eurocat

european surveillance of congenital anomalies

EUROCAT Operating Grant 2014

Funding was received from the European Union in the framework of the Health Programme (2008-2013) (Grant Agreement 2013 3307)

Start date: 1st January 2014
Duration: 12 months

University of ULSTER

Executive Agency for Health and Consumers

Health Programme 2008-2013

BACKGROUND

EUROCAT, in existence since 1979, is a European network of geographically defined population-based registries (representing the unselected experience of all who live in the population) for epidemiologic surveillance of congenital anomalies (CA). EUROCAT currently surveys over 1.7 million births per year in Europe (31% of the EU birth population), via 37 registries in 21 countries. Through the network of high quality multiple source population-based CA registries ascertaining live births, still births/fetal deaths, and terminations of pregnancy following prenatal diagnosis of CA, EUROCAT enables provision and dissemination of accessible and updated epidemiological information, including prevalence, prenatal diagnosis and perinatal mortality data, and the pooling of population-based data on monogenic syndromes and rare chromosomal abnormalities. EUROCAT member registries send anonymised individual case data or summary data to a EUROCAT Central Database (ECD) at EUROCAT Central Registry (University of Ulster, UK), also a WHO Collaborating Centre for the Surveillance of CA.

Congenital Anomalies (CA) are a major cause of perinatal mortality, childhood morbidity and disability, with a total prevalence of 2.5% of births in the EU each year. Most CA are Rare Diseases (RD) (<5 per 10,000 population). The live birth prevalence of rare CA in 2010 was 96.2 per 10,000 births, extrapolating to approx 4.7M affected persons in the EU, 12-15% of the total estimated persons affected by RD.

EUROCAT's mission...

is to support the primary prevention of CA and the provision of appropriate services to pregnant women, affected children and their families by the ongoing collection, analysis, interpretation and dissemination of population-based epidemiologic data. Epidemiologic surveillance should reduce teratogenic risks preconceptionally and in early pregnancy, inform policies and interventions in order to secure high quality diagnostics, treatment and counseling and to reduce the size of, and inequalities in, the public health burden of CA.

- EUROCAT aims to provide essential up to date comprehensive epidemiologic information on prevalence of CA in Europe. The EUROCAT website allows visitors to interrogate anonymous aggregate prevalence data (updated biannually), by registry, year and 89 CA subgroups of interest ie. Spina bifida, Down syndrome.

  During the 2014 Operating Grant EUROCAT will conduct core database related activities:

  - transmission of birth year 2012 CA data from all full and associate member registries (deadlines Feb 15 2014, October 15, 2014)
  - validate data and update the ECD to include birth year 2012
  - update prevalence, perinatal mortality, and prenatal diagnosis tables on website, to include 2012 data, in March and November 2014; after reception of the data at the biannual deadlines
  - provide updated Data Quality Indicators
  - provide updated descriptions of registries on the website
  - monitor implementation of EUROCAT Guide 1.4 for registration of cases born from 1st January 2013
  - provide technical support to registries in use of EUROCAT Data Management Program (EDMP)

Access EUROCAT's Prevalence Tables Online
http://www.eurocat-network.eu/accessprevalencedata/prevalencetables

Access EUROCAT's Prenatal Detection Rate Tables Online
http://www.eurocat-network.eu/prenatalscreeninganddiagnosis/prenataldetection(pd)rates

Access EUROCAT's Guide – Instructions for the registration and surveillance of CA
http://www.eurocat-network.eu/aboutus/datacollection guidelinesforregistration/guide1_4

Access EUROCAT's Data Quality Indicators Online
http://www.eurocat-network.eu/aboutus/datacollection/dataquality/dataqualityindicators

- EUROCAT serves as a reference centre in Europe for questions on coding and classification of CA. During 2014 EUROCAT's Coding and Classification committee will continue to:
  - work with the WHO's International Classification of Diseases Rare Disease Task Advisory Group to impart expertise for revision of the malformation chapter
  - update coding and classification tools as required to improve malformation coding within EUROCAT
  - review multiply malformed cases by medical geneticists within the committee
  - review epidemiological information on genetic syndromes for publication in website tables or papers

- EUROCAT values collaboration and mutual interdependence. All registries make a valuable contribution to, and derive benefit from, the European network irrespective of disciplinary, geographic, institutional or other origin. In 2014 EUROCAT will continue to operate its Registry Advisory Service and aims to establish new member registries in Europe collecting comparable, standardised data to enable the sharing of knowledge and expertise and a widening contribution to public health planning.

- Many CA are potentially preventable (eg. periconceptional folic acid to prevent neural tube defects) but total prevalence has not declined in recent decades. EUROCAT uses epidemiologic data to raise awareness of the need and potential to accelerate the slow progress towards reducing the number of affected live births, perinatal deaths and terminations. Many risk factors for CA are increasing: delayed childbearing, diabetes, obesity, assisted reproduction, use of medications, recreational drugs, and alcohol and smoking in some countries. EUROCAT surveillance is needed to evaluate the impact of these changes and measures taken to alleviate

them. In 2014 EUROCAT in collaboration with the European Centre for Disease Control will conduct analysis of EUROCAT data on congenital rubella.

EUROCAT in collaboration with EUROPLAN developed "Recommendations on Policies to be considered for Primary Prevention of CA in National Plans and Strategies on Rare Diseases". EUROCAT is liaising with EUROPLAN to discuss measures to monitor the inclusion, implementation and impact (across MS) of the recommendations in 2014 and beyond.

- Despite the thalidomide epidemic, there is still no effective postmarketing surveillance of drug use in pregnancy. The safety of most medications for use in early pregnancy is unknown, yet women, particularly those with chronic diseases, need safety information to guide treatment choices. During 2014 EUROCAT (in combination with EUROmediCAT, a daughter FP7 funded project) will continue to develop a European postmarketing pharmacovigilance tool in relation to medication use in pregnancy and risk of CA by building and analysing a population-based database of worldwide importance (now one of the largest data sources on CA with medication exposure in 1st trimester pregnancy worldwide), and by exploiting new possibilities for linkage with prescription data.

- The importance of rapid response to emerging health threats and clusters of CA has been illustrated by major safety concerns (e.g. thalidomide, Chernobyl, early invasive prenatal tests, swine flu). EUROCAT is the only organisation annually monitoring (including in 2014), on an EU, country and regional basis, trends and clusters of CA in time to detect signals of new and increasing teratogenic exposure that may require public health action. EUROCAT aims to monitor and respond to emerging health threats and exposures in a timely manner, and communicate the results to public health authorities.

Access EUROCAT's Annual Statistical Monitoring Reports Online
http://www.eurocat-network.eu/clustersandtrends/statisticalmonitoring/statisticalmonitoringintroduction

- Prenatal screening, diagnosis technology and policy are constantly changing, and unequally implemented across health systems and countries. EUROCAT population-based data on prenatal diagnosis, such as the proportion of cases prenatally diagnosed, the proportion first detected by different screening tests, the gestational age at diagnosis are of great value in evaluating these changes (including geographic inequalities) for individual types of CA, and pregnancy outcomes (including terminations). EUROCAT aims to assess the impact of developments in prenatal screening, diagnosis and policy at population level.

Operating Grant Activities

- **Coordination:**
  Prof. Helen Dolk (University of Ulster, UK)
- **Future sustainability of EUROCAT:**
  Prof. Ingeborg Barisic (Croatia)
- **Dissemination:**
  Prof. Ingeborg Barisic (Croatia)
- **Evaluation:**
  Dr. Rhonda Curran (University of Ulster, UK)
- **EUROCAT Central Database:**
  Dr. Maria Loane (University of Ulster, UK)
- **Coding and Classification:**
  Dr. Ester Garne (Denmark)
- **EUROCAT Network Procedures:**
  Dr. Rhonda Curran (University of Ulster, UK)
- **Surveillance - publication of epidemiological tables on EUROCAT website:**
  Dr. Maria Loane (University of Ulster, UK)
- **Surveillance - detection and investigation of clusters, trends and exposures:**
  Dr. Maria Loane (University of Ulster, UK)
- **New Registries/Network Expansion/Registry Advisory Service:**
  Prof. Ingeborg Barisic (Croatia)
- **Pharmacovigilance:**
  Prof. Helen Dolk (University of Ulster, UK)
- **Annual Registry Leaders Meeting:**
  Dr. Rhonda Curran (University of Ulster, UK)

Strategic relevance and contribution to European policies

EUROCAT has EU added value concerning EU-level action in areas where national action is not feasible or effective, specifically for Rare Diseases. The Council Recommendation 2009 on an action in the field of Rare Diseases and the Commission Communication on Rare Diseases: Europe's Challenges 2008, recognise the need for registries and databases co-ordinated at European level, for pooling of expertise, improving the coding and classification of Rare Diseases, for comparable epidemiological data at EU level, and for identifying the possibilities for primary preventive measures, such as through the National Plans for Rare Diseases. Through a Rare Disease platform the EC aims to support and sustain registries/networks - key instruments in increasing knowledge of Rare Diseases, in developing clinical research and the only way to pool data in order to achieve a sufficient sample size for epidemiological and/or clinical research. EUROCAT achieves EU added value through:

- Pooling of data
- Comparison of data between countries
- Sharing of expertise/resources
- Joint approach to European public health questions

EUROCAT Project Leader

Prof. Helen Dolk
University of Ulster, UK

Steering Committee of **EUROCAT** Association

- Prof. Ingeborg Barisic (Croatia), President of the EUROCAT Association
- Dr. Fabrizio Bianchi (Italy)
- Dr. Ester Garne (Denmark)
- Dr. Vera Nelen (Belgium)
- Dr. Diana Wellesley (UK)
- Dr. Babak Khoshnood (France) - until June 2014
- Dr. Amanda Neville (Italy) - from June 2014

EUROCAT Project Manager

Dr. Rhonda Curran
University of Ulster, UK

EUROCAT Full Member Registries

- Prof. Martin Haeusler (Austria, Styria*)
- Dr. Vera Nelen (Belgium, Antwerp*)
- Prof. Christine Verellen-Dumoulin (Belgium, Hainaut-Namur*)
- Dr. Ingeborg Barisic (Croatia, Zagreb*)
- Dr. Ester Garne (Denmark, Odense*)
- Dr. Babak Khoshnood (France, Paris*)
- Dr. Hanitra Randrianaivo (France, Ile de la Reunion)
- Dr. Bruno Schaub (France, French West Indies)
- Dr. Annette Queisser-Luft (Germany, Mainz)
- Dr. Anke Rissmann Germany, Saxony-Anhalt)
- Dr. Melinda Csaky-Szunyogh (Hungary*)
- Dr. Mary O'Mahony (Ireland, Cork & Kerry*)
- Dr. Bob McDonnell (Ireland, Dublin*)
- Dr. Catherine Lynch (Ireland, South East*)
- Dr. Amanda Neville (Italy, Emilia Romagna*)
- Dr. Fabrizio Bianchi (Italy, Tuscany*)
- Dr. Miriam Gatt (Malta)
- Dr. Hermien de Walle (Acting) (Netherlands, North*)
- Dr. Marta Ebbing (Norway*)
- Prof. Anna Latos-Bielenska (Poland, Wielkopolska*)
- Dr. Carlos Matias Dias (Portugal, South)
- Dr. Larraitz Arriola (Spain, Basque Country)
- Dr. Oscar Zurriaga, Registry Leader (Spain, Valencia Region*)

- Dr. Marie-Claude Addor (Switzerland, Vaud)
- Dr. Natalya Zymak-Zakutnia (Ukraine, OMNI-Net)
- Ms. Sylvia Stoianova / Mr. Ben Wreyford (UK, SW England (SWCAR)*)
- Prof. Judith Rankin (UK, Northern England*)
- Dr. Catherine Rounding (Acting) (UK, Thames Valley*)
- Prof. Elizabeth Draper (UK, East Midlands & South Yorkshire*)
- Mr. David Tucker (UK, Wales (CARIS)*)
- Dr. Diana Wellesley (UK, Wessex*)

EUROCAT Associate Member Registries

- Dr. Antonin Sipek (Czech Republic)
- Dr. Annukka Ritvanen (Finland*)
- Dr. Emmanuelle Amar (France, Rhone-Alps (REMERA))
- Dr. Anna Latos-Bielenska (Poland)
- Prof. Maria-Luisa Martinez-Frias (Spain, Hospital Network (ECEMC))
- Dr. Karin Kallen (Sweden)

** The EUROCAT budget for 2014 is funded from the EU and from a Membership Fee from participating Full and Associate Member Registries*

"Post 2014, EUROCAT will be moving to the EU Joint Research Centre at ISPRA in Italy, as part of the new Public Health Unit of the Institute for Health and Consumer Protection. This is a considerable success for EUROCAT in achieving a long term sustainable future."

For further information contact:

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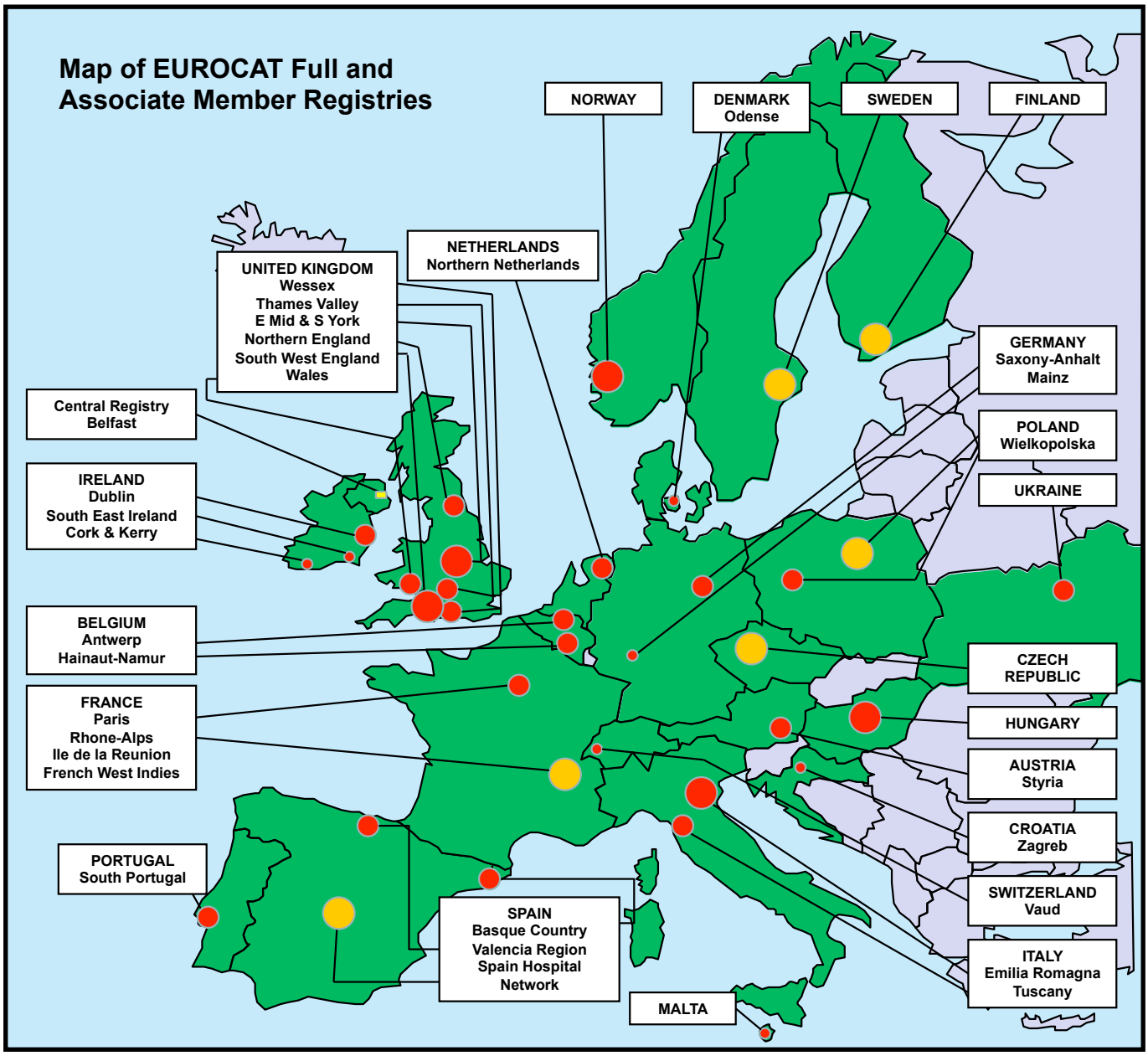

Full member

Associate member

Size of circles

<10,000 births per year

10,000-40,000 births per year

>40,000 births per year