Main features of the EPSA|ERNICA

Background information
Start registrations: 2014
Number of patients included: *2500*
Number of hospitals participating: *6 (Netherlands), 19 (Europe)*
The initiator: European Pediatric Surgical Audit (EPSA), Nederlandse Vereniging voor Kinderchirurgie (NVKC)?

Introduction
The European Pediatric Surgical Audit (EPSA) was developed by the Dutch Institute for Clinical Auditing in 2014 in collaboration with the Dutch Pediatric Surgical Association, registering four diseases seen in Dutch, new-born children (Hirschsprung's disease, Congenital Diaphragmatic Hernia, Esophageal Atresia and Anorectal Malformation). In 2017 the audit was extended to include patients with Omphalocele and Gastroschisis. In the EPSA, data is entered anonymously and then processed by MRDM, in accordance with GDP Regulations.
Since then ERNICA has obtained financial support from the European Commission to create a comprehensive registry for all European children with rare inherited diseases and congenital anomalies, the EPSA.
The primary aim of the EPSA | ERNICA Registry is to improve the quality of patient care. For instance, by enabling health care providers to get insight in their outcomes, as well as the overall outcomes, using quality indicators selected by international experts in the field. Additionally, cumulative data in the EPSA can be used to conduct scientific research, for example to compare treatments or identify certain risk factors for complications.

Inclusion criteria
All patients undergoing surgical treatment for Hirschsprung's disease, Congenital Diaphragmatic Hernia, Esophageal Atresia, Anorectal Malformations, Omphalocele or Gastroschisis.

Online data is self-registered in a secured web form
In order to register your patients, apply to the EPSA|ERNICA registry by sending an email to epsa@dica.nl.
For any additional information and questions, contact the DICA Servicedesk (+31 88 570 00 10)

Feedback
Information regarding volume, performance indicators and outcomes of care are presented online to individual hospitals. Each participating hospital has access to its own secured website. Data are weekly updated. Results of the hospital are presented in relation to the national average and in relation to results of other anonymised hospitals.

Codman Dashboard
In the Codman Environment, health care providers gain insight in their own outcomes and how those compare to the European averages (benchmark information). This is done using 'Codman Indicators' and 'Codman Explorative". This information is updated weekly and is not made public. Yearly reports will be published in November.

Codman Indicatoren
In 'Codman Indicators' you can find all quality indicators. Per indicator the calculation rule, as well as the inclusion- and exclusion criteria (to which patients the indicator applies) are displayed.

Codman Explorative
'Codman Explorative' enables you to filter information on treatment results by for example age, comorbidity or surgical technique. By applying the correct filters, you will receive accurate, uncorrected information about these specific patients. The results of your center will be compared to others in a European benchmark. Here you will also find an overview of all your registered patients and consequently the total number of registered patients in the Audit for your center.

Procedure on the request of data from the quality registration of the Dutch Institute for Clinical Auditing

Preface
The data collected by the Dutch Institute for Clinical Auditing (DICA) of the quality registrations are available for doing the scientific research.Specifically regarding the EPSA, only the data registered by Dutch centers was made available in August 2023 following a dataverification project. The European data is not yet available for research, even though it is expected that this will happen in the near future.

Procedure for requesting scientific research
You can make a request for data at DICA by filling in the 'application form'. On the DICA website you can check under 'paying research requests' which research has already been performed on your subject. The application is judged against the criteria as drawn up by the Privacy Committee. The application is then assessed by one of the members of the Clinical Audit Board (CAB) of the quality registration concerned, supported by an employee of the DICA scientific office. The quality of your application determines the probability of data access..In some instances the DICA Methodological Council is asked for advice on this matter. Only the data that are relevant to the research question can be provided. Note: it is not possible to ask the complete list of variables.

Who can submit an application?
The submission of an application is reserved for participants in the relevant quality registrations and members of the Methodological Council with regard to the development of the methodology.

How should the application look?
This contains the following information:
o Request form.
o Ticked list of required variables (can be downloaded from the website, https://support.mrdm.com/en/downloads/documents/?org=dica&set=epsa).
o If applicable: signed forms 'Consent to the opinion of third parties' (see page 2).

To whom should the application be addressed:
You can address your request to: Onderzoek@dica.nl

To which quality registrations can a scientific application be submitted?
The Clinical Audit Board (CAB) of each quality registration determines whether the data is suitable for external scientific publications. You can find this list on the DICA website. Data can only be requested when it is already availble; this is determined by DICA in consultation with the CAB. It is not intended that research questions should be submitted on data that will be added to the audit in the future.

You can request data for an entire year?
Full data of one year is only avaible at the end of the calender year. This is when the transparency portal closes. This data is avaible from March onward. So in March 2019, the full data of 2018 is complete. If quality registration does not yet participate in the policy portal, the data will be available earlier.

How many publications can you deliver from one research request?
With the data from one data request, one scientific research paper can be submitted. If you would like to write a second article, you must submit a new application, by a reduced rate.

How is the anonymity of hospitals guaranteed?
No hospital nformation is provided when distributing data scientific publications. If anonymity is not desired, the hospitasl must give separate permission for providing additional information via the form 'Permission to notify third parties'. You are responsible for these permissions yourself.

How is the anonymity of patients guaranteed?
No name and address details are provided when distributing data to advertisements. This indirectly identifying information is gender and year of birth. Depending on the issue, birth year can be converted to classes of years. The DICA Privacy Committee also oversees this. The data file must be deleted within a period of two months after the applicant's objective has been achieved.

Costs for reviewing the application
The quality registrations have the possibility to charge an amount of € 141.50 for reviewing the application.

Costs associated with the delivery of data
For the delivery, a huge amount is charged depending on the size of the extensive data set and the frequency of the delivery.

There are 5 types of applications:

• Simple request: € 250 (excl. VAT)
Requests with a maximum of 50 variables, one-time delivery.
• Average request: € 400 (excl. VAT)
Request for more than 50 variables, one-time delivery.
• Request extra variables: € 150 (excl. VAT)
Request for additional variables on an existing research request.
• Publication of second article: € 150 (excl. VAT)
If you would like to publish a second article of the data from an existing research application, a reduced rate applies.
• Extensive request: customized offer
Requests for which multiple deliveries are required, or separate requirements for calculations, constructions and the like.

What do you receive from DICA?
An encrypted and secured database with raw data (so no calculated variables or analyzes); this is a .csv file.

How does the procedure work after my application?
You will receive a response within two weeks and an assessment of your application within eight

weeks.If the application must be submitted to the Methodological Council, an additional four weeks are added. After approval a contract is made.

When does a request expire?
If the research request has been approved by DICA, you will actually receive the data. There may be uncertainties about the application; in this case the coordinator will then contact you. If you do not respond to the questions within 3 months, the application will be canceled. You must then submit a new application.

After publication
A draft of the publication must be sent to DICA, after which it will send to the scientific committee of the relevant quality registration for assessment.