

Evaluating Acceptability and Completeness of Overseas Immunization Records of Internationally Adopted Children

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ABSTRACT. *Background.* Increasing numbers of families in the United States are adopting children who were born in other countries. Appropriate immunization of internationally adopted children provides a challenge to pediatricians who must evaluate documentation of vaccines administered overseas and fulfill the recommended US childhood immunization schedule. The acceptability of vaccinations received outside the United States was addressed by the Advisory Committee on Immunization Practices in 1994, but few population-based studies assessing these vaccinations have been reported.

Methods. We performed a retrospective cohort study of 504 children who were adopted from other countries and evaluated in 1997 and 1998. Our goal was to determine the acceptability of overseas vaccinations for meeting US immunization requirements. We assessed immunization records for both valid documentation of receipt of vaccine and comparability with the recommended US schedule. We also determined the number of children who were up to date (UTD) for diphtheria-tetanus-pertussis, polio, hepatitis B, and measles-mumps-rubella vaccines under the US schedule.

Results. The children's mean age at initial US evaluation was 19 months; 71% were girls, and most (88%) had resided in orphanages. They were adopted from 16 countries, most frequently from China (48%) and Russia (31%). Thirty-five percent (178) of children had overseas immunization records, 167 (94%) of which were considered valid. Most children with valid records (112 [67%] of 167) were UTD for 1 or more vaccine series under the US schedule.

Conclusion. The majority (65%) of internationally adopted children had no written records of overseas immunizations. Among the 178 children with documented overseas immunizations, 167 (94%) had valid records and some vaccine doses that were acceptable and UTD under the US schedule. Additional research and more specific guidance in the most cost-effective approaches to evaluation of overseas vaccinations are needed to ensure appropriate state-side vaccination and to improve the health of these children and their communities. *Pediatrics* 2002;109(2). URL: <http://www.pediatrics.org/cgi/content/full/109/2/e22>

international adoption, immunization, vaccine-preventable disease.

ABBREVIATIONS. WHO, World Health Organization; ACIP, Advisory Committee on Immunization Practices; INA, Immigration and Nationality Act; UTD, up to date; DTP, diphtheria-tetanus-pertussis; HB, hepatitis B; CI, confidence interval; RR, relative risk; ELISA, enzyme-linked immunosorbent assay.

Many American families are adopting children who were born in other countries, and the numbers have increased rapidly in the past decade. The US Department of State estimates that from 1989 to 1994, an average of 7738 children were adopted from other countries annually; in 1997 and 1998, 12 743 and 15 774 children were adopted, respectively.¹ Most were born in Russia, China, South Korea, Guatemala, Romania, and Vietnam.¹ Internationally adopted children are a particularly vulnerable population, as they often come from underdeveloped countries with inadequate health care resources. Many of these children arrive with incomplete medical records, including documentation of immunizations. In addition, these children's countries of origin often have immunization policies and schedules that differ from the recommended childhood immunization schedule in the United States.² Differences between the US immunization schedule and those recommended by the World Health Organization (WHO) for other countries include the vaccines administered, the recommended ages of administration, and the number of doses and dose intervals recommended.³

Appropriate immunization of internationally adopted children therefore provides a challenge to US pediatricians who must evaluate documentation of vaccines administered overseas and fulfill the recommended US immunization schedule. The Advisory Committee on Immunization Practices (ACIP) first addressed the acceptability of vaccines administered outside the United States in the 1994 General Recommendations.⁴ This document stated that "the acceptability of vaccinations received outside the United States depends primarily on whether receipt of the vaccine was adequately documented and whether the immunization schedule was comparable with that recommended in the United States. Any dose (with written documentation) administered at the recommended minimum intervals (and ages) can be considered valid."

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In addition, in 1996 the US Immigration and Nationality Act (INA) was amended to require people who apply for permanent US residency to show proof of having received the vaccines required by the ACIP.⁵ The act mandated that immigrant children (including foreign-born orphans [internationally adopted children]) show documentation of previous immunizations or undergo vaccination with at least the first vaccine of each required vaccine series before admission to the United States. On November 12, 1997, an Immunizations Requirements Exemption for foreign-born orphans adopted by US citizens was made law. This law exempted internationally adopted children who are 10 years of age or younger from the immunization requirements of the INA if the new parent(s) ensured that the child would receive vaccination within 30 days of US entry.

Since issuance of the ACIP recommendations and enactment of the INA amendment and exemption, few population-based studies evaluating the acceptability of overseas vaccinations in immigrant children, including internationally adopted children, have been reported. This article retrospectively assesses overseas immunization records in a cohort of 504 internationally adopted children evaluated in 1997 and 1998 at a New York City area practice that specializes in the initial diagnosis and treatment of these children and discusses practical approaches to ensuring appropriate and complete immunization of internationally adopted children in the United States.

METHODS

Study Design and Objectives

A retrospective cohort study was performed, including all 504 internationally adopted children who were evaluated at the adoption practice of 1 coauthor (J.A.), in Mineola, New York, during 1997 and 1998.⁶ These initial state-side pediatric evaluations are performed to provide appropriate treatment and preventive therapies, to prevent transmission of infections, and to alleviate parental anxiety.⁷⁻¹⁰ Demographic data collected from study subjects included country of origin, date of birth, age at adoption and age at first medical evaluation, and the setting where the child lived before adoption (eg, orphanage, foster care). Additional information collected included the type and number of vaccine doses received overseas and the dates of vaccine administration. Our study goals were to assess how many children had valid documentation of receipt of any childhood vaccines in their countries of origin and to compare the characteristics of children with valid immunization records with those without such documentation. In addition, we determined the number of children with vaccine doses that were considered to be acceptable in the United States according to ACIP recommendations and the number of children who were up to date (UTD) for 1 or more selected vaccine series under the US childhood schedule. The study protocol was approved by institutional review boards at the Centers for Disease Control and Prevention, Columbia University College of Physicians and Surgeons, and the Winthrop University Hospital.

Valid Documentation of Overseas Immunization Records

To assess the validity of the documentation of overseas immunizations, we used the standards set by the ACIP.⁴ A vaccine dose was considered valid when the vaccine record was written and included the type of vaccine and date of administration. We also reviewed the dates of vaccine administration to determine whether any doses were recorded as being administered before the child's birth date.

Criteria for Invalid Doses

A specific recorded vaccine dose was considered invalid when no administration date was recorded. All vaccine doses for a given child were considered invalid when the date of administration for any dose preceded the child's birth date.

Acceptability of Overseas Immunizations Under the US Schedule

We considered valid vaccine doses acceptable in the United States when the age at initial administration and the interval between vaccine doses fit the minimum ages and intervals recommended by ACIP.⁴ The overseas vaccines assessed for acceptability under the US schedule were diphtheria-tetanus-pertussis (DTP), polio, hepatitis B (HB), and measles-mumps-rubella. All 4 vaccines are routinely given both overseas and in the United States.^{2,3} The youngest age for first administration and minimum intervals between doses for each vaccine under the US schedule are shown in Table 1. We also determined the number of children who had UTD immunization status under the US schedule and then assessed UTD immunization status among children in 2 age categories: 6 months to 11 months of age (UTD status defined as 3 DTP doses, 2 polio doses, and 2 HB doses) and 12 months of age or older (UTD status defined as 3 doses of DTP, 3 doses of polio, 3 doses of HB, and 1 dose of measles-mumps-rubella; thereby excluding children <6 months of age [$n = 17$] from analysis, because many vaccines are scheduled for administration between birth and 6 months of age).

Data Collection and Statistical Analysis

A computerized data form was used for medical record abstraction. All data were entered into Microsoft Access 97 (Microsoft Corp, Redmond, WA) and exported into SAS (SAS, Inc, Cary, NC). A descriptive analysis of patient demographics and immunization status was performed using Epi Info (Centers for Disease Control and Prevention, Atlanta, GA). Factors associated with immunization status were calculated as relative risks and 95% confidence intervals (CI) using SAS.

RESULTS

Demographic Characteristics of Study Subjects

The mean age of the 504 study subjects at initial US medical evaluation was 19 months; 71% were girls, and the children were born in 16 countries, most frequently China (48%) and Russia (31%). Most children (88%) resided in an orphanage before adoption, including 95% of children from Russia and 84% of children from China.

Valid Documentation of Overseas Immunization Records

Approximately one third of the children (178 [35%] of 504) had overseas preadoption immunization records; 11 had immunization records that were considered to be invalid. Among the 11 children with invalid overseas immunization records, 8 children had records that included only vaccine doses and lacked administration dates and 3 had 1 or more

TABLE 1. ACIP Recommended Minimum Age and Dosage Interval for Selected Vaccines

Vaccine	Minimum Age	Minimum Interval	
		Dose 1-2	Dose 2-3
DTP#	6 wk	4 wk	4 wk
Polio	6 wk	6 wk	6 wk
MMR	12 mo	1 mo	
HB	Birth	1 mo	2 mo*

MMR indicates measles-mumps-rubella.

* Minimum age for final dose is 4 months.

vaccines with administration dates that preceded their dates of birth.

A comparison of the characteristics of the 167 children with valid overseas vaccine records with children without such documentation is shown in Table 2. Children with valid overseas preadoption immunization records were more likely to be boys (relative risk [RR]: 1.35; 95% CI: 1.05–1.74). A valid overseas immunization record was not associated with age, previous residence in an orphanage (RR: 0.99; 95% CI: 0.68–1.45), or birth in Russia (RR: 0.90; 95% CI: 0.68–1.19). Children who were born in China were 2 times more likely to lack a valid overseas immunization record than those who were born in other countries (RR: 1.96; 95% CI: 1.44–2.68).

Acceptability of Overseas Immunizations Under the US Schedule

Table 3 shows the number of internationally adopted children with valid overseas immunization records by distribution of vaccine dose type and number of children with any vaccine dose acceptable under the US childhood immunization schedule. Among the 167 internationally adopted children with valid overseas immunization records, 154 (92%) different children had at least 1 vaccine dose that was considered acceptable in the United States using ACIP standards.⁴

On additional analysis, we found that, overall, 112 of the 167 children (67%) with valid overseas immunization records were UTD for at least 1 vaccine series under the US childhood schedule. We next evaluated the number of children who were UTD for 1 or more vaccine series under the US schedule in 2 age categories: 6 months to 11 months of age and 12 months of age and older (thereby excluding children <6 months of age [$n = 17$] from this analysis; Tables 4 and 5). For the 150 children from both age categories combined, 112 (75%) were UTD for at least 1 vaccine series, and 14 (9%) were UTD for all vaccines recommended for their age group. Children aged 6 to 11 months were more likely than children aged 12 months or more to be UTD for all vaccines recommended for their age group (10 of 50 vs 4 of 100; $P = .005$).

DISCUSSION

The special medical needs of internationally adopted children have been recognized since the 1980s; previous reports focused on the importance of

TABLE 2. Characteristics of Internationally Adopted Children With and Without Immunization Records

	Valid Immunization Record	
	Yes ($n = 167$) (n [%])	No ($n = 337$) (n [%])
Male	59 (35)	86 (26)
Median age	19.5 mo	16.5 mo
Birth country		
Russia	63 (38)	92 (27)
China	56 (34)	187 (56)
Other	48 (28)	58 (17)
Lived in orphanage	147 (88)	297 (88)

TABLE 3. Distribution of Valid Overseas Vaccine Doses Among 167 International Adoptees

Valid Dose	Vaccine			
	DTP*	Polio	HB*	MMR*
Overseas 1	136	138	95	75
Overseas 2	114	115	64	22
Overseas 3	88	98	43	*
Overseas 4	18	35	*	*
Overseas 5	0	*	*	*

MMR indicates measles-mumps-rubella.

* No doses recorded.

TABLE 4. UTD Immunization Status Among International Adoptees by Vaccine Combinations: UTD Status for 12- to 15-Month Vaccine Series Among 100 Adoptees Aged 12 Months or Older

	Number UTD (n [%])
Four vaccines	
DTP, polio, HB, MMR	4 (4)
Three vaccines ($n = 27$)	
DTP/polio/MMR	19 (19)
DTP/HB/polio	4 (4)
DTP/HB/MMR	4 (4)
Two vaccines ($n = 28$)	
DTP/polio	9 (9)
Polio/MMR	8 (8)
DTP/HB	4 (4)
DTP/MMR	4 (4)
MMR/HB	2 (2)
Polio/HB	1 (1)
One vaccine ($n = 25$)	
MMR	15 (15)
DTP	9 (9)
HB	1 (1)

MMR indicates measles-mumps-rubella.

TABLE 5. UTD Status for 6-Month Vaccine Series Among 50 Adoptees Aged 6 to 11 Months

	Number UTD (n [%])
Three vaccines	
DTP/polio/HB	10 (20)
Two vaccines ($n = 14$)	
DTP/polio	10 (20)
HB/polio	4 (8)
One vaccine ($n = 4$)	
Polio	3 (6)
DTP	1 (2)

appropriate screening and treatment of infectious diseases such as tuberculosis, HB, syphilis, human immunodeficiency virus, and gastrointestinal pathogens.^{11–14} However, the care of these adoptees also poses challenges to health professionals who must determine the acceptability of overseas vaccinations and complete the recommended US schedule of immunizations.

We assessed immunization records from a retrospective cohort of 504 internationally adopted children and found that the majority (65%) had no written documentation of receipt of overseas immunizations. These findings are consistent with a 1995 study of pediatric refugees in upstate New York that found that only 39% of children had documented adequate immunizations.¹⁵ Because our study did

not perform simultaneous serologic testing for all vaccines to measure antibody titers and immune status, it is not possible to determine whether children without valid records had not received vaccinations or they had received vaccinations but had incomplete or missing immunization records. It is also not clear what role, if any, the 1997 Immunizations Requirements Exemption for orphans born overseas may have played in contributing to the lack of vaccinations among internationally adopted children or poor documentation of overseas vaccination records.

Among the minority (35%) of children in this study who had documented overseas immunizations, most (167 [94%] of 178) had valid records. Three children had vaccine doses supposedly administered before birth; these discrepancies might be fraudulent or represent an uncertain birth date or missing information. It is possible that children may have gotten vaccines that were not documented. In a previous analysis of the adoptees in this study,⁶ 404 children who underwent tuberculin skin testing were evaluated for BCG immunization; 220 (54%) children had a BCG scar, but only 83 (21%) had a vaccination record indicating BCG immunization. These findings—a BCG scar but no documentation of the administration of BCG—indicate that some children in this study did get immunizations that were not recorded.

It is not surprising that only 9% of children with valid overseas immunization records were UTD for the US schedule. Under the WHO immunization schedule, many internationally adopted children get their first dose of polio vaccine at birth and a measles vaccine at 9 months of age, making both doses unacceptable in the US. Others may have been immunized during National Immunization Days, which do not consider age criteria or dosing intervals for immunization schedules.^{16,17}

This study does demonstrate that immunization schedules around the world have some commonality. The majority (154 [94%] of 167) of children with valid overseas immunization records had at least 1 vaccine dose acceptable in the US, and more than two thirds of the children (112 of 167) were considered UTD under the US schedule for 1 or more of the vaccine series.

However, some pediatric experts recommend re-immunizing all internationally adopted children no matter which vaccines were received overseas. This advice is based on the conflicting results of 5 recent studies regarding whether written immunization records are a reliable predictor of immune status for specific vaccines.

A previous analysis of antibody response after HB immunization among the adoptees in this study found detectable antibody to hepatitis B surface antigen among 29 (69%) of 42 children who had received 3 doses, 14 (67%) of 21 who had received 2 doses, and 8 (24%) of 33 who had received 1 dose.⁶ Two evaluations of adoptees, primarily from China, Russia, and Eastern Europe, reported that <40% of children with written verification of 3 or more DTP vaccinations had antitoxin titers to diphtheria and tetanus, measured using hemagglutination as-

says.^{18,19} In contrast, a fourth study of 51 adoptees from China, Russia, Eastern Europe, and Asian countries (all with 2 or more DTP doses) found that all had evidence of basic protection against diphtheria (enzyme-linked immunosorbent assay [ELISA] >0.01 IU/mL), 94% had full protection against diphtheria (ELISA >0.1 IU/mL), and 84% had protection against tetanus (ELISA >0.5 IU/mL).²⁰ Most recently, Miller et al²¹ studied 70 adoptees and found that many lacked adequate immunity to polio, rubella, and mumps but that 90% had adequate immunity to measles and 88% had adequate immunity to diphtheria. The laboratory methodology for measuring antibody titer was not specified.

Reasons for the differences in such studies are unclear but may involve the different laboratory methodologies used.^{22,23} The results of the hemagglutination assays tend to underestimate protection and cannot be directly compared with antibody concentration.²² ELISA assays for diphtheria antibodies are reliable in measuring sera with levels >0.1 IU/mL but may overestimate some sera below 0.1 IU/mL.²³

The current data are inconclusive as to the reliability of overseas immunization records. Generalizability of these data are further limited by the small number of children studied from different countries, lack of standardization in the methods used to assess validity and acceptability of vaccine records, and difference in testing to assess immunity. The ACIP is formulating new and more specific recommendations on vaccination for internationally adopted children from developing countries.²⁴

Guidance from the Red Book²⁵ suggests that internationally adopted children should receive immunizations according to the recommended schedules for US children. In general, written documentation of immunizations should be accepted as evidence of previous immunization if the vaccines, dates of administration, intervals between doses, and age of the child at the time of immunization are comparable with the current US schedule or WHO recommendations. Although some vaccines with inadequate potency have been produced in the past, most vaccines used worldwide are produced with adequate quality control standards and are reliable.

If there is any question as to whether vaccines were administered or were immunogenic, repeating immunizations is a recommended and acceptable option. Repeating immunizations is generally safe, as there is no evidence of harm from extra doses for most vaccines,²⁶ although the ACIP recommends that children not receive more than 6 doses each of diphtheria and tetanus toxoids before age 7 because extra doses may cause adverse local and systemic effects.^{27,28} However, judicious use of serologic testing of antibody levels to ensure immunity is another acceptable option and may be helpful in decreasing the possibility of vaccine side effects, especially those noted with DTP.^{28–30}

Pediatricians may try to reduce the number of unnecessary injections and decrease extraimmunization,³¹ particularly among older adoptees. Extraimmunization costs among internationally adopted

children have not been examined, but 21% of US-born children receive 1 or more redundant doses for a total estimated cost of \$26.5 million.³²

Only limited data are available to determine the most cost-effective approach to ensuring complete vaccination while avoiding extrimmunization among internationally adopted children. Additional studies using standardized methodologies to evaluate the acceptability of overseas immunization in the United States, paired with simultaneous serologic testing to measure antibody titers and immune status, stratified by country, are needed to determine conclusively the magnitude of the problem. Future research efforts should focus on the development and evaluation of rapid and effective "point of care" antibody assays with the ability to provide immediate results regarding immune status to vaccine-preventable diseases.

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