

Quality of Care Initiative

Service Evaluation

Description of the Quality of Care (QoC) Initiative

The European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) aims to contribute to the improvement of the quality of care for children and adolescents in Europe with diseases of the gastrointestinal tract and liver. The Quality of Care (QoC) initiative meets the criteria of a **service evaluation** as defined by the National Health Service (NHS) guidance on research, service evaluation, and clinical audit; service evaluations do not require a review by a Research Ethics Committee (REC) (1).

The QoC project is designed and conducted to assess and judge how well a service achieves its intended skills without reference to a standard. The information collected in the QoC will be purely used to feedback to the care service, not to individual patients. We provide educational materials to improve future care; the use is optional, not mandatory. Though benchmarking may be used in the QoC initiative to compare the quality of care between different hospitals in Europe, the evaluation will not involve any measures against pre-determined standards. Thus, the QoC initiative differs clearly from a clinical audit (1).

The methods we apply include survey on general hospital data in terms of accessibility and availability (no financial data), staff survey and retrospective review of patient files or discharge letters on performed care. No survey or questionnaire will be completed by patients or their caregivers. The gathered information in the QoC initiative is not directed to the clinical data of patients. Therefore, the QoC initiative in terms of registry study is also not applicable (2).

The data protection officer of the Ludwig Maximilian University (LMU) Hospital of Munich, Germany, has legally reviewed the concept and the questionnaires. He confirmed that **the criteria for anonymous data collection in accordance with the European Union's General Data Protection Regulation (GDPR) (2) are fulfilled**. Based on the strict data protection concept and the statement of the data protection officer, the ethics committee of the LMU Hospital of Munich has granted a waiver to the applicant (Prof. Dr Sibylle Koletzko), i.e., the Quality of Care project does not require a review or ethical approval due to its design:

- “The Quality-of-Care project of ESPGHAN observes national public data and involves survey procedure (questionnaires) on hospital level collecting data which relate to hospital as institution and not to any identified or identifiable natural person.”
- “The Quality-of-Care project of ESPGHAN involves questionnaires to data rendered anonymous on patient level which are irreversibly anonymised and will not allow any identification of single subject.”

1 Scope and Purpose

To align and harmonise ESPGHAN initiatives to improve the practical delivery of quality of care to all children suffering from disorders in Gastroenterology, Hepatology and Nutrition.

The WHO defines QoC as “the extent to which health care services provided to individuals and patient populations improve desired health outcomes. In order to achieve this, health care must be **safe, effective, timely, efficient, equitable and people centred**” (3).

Assessment of QoC: The QoC assesses the current status of quality of care in **Structure, Process, and Outcome** in a network of European hospitals, to identify gaps between reality and ideal (evidence-based ESPGHAN guidelines), initiate interventions to decrease this gap (implementation of educational material), and assess changes in QoC over time.

2 Structure of Network

The network and structure of the concept ensure long-term success:

- **Mutual benefits for all stakeholders:** ESPGHAN, national societies and their presidents, Director, Chief of Paediatric Hospitals, Departments or Divisions, QoC representatives in hospitals
- **Voluntary participation** of every hospital
- **Anonymous data reporting** for benchmarking (code: Country, Hospital)
- **Concept on data collection and data protection** which qualifies for a waiver from Ethical committee and data protection office
- **Transparency:** open access to collected data for stakeholders (country, hospital)
- **Educational material** provided for free by ESPGHAN to stakeholders

3 Data protection concept for Network and Tasks

The structure of the network and data protection is organised as follows:

Countries, National Societies, National Presidents and ESPGHAN Members: Use of open access information with readily accessible data from the public domain.

Hospitals and Hospital Director: Pseudonymized data by a system of coding, not readily identifiable to anyone outside of the administration of the project.

Patients and QoC representatives from National Societies: Anonymous data collection on patient care, completely anonymized data, not identifiable in any way.

Education, information, and benchmarking: ESPGHAN provides educational material and national /local results for benchmarking and national/local use (hospital codes). Participating hospitals and QoC representatives receive an ESPGHAN-Certificate and training.

4 Data Collection Procedures

Data collected in QoC Database for non-commercial and educational purposes will be anonymized for patients and pseudonymized at the hospital level (unique random ID Number) and will not be exchanged with any third party outside the QoC network.

QoC hospital representatives collect and enter data into Castor EDC after receiving access from the Data Manager (DM).

Data protection: All data (national, hospital and patient level) is aggregated in a secured database on Castor EDC (**Castor EDC, Amsterdam, The Netherlands**). Castor EDC is independent of academic institution or hospital and compliant with the highest data security requirements of GDPR.

National and hospital data are not related to identifiable persons. Patient data are rendered non-identifiable to maintain the confidentiality of clinicians and patients. It is impossible to identify any involved clinician or patient once data are submitted and stored in Castor EDC. In case of presentations

or publications, hospital data confidentiality is maintained. All results will be presented in non-identifiable statistics. Criteria of data anonymization and GDPR compliance are fulfilled.

Survey/Questionnaire according to the focus of every year. Data is evaluated and reported in anonymous statistics accordingly.

Responsibilities of the Database Management: Management of data platform (Castor EDC) and questionnaires; assignment of hospital codes, confidential management of ID list with Administration Management (Chair and members of the ESPGHAN QoC Taskforce are blinded); management and analysis of collected data, feedback to hospitals and National Societies.

Responsibilities of the Administration Management: Administrative duties and logistic support of the project.

5 Ownership of Database

Collected data is stored on Castor EDC, which is not connected to any institute/university/hospital server. ESPGHAN is the sole owner of the data and has full access to all collected data. The data will be provided in general for public access if this serves the goal to improve quality of care.

The data will be regularly presented at annual ESPGHAN meetings or published in international journals. After approval from ESPGHAN, National presidents may present or publish the national data from their country in local meetings or journals.

6 Finances

The QoC Initiative is financially supported by the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN). The Chair and members of the QoC Taskforce are independent of the financial supporter in the design of the service evaluation, data analysis, reporting and interpretation.

References:

- (1) Defining Research - NRES guidance to help you decide if your project requires review by a Research Ethics Committee [https://www.strath.ac.uk/media/committees/ethics/Defining_Research_Leaflet1_\(3\).pdf](https://www.strath.ac.uk/media/committees/ethics/Defining_Research_Leaflet1_(3).pdf)
- (2) Recital 26 Not Applicable to Anonymous Data of the European Union's General Data Protection Regulation (GDPR) <https://gdpr-info.eu/recitals/no-26/>
- (3) https://www.who.int/maternal_child_adolescent/topics/quality-of-care/definition/en/