**NBDPN Data Call Template for a Multistate Project with Examples**

**Project Title: \_\_\_\_\_ Interpregnancy Interval and Prevalence of Selected Birth Defects\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator name, title, affiliation, address and email:\_\_\_\_\_Jane Doe, PhD, Director,**

**Birth Defects Monitoring Program, 250 Washington St., Boston, MA 02108, jane.doe@state.gov\_**

**Lead program contact name, affiliation, address, and email: \_\_\_Zane Smith, Birth Defects Monitoring Program, 250 Washington St., Boston, MA 02108, Zane.smith@state.gov\_\_\_**

**Initial Request Date:\_\_\_\_\_\_\_4/11/22\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Funding source(s), if applicable:\_\_\_\_\_No outside funding\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Program Project Investigators/Study Personnel Contact Information and Backup Contact information**

*Provide contact information below for the lead study contact, principal investigator, and any co-investigators at your site involved in the study, as well as their level of access to confidential data below:*

Note: At the time of initial participation and at least once a year thereafter, participating programs will be asked to review the list of study personnel with their contact information and level of data access and provide updates as needed.

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| **Name, Degree, and Title**  | **Email** | **Phone numbers(s)**  | **Affiliation and address** | **Role in study** | **Access to confidential data (including unsuppressed small cell counts?) Y/N** |
| **Zane Smith, MPH, Epidemiologist** | Zane.smith@state.gov | O: 444-444-4444 | MA Birth Defects Monitoring Program, 250 Washington St., 5th Floor, Boston, MA 02108 | Study Lead | Y |
| **Jane Doe, PhD, Director** | Jane.doe@state.gov | O: 555-555-5555C: 222-222-2222 | MA Birth Defects Monitoring Program, 250 Washington St., 5th Floor, Boston, MA 02108 | Principal Investigator | Y |
| **Jean Day, ScD, Postdoctoral Fellow** | Jean.Day@state.gov | C: 333-333-3333 | MA Birth Defects Monitoring Program, 250 Washington St., 5th Floor, Boston, MA 02108 | Co-investigator | Y |
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*Note: Any personnel with confidential access must have completed human subjects training, with proof submitted as part of IRB application.*

**Key requirements for participation**

*Note: This section should include the most important requirements for study data to help programs quickly determine whether they can participate.*

*Please include here a brief list of the criteria that states must meet in order to be able to participate, such as:*

* + ***Study years: At least 3 consecutive years within 2015-2018***
	+ ***Data structure: individual or aggregate: Individual, line level data***
	+ ***Required defect(s):*** *(List in Appendix if needed)* ***See Appendix 1***
	+ ***Estimated deadline for data submission: 9/1/2022***
	+ ***Number of years of follow-up,*** *if applicable: N/A*
	+ ***Data Sources:*** *(List all data sources for Numerator and Denominator (live births). Examples: Vital Records, Birth Defects program, National Death Index, etc.):* ***MA Birth Defects Monitoring Program, Vital Records***
	+ ***Birth Outcomes for cases: Live births and stillbirths***

**Study Proposal**

**Introduction/Background**

*Include a brief description of the research question/What is known and not known, including references and description of the public health impact/importance of the question:*

Short interpregnancy intervals (IPI), typically defined as those less than 6 or 12 months, have been consistently identified as a risk factor for a number of adverse pregnancy outcomes including low birth weight, preterm birth, and small-for-gestation age (1). Short IPIs have also been associated with a modest increase in the overall risk for any major congenital malformation and sub-analyses by system revealed increases in cardiovascular and musculoskeletal defects, specifically (2). Utilizing such overly broad outcomes could potentially obscure larger increases in risk for specific defects. Separate studies identified an increased risk for neural tube defects (3) and gastroschisis (4). In contrast, another study reported an inverse association between short IPI and cleft palate (5), but it has been suggested that this association may be an artifact of classification errors in the operationalization of the interpregnancy intervals, specifically using categories of IPI that were too wide (6). Some investigators attribute the higher risk of adverse outcomes to factors related to short IPI, such as maternal socioeconomic and lifestyle characteristics; however, evidence from studies that have controlled for such factors suggest that the results are not completely explained by confounding (1). The nutritional depletion hypothesis has been proposed as an explanation specific to short interpregnancy intervals. It postulates that between closely spaced pregnancies there is insufficient time for repletion of nutritional reserves needed to support fetal development in the subsequent pregnancy (7, 8, 9). During pregnancy and lactation, maternal stores of important micronutrients, such as vitamins A, B6, B12, D3, zinc, and folate decline during pregnancy, and while most have been shown to rebound relatively shortly after delivery, vitamin D3 and folate may take several months (10, 11). Certain subpopulations, including teenagers and black women, may require longer intervals to replenish nutrient stores between pregnancies (7, 12).

Pooling of data from multiple states within the National Birth Defects Prevention Network (NBDPN) will provide enhanced numbers allowing for assessment of risks for a wide range of specific defects in relation to interpregnancy interval.

**Study Objectives**

 **Primary aim:** *If you are hypothesis-testing, please state the hypothesis*

* To evaluate the relationships between interpregnancy interval and the occurrence of specific major congenital malformations

**Secondary aim(s) (if applicable):** *If you are hypothesis-testing, please state the hypothesis*

* To evaluate the relationships between interpregnancy interval other adverse outcomes, such as preterm birth, low birth weight, and small-for-gestational age
* To evaluate the compatibility of observed associations with the nutritional depletion hypothesis

**Study Design and Data Collection/Study Population**

For Primary Aim I and Secondary Aim 1

All live births and fetal deaths identified through vital statistics and birth defects surveillance data occurring between 2010 and 2018 born to mothers who had at least one previous pregnancy. Cases will include births with any of the birth defects of interest listed in **Appendix 1.**

Live births and stillbirths to mothers with at least one previous pregnancy should be identified as those in which the following birth or fetal death certificate data fields sum to greater than zero: Number of Previous Live Births Now Living, Previous Live Births Now Dead and Number of Other Pregnancy Outcomes (includes spontaneous and induced losses and ectopic pregnancies).

We acknowledge that the range of birth defects monitored differs between states. Each participating state must provide a list of the birth defects used to identify births without congenital malformations.

NOTE: This study does not require linkage of records for consecutive births to the same mother, since all requested information can be obtained directly from a birth certificate or from the birth defects registry.

**Detailed Study Inclusion and Exclusion Criteria:**

**Note: Detailed variable information and variable coding, including defects required are provided in Appendices.**

1. Case information, including birth outcomes requested, and coding system used

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| **ICD-9-CM** | **ICD-10-CM** | **CDC/BPA** |
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1. ***Provide Appendices Listing Defects and Other Variables Requested.*** *Please note any of the requested defects that your state does not collect on the accompanying Data Submission Questionnaire Form.*
2. *Inclusion criteria (list below):*

Live births to those in 2015-2018 who had at least 1 prior live birth

1. *Exclusion criteria (list below):*

Nonlive births, Those without a prior pregnancy resulting in live birth

1. Data Sources: Vital Records and Birth Defects Registry records—linkage optional
2. **List of Variables required for cases (Attach in Appendix if necessary):** *Please note any variables not collected in your state program or not available during the requested time period* *in the accompanying Data Submission Questionnaire Form.* See Appendix 1 for birth defects and Appendix 2 for covariates.
3. **List of Variables required for denominator/controls (Attach in Appendix if necessary):** See Appendix 2 variables described as source BC.
4. Requested Data Structure (Line level or aggregate, separate numerator and denominator files, etc.)

Line level data are requested.

1. Time period of data requested (birth cohort years) and follow-up time period, if applicable:

Requested years are 2015-2018, but any consecutive 3 year period within these years is acceptable.

***If for some reason, participating programs cannot meet the above requirements, differences should be noted on the Data Questionnaire that accompanies the data submission.***

**Analysis Plan**

***Predictor Variable(s): Interpregnancy Interval***

Interpregnancy interval will be calculated as the time period in completed weeks between the more recent of either the Date of Last Live Birth and the Child Date of Birth, minus the Obstetric Estimate of Gestation (in completed weeks) using information from birth certificate information provided by participating states. If the Obstetric Estimate of Gestation is missing then gestational age based on last menses will be used. If the day is missing for the end the previous pregnancy, then the 15th of the month will be used to compute interpregnancy interval.

Interpregnancy interval will be separately evaluated as a continuous and a categorical predictor of each of the outcomes of interest. Consistent with the literature, we will look at intervals less than 6 months, 6-11 months, 12-17 months, 24-59 months, and greater than or equal to 60 months relative to intervals of 18-23 months.

***Outcomes of Interest***

***Birth Defects***

The defects to be included in the project are itemized in Appendix 1 and include defects from the NBDPN national prevalence estimates project (13, 14) among live births and stillbirths. We provide both the CDC/BPA codes and the ICD-9 and ICD-10 codes for the requested defects, along with comments regarding relevant exclusions and inclusions for the defects of interest.

***Other Outcomes***

In addition to the selected birth defects, we are also interested in examining the relationship between interpregnancy interval and other pregnancy outcomes. Birth weight and gestational age will be assessed as continuous outcomes and will also be dichotomized to assess low birth weight and preterm, respectively. Low birth weight will be defined as a birth weight less than 2500 grams. Preterm will be defined as a gestational age less than 37 weeks. Small-for-gestational age will be defined as birth weight below the 10th percentile for gestational age on the basis of a sex-specific standard. We plan to derive the standard using all nonmalformed singleton births from 2010-2018 to mothers with at least one previous live birth from participating centers.

**Analysis Plan**

We will describe the counts and prevalence of each outcome over the range of interpregnancy intervals during the years provided. Prevalence will be evaluated by categories of IPI for each birth defect overall and evaluated by maternal age at prior live birth, state/program, and race.

Stratified analysis will be conducted to evaluate whether maternal race, maternal age or other covariates modify the relationships between short interpregnancy interval and the occurrence of each adverse pregnancy outcome.

Prevalence ratios and 95% confidence for short and long IPI compared to IPI of 18-23 months will be calculated using generalized linear models.

Sensitivity analyses will be performed to look at those missing data on date of last live birth, limiting to active surveillance programs, and limiting to states with no more than 10% missing IPI information.

**Documentation of status of IRB approval**

See attached approval letter from the MA Department of Public Health IRB.

**Data submission method**

*Please describe secure file transfer method requested and note what types of files participating programs can submit.* *(N/A if not applicable).*

Unless different arrangements are made, all participating states will submit their data using the Massachusetts Secure File Transfer system, Interchange, which requires an invitation to enroll. Transferred files are automatically deleted after 14 days. Data should be submitted either as SAS datasets or in Excel files.

**How will data be stored securely?** Brief description of where and how data will be stored by lead state.

After being received through the Interchange Secure File Transfer system or other secure transfer, data will be stored on a secure server at the Massachusetts Department of Public Health. Data will be stored in a directory with restricted access so that only authorized study personnel may access the data. Network access is protected by requiring a user to login to an Active Directory system with a username and password. Access to directories and files are restricted by user membership to network security groups. Network security group access is granted only if a user is affiliated with a research study or group. When a user is not affiliated with a research study or group, access is denied or removed. We do not anticipate any need for paper copies with identifying information; however, if the need for paper copies arises, they will be kept in locked cabinets, and only authorized study personnel will have access to the files.

**Data Destruction Plan**

All study files will be deleted from the network 10 years from the study start date (estimated 9/1/2022) or 3 years following publication of the data, whichever comes first. This 3-year holding period after publication will allow any questions regarding the published data to be answered. In addition to deleting files, access to the restricted folders will be revoked at the same time that the files are deleted.

**Anticipated Study Start and End dates**

**Anticipated Start Date:** Analysis will begin once all data from participating states has been received, estimated to be April 2023.

**Anticipated End Date:** We anticipate data analysis to be completed by April 2024.

**List of other participating programs, if known:** \_TX, AZ\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\***Lead Program Primary Contact Information for Data Submission Questions (name, address, phone, email)**

\_Zane Smith, 250 Washington St., Boston, MA 02108, 444-444-4444, Zane.smith@mass.gov\_

*List any other lead program contact information below, if applicable (for example, Vital Records contact or IRB contact):*

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***Detailed description of Case Data with required formats should be provided in Appendices.***

**REFERENCES**

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*Appendix Examples below.*

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| Appendix 1. Birth Defects Requested (Line Level data)  |
| Birth Defects | ICD-9-CM Codes | ICD-10 CM codes | CDC BPA Codes | Notes |
| Anencephalus | 740.0 – 740.1 | Q00.0–Q00.1 | 740.000 – 740.100 |  |
| Spina bifida without anencephalus | 741.0-741.9 without 740.0 – 740.1 | Q05.0–Q05.9, Q07.01, Q07.03w/o Q00.0–Q00.1 | 741.000 – 741.990 without 740.000 – 740.100 |  |
| Encephalocele | 742.0 | Q01.0–Q01.9 | 742.000 – 742.090 |  |
| Anotia/microtia | 744.01, 744.23 | Q16.0, Q17.2 | 744.010, 744.210 | Exclude Type I microtia as per NBDPN “Abstractor’s Instructions” |
| Common truncus | 745.0 | Q20.0 | 745.000 – 745.010 |  |
| Transposition of great arteries | 745.10 – 245.12, 745.19 |  | 745.100 – 245.120, 745.190 |  |
| Tetralogy of Fallot | 745.2 | Q21.3 | 745.200 – 745.210, 746.840, 747.310 | Include pulmonary artery atresia with septal defect (BPA code 747.31, “tetralogy with pulmonary atresia”) |
| Hypoplastic left heart syndrome | 746.7 | Q23.4 | 746.700 |  |
| Total anomalous pulmonary venous return | 747.41 | Q26.2 | 747.420 |  |
| Tricuspid atresia | 746.1 | Q22.4 | 746.100 | Exclude stenosis only |
| Cleft palate without cleft lip | 749.0 | Q35.1–Q35.9 | 749.000 – 749.090 |  |
| Cleft lip with and without cleft palate | 749.1, 749.2 | Q36.0–Q36.9, Q37.0–Q37.9 | 749.100 – 749.290 |  |

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| Esophageal atresia/ tracheoesophageal fistula | 750.3 | Q39.0–Q39.4 | 750.300 – 750.350 |  |
| Rectal and large intestinal atresia / stenosis | 751.2 | Q42.0–Q42.9 | 751.200 – 751.240 |  |
| Reduction deformity, upper limbs | 755.20 – 755.29 | Q71.0–Q71.9 | 755.200 – 755.290 |  |
| Reduction deformity, lower limbs | 755.30 – 755.39 | Q72.0–Q72.9 | 755.300 – 755.390 |  |
| Reduction deformities, total (including unspecified limb) | 755.20 – 755.4 | Q73.0–Q73.8 | 755.200 – 755.490 |  |
| Diaphragmatic hernia | 756.6 | Q79.0, Q79.1 | 756.610 – 756.617 | Exclude eventration of the diaphragm, as per NBDPN “Abstractor’s Instructions” |
| Gastroschisis | 756.79, 756.73 (as of 10/1/2009) | Q79.3 | 756.710 | If your state uses ICD-9 codes, please indicate if you have another method to distinguish between gastroschisis and omphalocele. If not, do not report. |
| Omphalocele | 756.79, 756.72 (as of 10/1/2009) | Q79.2 | 756.70 | If your state uses ICD-9 codes, please indicate if you have another method to distinguish between gastroschisis and omphalocele. If not, do not report. |
| Down syndrome | 758.0 | Q90.0–Q90.9 | 758.00 – 758.09 |  |
| Trisomy 13 | 758.1 | Q91.4–Q91.7 | 758.10 – 758.19 |  |
| Trisomy 18 | 758.2 | Q91.0–Q91.3 | 758.20 – 758.290 |  |

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| **APPENDIX 2: Individual level data elements for infants and mothers to be included in “Call for Data”** |
| Variable | Source (C=Created, BC=birth certificate) | Variable name | Variable type | Notes |
| Random ID | C | C\_ID | Char | Pos 1-2 = 2-digit state codePos 3-4 = 2-digit birth yearPos 5-11 = Sequential number (e.g., NY00001). Other means accepted, such as birth year and cert number |
| Maternal Resident State at Child’s Birth | BC | STATE | Char | 2 letter US postal abbreviation |
| Child Sex | BC | SEX | Num | 1=male2=female3=undetermined9=unknown |
| Child Date of Birth | BC | CHILD\_DOB | Date | MM/DD/YYYY |
| Maternal Age at Birth | BC | MOM\_AGE | Date | Years (Month and year of mother birth can be provided instead) |
| Maternal Race | BC | MRACE | Num | 1= white2= black3= American Indian/Alaska native 4=Chinese5=Japanese6=Hawaiian7=Filipino 8=Korean10=Asian Indian11=Vietnamese12=Other Asian/Pacific Islanders88=multiple race99=other/unknown |
| **APPENDIX 2 cont.: Individual level data elements for infants and mothers to be included in “Call for Data”** |
| Maternal Hispanic Ethnicity | BC | METHN | Num | 1= not Spanish/Hispanic/Latina2= Hispanic – Mexican, Mexican American, Chicana3= Hispanic – Puerto Rican4= Hispanic – Cuban 5= Hispanic – Other Spanish/Hispanic/Latina9= unknown |
| Maternal Education | BC | MEDUC | Num | 1= <12th grade, no HS diploma2= HS diploma or GED3= Some college, no degree4= Associate degree5=Bachelor’s degree6= Master’s degree7= Doctorate or Professional degree |
| Mothers height | BC | MOM\_HT | Num | Inches8888 = refused9999 = unknown |
| Mother’s pre-pregnancy weight | BC | MOMWT | Num | Pounds8888 = refused9999 = unknown |
| Previous Live Births Now Living (not including this child) | BC | LBLIVE | Num | 888=refused999=unknown |
| Previous Live Births Now Dead (not including this child) | BC | LBDEAD | Num | 888=refused999=unknown |

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| **APPENDIX 2 cont.: Individual level data elements for infants and mothers to be included in “Call for Data”** |
| Date of Last Live Birth  | BC | DLLBTH | Date | MM/DD/YYYY99/DD/YYYY = missing monthMM/99/YYYY = missing dayMM/DD/9999 = missing year |
| Date Last Normal Menses Began | BC | LMP | Date | MM/DD/YYYY99/DD/YYYY = missing monthMM/99/YYYY = missing dayMM/DD/9999 = missing year |
| Average number of Cigarettes Smoked Daily Prior to Pregnancy | BC | PRESMK | Num | 8888=refused9999=unknown |
| Average number of Cigarettes Smoked Daily During Pregnancy | BC | DURSMK | Num | 8888=refused9999=unknown |
| Delivery Payment Method  | BC | PAY | Num | 1=private insurance 2=public/Medicaid 3=self-pay 9=other/unknown |
| Maternal Diabetes | BC | MDIAB | Num | 0=none 1=pre-pregnancy 2=gestational 3=non-specific 9=unknown |
| Maternal Hypertension  | BC | MHBP | Num | 0=none 1=chronic pre-pregnancy 2=gestational 9=unknown |
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| **APPENDIX 2 (continued): Individual level data elements for infants and mothers to be included in “Call for Data”** |
| Pregnancy Resulted from Infertility Treatment | BC | FERTGATE | Num | 1=yes2=no9=unknown |
| Fertility enhancing drugs, artificial insemination, or intrauterine insemination used | BC | TRTFERT | Num | 1=yes2=no9=unknownOnly applicable if FERTGATE = 1. |
| Assisted reproductive technology (e.g., in vitrofertilization (IVF), gamete intrafallopian transfer (GIFT)) | BC | ARTPROC | Num | 1=yes2=no9=unknownOnly applicable if FERTGATE = 1. |
| Obstetric Estimate of Gestation | BC | GA\_CLIN | Num | weeks 99=unknown |
| Gestational age, based on LMP | BC | GA\_LMP | Num | weeks 99=unknown |
| Birth weight (grams) | BC | BWT\_GM | Num | grams9999=unknown |
| Plurality | BC | PLURAL | Num | 1= singleton2= twin3= triplet4= quadrupletEtc.999 = unknown |

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| **APPENDIX 2 (continued): Individual level data elements for infants and mothers to be included in “Call for Data”** |
| Birth Defects Code | BDR | BD\_DX1 - BD\_DX24 | Char | Up to 24 codes with each code left-justified OPTIONALUse 6 spaces per code with no decimals; leave trailing blanksLeave blank for non-malformedOPTIONAL (only include for linked records) |
| Birth Defects Verbatim Diagnosis | BDR | BDTXT1 – BDTXT24 | Char | Verbatim birth defect diagnosis separate column for each unique defect.Leave blank for non-malformedOPTIONAL (only include for linked records) |
| Coding system utilized | BDR | CODSYS | Num | 1= ICD-92=BPA 3=ICD10 |
| Program Ascertainment Type | BDR | SURVtype | Num | 1=Active, 2=Passive, 3=Other |