

# A New Registry of Congenital Anomalies in Iran

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**Abstract:** **Background.** Registration of the occurrence of birth defects is now being performed in about 50 countries in the world as the baseline system for control and prevention of congenital anomalies. The principal aim of this program was to introduce and establish a monitoring system of congenital anomalies in the Northwest of Iran as a basis for planning and assessing prevention and control interventions. **Methods/Design.** Some of the registry systems of the European network countries, the United States of America, and the United Arab Emirates were studied in terms of data collection, process, analysis, use, and evaluation of the system to find the minimum requirements for setting up a local registry in Iran. Key end users of the local Iranian system met and determined the minimum requirements for operation of the registry. **Results.** End users identified the minimum data required to establish a local hospital-based registry as: child/mother identification number, child/mother hospital record number, type of anomaly, gender, date of diagnosis, mother's age at delivery, family history of anomaly (optional field), familial marriage (optional field), date of death (if any). Initial results show a birth prevalence rate of 1.7% for all reportable defects combined. **Conclusion.** This program will provide some essential data as an epidemiological tool for local investigations, information for health service planners, for clinicians, and for genetic counseling. The program may also help to identify regional interventions that could help to prevent and control congenital anomalies in the study population. Some of these interventions may be specific to the study population while others may have more general applications in similar areas and communities.

**Key words:** birth defects, congenital anomalies, epidemiology, Iran, registry

## Background

The occurrence of congenital anomalies varies between different countries ranging from 2% to 10% of births.<sup>1-13</sup> Congenital anomalies are now making a proportionally greater contribution to ill health in childhood. They are a leading cause of perinatal mortality, childhood morbidity, and disability in many countries.<sup>1-2,8-9,14</sup> Although the prevalence of congenital anomalies in both developing and developed countries is similar, their impact is higher in the developing world as there are fewer available resources to provide services to affected children.<sup>8</sup>

Prevention and control of congenital anomalies requires epidemiological data based on a surveillance system. Monitoring and registration of the occurrence of birth defects is now being performed in about 50 countries in the world as the baseline system for control and prevention of congenital anomalies. The principal aim of this program was to introduce and establish a monitoring system for congenital anomalies in the Northwest of Iran as a basis for planning and assessing prevention and control interventions.

## Methods

Some of the registry systems of the European network countries (EUROCAT), the United States of America (USA), and the United Arab Emirates (UAE) were studied in terms of data collection, process, analysis, use, and evaluation of

the system to determine the requirements for setting up a local registry in Iran.<sup>5,13,17-19</sup> In order to hold down the cost of the system, to promote widespread acceptance by facilities and clinicians, and to promote availability of information gathered in the region, the key end users of the system discussed and determined the minimum requirements for the registry. Then the feasibility of establishing a registry in the region was evaluated based on the minimum data requirements and the pilot registry program launched. Because of the limited funds and staff, the program was started as a pilot based on the minimum of data required for a registry of birth defects. The program is now called Tabriz Registry of Congenital Anomalies (TRoCA),<sup>18</sup> which has been authorized and funded by local public health authorities.

The pilot registry program covered about 15,000 births (annual average), including live births and stillbirths, from 3 facilities in the area. About 350 newborns from this population had one or more congenital anomalies. All infants in the 3 system facilities are routinely examined by a gynecologist, obstetrician, neonatologist, or pediatrician—both at birth and at hospital discharge—for possible intervention and treatment. The examinations include assessment of general health, maturity, and congenital anomalies. The end users defined the congenital anomalies for the purposes of this program based on the standard coding system of the International Classification of Diseases and British

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Paediatric Association<sup>15</sup> under one of the following main headings (according to the primary diagnosis of anomaly): nervous system anomalies; genito-urinary tract and kidney; anomalies of limb; chromosomal anomalies; cleft lip with/without palate; congenital heart disease; musculoskeletal and connective tissue anomalies; digestive system anomalies; eye and ear anomalies; and other anomalies. Pathologic confirmation of the defect is used as criteria of inclusion of fetal deaths or stillbirths in this registry. A midwife, a nurse, and a medical coder have been assigned in this program to code/classify the birth defects.

To create and assess the system, 2 to 3 meetings (per year) are held by end users and registrars. The details of the process and possible problems and difficulties are discussed in these meetings.

For inclusion in the registry, an infant must have been born to a woman who resided in the defined population area of Tabriz at the time of the infant's birth. Total prevalence is calculated by dividing the numerator (registered cases of congenital anomalies) by the relevant denominator (total live and stillbirths) for the same period of time at the same place. An infant/fetus with more than one anomaly is counted once only in the numerator. This is the standard definition of the total prevalence recommended by Clearinghouse for Birth Defects, Surveillance, and Research.<sup>19</sup>

## Results

The findings presented here are based on the results from meetings of the end users of the registry system. Key components of the registry system were extracted from comparative studies in the EUROCAT, USA, and UAE.

### *Data Management*

The end users recommended a "passive" method of data collection and prepared inclusion and exclusion lists for data entry in the registry system. The end users preferred that the responsible persons (as registrar) for collection be nurses, midwives, or medical documentation officers of a local hospital or health center. They recognized that collecting the data by one specialist group could result in more consistent information than that by different specialist groups. Medical coders, for instance, with skills of abstracting data seem to be the most competent individuals for collecting data in the system.

Medical records (live birth and stillbirth) at delivery and routine hospital discharge forms were the data sources from which the registrar at the facilities collected the data. The end users and hospital administrators and authorities agreed to establish the database in an electronic format, as it can be useful in taking the maximum advantage of collected data for intended purposes. It can also facilitate re-using of the data.

In each hospital, a TRoCA officer abstracts the data from medical records and completes the standard form of the registry. Completed forms are sent every 3 months to the central registry. Data sent to the registry are originally paper-based and there is no secure way in place to transmit the data electronically from the facilities to the registry. Data is transferred by a dedicated carrier or person allocated for this purpose. The registrar enters the data received from

different sources and facilities into the computerized database designed for the purpose of the registry. Principles of privacy and confidentiality are strictly considered in every part of the data handling and registration. Strict safeguards have been established to prevent unauthorized access to the registry data, particularly to the sensitive data including identity-related information.

Minimum data required to establish a local hospital-based registry were identified as the following:

- Child/mother identification number
- Child/mother hospital record number
- Type of anomaly
- Gender
- Date of diagnosis
- Mother's age at delivery
- Family history of anomaly
- Familial marriage
- Date of death (if applicable)

In case facilities wish to further minimize the data elements they report into the system, the end users determined the reporting of "Family history of anomaly" and "Familial marriage" as optional items. However, they noted that information contained in the optional elements can be beneficial to some intended purposes of the registry. End users and registry staff will continue to meet and discuss the inclusion into the data set of other potential items that may benefit the intended purposes of the registry. The end users designed a form based on the data elements, and prepared a manual for the registry system. It includes procedures for using the registry data along with the mechanisms of access to the data and the list of authorized people for access.

Periodic evaluation of the registry system is important to assure the quality (accuracy and completeness) of the data. This will provide essential feedback required to improve system weaknesses. The framework for periodic evaluation has been agreed upon between end users and hospital administration.

### *Epidemiology*

Total prevalence of congenital anomalies was 1.7 per 100 births between 2000 and 2008. Genito-urinary tract and kidney defects, anomalies of nervous system, and limb anomalies accounted proportionally for more than 68% of anomalies in the region. There was an increasing trend in the prevalence of congenital anomalies in the study area from 2000 (1.05 per 100 births) to 2008 (2.45 per 100 births). This time trend was not however significant using linear regression statistical analysis where the dependent variable was the prevalence of congenital anomalies and the predictor was the birth year from 2000 to 2008 ( $P = 0.07$ ).

## Discussion

This article briefly describes how we established a local registry for congenital anomalies in Northwest Iran. The registry aims to implement some control on prevention strategies in the area to reduce the occurrence of birth defects at the community level. We applied the pattern and procedures used by some developed/regional countries for the registration, control, and prevention of

congenital anomalies.<sup>3,5,7,8,10,13,16,19</sup> The end users agreed upon the minimum key requirements for registration.

We found that the total prevalence of congenital anomalies in the area falls within the world range of prevalence reported from different places and countries.<sup>1-13</sup> The rate reported from TRoCA might have underestimated the prevalence of birth defects in the region because of the lack of cytogenetic and teratology investigations or autopsies for stillbirths and neonatal deaths.

Information from this study in the Northwest of Iran may be used as the basis to establish a system of hospital-based registries of birth defects in the area for health care and research purposes. This program will provide some essential data as an epidemiological tool for local investigations, information for health service planners, clinicians, and for genetic counselling. The program may also help to identify regional interventions that could help to prevent and control congenital anomalies in the study population. Some of these interventions may be specific to the study population while others may have more general applications in similar areas and communities.

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