EPSA|ERNICA Registry

Core Values and Governance

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Preface

This document serves as an addition to the DICA Regulations. If these two documents differ, the DICA Regulations prevail (appendix 1.). Moreover, this is a dynamic document. Decisions on governance, registry quality, registry monitoring, authorships, scientific application procedures, and conditions may evolve as the registry ripens and more patients are enrolled. Therefore, this document will be evaluated annually and revised if necessary by the scientific committee of the EPSA. Changes will be documented.

Contents

1. General

In the European Pediatric Surgical Audit (EPSA), participating hospitals record their patient's data in the audit and are subsequently provided with reliable analyses of this data in the form of quality indicators to establish quality assurance and accountability of care. The resulting pseudonymized data can also be used for scientific research, within the bounds of the regulations and only after going through the application process.

Recorded patient data is processed and stored by MRDM conform GDPR and local legislation. Hospitals themselves are the data controller and can thus request and receive their patient data at any point in time. DICA hosts the clinical audit, analyses pseudonymized data, and provides programming and dashboarding meant to make data available and insightful for the healthcare providers of the participating hospitals. DICA has a General Advisory Council, a Privacy Committee, and a Methodological Advisory Council to support and advise the clinical audit and its scientific committee.

2. Definitions

In this document, the following definitions apply:

Scientific committee: the committee that takes note of scientific applications and judges these according to this document and is responsible for the tasks in chapter 1.

Clinical Audit Board EPSA: executive board of the clinical audit EPSA, responsible for daily management such as communications with MRDM, DICA, or other involved parties. Deputies of the scientific committee in several meetings with stakeholders and other parties.

(Scientific) application: request to utilize EPSA data for research purposes, submitted to the scientific committee.

Applicant: the person who requests EPSA data for research purposes and submits the application form to that end. Is the principal investigator. Has to understand the principles of clinical research, as confirmed in a course or via a publication record.

Research proposal: an account of the intended research, including the aims, methodology, statistical aspects, and practical research preparations.

Recommendation: the decision of the scientific committee, stating if the EPSA-data disclosure as requested and substantiated in the application is granted, following this document and based on the received research proposal.

3. Scientific committee

The European Pediatric Surgical Audit (EPSA) is a clinical audit *by* clinicians *for* clinicians, illustrated by the governance through a Scientific Committee (SC). This committee advises and decides on all matters of the EPSA.

Tasks of the scientific committee:

1. yearly assessment of indicators regarding the (surgical) aspect of the treatment of pediatric congenital anomalies, to be used in the EPSA; evaluating utilized dataset and proposing changes if necessary;
2. publishing an annual scientific report;
3. proposing analyses for clinical improvement;
4. assessing scientific applications

4. Composition scientific committee

The scientific committee comprises at least five members. Scientific Committee members will hold these positions for a maximum of four years, with the possibility of extending this period once for another four years. Granting an extension of membership periods must also consider continuity of governance and allow for overlap between old and new members, to ensure a smooth transfer of responsibilities. Scientific committee members are asked to attend a minimum of one meeting of the EPSA scientific committee every year and must be available to assess scientific applications if necessary.

At this time, every hospital participating in ERNICA and EPSA (EPSA member) is allowed one expert representative on the scientific committee. Expert clinicians working at hospitals participating in the EPSA can announce their wish to join the scientific committee to the clinical audit board secretary. If more than one expert of a particular hospital wishes to join the committee, the final choice will be made by the ERNICA hospital representative of that hospital.

ERNICA has disease-specific workstreams, consisting of European experts in the concerning field. These workstreams could aid the scientific committee of the ERNICA|EPSA Registry with disease-specific tasks such as reviewing the dataset or reviewing disease-specific scientific applications. One scientific committee member is appointed per workstream and is responsible for communicating and discussing registry-specific topics to and with the workstream. This disease-specific scientific committee representative should be an expert in the pertaining disease. Patient representatives for different diseases from within ERNICA can be consulted for advice and invited to participate in scientific committee meetings or research projects, depending on the specific topic.

With increasing numbers of participating hospitals, the procedure mentioned above might become insufficient. Therefore, the committee and its size and composition will be assessed annually. If the number of EPSA members exceeds 25, it is up to the EPSA members to decide who will take a seat in the scientific committee. The scientific committee will be responsible for implementing a fair selection process. The starting point will always be that the committee strives to reflect participating hospitals and regions or countries, specialties, and represented EPSA diseases.
After careful consideration, the decision has been made to maintain the abovementioned regulation for the current year and reassess in 2023 and 2024 to evaluate their efficacy, particularly with the expected growth of memberships to over 25 members. The reassessment will inform any necessary changes to the current regulations, and will be communicated to all members in a timely and transparent manner.

The clinical audit board (CAB) is elected from the scientific committee and is responsible for daily management such as communications with MRDM, DICA, or other involved parties. They serve as deputies of the scientific committee in meetings with stakeholders and other parties. SC members can announce their wish to join the CAB to the clinical researcher attached to the EPSA. Two to five members will be elected. Voting takes place during a scientific committee meeting and is blind. Absent SC members can vote beforehand. Roles within the CAB (chairman, secretary) are divided by the CAB members.

5. Scientific Committee Meetings

Annually there are at least four scientific committee meetings. These will usually take place via teleconference, considering the international character of the EPSA. During these meetings, progress and monitoring of the registry will be discussed. The scientific committee will also discuss new scientific applications.

6. Accountability and member involvement

When the number of EPSA members exceeds 25, the EPSA members will select the scientific committee responsible for maintaining and developing the EPSA. All EPSA members will then unite in the "EPSA Sounding Board." Currently, all EPSA members are represented in the scientific committee, automatically involving all members in decision-making. The scientific committee can seek its advice, opinions, and suggestions on various topics. It will report at least annually to the Sounding Board presenting the results, course, and fundamental decision-making for the EPSA, for example, during an ERNICA meeting.

The scientific committee can additionally call a general meeting, inviting all representing clinicians of participating medical centers to discuss extensive studies or analyses using EPSA-data. Such a meeting can lead to new research ideas for which scientific applications will be encouraged. It can also be decided that the clinical researcher attached to the EPSA will submit the scientific application and execute the proposed research.

7. Recording data in the EPSA

Inclusion criteria

At this moment, six diseases are being registered in the EPSA: esophageal atresia; congenital diaphragmatic hernia; Hirschsprung's disease; anorectal malformation; omphalocele; gastroschisis. All patients receiving primary treatment in the participating hospital must be recorded. The date of diagnosis decides the calendar year of registration. So if a neonate was born on 30-12-2021 but diagnosed on 02-01-2022, the patient must be registered in the registration year 2022. The patient is registered in the hospital in which it receives primary treatment.

Mandatory character

All patients treated in the participating centers must be recorded to prevent bias in the benchmarking process. In case a hospital works with local informed consent (due to regional legislation), the number of patients refusing to participate must be recorded to enable an informed comparison of the hospital's data in the audit. The deadline for recording patients of a particular calendar year is the 31st of March of the following year.

Transparency

Quality Indicator Information is for "internal" use only. The EPSA results regarding individual hospital performance are not accessible to organizations other than DICA/MRDM and the participating hospital itself. On the 22nd of March 2023 the Scientific Committee has voted for the implementation

of "data completeness" as an external indicator visible via the Codman platform to all participating members. For this a specific process is being developed.

Verification

Data verification in other DICA audits is performed by taking a representative sample to check whether the Participant has registered the data thoroughly and correctly. Additionally, the accuracy of patient numbers is verified. Because of the international character of the EPSA, verification is complicated, mainly due to language differences in patient reports. A reliable, sustainable verification process will be developed in 2023.

8. Year cycle

January

- 1st of January: start registration year
- Annual evaluation and (if necessary) adaptation of the document "EPSA: Core values and Governance."
- Scientific committee meeting 1
- Announcement of dates for next four scientific committee meetings

March

- Scientific committee meeting 2
- 31st of March: deadline for recording patients in the preceding registration year

June

- 1st of June: deadline for proposing changes to the dataset and quality indicators
- Scientific committee meeting 3

September

- Scientific committee meeting 4

October

- 1st of October: notification to all participating hospitals regarding changes in the dataset of the coming registration year.

December

- 31st of December: end registration year

8. Scientific Application and Research Protocol

Before utilizing EPSA data for research purposes, all conditions in this protocol must have been met, and the scientific committee must have approved the research proposal. Disclosed data will always be pseudonymized, thus not directly retraceable to individual patients. Additionally, published data will be non-retraceable to individual centers.

In 2023, international EPSA data will not yet be made available for external scientific analyses, as data quality in the beginning stage of the registry is limited. In 2023 we will evaluate the registering process and document a process for international data verification. The data unavailability does not necessarily apply to the Dutch proportion of the EPSA data, as the original six hospitals have registered their patients for more than five years and ongoing data verification. This year, the Dutch

hospitals will allow the scientific use of Dutch data (2023) after completing its verification. The scientific application procedure as depicted below will be followed.

Conditions Scientific Application

The scientific application must adhere to the following conditions:

1. A scientific application must follow the digital DICA template for scientific applications, available on the EPSA|ERNICA Registry website
2. A complete list of requested variables needs to be attached to the application form
3. At least one of the applicants must be from a medical specialty (e.g., pediatric surgery, pediatric gastroenterology) that records their patients in the EPSA|ERNICA Registry
4. To stimulate collaboration between participating members, the first two and last two authorships must be divided between two or more centers, ideally from different countries.
5. Hospital identifying data will not be distributed and published, unless this information is specifically applied for. The application should then be accompanied by the "Permission to distribute information to third parties-Form", which has to be signed and approved separately by all Boards of Directors of the involved hospitals.

Submitting a scientific application

Applicants must submit their applications to the coordinator of scientific applications of the Dutch Institute for Clinical Auditing digitally. The applications must contain the research proposal, a list of requested variables, and any other document relevant for judging the scientific application.

Review of scientific applications occurs quarterly. The application should be submitted at least four weeks before the next meeting of the scientific committee. The dates of these meetings can be found on the EPSA website (https://ern-ernica.eu/registry/research/). The application should contain a summary of a maximum of two pages describing the background and aims of the research, the research methods, and expected results. Preferably the application also contains the research protocol.

Application process

The completeness and adequacy of each scientific application must be evaluated within six weeks by the clinical researcher attached to the EPSA|ERNICA Registry and by the Scientific Bureau of DICA. The application is judged explicitly on the completeness of data, requested data availability, and relevance to the proposed research question. If deemed adequate, the application will be taken under review officially.

Before the following scientific committee meeting, the scientific committee receives all scientific applications. Subsequently, two scientific committee members specialized in the concerning disease (one of which must be the disease-specific scientific committee representative) will be appointed to review and assess the applications. As the registry comprehends multiple diseases, it might be necessary to extend the review invitation to members of the disease-specific workstream connected to the EPSA|ERNICA Registry to ensure the reviewers are experts in the disease-specific domain. After reviewing the application, they compose an official recommendation to the committee. Subsequently, the research group will get a chance to illustrate their application during the scientific meeting. The two previous steps will be omitted if all scientific committee members are involved in the proposed research project. Hereafter, the committee's official recommendation will follow (approved, disapproved, or approved with reservation). If an application is approved with reservation, the scientific committee reviewing members are responsible for directing revisions and discordances. The reviewer may review and discuss the application again in the subsequent scientific committee meeting if doubts still exist afterward.

The (reviewing members of the scientific) committee base their recommendation on the following criteria:

1. The research will reasonably lead to new insights in medical science and a sound publication
2. The research proposal assures an adequate methodology of scientific research
3. Data in the EPSA|ERNICA Registry is sufficiently available and relevant for the intended purpose, as judged by the committee and by DICA
4. No similar research proposal using EPSA data is concurrently under review of the EPSA Scientific Committee

The scientific committee will express its recommendation to the coordinator of scientific applications at the Scientific Bureau of DICA. This coordinator is responsible for gathering all necessary documents, adequately following the procedure, and communicating with all involved parties. All submitted documents will naturally be treated confidentially and will not be disclosed to others not involved in the application during the assessment procedure. An overview of the governance structure and assessing committees can be found in appendix 4.

Completion of an application

The following recommendations are possible:

1. The application was discussed during a committee meeting, and at least 80% of the (present) committee members approved the application. The vote is blind. Scientific committee members that are part of the research group are withheld from voting.
2. The application was discussed during a committee meeting, additional information was requested, or revisions were advised.
3. The application was not approved

If necessary, for example, if specific patient data or hospital data is requested, the privacy committee of the Dutch Institute for Clinical Auditing (DICA) assesses the application next. The privacy committee bases its recommendation on the following criteria:

1. The disclosure of data is in keeping with the purpose of the clinical audit
2. The protection of patients' privacy is sufficiently safeguarded
3. The likeliness that applicant will make responsible use of the data in all other respects
4. The disclosure of data will not jeopardize the Clinical Audit
5. The disclosed data is not directly retraceable to patients and treating medical centers

The Scientific Bureau of DICA definitively decides if a scientific application is approved within three weeks of the final recommendation of the scientific committee. Recommendations of the committees as mentioned earlier (Scientific Committee EPSA, Privacy Committee DICA) are considered leading. If either of these recommendations is negative, the application will not be granted. The scientific committee and privacy committee will be notified of disclosure decisions in writing. After approval of disclosure, contact will be made with the applicant regarding approval and data disclosure conditions. If a scientific application has not been granted, the applying research group will be presented with the argued rationale behind the final decision. Of course, it is possible to resubmit a revised proposal. Depending on the advised revisions and criteria set during the SC meeting, applications may be approved after resubmission without awaiting the next SC meeting.

Upon completing a manuscript based on EPSA data, the final draft must be sent to the coordinator of scientific applications (onderzoek@dica.nl). The clinical researcher of EPSA will then add a blank authorship for every participating center as specified in chapter 6. After that, he or she will send the manuscript to the participating centers to specify the names of the authors and give them the chance to make final comments or suggest revisions to the first author. The participating centers will have two weeks to submit these suggestions and claim the specified authorship. After the revision of the

manuscript, the final draft will be sent to all collaborating authors one last time as the last verification before submission to a (medical) journal. If no answer is received within two weeks, this will be recorded as consent to publication.

Through the participation agreement, medical centers participating in the EPSA mandated the scientific committee to approve or disapprove scientific applications and the consequent use of EPSA data in scientific research. However, a medical center can always object to the use of their hospital data in research projects. All medical center's official ERNICA representatives will be informed of granted scientific applications. In case of objection to use of data, this representative needs to notify the scientific committee within four weeks. The individual hospital data will then be excluded from that particular research project. Any authorships for that hospital in the research project will be forfeited correspondingly.

Applications for a proportion of EPSA data

It is possible that scientific applications only request a proportion of EPSA data, for example, data of only certain hospitals or country-specific data. In that case, the aforementioned scientific application process and conditions apply, with two exceptions: collaborative authorship is solely for those hospitals that have contributed to the requested proportion of the EPSA data. Additionally, notification of granted scientific applications is only given to the hospitals contributing to that requested data portion.

Authorships

(Co-)authorships on scientific publications emerging from EPSA|ERNICA Registry data are based on the ICMJE criteria, as listed below[1].

To be listed as an author, a considerable contribution must have been made to:

1. conception, research design or the acquisition or gathering of data and its analysis and interpretation; AND
2. drafting the manuscript or critical review of the scientific contents thereof; AND
3. reading and approving the final manuscript to be published; AND
4. agreement to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In practice, these criteria will be interpreted as follows: for every granted scientific application, the reviewing disease-specific representative on the scientific committee must be a co-author. On behalf of the EPSA scientific committee, he or she councils the manuscript's authors and is involved in all parts of the writing process, thereby warranting quality of analyses, the resulting manuscript, and the adherence to the original scientific application. During the 'scientific application pitch,' more scientific committee members can express their wish to take on the role of active author and naturally fulfill the associated tasks; however, their acceptance in the research group is not mandatory.
It is crucial to state here that the authorship criteria for specific projects will be evaluated and defined upfront during the assessment of the research application.

Substantial contributions by **acquiring or gathering data** are defined by measuring patient enrollment. At this time, all medical centers participating in and contributing data to an EPSA|ERNICA Registry will receive a mention as a group author (collaborator), which will be traceable on Pubmed and will contribute to their individual H-index. It is up to the medical center's official ERNICA representative to name the contributing clinician that shall receive this mention on the condition that the clinician must be specialized in the studied disease. The affiliation listed should be the registered patients' medical center. The sequence of listing of group authors will follow the number of patients

entered in the EPSA|ERNICA Registry for that particular disease. In the future, the appointment of collaborative authorship will likely be based on both the absolute number of patients and the fraction of patients relative to the total number of patients treated in the medical center.

Naturally, all authors, including collaborating authors, must be offered the final manuscript for revisions before submission to a medical journal. A (co-)author must be informed of every author's contribution and have complete confidence in these contributions' accuracy and integrity. If an author does not contribute to the manuscript after being sent at least two reminders, authorship is automatically forfeited.

Acknowledgments

Principal investigators must mention the following text in the acknowledgments of all manuscripts resulting from EPSA data:

"This article is supported by ERNICA. The authors would like to thank all recorded patients and all medical specialists, clinicians, and administrative nurses for data registration in the EPSA|ERNICA Registry, as well as the European Pediatric Surgical Audit group for scientific input."

9. Scientific Committee Goals for 2023

1. Elect disease-specific Scientific Committee Representatives
2. Dataset revision of EPSA conditions and new conditions
3. Establish a fair selection process for a representative scientific committee of the EPSA to implement when EPSA members exceed 25.
4. Establish a reliable, sustainable verification process to warrant data quality in different countries
5. Establish a process for making certain quality indicators accessible to all participants, specifically "case completeness" in 2023.

10. Reconsiderations 2024

1. Reconsider availability of EPSA data for scientific purposes
2. Reassess (co-)authorship criteria
3. Reconsider making center volumes external indicators.

References

1. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, ICMJE, version dec2014: http://www.icmje.org/recommendations/

Governance structure EPSA|ERNICA Registry