

**Progress on the Implementation of IC 16-38-4-7 (Birth Problems Registry) as
amended in First Regular Session 112th General Assembly (2001)
Reporting Period: July 2009 – June 2010**

The Indiana Birth Defects and Problems Registry is a population-based surveillance system that seeks to promote fetal, infant, and child health. The purpose of the Registry is to prevent birth defects and childhood developmental disabilities and to enhance the quality of life of affected Indiana residents.

Birth defects are conditions present at birth that affect the structure or function of an infant's body. They can cause physical, mental, or medical problems. Approximately 1 in 33 babies is born with a major birth defect each year in the United States. Birth defects are the leading cause of death in infants, accounting for more than 20% of all infant deaths. Babies born with birth defects also have a greater chance of illness and long-term disability compared to babies born without birth defects. Annual costs for birth defect-related conditions are nearly \$2.5 billion (*Morbidity and Mortality Weekly Report*, January 19, 2007). Some of these causes are entirely preventable, while others could be identified early and treated or managed in order to improve the quality of life of affected infants and their families.

The 1986 Indiana General Assembly enacted a law (IC 16-4-10-6) to establish the Birth Problems Registry by January 1, 1987. In 2001, the Indiana Birth Problems Registry law (IC 16-38-4-7; 410 IAC 21-3) was amended to allow additional data sources to be used to improve the quality of the data. Data from the Indiana Birth Defects and Problems Registry (IBDPR) will be used to detect trends in birth defects and suggest areas for further study; to identify epidemiological factors associated with birth defects; to address community concerns about the environmental effects on birth outcomes; to evaluate education, screening, and prevention programs; and to establish efficient referral systems that provide special services for the children with identified birth defects and their families.

Indiana State Department of Health staff obtained a three-year CDC Cooperative Agreement, a four-year Health Resource Service Administration (HRSA) Genetics Implementation Grant, a HRSA State Systems Development Initiative (SSDI), and HRSA's Title V Block Grant to fund the development of the enhanced IBDPR both programmatically and technically.

Case Ascertainment

The Indiana Birth Defects and Problems Registry (IBDPR) is considered a "passive" system because initial case ascertainment is through the electronic submission of hospital discharge data (HDD), with defined ICD-9-CM codes that identify birth defects and problems. However, in the early stages of program development, it was determined that up to 25% of the HDD was invalid. Therefore, the program protocol includes completing chart audits (which is indicative of an "active" birth defects registry) on the 44 CDC-targeted conditions to ensure the data submitted to the CDC is as valid as possible and to

ensure that appropriate information is sent to families of children reported with at least one birth defect.

Hospital Reporting:

All 111 reporting hospitals submit monthly discharge data using the Gateway web portal. By the end of August 2010, 68 hospitals had completed reporting up to June 2010, 11 hospitals had reported up to May 2010, and 8 hospitals up to March 2010. The remaining hospitals, with the exception of three (3) facilities, have submitted reports covering the November 2009 – February 2010 time period. Hospitals are required to report birth defects data to the IBDPR when they finish coding hospital discharge records for each month. The changes in data collection and recording systems and lack of resources, such as medical records or information technology staff, have been presented as reasons for the delays or irregularities in data reporting. An additional factor leading to a lower number of up-to-date HDD reporting (compared to last year) involved non-operation of the feedback and reminder e-mail system associated with the HDD application during a three-month reconstruction period. IBDPR staff is working to re-implement this e-mail system and calling facilities to request missing HDD data.

Physician Reporting:

The IBDPR uses physician reporting to identify children with birth defects that may not be diagnosed at birth and may, therefore, be diagnosed in a doctor's office rather than a hospital. The IBDPR staff considers a physician's submission to be confirmation of a diagnosis. No chart auditing is done on charts in a physician's office. If the IBDPR has received duplicate information from a hospital and no chart audit has been completed, the physician's report will be confirmation of that birth defect and no chart audit will be done at the hospital. IBDPR staff expects that reports of children with autism and fetal alcohol spectrum disorder will be ascertained primarily from physician reporting, as the diagnostic criteria for both conditions include developmental delays that are not detectable at birth.

In recognition of "Birth Defects Awareness Month" and to encourage the use of the online Physician Reporting System, information packets were mailed to 5,585 Indiana health care providers in January 2010. These packets included a letter from the Health Commissioner containing a reminder about the legal requirements for reporting to the IBDPR, instructions for creating an account for and accessing the online Physician Reporting System through the Gateway web portal, a list of all reportable conditions, a poster for display and a fact sheet about hearing loss. Since the mailing of this information packet in January 2010 through June 2010, 28 new users have registered to use the online Physician Reporting System.

With the cooperation of the Indiana State Medical Association (ISMA), the Indiana Academy of Family Physicians (IAFP), the Indiana Academy of Pediatrics (IAP), and the Indiana Psychology Association (IPA), an article about the online Physician Reporting System was also published in each organization's newsletter. This article contained a

brief introduction to the IBDPR and registration instructions for the online Physician Reporting System.

During this reporting period (July, 2009- June, 2010), 526 children with birth defects were reported by physicians; 15 children were reported by psychologists; and 32 children were reported by other authorized health care providers, such as osteopathic physicians and medical residents. During this twelve-month period, 581 reports were received via the online Physician Reporting System, representing a total of 573 children. No children were reported through the formerly-used Teleform system, which was taken out of service in May 2009.

Application Development

Due to the transition from the Operational Data Store (ODS) to the Indiana State Department of Health (ISDH) Repository (formerly called the Integrated Data System, or IDS) in spring 2009, some of the ODS-based applications, including the Hospital Discharge Data (HDD) application, lost partial functionality and required updates. As a direct result of this need for updates, the data processor component of the HDD application was not available from mid-April through mid-July 2010. The Repository development team is currently reconstructing the e-mail system and developing new applications to analyze birth defects data collected from hospitals and health care providers across the state.

Program Development

The goals of the IBDPR Program are to improve the quality of the data available on birth defects in Indiana and to provide information related to understanding the birth defect(s) and available resources to families of children with confirmed birth defects, as well as their health care providers.

Each time a change occurs within the rules regarding case ascertainment, IBDPR staff has ensured that all appropriate personnel, including health care providers and birthing facility staff, have received notification of the legislative change.

Indiana received a grant award from the Great Lakes Fetal Alcohol Spectrum Disorders (FASD) Regional Training Center (GLFRTC) through the University of Wisconsin. These funds are designated for use to provide trainings to health care providers who are interested in learning about FASD and becoming CDC-certified FASD Trainers. In December 2009, the ISDH Maternal & Child Health (MCH) Public Health Nutritionist was certified by the CDC as an FASD trainer. At this time, additional trainings for health care providers in Indiana are being scheduled; they will be hosted by the MCH Public Health Nutritionist.

Due to both staff changes within the program and the transition from the ODS to the ISDH Repository requiring updates to the HDD application and other components of the IBDPR, IBDPR staff postponed implementing the mailing of educational information and

resource packets to parents/guardians of children with at least one confirmed birth defect. All educational information and resource information are in the process of being translated into Spanish, so that families will receive the information with English on one side of a sheet and Spanish on the other side.

When the electronic application to send these packets is implemented, IBDPR staff will begin sending packets to the families of children with at least one confirmed birth defect who were born in 2009 or later. The effectiveness of these mailings will be evaluated once this component of the program is fully functioning.

National Meetings Attended

The Center for Disease Control and Prevention (CDC) offered one IBDPR staff member complete funding to attend the 13th annual meeting of the National Birth Defects Prevention Network (NBDPN), which was held in Washington, DC in March 2010. The meeting was titled “Advances and Opportunities for Birth Defects Surveillance, Research, and Prevention.” The conference was designed to enhance relationships between federal, state, and professional organizations that are working toward common goals and also to provide an opportunity to discuss successful efforts related to reducing and preventing birth defects.

Statute Requisites

As the IBDPR collects data daily on children from birth to three or five years of age, the same report for the same time period, compiled on different dates, may indicate different values. The data for this report was compiled on 06/23/2010. Due to the small numbers of birth defects per year, data is grouped in multiple years, as required by CDC for national publication. This report includes Indiana data available during the following five years: 2003, 2004, 2005, 2006 and 2007. According to Vital Records data, there were 437,493 live births in Indiana from 2003 through 2007.

1) The numbers and types of birth problems occurring in Indiana by county:

The data presented in Tables 1 – 3 were obtained by the data files submitted to the IBDPR by statewide hospitals as required by the Birth Problems Registry law (IC 16-38-4-7; 410 IAC 21-3). The hospitals extract this data from their hospital discharge (UB-92) records.

To verify the accuracy of hospital discharge data, the IBDPR targets 46 specific birth defects from the list of reported conditions for chart auditing by ISDH staff/contractors. These 46 defects are recommended by the National Birth Defects Prevention Network and are published for most states annually in *Birth Defects Research Part A: Clinical and Molecular Teratology*. IBDPR chart auditors visit hospitals and review the medical records of children that have been reported to the IBDPR with one or more targeted conditions in order to confirm the conditions or to determine them as probable (Table 5).

About 52% of the birth defects reported through hospital discharge data were determined to be confirmed conditions based on medical chart audits for 2003 – 2007 births. Of the targeted birth defects reported and confirmed, approximately 82% occurred in non-Hispanic white children, 9% in non-Hispanic black children, 7% in Hispanic children, 1% in Asian and Pacific Islander children, <1% in the children of American Indian descent and other races/ethnicities.

The following explains the attached tables:

Table 1 shows the number of children reported by the hospitals through ICD-9-CM codes at discharge for each reportable condition category. These are unduplicated children for each condition category. However, many children with birth defects or problems have more than one defect, so some children may be included in multiple condition categories. These numbers do not reflect confirmation of the defect, merely hospital reporting.

Table 2 shows the number of children reported with only one reportable condition and Table 3 shows the number of children reported with more than one reportable condition; the count is unduplicated by condition category. These tables are subsets of Table 1 and, again, do not reflect whether there is a confirmed diagnosis that supports the discharge code.

Tables 4A and 4B reflect the sources of case ascertainment for the targeted conditions and non-targeted reportable conditions. According to these tables, 11% of occurrences of autism, 33% of fetal alcohol syndrome (FAS), and 29% of autism spectrum and other pervasive developmental disorders were reported to the IBDPR only via physician reporting. Therefore, direct physician reports are imperative for accurate reporting of the prevalence of these conditions, as they are not commonly diagnosed at hospitals.

Table 5 reflects the targeted condition categories reported to the IBDPR by hospital discharge date for children born in 2003 – 2007, where the condition was determined to be confirmed or probable, based on information obtained during the chart audit. A “probable” condition is one that has been audited, where the criteria for confirmation was adequate enough to determine the condition to be likely, but not enough to confidently confirm the condition. The percentage of confirmed vs. reported conditions reflects the validity of the hospital discharge data reported by the hospitals. Approximately 52% of all targeted conditions reported for live births during the five-year period were determined to be probable or confirmed based on information obtained during chart audits. This value was unchanged compared to last year’s, which was the result from four years of available data.

Less than 50% of all reported cardiovascular anomalies were confirmed, indicating the need to conduct hospital chart audits. The ICD-9-CM codes listed on hospital discharge data often represent conditions that may possibly be present, but require additional testing or information to accurately confirm or rule out.

Table 6 provides the counts and rates (by race, per 10,000 births) of confirmed and probable targeted conditions for Indiana children born between 2003 and 2007 who have been reported to the IBDPR. Conditions determined to be “probable” are included with the confirmed conditions for counts and rates. The overall rate of 284 per 10,000 births is within national estimates.

Table 7 indicates trisomy counts and rates of infants born in 2003 – 2007, sorted by maternal age. Children with trisomy conditions have three, rather than the expected two, copies of a chromosome—for example, children born with a third copy of chromosome 21 have Down syndrome, also called trisomy 21.

Table 8 shows the counts and rates per 10,000 live births of confirmed and probable targeted birth defect conditions for children born between 2003 and 2007 to mothers who were Indiana residents; this data is sorted by county. Any count that is less than five (5), either for the entire county or for a specific birth defect, is indicated as “less than reportable numbers” and symbolized by an asterisk (*).

2) The amount of use of the birth problems registry by researchers:

Indiana data for 2003 – 2007 births (Table 6) was submitted to the National Birth Defects Prevention Network (NBDPN) in June 2010; this data will be published in *Birth Defects Research Part A: Clinical and Molecular Teratology* in December 2010.

IBDPR data was requested by researchers for use in the following projects during this fiscal year:

- Assessment of temporal trends based on gestational periods in the context of environmental data on teratogens; more specifically, a possible increase in fetal problems/defects for children whose first trimester gestation period occurred between December and March of a given year. This project is in progress; no information about the results of this project have been released at the time of this report’s publication.
- Assessment of a possible increase in the number of children born with gastroschisis (an opening in the abdominal wall) within St. Joseph county. Evaluation of the number and rate of gastroschisis within St. Joseph county was performed by IBDPR staff, including the MCH Epidemiologist; no significant increase in the rate was identified.

All requests for IBDPR data must be submitted to the Indiana State Department of Health (ISDH) Data Release Committee (DRC) for evaluation and approval. Data that is released to researchers is placed in a limited data set; each individual record is labeled with a unique person identifier (PID); names and other identifying information are not released to researchers. If a researcher requests a data set that includes fewer than five (5) total records for a given defect or within a given geographical area, IBDPR staff will only report that data as “fewer than five records.” No additional information about those records is released.

3) Proposals for the prevention of birth problems occurring in Indiana:

Currently, the IBDPR contains five years' worth of information on birth defect rates within the state. IBDPR staff members continue to work with the Maternal and Child Health (MCH) Epidemiologist to review IBDPR data in order to evaluate the presence of trends and/or clusters and, therefore, the need for specific prevention campaigns.

Curricula related to education and prevention of fetal alcohol syndrome (FAS) and the benefits of folic acid were developed and distributed to middle and high school consumer family sciences and biology teachers during this fiscal year. This information was also presented at the annual Hoosier Association of Science Teachers, Inc. (HASTI) conference in February 2010; the ISDH intends to present this information again at the 2011 HASTI conference. IBDPR staff members are requesting and collecting feedback based on the teachers' use of this information, and intend to evaluate the effectiveness of the curricula at the earliest opportunity.