tum cultures varies by clinical presentation. Greenbaum et al.[5] calculated culture sensitivity to be 96% for patients with cavitary disease on chest radiograph,compared with 70% for those patients with localized infiltrates.

Failure to report disease in patients with acid-fast bacilli–positive smears when a culture cannot be obtained may also result in underreporting. Two studies reported smear specificities of greater than 99% in patients not coinfected with HIV.[5,6] Nevertheless, every effort should be made to obtain sputum cultures from all persons in the United States suspected of having pulmonary tuberculosis.

CDC is currently evaluating the 1990 tuberculosis surveillance case definition for sensitivity and specificity, particularly for children and patients with immunocompromising conditions. Our findings document the need for CDC to work with other appropriate partners in the development of uniform criteria for national tuberculosis surveillance. Uniform criteria are essential for appropriate analysis and interpretation of national trends in case rates, of trends in the clinical and demographic characteristics of national tuberculosis morbidity data, and for comparisons between geographic areas. □

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The Surveillance of Birth Defects: The Usefulness of the Revised US Standard Birth Certificate

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ABSTRACT

To assess the sensitivity and positive predictive value of birth defects reported on the 1989 revision of the US Standard Birth Certificate, a population of 76 862 Atlanta-area births during 1989 and 1990 was used as the basis for comparing 771 birth certificates that reported birth defects with 2428 live-born infant records in a birth defects registry that uses multiple sources of case ascertainment. Only 14% of birth defects in the registry records were reported on birth certificates. After the analysis was restricted to defects recognizable at birth, the sensitivity and positive predictive value of the birth certificates were 28% and 77%, respectively. Birth certificates underestimate birth defect rates and should be used cautiously for birth defect surveillance and epidemiological studies. (*Am J Public Health.* 1996;86: 731–734)

Introduction

About 3% of all live-born infants have one or more major birth defects.[1] Birth defects are the leading cause of infant mortality[2] and, in 1991, were the sixth leading cause of years of potential life lost before age 65.[3] Birth defect surveillance is useful for monitoring the distribution of and changes in birth defect incidence and for detecting unusual patterns suggesting environmental influences. Surveillance data provide information for epidemiological studies and support for health policy decisions, health services planning, and prevention activities.

Birth certificates are an attractive source of information about birth defects because they are universal (one certificate per child), standardized across the United States, and inexpensive and convenient for case ascertainment. However, numerous studies[4–10] have reported the inadequacy of birth defect reporting on the pre-1989 standard birth certificate, which used an open-ended question format that was poorly completed and difficult to analyze. The 1989 revision of the US Standard Birth Certificate replaced the open-ended format with a checkbox format to simplify and improve the reporting of birth defects and other birth information.[11–13] Although studies have suggested that the use of a checkbox improves reporting of birth outcome information on vital records,[14,15] few studies have assessed the validity of data derived from the revised birth certificate. Buescher et al. described the quality of several data

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TABLE 1—Sensitivity and Positive Predictive Value of Birth Certificate Data on Selected Birth Defects Compared with Data from the Metropolitan Atlanta Congenital Defects Program, 76 862 Births, 1989 to 1990

Birth Defect	Sensitivity (%)	Positive Predictive Value (%)
Anencephaly	6/7 (86)	6/6 (100)
Spina bifida	14/35 (40)	14/14 (100)
Rectal atresia or stenosis	3/30 (10)	3/4 (75)
Esophageal atresia	2/17 (12)	2/3 (67)
Omphalocele/gastroschisis	14/30 (47)	14/14 (100)
Cleft lip and/or palate	43/113 (38)	43/44 (98)
Clubfoot	32/147 (22)	32/39 (82)
Diaphragmatic hernia	7/21 (33)	7/11 (64)
Down syndrome	16/84 (19)	16/43 (37)
Overall (total)	137/484 (28)	137/178 (77)

TABLE 2—Sensitivity and Positive Predictive Value of Birth Certificate Data on Birth Defects Identifiable at Birth Compared with Data from the Metropolitan Atlanta Congenital Defects Program, by Sex and Race of Infant, 76 862 Births, 1989 to 1990

	Sensitivity (%)[a]	Positive Predictive Value (%)[a]
Sex		
Male	72/273 (26)	72/94 (77)
Female	63/208 (30)	63/78 (81)
P[b]	.39	.63
Race		
White	79/280 (28)	79/95 (83)
Other race	53/203 (26)	53/72 (74)
P[b]	.68	.19

[a]Totals are less than those in Table 1 because of missing sex and race data on birth certificates.
[b]*P* value, chi-square test for homogeneity.

items from it but did not assess data on congenital anomalies.[16] Piper et al.[17] found a low yield of birth defects reported on the birth certificates compared with medical record reviews in a special population of infants who weighed less than 1500 g or who died during the first month of life. The current study represents the first investigation to assess the completeness and accuracy of birth defect data from the newly revised birth certificate against a population-based birth defect registry that uses multiple data sources.

Methods

To evaluate the sensitivity and positive predictive value of the revised birth certificates for selected defects, data from Georgia birth certificates were compared with data from the Metropolitan Atlanta Congenital Defects Program. This program, one of the oldest population-based birth defect registries in the United States, monitors major structural birth defects among infants in the metropolitan Atlanta area. The case definition includes the following criteria:

- Maternal residence in the five-county metropolitan Atlanta area
- Gestational age of at least 20 weeks or birthweight of at least 500 g
- Presence of a structural or genetic defect that can adversely affect health and development
- Diagnosis of the defect or recognition of its signs or symptoms within the child's first year of life
- Abstraction of information from medical records by the child's sixth birthday

Program case reports are collected by trained abstractors who do case ascertainment using multiple sources, including records from birth hospitals, pediatric referral hospitals, cytogenetic laboratories, specialty clinics, and vital statistics. At the birth hospitals, these abstractors routinely review discharge diagnosis indices, delivery and nursery logs, and pathology records.

Program data include records of both live-born and stillborn infants. For this study, only live-born infant records were used because birth certificates are not completed for fetal deaths. The study population consisted of 76 862 live-born infants born during 1989 and 1990 in hospitals within the five-county metropolitan Atlanta area to residents of those five counties. The birth certificates of 771 infants who had at least one congenital anomaly were cross-checked against program records of infants with birth defects (n = 2428). Child's birth date and hospital, as well as mother's name, address, and birth date, were used in the cross-check.

The congenital anomalies section of the 1989 revised State of Georgia Certificate of Live Birth includes checkboxes for 21 congenital anomaly categories and is identical to that of the US Standard Certificate of Live Birth. Sensitivity was defined as the proportion of birth defects reported in the Congenital Defects Program and detected by birth certificates; positive predictive value was defined as the proportion of birth defects identified by birth certificates that were also identified by the Congenital Defects Program.

Since many defects are not readily recognizable at birth and therefore are often not identified on the birth certificate, the analysis was restricted to selected defects that are readily identifiable within a child's first few days of life: anencephaly, spina bifida, rectal atresia or stenosis, esophageal atresia, omphalocele/gastroschisis, cleft lip/palate, clubfoot, diaphragmatic hernia, and Down syndrome. Excluded were categories that included defects not always easily identifiable at birth (e.g., heart malformations) and categories that grouped nonspecific defects together (e.g., other circulatory/respiratory anomalies). Categorization of birth defects was limited to those categories used on the birth certificate. After exclusions, the sample consisted of 178 birth certificates and Congenital Defects Program records of 484 babies with defects. With this sample, defect-specific sensitivity and positive predictive value rates were calculated.

Results

Only 14% of birth defects (not restricted to readily recognizable defects) in the Atlanta program's records were reported on the birth certificates. After the analysis was restricted to defects recognizable at birth, the sensitivity of birth certificates increased to only 28%

for these defects combined, ranging from 86% for anencephaly to 10% for rectal atresia or stenosis (Table 1). The combined positive predictive value was 77%, ranging from 100% for anencephaly, spina bifida, and omphalocele/gastroschisis to 37% for Down syndrome. Sensitivity and predictive values were not significantly affected by an infant's race or sex ($P > .1$, chi-square test for homogeneity; Table 2).

Discussion

The use of checkboxes for congenital anomalies on the newly revised birth certificate has resulted in little improvement in the sensitivity of birth certificates for detecting congenital anomalies in metropolitan Atlanta. Data from a similar study using 1984 to 1988 data from the Metropolitan Atlanta Congenital Defects Program and prerevision birth certificates showed the birth certificates to have a sensitivity of 9% for detecting all defects (Edmonds, Centers for Disease Control and Prevention, personal communication, March 1994), compared with 14% in our study. In addition, data published in a similar study of prerevision birth certificates in California in 1983[4] demonstrated a sensitivity rate of 20% for birth defects recognizable at birth, compared with 28% in our study. The positive predictive value for these defects in the California study was 80%, approximating our study's value of 77%.

The low positive predictive value of 37% for Down syndrome was unexpected. Data from studies by Johnson et al.[18] and Hexter et al.[4] show a positive predictive value of greater than 90% for Down syndrome, although the methodologies and birth certificate formats for the reporting of congenital anomalies in these studies differed from those in our study. Johnson et al. found a higher rate of false-positives (i.e., equivalent to a lower positive predictive value) for Down syndrome among non-Whites.[18] In our study, the false-positives were distributed over several hospitals and occurred at an approximately equal rate among Whites and non-Whites. Upon reexamining the birth certificates, we noted that in four instances, the congenital anomaly checkboxes for both "none" and "Down syndrome" were checked. This calls into question, at least in some instances, the accuracy and care with which the checkbox format is completed. Reasons for the other Down syndrome false-positives are unknown.

In times of limited resources for surveillance activities, potentially useful sources of information should not be abandoned. As long as one remains cognizant of the limitations of birth certificates for birth defect surveillance, these documents can make a useful contribution, providing at least low-end estimates of birth defect rates. However, birth certificates should be used cautiously for case ascertainment in case–control studies. Cases could be differentially reported on birth certificates, which could lead to an ascertainment bias in epidemiological studies. Although the positive predictive value was relatively high for selected defects, birth defects reported on a birth certificate should be validated through medical records review.

Not only do birth certificate data lack sensitivity for birth defect surveillance, they also lack precision and provide users with limited ability to detect multiple defects and syndromes. For every checkbox marked on the birth certificate, there was an average of four defects reported by the Metropolitan Atlanta Congenital Defects Program. Because many human teratogens and chromosomal abnormalities are associated with multiple birth defects, improved ascertainment of multiple defects and syndromes can enhance the detection of human teratogens and the classification of and surveillance for chromosomal abnormalities.[19] Therefore, a surveillance system based solely on birth certificates would be unsuitable for many epidemiological studies.

There are many possible reasons for the poor reporting of birth defects on birth certificates. Birth defect diagnoses may be uncertain at the time of a newborn's hospital discharge or the birth certificate's completion, and so they may not be fully documented in the medical record, which is often used to complete the birth certificate. Furthermore, birth certificates are often completed by persons not involved in the care of infants (e.g., hospital clerks, medical records technicians), some of whom lack the knowledge to complete the birth defects section accurately. For example, a clerk may not know that trisomy 21 equates to Down syndrome or that talipes is clubfoot. Abstracted data can only be as good as the degree of documentation in the record, the thoroughness of record review, and the knowledge of the personnel completing the certificate. Minton and Seegmiller demonstrated a marked improvement in the birth certificate reporting of birth defects when a reporting sheet was placed in each newborn's file, the newborn's physician was made responsible for reporting defects, and a specially trained medical records person was appointed.[20]

We evaluated birth certificate data from the first 2 years during which a revised birth certificate was used, a transitional period. Data quality may improve as hospital personnel gain experience with the new form and the use of electronic registration becomes more widespread.

Surveillance of birth defects provides data for epidemiological research to identify causes or risk factors such as drugs, nutritional factors, environmental exposures, maternal illnesses, and genetic factors. This is especially important because the causes of many birth defects are unknown. Surveillance also provides data for developing and evaluating prevention strategies when the cause is known. In this study, we show that although birth certificates can provide some useful data, they should not be relied upon as the sole data source for epidemiological studies of birth defects. □

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Reporting Vaccine-Associated Paralytic Poliomyelitis: Concordance between the CDC and the National Vaccine Injury Compensation Program

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ABSTRACT

This paper compares cases of paralytic poliomyelitis reported to the systems operated by the National Vaccine Injury Compensation Program and the Centers for Disease Control and Prevention (CDC) for reporting of adverse events associated with vaccination. Of the 118 cases of vaccine-associated paralytic poliomyelitis determined by either system, 18 were reported initially only to the compensation program, 50 only to the CDC, and 50 to both. The annual incidence of vaccine-associated paralytic poliomyelitis determined from data from both systems varied from 6 to 13 cases (mean = 9.1) a year, with an increase of 1.4 cases a year when initial reports only to the compensation program are included. Thus, the compensation program provides important supplemental incidence data. (*Am J Public Health.* 1996;86:734–737)

Introduction

The National Vaccine Injury Compensation Program is a federal "no-fault" system to provide compensation for individuals who were injured or who died as a result of specified immunizations. A division of the US Department of Health and Human Services, the program was established under the National Childhood Vaccine Injury Act of 1986 and became effective on October 1, 1988.

For oral poliovirus vaccine cases, the act requires proof that an individual either received a polio vaccine other than inactivated polio vaccine or contracted polio from another person who received oral poliovirus vaccine.[1] The Vaccine Injury Table for oral poliovirus grants the presumption of vaccine causation if the first symptom of paralytic poliomyelitis occurs (1) in a nonimmunodeficient recipient within 30 days, (2) in an immunodeficient recipient within 6 months, or (3) in a vaccine-associated community case without regard to the date of vaccination. If paralytic polio occurs within the time period prescribed above, any complication (including death) is entitled to a presumption of causation.[2] Paralytic poliomyelitis or other conditions can be determined to be caused in fact by the oral vaccine by a preponderance of medical evidence, which is anything that is more than 50% or is more likely than not. In addition to the above medical requirements, a petition filed with the US Court of Federal Claims must meet certain unrelated statutory requirements for compensation.[3]

Since March 21, 1987, federal law has required health care providers to report to the Vaccine Adverse Event Reporting System (VAERS) the occurrence of any condition set forth in the Vaccine Injury Table.[4] The national surveillance system at the CDC learns of suspected cases of poliomyelitis from (1) VAERS, (2) direct voluntary reporting, (3) an enterovirus surveillance system

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