An Analysis of Registries with Birth Defect Data Using an Online Database Resource

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BACKGROUND

- Birth defects are a major cause of morbidity and mortality. Many regions of the world need to **systematically monitor birth defects**.
- There is no standard method for **developing a registry to collect birth defect data**, and few tools are available to aid this process.
- B.R.I.D.G.E. TO DATA® (www.bridgetodata.org), an **international resource of database profiles**, may serve as a guide for determining what data should be included in such a registry.

OBJECTIVE

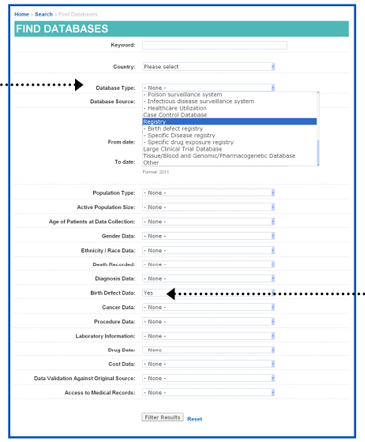
To identify the set of **core data fields** used in registries with birth defect data.

METHODS

Box 1. A search was conducted in B.R.I.D.G.E. TO DATA® to identify registries that collect birth defect data using the search criteria:

Database Type = Registry; and ***Birth Defect Data = Yes*** (**Figure 1**).

Figure 1. B.R.I.D.G.E. TO DATA® Search Page



Box 2. Eighty-eight (88) profiles matched at least one criterion (see **Figure 2**):

a. Twelve (12) registry profiles matched both criteria.
b. Search results were further narrowed by excluding 3 profiles that did not limit the *Population Type* to neonates, infants, or pregnant women, leaving 9 registry profiles.

Box 3. Each of the 75 data fields used in B.R.I.D.G.E. TO DATA® structured profiles was compared among the 9 registries (**Table 1**).

Box 4. For each profile, frequency counts of data field usage in the registry (e.g., *Date of Birth* captured or not) were obtained.

Box 5. Data fields were grouped based on the frequency of usage among the 9 registries with birth defect data.

Box 6. The categories were grouped as: 35 ***Core Data Fields*** with similar frequency of use among the registries, and 33 ***Additional Data Fields*** present in some registries with birth defect data.

RESULTS

Table 1. Examples of Data Fields Used in Profiles (by Category)

Category	Data Fields
Summary	Database description, Database source, Years covered, Population type, Date of last update
Population Dynamics	Population size, Sample weights – Extrapolation factors
Demographic Data	Age, Gender, Date of birth, Death recorded, Other demographic data
Physician & Practitioner Info	Physician ID & Specialty, Pharmacy ID
Diagnoses/Signs & Symptoms	Diagnosis data, Diagnoses coded (coding systems), Max. number of codes, Physical exam findings, Environmental exposures, Behavioral data elements
Procedures	Procedure data, Procedures coded (coding systems), Laboratory information
Drug Information	Drug data, Drug dosage, Drug coding system(s), Additional drug information
Economic Data	Type of cost data (if applicable)
Validation & Linkage	Data validation, Access to medical records, Linkage to other databases
Administrative Data	Database contact data, Database usage restrictions, References of studies using/describing the database

Figure 2. Criteria-based search conducted in www.bridgetodata.org for registries collecting birth defect data (131 Database Profiles worldwide as of August 4, 2011)

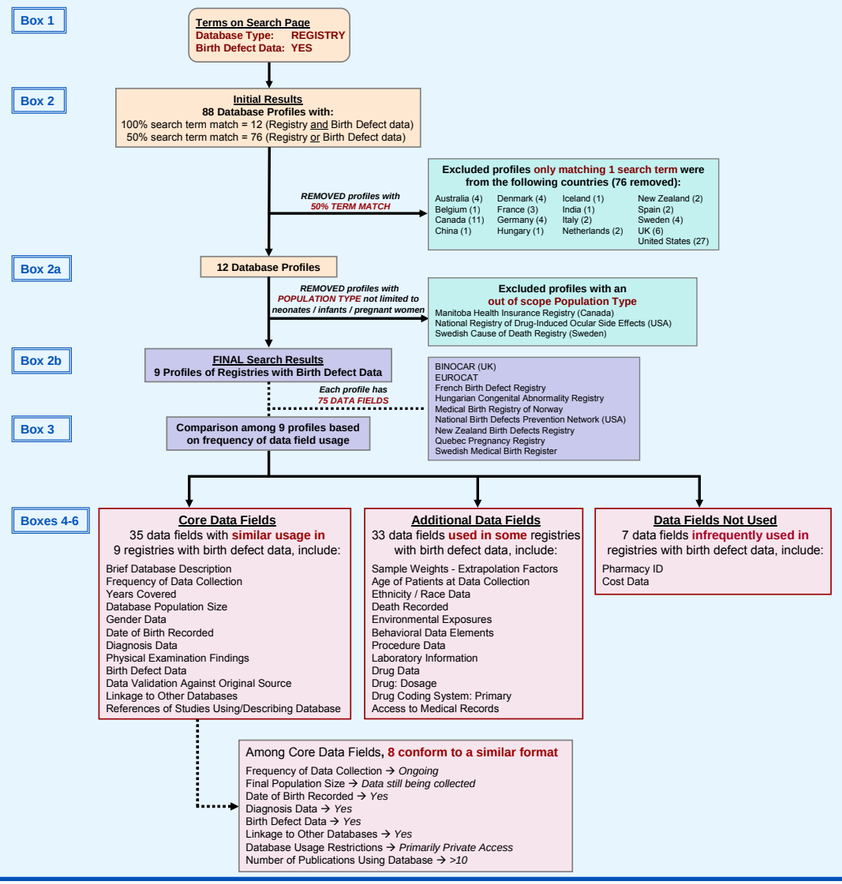


Table 2. Excerpt from B.R.I.D.G.E. TO DATA® comparing data elements in 3 selected registries

FIELD NAMES	British Isles Network of Congenital Anomaly Registers (BINOCAR) (UK)	Hungarian Congenital Abnormality Registry (HCAR) (HUNGARY)	QUEBEC PREGNANCY REGISTRY (CANADA)
Region	England, Ireland, Scotland, Wales	All regions of Hungary	Quebec
Frequency of Data Collection	Ongoing	Ongoing	Ongoing (Data are collected routinely as part of normal and universal health care)
Years Covered	1985 - Present Each register started at a different time. The first register (Northern Congenital Abnormality Survey) started in 1985. The regional and disease-specific registers joined together in 1998 to form BINOCAR.	1970 - Present	1997 - 2010 (Database updates are performed every 2 years; it was last updated in 2009.)
Patient Type	Inpatient and Outpatient	Inpatient and Outpatient Emergency Room (ER/ED)	Inpatient and Outpatient (Pregnant women in Quebec)
Database Population Size	<200,000	<200,000 (~180,000 cases thus far)	<0.5 Million (420,000 pregnancies and 350,000 mothers and children)
Final Population Size	N/A (Still collecting data)	N/A (Still collecting data)	N/A (Still collecting data)
Gender Data	Yes	Yes	Yes
Date of Birth Recorded	Yes Date of birth / Gestation are recorded	Yes (Date / Month / Year)	Yes These data are recorded for pregnant women and offspring
Diagnosis Data	Yes These include: Pregnancy Outcome; Anomaly description; Anomaly ICD-10 code; Anomaly status (suspected, probably, confirmed); Antenatal detection; Date of diagnosis	Yes The diagnosis of CAs reported by medical doctors is checked in the HCAR by an expert and it results in a good validity of the CA diagnoses. The previous classification of CAs was based on their anatomical location. The optimal classification would be an etiology-based classification but unfortunately at present some CAs have unknown etiology. Thus a compromise is a pathogenetic-oriented classification. CAs are differentiated into isolated (including single, sequence and complex groups) and multiple or syndromic (including CA-syndromes, CA-associations and random combinations) categories. The multimalformed cases have 2 or more different CAs with or without minor anomalies, thus the unit of recording is the person and not the CA in the HCAR.	Yes The registry contains information on medical services (diagnoses and procedures) received from physicians
Physical Examination Findings	Yes Birthweight is measured in grams and is notified to the local health authority by the hospital where the birth took place, or by the midwife or doctor in attendance. These details are then supplied to the registrar. For stillbirths, details of fetus weight are supplied on a certificate or notification by a doctor or midwife. The certificate or notification is then taken by an informant to the registrar.	Yes	Yes Everything is coded (diagnoses and procedures)
Birth Defect Data	Yes A congenital anomaly is defined as any defect, probably originating before birth, and includes structural, chromosomal, genetic and biochemical defects and malformations. Cases notified to the Register as having a syndrome are coded as such. In addition, the specified individual anomalies are also coded. Anomalies that have not been confirmed by clinical or diagnostic tests are recorded as such and followed up for confirmation. These suspected anomalies are largely confined to those anomalies found on ultrasound examination in pregnancies that have not yet delivered. Ultrasound diagnosed soft markers are also notified to the registers used in the evaluation of prenatal diagnosis and screening.	Yes (Partly, e.g., type of birth defect, outcomes, age of mother)	Yes Birth defect data in the registry are validated
Data Validation Against Original Source	Yes Anomalies that have not been confirmed by clinical or diagnostic tests are recorded as such and followed up for confirmation. These suspected anomalies are largely confined to those anomalies found on ultrasound examination in pregnancies that have not yet delivered. Ultrasound diagnosed soft markers are also notified to the registers used in the evaluation of prenatal diagnosis and screening. Notifications relating to the same case from multiple sources are encouraged since this maximizes the details available, but then undergoes a validation process to identify multiple reporting (via patient identifiers). BINOCAR validation group includes members from regional registries at NorCAS, EMSYCAR, CAROBB, EUROCAT and WMCAR.	Yes The diagnosis of CAs reported by medical doctors is checked in the HCAR by an expert and it results in a good validity of the CA diagnoses	Yes Validated against medical records, pharmacy records, and maternal recall
Access to Medical Records	Yes	Yes However, only aggregate data from medical records can be given	Yes Access to medical records is possible in collaboration with the investigators who assembled the database - The Commission d'accès à l'information (CAI) (Ethics Committee overseeing linkage between administrative databases)
Linkage to Other Databases	Yes	Yes Hungarian Congenital Case-Control Surveillance of Congenital Abnormalities (HCCSCA) NOTE: The Hungarian Surveillance of Germinal Mutations was established in 1980 and is based on a subset of outcomes from HCAR which are considered to be indicator conditions of germinal mutations. Three groups of conditions are included: (1) A group of 15 sentinel anomalies indicate dominant gene mutations; (2) Down Syndrome indicates numerical and structural chromosomal mutations; and (3) Unidentified multiple congenital abnormalities (two or more different developmental defects in the same individual without the recognition of delineated syndromes) indicate germinal dominant gene and chromosomal mutations.	Yes This is a multi-linked database
Database Usage Restrictions	Private and Public Access Aggregate data will soon be available on the BINOCAR website and is also currently available on the EUROCAT website. De-identified aggregate data are available. All requests have to be approved by BINOCAR Management Committee.	Private Access Only aggregate data of medical records can be provided	Private Access Only in collaboration with the Berard Research Group
Number of Publications Using Database	>10	>10	>10

LIMITATIONS

This analysis was done using registries currently profiled within B.R.I.D.G.E. TO DATA®. More profiles of data sources are continually being added to this resource.

CONCLUSION

The online resource, www.bridgetodata.org, is a useful tool to identify pertinent core data fields common to registries that collect birth defect data. This resource may serve as a guide when designing such registries.

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