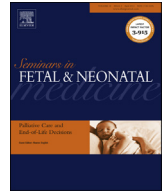




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## Review

## The National Birth Defects Prevention Study: How to communicate data



Anthony R. Scialli\*

Tetra Tech Sciences, 2200 Wilson Blvd Ste 400, Arlington, VA 22201, USA

## S U M M A R Y

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The National Birth Defects Prevention Study is a population-based case–control study. The study has actively sought to identify children with any of 34 specified types of malformation. The mothers of affected and unaffected children have been interviewed with regard to demographic information, life-style factors, and exposures. A large number of published studies have appeared and continue to appear on diverse exposures and outcomes. An example of such a study identified an increased odds ratio for ondansetron use among the mothers of children with cleft palate. Possible explanations for associations between exposures and outcomes are chance, error, and causation. The ondansetron–cleft palate association may have arisen by chance given the large number of comparisons made in the study. Error appears unlikely as an explanation of the association. The assessment of causation in teratology uses a systematic evaluation based on the Hill criteria or similar criteria of Shepard or Brent.

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## 1. Introduction

Because we counsel families about the risk for developmental abnormalities from exposures, we find ourselves in the business of interpreting data. Our pregnant patients who have been exposed to a medication or an environmental chemical want to know, 'Is it safe?', and our patients who have had a child with a developmental problem want to know, 'What caused this problem?' The published literature does not give us a direct answer to these questions. Instead, the literature gives us data, and we have to bring our expertise and analytical skills to bear on turning the data into answers that are useful to our patients. In this paper, I describe the National Birth Defects Prevention Study (NBDPS), which has become an important source of data, and I suggest how these data can be incorporated into our practices using as an example a study of medications for nausea and vomiting of pregnancy.

## 2. What is the National Birth Defect Prevention Study?

The NBDPS is an ongoing population-based case–control study sponsored by the US Centers for Disease Control and Prevention (CDC, Atlanta, GA, USA). The study saw its origins in an act of Congress in 1996 that directed CDC to establish Centers for Birth Defects Research and Prevention. These centers include the birth

defects surveillance and research programs of Arkansas, California, Georgia, Iowa, Massachusetts, New Jersey, New York, North Carolina, Texas, and Utah.

The centers identified infants with any of 34 congenital malformations or types of malformation (Box 1). The selection and classification of abnormalities followed detailed guidelines that were used by all centers in the program [1]. These guidelines provided criteria for case definition and policies for the exclusion of genetic syndromes and for the categorization of infants with multiple malformations. There were differences between centers in whether stillborn infants and elective terminations of prenatally diagnosed malformations were included [2]. Control children were randomly selected from birth certificates or birth hospitals. Mothers were interviewed by female personnel using a standard computer-assisted telephone interview in English or Spanish. Prior to the interview, each mother was mailed an information packet, a calendar that included the dates of her pregnancy, and a money order for \$20. Interviewing was stopped on 31 March 2013.

Questions were asked about exposures that occurred from three months before conception through the end of the pregnancy. Most questions were structured with coded response lists, but some questions were open-ended, for example questions about occupation and occupational exposures. Interviews were performed no sooner than 6 weeks after the estimated date of delivery and no later than 24 months after the estimated date of delivery, with a target date of 6 months after the estimated date of delivery [2]. The information collected by the maternal interview is summarized in

\* Tel.: +1 571 527 1709.

E-mail address: [Tony.Scialli@TetraTech.com](mailto:Tony.Scialli@TetraTech.com).

**Box 1**

Malformations included in the National Birth Defects Prevention Study<sup>a</sup>

## Cardiovascular

Anomalous pulmonary venous return  
Conotruncal heart defects  
Heterotaxy  
Hypoplastic left heart syndrome  
Obstructive heart defects  
Septal heart defects  
Single ventricle

## Central nervous system

Anencephaly  
Dandy–Walker malformation  
Encephalocele  
Holoprosencephaly  
Spina bifida

## Eye

Anophthalmia/microphthalmia  
Congenital cataract  
Glaucoma

## Ear

Anotia/microtia

## Orofacial

Choanal atresia  
Cleft lip  
Cleft palate

## Gastrointestinal

Biliary atresia  
Esophageal atresia and tracheo-esophageal fistula  
Intestinal atresia

## Genitourinary

Hypospadias (2nd or 3rd degree)  
Renal agenesis (bilateral)

## Musculoskeletal

Bladder exstrophy  
Cloacal exstrophy  
Craniosynostosis  
Diaphragmatic hernia  
Gastroschisis  
Limb deficiency  
Omphalocele  
Sacral agenesis/caudal regression

## Non-system-specific

Amniotic band sequence

<sup>a</sup>Terminology as presented on the NBDPS web site at <http://www.nbdps.org/aboutus/bd.html>.

**Box 2.** There were also questions about paternal demographic and lifestyle factors. After the interview, women were sent a kit for collecting buccal cells from the child, if living, and the parents, and parents were sent another \$20 money order. These cells are being used for genetic studies.

The data collected from study participants were pooled and are available to all participating centers. Investigators at the centers have published and continue to publish study data, often in conjunction with additional authors. Since the first results appeared in 2001, there have been more than 170 publications covering diverse exposures including medications, diet, obesity, and lifestyle factors among others (see [Appendix](#)).

**Box 2**

Categories of information collected by maternal interview<sup>a</sup>

## Maternal health

## Illnesses

Diabetes  
Fever  
Hypertension  
Respiratory illnesses  
Seizure disorder  
Urinary tract infection  
Other illnesses

## Injuries

Medication exposure (prescription and non-prescription)  
X-ray exposure

## Pregnancy

## Assisted reproductive techniques

Contraception  
Nausea and vomiting  
Prenatal care  
Pregnancy history

## Substance use and diet

Alcohol  
Caffeine  
Food supplements  
Illicit drugs  
Tobacco  
Vitamins  
Assessment of diet

## Home and work

Hot tub/sauna  
Military service  
Occupation  
Residence

## Water

Bathing  
Drinking water sources  
Swimming pool use  
Other water uses

<sup>a</sup>Adapted from Yoon et al. [2]

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