make it difficult for parents to bring their children to the hospital, particularly if the child's condition is regarded as non-life threatening. Differential underreporting of cases by time period is an unlikely explanation for the observed secular trend in risk, however, because the magnitude of the increased risk observed was large and because identification of cases was determined primarily by the individual family members' ability to seek care at the hospital and not on any particular awareness of BCG-related complications among the hospital's clinical staff.

The results strongly suggest that a secular increase in the risk of BCG-related complications in Haiti began in 1990 and continued through the first quarter of 1991 (the last period of observation). The probable explanation for the increase was a change in the vaccine strain or in the re-

actogenicity of the Pasteur strain. Unfortunately, it was not possible to relate any change in vaccine strain or lot number directly to the increased risk of complications related to the vaccine because Hospital Albert Schweitzer does not routinely record the lot number of BCG vaccines used.

Praveen et al. were unable to identify a single cause for the BCG-related complications in Jamaica and attributed them instead to an increased reactogenicity to the Pasteur strain.⁷ Vaccine-associated complications in Jamaica stopped after the Pasteur BCG vaccine was discontinued. Helmick et al. reported the occurrence of vaccine-related complications in St. Lucia in 1982 when a Connaught BCG vaccine was used; these complications ceased after a change to a Glaxo vaccine in 1983.⁸

The study results confirmed the findings of DeSouza et al.¹² with respect to the increased risk of BCG-related complications among infants less than 5 months old compared with older children. In the present study, 75% of all complications were found in infants 1 to 4 months old.

Adverse reactions to vaccines may jeopardize public acceptance of immunization programs. Thus, surveillance of vaccine reactions is a key component of these programs. Hospital Albert Schweitzer's experience demonstrates the importance of such surveillance, the identification of increased reactions through surveillance, and the need to change the vaccine strain. □

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References

1. BCG Vaccination Policies: Report of a WHO Study Group. Geneva, Switzerland: World Health Organization; 1980. WHO Technical Report Series No. 652.
2. Anonymous. BCG vaccination in the newborn. *Br Med J*. 1980;281:1445–1446.
3. Miller FJW. *Tuberculosis in Children*. New York, NY: Churchill Livingstone Inc; 1982.
4. Ten Dam HG, Hitze KL. Does BCG vaccination protect the newborn and young infants? *Bull WHO*. 1980;58:37–41.
5. Lotte A, Wasz-Hockert O, Poisson N, Dumitrescu N, Verron M, Couvet E. BCG complications. *Adv Tuberc Res*. 1984;21:107–193.
6. Mandell GC, Douglas RC, Bennett JE.

- Principles and Practices of Infectious Disease*. New York, NY: Wiley; 1979;2:923-924.
7. Praveen KN, Smikle MF, Prabhakar P, Pande D, Johnson B, Ashley D. Outbreak of *Bacillus Calmette-Guérin* associated lymphadenitis and abscesses in Jamaican children. *Pediatr Infect Dis J*. 1990;9:890-893.
 8. Helmick CG, D'Souza AJ, Goddard N. An outbreak of severe BCG axillary lymphadenitis in Saint Lucia, 1982-83. *West Indies Med J*. 1986;35:12-17.
 9. Vig-Neilson I, Madsen M, Allfather J, et al. Suppurative lymphadenitis following intradermal BCG vaccination of preschool children. *Bull WHO*. 1955;12:143-146.
 10. Martinez Barrow J. Complications de la vacunacion con BCG. *Semin Med Cent Am Panama*. 1971;17:295.
 11. Carballo DC, Sanchez GA. Regional lymphadenitis following BCG vaccination. *Clin Pediatr*. 1972;11:693-697.
 12. DeSouza GRM, Sant 'Anna CC, Lapae Silva JR, et al. Intradermal BCG vaccination complications: analyses of 51 cases. *Tubercle*. 1983;64:23-27.

The Alcohol Warning Label and Adolescents: The First Year

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ABSTRACT

Awareness of the alcohol labeling law and exposure to, beliefs about, and memory for the government-mandated alcohol warning label were measured in a sample of adolescents immediately before the label was required to appear (in the fall of 1989) and 1 year after the label was required. After the label was required, there were increases in awareness, exposure, and recognition memory, but there were not substantial changes in alcohol use or beliefs about the risks written on the warning. (*Am J Public Health*. 1993;83:585-587)

Introduction

The purpose of this study was to determine awareness of the alcohol labeling law, exposure to the warning label,¹ and beliefs about and memory for the risks listed on the label, in groups of adolescents sampled before and after enactment of the legislation requiring the label. Adolescents are studied because it is during adolescence that health behaviors are being established and experimentation with alcohol and other drugs first occurs.²

According to the health belief model,^{3,4} the warning label may be considered as a cue to avoid alcohol. McGuire's communication model⁵ provides a framework for how the cue may lead to behavior change. Because the second set of data was collected 1 year after the label was required to appear on alcoholic beverage containers, we expected to find early stages of behavior change—consisting of increased awareness of the law, increased exposure to and memory for the risks on the label, small changes in beliefs, and little change in alcohol use.

Methods

Sample

The subjects were 1211 12th grade students surveyed during September ($n = 934$) and October ($n = 277$) 1989, just before the enactment of warning label legislation on November 18, 1989, and 2006 12th grade students measured during October 1990 ($n = 1160$), November 1990 ($n = 698$), December 1990 ($n = 79$), and February 1991 ($n = 69$), after the legislation was enacted. (The postlegislation sample is referred to as the fall 1990 sam-

ple even though 69 subjects were measured in February 1991.) All 27 public, parochial, and private (with more than 25 students in grade 12) schools in Marion County, Indiana, were assessed in both years. The pre- and postlegislation samples were independent; for both, classrooms of students were randomly selected from each school. The samples were selected to be probability samples of Marion County 12th grade students. The postlegislation sample is larger because more data collection resources were available.

Measures

A questionnaire was used to measure the variables of interest in this report. Awareness, beliefs, and exposure measures had four response options ("Yes, definitely," "Probably," "I don't think so," and "No"). It was decided after the 1989 measurement to dichotomize these items for analysis so that the "Yes, definitely" response equaled 1 and all other responses equaled 0. Responses were dichotomized to simplify presentation of the results and because most of the students responded "Yes, definitely" or "Probably" to the beliefs questions. Four forms were used in the 1990 data collection to increase the number of variables available

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