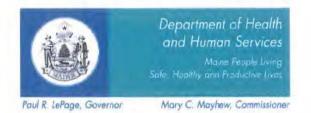
MAINE STATE LEGISLATURE

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November 18, 2016

Senator Eric L. Brakey, Chair Representative Drew Gattine, Chair Joint Standing Committee on Health and Human Services #100 State House Station Augusta, Maine 04333-0100

Dear Senator Brakey, Representative Gattine, and the Joint Standing Committee on Health and Human Services:

Enclosed please find the 2016 Annual Report to the Legislature for the Maine CDC Birth Defects Program submitted by the Department of Health and Human Services. This report is required under Title 22 of the M.R.S.A., Chapter 1687.

The report discusses the Birth Defects Program's activities and accomplishments in 2016 as well as planned activities for 2017.

Sincerely

Mary C. Mayhey

Commissioner

MCM/klv

Enclosure

Maine **CDC** Birth **Defects** Program



January 1, 2016 - December 31, 2016

Submitted to the Joint Standing Committee on Health and Human Services

2016 Annual Report



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EXECUTIVE SUMMARY December 2016

Background

In May, 1999 the Department of Health and Human Services was authorized to collect information on birth defects in Maine by statute (Title 22: Health and Welfare: Subtitle: Facilities for Children and Adults; Chapter 1687; Birth Defects Program; §8941-§13375). The Maine CDC Birth Defects Program was established within the Department of Health and Human Services, Maine Center for Disease Control and Prevention (Maine CDC).

Purpose

The overall objectives of the Maine CDC Birth Defects Program (BDP), using a public health approach, are:

- to assess the full impact of birth defects on Maine children and their families.
- to improve access to specialty services for families and locate resources for emotional and economic support, which includes referring the infant with a confirmed birth defect to the Department of Education Part C - Child Development Services (CDS) Program,
- to monitor trends related to prevalence of selected birth defects in Maine, and
- to educate the provider community and the general public on prevention strategies to decrease the incidence of birth defects in Maine.

Highlights

This 2016 annual report summarizes the current activities of the Maine CDC Birth Defects Program (BDP), the ongoing and upcoming activities for calendar year 2017 and shows selected birth defects counts and birth prevalence for the years 2009 – 2013. In 2016, the Maine CDC BDP:

- Contacted families with a baby with a confirmed birth defect to offer support and information regarding birth defects.
- Completed and submitted the Annual Report of selected birth defects to the U.S. Centers for Disease Control and Prevention, National Birth Defect Prevention Network.
- Continued to make referrals for babies with a confirmed birth defect to the Maine Department of Education/Child Development Services (CDS) – Individuals with Disabilities Education Act (IDEA) Part C Agency.
- Met regularly with the Maine CDC Environmental Public Health Tracking Unit to discuss updates to the Environmental Tracking Portal related to birth defects. The Birth Defects data on the portal was updated in 2016.
- Met regularly with the two abstractors that work with the Maine CDC BDP to develop skills. Information discussed included:
 - Specific criteria and definition for the current list of birth defects being abstracted
 - Issues around access to medical records

- Provided educational materials about the prevention of birth defects to parents, health providers and other interested parties.
- Convened the Maine CDC Birth Defects Advisory Committee three times to discuss relevant birth defect program issues and activities.
- Participated in the New England Birth Defects Consortium (NEBDC). The NEBDC is a regional collaboration of New England states (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont) established in 2008 to improve services for infants and children in New England with birth defects by promoting regional collaboration in data sharing, research, prevention and health care quality activities, http://www.nebirthdefects.org/ The current initiative is focused on collecting data in Region I regarding risk factors related to critical congenital heart defects (CCHD). This initiative was completed in the summer of 2015. A manuscript was completed in 2016. It was submitted for publication to Public Health Reports but was rejected. The manuscript will be resubmitted in October 2016.
- Participated in the online annual National Birth Defects Prevention Network Meeting which occurred June 7 and 8, 2016.
- Met regularly with ChildLINK staff to discuss issues with the database as well as to work toward expanding and increasing its use.
- Met regularly with Children with Special Health Needs (CSHN) staff to work on the continued development of the ChildLINK database.
- Developed a Down syndrome website. http://www.maine.gov/dhhs/mecdc/population-health/mch/cshn/birth-defects/families.html
 This site provides information that expectant or new parents and others including prenatal care providers can access to get information related to Down syndrome.
- Continued to work with the birth hospitals to support them sending critical congenital
 heart defects data electronically to the ChildLINK database. Eastern Maine Medical
 Center (EMMC) is currently in the process of participating in a trial process of sending in
 their data electronically.
- Started the process of updating the Maine Birth Defects Program rules to reflect the recommended birth defects list from the National Birth Defects Prevention Network and Federal CDC.

For more information on the Maine CDC Birth Defects Program:

Contact Diane Haberman, Program Coordinator, daine.haberman@maine.gov or 207-287-8424 http://www.maine.gov/dhhs/mecdc/population-health/mch/cshn/birth-defects/index.html

Full Report

Background

A birth defect is defined as an abnormal condition that occurs before or at the time of birth. Birth defects include a wide range of abnormalities with varying levels of impact. Some birth defects are serious and can result in death, while others are less severe and can be treated with appropriate medical services. Birth defects may be caused by genetic factors, environmental, drug or medication exposures while others remain unexplained. Birth defects can cause both mental and physical disabilities that affect children and their families for life. ¹

Birth defects affect about one in every 33 babies born in the United States each year. They are the leading cause of infant deaths, accounting for more than 20% of all infant deaths. Babies born with birth defects have a greater chance of illness and long-term disability than babies born without birth defects.² In order to prevent birth defects, it is essential to know what types of birth defects are occurring. A population-based birth defects surveillance program that uses multiple sources of data allows a surveillance program to accurately quantify morbidity and mortality, detect temporal trends, and assess the financial burden on families and State programs that birth defects may cause.³ Many children who survive have a lifetime of major expenses from essential services such as, specialty medical care, special education, rehabilitation and developmental services.

The Maine CDC Birth Defects Program (Maine CDC BDP) is committed to fulfilling its mission that all infants with birth defects are identified early and referred to an established network of services, in order to achieve optimal health and develop to their fullest potential. The Maine CDC BDP is a comprehensive surveillance program that benefits the residents of Maine through the early identification of infants who have birth defects. Early identification ensures timely and appropriate access to systems of care that are family-centered, culturally competent and community-based. It is the intention of the Maine CDC BDP to participate fully in epidemiological investigations as a means of informing public policy, to develop prevention strategies in order to reduce birth defects and to assess for timely referrals and follow-up care to reduce mortality and morbidity among children identified with birth defects.

Legislation and Rules

Legislation supporting the Maine CDC BDP has and continues to define the purpose of the program. The statutes defining these roles and responsibilities are listed below.

2 http://www.cdc.gov/node.do/id0900f38000dffe

¹ Trust for America's Health "Birth defects and Developmental Disabilities: A Major Public Health Challenge"

³ National Birth Defects Prevention Network http://www.nbdpn.org/

May 1999 - Public Law (P.L.) 1322, 22 M.R.S.A. c. 1687, established the Maine CDC BDP within the Maine Department of Health and Human Services. Program rules were formally adopted April 2003 outlining reporting responsibilities and access to medical records. Mandated reporting began May 2003.

May 2008 - Rules were updated to include three additional reportable birth defects.

April 2011 – Rules were amended to include the 45 birth defects recommended by the U. S. CDC and the National Birth Defects Prevention Network. Referral to the Part C Agency, Child Developmental Services (CDS) was also included.

Stakeholders

The following is a brief listing of organizations that have a strong association with the Maine CDC Birth Defects Program. The March of Dimes and the National Birth Defects Prevention Network are also key national-level partners.

Consumers Parents and fami	es Early Intervention Agencies O Department of Education – Child Development Services
 External groups involve follow-up and diagnosis Hospitals and the Nurses Primary care pro Specialist physic Genetic counselo 	r staff O Maine CDC Newborn Hearing Screening Program O Maine CDC Newborn Bloodspot Screening Program O Maine CDC Environmental Public Health Tracking O Maine CDC Data, Research and
	Vital Statistics Office of MaineCare Services

Maine CDC Birth Defects Advisory Committee

The Advisory Committee meets at least annually and at times more frequently. The Committee consists of interested parties including parents, health professionals, outside agencies including the Maine Chapter of the March of Dimes and other State, community and private sector agencies, as well as the Maine CDC Children with Special Health Needs staff. The group provides consultation to the Maine CDC BDP on development, implementation and evaluation of program policies, procedures and activities.

Summary of Activities

The Maine CDC Birth Defects Committee met three times this past year. Items discussed included:

· Review of options to share existing data with interested parties,

- Methods to reach out to families and other interested parties to spread the word about birth defects prevention,
- Methods of outreach to parents at the birth hospital with information and support,
- Updates to implementation of Critical Congenital Heart Defects (CCHD) screening and follow up within New England and Maine,
- Sharing information on Down syndrome both electronically and through other means including postcards & sharing information at existing meetings with interested parties,
- Expanding the list of birth defects highlighted on the CSHN Birth Defects web page,
- · Expanding the membership of the Committee, and
- Reviewing and updating the birth defects program procedures as they relate to the updated rules and other changes.

Maine CDC Birth Defects Program Summary

Program Description

The Maine CDC Birth Defects Program began developing a birth defects surveillance system in 1999 with funding from the U.S. Centers for Disease Control and Prevention (CDC). The Maine CDC Birth Defects Program was established within the Maine CDC to identify newborns with birth defects, ensure that they receive appropriate specialty services and to monitor birth defect trends.

As a surveillance unit, the Maine CDC Birth Defects Program began passive case ascertainment with confirmation of cases by active case ascertainment on May 1, 2003. Passive case ascertainment with active case ascertainment is an approach whereby the surveillance program receives case reports of birth defects from a variety of data sources and then follows up with a review of the case. As required by statute, those entities licensed under Title 22: Hospitals and Title 32: Licensed Professionals are required to provide or make available health records and information relating to the occurrence of birth defects. Passive data sources include hospital case reports, birth and death certificates and medical discharge records using diagnostic codes. Once a case is identified as a possible reportable birth defect, the case is assigned to an abstractor. The abstractor visits the hospital to review records to confirm the presence of a birth defect.

The Maine CDC Birth Defects Program recently updated the listing of reportable birth defects to reflect the birth defects surveillance guidelines developed by the CDC National Birth Defects Prevention Network. The current listing of reportable birth defects may be found in Appendix A.

The Maine CDC BDP receives medical discharge data electronically from all birthing hospitals at this time. Maine CDC BDP sends all hospitals a monthly electronic reminder to submit data.

In order for a case to be considered by the Maine CDC BDP, it must meet one or more of the following criteria:

- Infant was live born, stillborn or prenatally diagnosed, with a gestational age of greater than 20 weeks,
- · Fetuses less than 20 weeks gestation but with a prenatal diagnosis,
- · Birth occurred in Maine and the mother was a Maine resident,
- · Diagnosis was made before the infant reached 1 year of age, and
- Birth defect is included in the Maine CDC BDP list of reportable birth defects.

Potential cases are identified through weekly downloads of both the electronic birth and infant death certificates and medical records discharge data. Once a potential case is identified, abstraction is performed using a comprehensive electronic abstraction method. Information collected includes the nature and details of the birth defect, demographics, mother's health history, prenatal information, cytogenic and laboratory data, family history, and, when available, father's history, and mother's exposure to illegal drugs, medications, smoking or alcohol.

The data collected by the abstractors is reviewed and entered in the birth defects surveillance and tracking system, called ChildLINK. ChildLINK was built and is housed at the University of Maine. ChildLINK was built to connect existing State information systems with data obtained from hospitals, health care providers and others mandated to report birth defects. Once a child is confirmed to have a birth defect, the child's family is notified by mail of services available to them.

Currently, the Maine CDC Birth Defects Program reports on and gathers information on 45 birth defects (see Appendix A for a complete listing of reportable birth defects). These cases are confirmed usually within the first three months after birth. However, this time frame can be longer depending on when the birth defect was reported and the ability of the abstractors to gather the necessary information from the birth hospital. There is also a lag time in verifying a birth defect because, by law, a birth defect can be diagnosed and reported within the first year of life.

Personnel and Funding Sources

The Maine CDC Birth Defects Program consists of one full-time coordinator and two part-time contractors. The Maine CDC BDP currently contracts with Maine Medical Center and a private individual for part-time abstraction services.

The Maine CDC Birth Defects Coordinator position is funded through the Maternal and Child Health Block Grant. The two abstractor positions are funded by contracts through the State General Fund.

Goals, Activities and Achievements

The Maine CDC Birth Defects Program gathers data about infants born each year with certain birth defects diagnosed within the first year of life. The statute requires that the "Program:"

- Collect, analyze and distribute information to identify the birth defects with regards to the following: causes, risk factors and strategies for prevention and the provision of services,
- Establish a system for data collection that identifies prevalence and incidence rates by region and population group and identifies the morbidity and mortality rates resulting from birth defects,
- · Contact families to provide information about available resources and services, and
- Conduct investigations to determine the nature, and extent of the disease or known or suspected causes of birth defects.
- Examples of Maine CDC BDP activity:
 - Collection and abstraction of data on 45 birth defects. The Maine CDC BDP submits data annually to the National Birth Defects Prevention Network and U.S. CDC.
 - Collaboration with the Maine CDC Environmental Public Health Tracking Unit to show 12 of the 45 birth defects on the Environmental Health Tracking Portal.
 - Connection with a family once a baby is identified with a confirmed birth defect. The baby identified with a confirmed birth defect is also referred to the Department of Education Part C Agency (CDS) for follow-up for early intervention services.
 - Work with the New England Birth Defects Consortium. The Consortium has collected regional data on risk factors in critical congenital heart defects in the summer of 2015. A written report is currently awaiting possible publication.
 - Worked with stakeholders to develop a website to share information related to Down syndrome with parents and those who work with women and babies.

Maine CDC Birth Defects Tracking System

Tracking System

Maine CDC BDP began collaborating with the University of Maine at Orono in 2001 to develop and implement a comprehensive surveillance and tracking system. Today, ChildLINK tracks approximately 13,000 infants born in Maine each year. ChildLINK links birth defect data with multiple data sources that include birth and death certificates, hospital discharge data and metabolic and newborn hearing screening data. ChildLINK maintains security/confidentiality of all records by assigning permission to access the system on an individual basis. Access is monitored by Symantec on a 24/7 basis. By linking information from these existing data sources ChildLINK can:

- Help assure that children with birth defects and their families receive information about resources and services that may be of assistance and
- Provide valuable public health data to State and national policy makers.

Process Overview

Once a month hospitals send a discharge report reflecting the previous month's birth defects data identified at the hospital to the BDP. An automatic reminder is sent from ChildLINK to the hospital if the data is not sent in by the fifteenth of the month. This information is put into an Excel format and then submitted electronically to the ChildLINK database system. Once the system receives the report, the report is reviewed for proper formatting and then uploaded to the ChildLINK system. The data is then linked to the birth certificate of the corresponding child.

Statistical Reports

The Maine CDC Birth Defects Program submits data annually for a specific span of years to the U.S. Centers for Disease Control and Prevention, National Birth Defects Prevention Network. The most recent data submitted to the Federal CDC was 2009 - 2013 which will be available for publication in February 2017. The 24-month lag time in Federal CDC data is based on the definition of a birth defect. By definition, a birth defect meets criteria and is included in the Maine CDC BDP count if the birth defect is identified within the first year of life. This means that the Maine CDC BDP may still be gathering data as late as December of the year after the birth of the baby. Consequently time is needed to abstract the data necessary to confirm the birth defect.

Birth Defects Counts	and Prevalence Rates (2009-2	013), Maii	ne	
Condition	Summary	Five year count	Prevalence per 10,000 Live Births	Notes
Anencephalus	One in 4,045 live births	16	2.5	
Cleft lip alone	One in 3,236 live births	20	3.1	
Cleft lip with cleft palate	One in 2,088 live births	31	4.8	
Cleft palate alone	One in 1,578 live births	41	32.1	
Coarctation of the aorta	One in 2,022 live births	32	4.9	
Common truncus (truncus arteriosus)	One in 21,573 live births	3	0.5	
Encephalocele	One in 10,786 live births	6	0.9	
Gastroschisis	One in 1,578 live births	41	6.3	1
Hypospadias*	One in 147 male live births	226	67.8	
Hypoplastic left heart syndrome	One in 2,397 live births	27	4.2	
Limb deficiencies (reduction defects)	One in 3,236 live births	20	3.1	
Omphalocele	One in 5,883 live births	11	1.7	2
Pulmonary valve atresia	One in 12,944 live births	5	0.8	
Spina bifida without anencephalus	One in 3,082 live births	21	3.2	
Tetralogy of Fallot	One in 2,311 live births	28	4.3	3

Transposition of the great arteries	One in 2,942 live births	22	3.4
Tricuspid valve atresia and stenosis	One in 12,944 live births	5	0.8
Trisomy 21 (Down syndrome)	One in 819 live births	79	12.2
Total Live Births 2009-2013		64,718	
Total Male Live Births (2009-2013)		33,331	

Notes

- 1. Gastrochisis is coded 756.73. Cases are also abstracted to determine diagnosis.
- 2. Omphalocele is coded 756.72. Cases are also abstracted to determine diagnosis.
- 3. Includes pulmonary atresia with septal defect.
- *Hypospadias: prevalence per 10,000 male live births; total male live births are provided for Hypospadias rates. Total live births and total male live births include babies born to Maine residents in and out of state.

Data Sources: Maine Birth Defects Registry and United States Department of Health and Human Services (US DHHS), Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS), Division of Vital Statistics, Natality public-use data 2007-2014, on CDC WONDER Online Database, February 2016. Accessed at http://wonder.cdc.gov/natality-current.html

General comments

Case-finding is limited to babies born in Maine to Maine residents and to birth defects identified in the first year of life. A baby can be born with multiple conditions, adding up the number of defects will not yield the number of babies born with defects. In addition, this list represents only a portion of reportable birth defects collected and tracked in Maine. National data can be found at the following link: http://www.nbdpn.org/previous annual reports.php

Public Awareness

Education and Informational Materials

The Maine CDC Birth Defects Program has a range of materials including brochures to send to interested parties and stakeholders that include prevention information regarding folic acid use, information on the various birth defects and other topics of interest regarding birth defects. The materials can be accessed at the Maine CDC website at the following internet address: http://www.maine.gov/dhhs/mecdc/population-health/mch/cshn/birth-defects/index.html

Maine CDC Birth Defects Program Calendar Year 2016 Accomplishments and Future Direction

Accomplishments

- As of December 31, 2016 it is estimated that 72 infants with a confirmed birth defect will be referred to the Department of Education – Part C Agency (CDS).
- Met regularly with abstractors to discuss ways to make the abstraction process more complete and to discuss other issues related to birth defects.
- Used social media and other options to raise awareness regarding prevention activities and birth defects to stakeholders, families and other interested parties.
- Continued discussions with hospital staff to allow birth defects abstractors to abstract
 individual medical records remotely. Internally, Maine Medical Center staff has been
 discussing access to the electronic (EMR) for outside users.
- Completed Critical Congenital Heart Defect (CCHD) project looking at risk factors in diagnosing a CCHD with the New England Birth Defects Consortium in 2015.
 Manuscript was completed in 2016. Manuscript has been submitted for publication.
- Met with Environmental Health staff quarterly. Began to participate actively with the Maine Tracking Network Advisory Group.
- Outreach with midwives throughout Maine to educate them regarding reporting requirements for CCHD in September 2016.

Future Direction

- Work to expand the ability to follow up with families to offer support by mail and phone on a timely basis.
- Work collaboratively with the other New England States on projects of mutual interest that will allow for increased understanding of the full impact of birth defects on Maine children and their families as well as throughout New England. Due to the small numbers of births in Maine and other New England states, working together provides for a larger number of cases and consequently more accurate data.
- Explore effective ways to share prevention information with stakeholders and interested parties using data collected through the abstraction process.
- Work with the Maine CDC Environmental Health Tracking Unit to expand the number of birth defects being reported on the portal. <a href="https://gateway.maine.gov/cognos/cgibin/cognosisapi.dll?baction=cognosViewer&ui.action=run&ui.object=%2fcontent%2ffolder[%40name%3d%27CDC%20EOHP%20EPHT%20AVR%27]%2freportView[%40name%3d%27Maine%20Environmental%20Public%20Health%20Tracking%20%28EPHT%29%20Network%20-
 - %20Public%20Data%20Portal%27]&cv.header=false&cv.toolbar=false
- Work with birth hospital staff to allow abstractors to have remote access to medical records. Currently the Maine BDP has ongoing conversations with staff at birth hospitals regarding barriers that exist for remote access. One hospital, Maine Medical Center, has been discussing developing a process outside their Electronic Medical Record (EMR) system that would allow outsider users to access the EMR remotely.

- The Maine BDP is exploring updating the rules in FY 2017/2018 to include seven Critical Congenital Heart Defects (CCHD) as well as other birth defects recommended by the National Birth Defects Prevention Network and Federal CDC.
- Update the Maine BDP's program manual and procedures to reflect new changes suggested by the National Birth Defects Program and Federal CDC to streamline the abstraction process.
- A pilot project began with Eastern Maine Medical Center (EMMC) to make sure the
 electronic submission of CCHD data to the ChildLINK database is working without
 issues. Successful completion of the pilot will support next steps with other birth
 hospitals in electronic submission of data.
- Continue to provide ongoing educational opportunities to hospital staff and others
 required to report the presence of a reportable birth defect in order to support completion
 and submittal of report forms correctly and on a timely basis.

Appendices

Appendix A Reportable Birth Defects Included in Case Definition for 2015

Birth Defect	ICD-9-CM Codes
Central N	ervous System
Anencephalus	740.0 – 740.1
Spina Bifida without anencephalus	741.0, 741.9 w/o 740.0 - 740.10
Hydrocephalus without Spina Bifida	742.3 w/o 741.0, 741.9
Encephalocele	742.0
Microcephalus	742.1
	Eye
Anophthalmia/microphthalmia	743.0, 743.1
Congenital cataract	743.30 – 743.34
Aniridia	743.45
	Ear
Anotia/microtia	744.01, 744.23
Cardi	ovascular
Common truncus	745.0
Transposition of great arteries	745.10, 745.11, 745.12, 745.19
Tetralogy of Fallot	745.2
Ventricular septal defect	745.4
Atrial septal defect	745.5
Endocardial cushion defect	745.60,745.61, 745.69
Pulmonary valve atresia and stenosis	746.01, 746.02
Tricuspid valve atresia and stenosis	746.1
Ebstein's anomaly	746.2
Aortic valve stenosis	746.3
Hypoplastic left heart syndrome	746.7
Patent ductus arteriosus	747.7
Coarctation of aorta	747.10

Orofa	cial
Cleft palate without cleft lip	749.0
Cleft lip with and without cleft palate	749.1, 749.2
Choanal atresia	748.0
Gastroint	estinal
Esophageal atresia/tracheoesophageal fistula	750.3
Rectal and large intestinal atresia/stenosis	751.2
Pyloric stenosis	750.5
Hirshsprung's disease (congenital megacolon)	751.3
Biliary atresia	751.61
Genitou	rinary
Renal agenesis/hypoplasia	753.0
Bladder exstrophy	753.5
Obstructive genitourinary defect	753.2, 753.6
Hypospadias and Epispadias	752.61, 752.62
Musculos	keletal
Reduction deformity, upper limbs	755.20 – 755.29
Reduction deformity, lower limbs	755.30 – 755.39
Gastroschisis	756.79
Omphalocele	756.79
Congenital hip dislocation	754.30, 754.31, 754.35
Diaphragmatic hernia	756.6
Chromos	somal
Trisomy 13	758.1
Down Syndrome (Trisomy 21)	758.0
Trisomy 18	758.2
Othe	er
Fetal alcohol syndrome	760.71
Amniotic bands	No code



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