COSI - Core Set of Indicators/ Standards for Primary Paediatric Care in Europe

- FEASIBILITY STUDY -

Study Protocol

Institute for Health Systems Research IGFo

Witten/Herdecke University, Germany

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1. Responsibilities

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Country Coordinators:

1. Austria (Daniela Kasparek)
2. Cyprus (Hadjigeorgiou Charis)
3. France (Marie Noelle Roebbebrecht)
4. Germany (Folkert Fehr)
5. Hungary (Alcos Kovacs or Peter Altorjai)
6. Israel (Shimon Barak)
7. Italy (Laura Reali)
8. Spain (Concha Sanchez, Carmen Villaizan)
9. Sweden (Björn Wettergren)
10. any other country- up to three more- to be determined after 9.11.2014

2. Background and COSI Project Status

With the project „COSI - Core Set of Indicators/Standards for Primary Paediatric Care in Europe" the European Academy of Paediatrics (EAP) and the European Confederation of Primary Care Pediatricians (ECPCP) aim at developing and implementing a manageable, valid and transparent core set of provider- and performance-oriented quality indicators (QIs) and standards for primary paediatric care (PPC) in Europe.

As a prerequisite, suitable QIs for PPC currently available and in use worldwide were identified in an initial, broad and comprehensive research in 2011. A working group from EAP systematically searched scientific literature and the Institute for Health Systems Research (IGFo) at Witten/Herdecke University, Germany, searched online QI databases. As a result, this initial literature research led to a comprehensive QI inventory containing 1516 QIs/standards for PPC.

In a first consensus process an expert panel (7 members of EAP and ECPCP) deleted QI duplicates, rated each of the remaining QIs by validity and feasibility and - after discussion - agreed upon a reduced QI inventory. Furthermore, the panel identified a number of subjects not yet covered by the inventory. In January 2013, IGFo conducted a second, supplementary search for QIs targeted at the missing subjects. If there were no QIs to be found, new QIs were formulated based on recommendations from established guidelines. In a second consensus process the expert panel and IGFo finally reduced the number of QIs in the inventory to 50 by May 2013.

During a two-step rating process (first: online rating; second: rating in a moderated session during a personal meeting) based upon the RAND/UCLA Appropriateness Method[1] an expert panel (members of EAP and ECPCP) rated each QI by validity and feasibility on a 9-point Likert scale. The online rating took place in July 2013 and 22 EAP/ECPCP-members took part in it. As a result, for 16 of the 50 QIs there were ratings with disagreements, i.e. QIs with major deviations between the ratings and QIs with equivocal ratings. These 16 QIs were discussed and re-rated in a moderated, personal meeting of 14 panellists in December 2013. Still there were 8 QIs with disagreements which were excluded from the inventory. Therefore, COSI compiled in January 2014 comprises 42 QIs, classified as follows:

- Health Promotion/Prevention/Screening (13 QIs)
- Acute Care (9 QIs)
- Chronic Care (8 QIs)
- Practice Management (3 QIs)
- Patient Safety (9 QIs)

After systematically selecting, formulating and rating QIs, the last step to finalise COSI is feasibility testing in a number of European PPC practices. COSI QIs shall be pilot tested in at least 100 PPC practices, which are at least 10 PPC practices in each of the 10 participating European countries. Paediatricians rate each QI by a number of criteria reflecting feasibility and applicability of COSI QIs in European day to day PPC practice, also giving information on time and effort needed to extract data for QI calculation.

3. Guiding Research Question

How do PPC practices in 10 European countries rate the feasibility of collecting and providing data for COSI-QI calculation?

4. Aims of the Study

COSI feasibility testing shall reveal information on the following aspects for PPC practices in each participating country:

[1] R. Brook, „The RAND/UCLA appropriateness method“, in *Clinical practice guidelines development:methodology perspectives*, Rockville, MD: Agency for Health Care Policy and Research, 1994.

1. The effort of PPC practices to extract and provide data for COSI-QI calculation shall be described. This includes:

- **Applicability** of each QI in PPC practices,
- **Availability** of data needed for each QI in PPC practices,
- **Feasibility** of data collection for each QI,
- **Effort** of data collection for each QI (time needed),
- **Relevance** of each QI for quality assessment in PPC,
- **Reliability** of data collection for each QI and
- **Acceptance** of each QI by the paediatrician.

2. Features of practice structure possibly influencing data collection shall be described.

3. If possible, conducive and hindering factors shall be described.

5. Study Design and Concept

Survey instruments (written questionnaire for structural features of PPC practices, written questionnaire to assess feasibility and effort for each QI, see 6.1.) and further documents (instruction for country coordinators and paediatricians, see 6.1.) are developed by IGFo and pre-tested by the study coordinator, Dr G. Huss. PPC practices are selected (see 6.2.) and contacted by the country coordinators using the survey instruments prepared by IGFo. On the basis of 10 randomly selected patient records that target one of the diseases covered by COSI each participating paediatrician collects data needed for each COSI-QI and estimates feasibility and effort. Data received by each paediatrician are collected by the respective country coordinator and sent to IGFo for further evaluation (qualitative and descriptive, see 6.4.). For each country, QI feasibility data is correlated with specific structural features of PPC practices. Conducive and hindering factors are described, if possible. All relevant outcomes are summarized in a report; country coordinators electronically receive a short description of the respective country's results.

6. Methods

6.1.Survey Instruments and Documents

All survey questionnaires and further documents will be provided in English language and in written form.

Questionnaire on structural features of PPC practices

The questionnaire on structural features of PPC practices includes the following variables:

- size of practice (number of physicians, number of paediatricians, number of medical employees, number of non-medical employees),

- structure of practice (physicians of other medical specialities, affiliation to a hospital, consultation hours, electronic or paper-based patient records, practice administration system (software)),
- location of practice (country; urban/rural; number of inhabitants at practice venue),
- paediatrician (age, sex, years of professional experience as a paediatrician),
- patients (number of patients per month/three months).

Additionally, in consultation with the study coordinator or the country coordinators, further country-specific items may be added. However, the questionnaire is one and the same for each country. The language of the questionnaire is English.

Questionnaire on feasibility and effort

For each COSI-QI, paediatricians assess the following criteria: applicability, availability, feasibility, effort, relevance, reliability and acceptance. Availability, feasibility and effort have to be assessed separately for each QI nominator and denominator whereas applicability, relevance, reliability and acceptance are assessed for each QI as a whole. All criteria are assessed for every QI; adaptions to questionnaires may be necessary according to specific QI contents. The questionnaire is one and the same for each country. The criteria assessed are described as follows:

- **Applicability** of each QI as a whole
  guiding question: Is information pertaining to the QI collected regularly in the PPC practice?
  - Is this QI applicable to your practice?

- **Availability** of data needed for each QI nominator and denominator
  guiding question: Is this QI collected and documented in the PPC practice?
  - Is this QI nominator/denominator information collected regularly in your practice?
  - Is this QI nominator/denominator information documented regularly in your practice?
  - Is this QI nominator/denominator information documented in written, paper-based form or electronically?

- **Feasibility** of data collection for each QI nominator and denominator
  guiding question: Can you access the information needed for the QI nominator/denominator via your current practice documentation?
  - Is there a query function in your practice administration software that allows you to electronically retrieve the information needed for the QI nominator/denominator?

- **Effort** of data collection for each QI nominator and denominator
  guiding question: How much an effort is data collection/documentation and QI calculation in day to day practice?
  - How much time would you approximately need to calculate this QI for all suitable patients of one year, if you used your current documentation source for this QI (i.e. written, paper-based records or electronic patient records)?

  - Under your given day to day practice routine, is this effort reasonable to you?

- **Relevance** of each QI as a whole
  guiding question: How relevant is this QI for the prevention/ screening/ treatment/ practice management/ patient safety aspect it describes?
  - What do you think: Is this QI suitable to meaningfully describe the quality of care in this specific clinical condition or practice management aspect?

- **Reliability** of data collection for each QI as a whole
  guiding question: How do you estimate the reliability of data collection for this QI?

- **Acceptance** of each QI as a whole
  guiding question: All in all, how do you assess feasibility and effort for this QI?
  - Would you accept if the quality of PPC was measured and rated by this QI?

Additionally, conducive and hindering factors can be recorded in free text.

Further survey documents

Every country coordinator receives a short study description and an instruction of his tasks and functions in English language. Every participating paediatrician receives a manual describing how to fill in the questionnaires and who to ask for further questions in English language.

6.2.Sample

It is a desirable aim to allow for between-country comparisons of COSI-QI feasibility data. According to sample size estimation, data from 58 PPC practices per country would be needed to statistically proof between-country feasibility differences at 20%-points (differences from 70% to 90% QI feasibility rates; further assumptions: power 80%, one-sided Chi-square test, p=0.05). It is not feasible under the given circumstances to study that number of practices in the planned time frame and project budget. Therefore, no inferential statistics but qualitative and descriptive analysis are performed to describe COSI-QI feasibility in each country and all outcomes reported are hypothesis-generating. The planned analysis considerably influences recruitment and composition of the study sample.

Recruitment and motivation of PPC practices is up to the country coordinators. Due to the qualitative descriptive analysis, the PPC practice sample in each country must not be selected randomly. It shall represent the full range of any possible organisational and structural practice characteristic in each country, e.g. urban/rural location, different social environments, number of paediatricians in the practice, variety of medical specialities in the practice, single or group practice, further aspects typical of the respective national health system etc. The country coordinators have to contact and recruit practices purposefully in this way. Proficiency in English and willingness to dedicate some hours to the study are important.

After initial nomination of the country coordinators by the study coordinator all data about address and Mail- contacts will be delivered to IGFo.

In each country, at least 10 PPC practices shall be recruited and provide data out of at least 10 randomly selected patient records. This should be reached in every participating country.

6.3.Study Conduct

Responsibilities during the study are as follows: IGFo provides survey instruments and documents, performs data analysis and produces the report as well as short descriptions of the main country-specific study outcomes for the country coordinators. IGFo also provides scientific support for the study coordinator who is the main contact person for the country coordinators. The country coordinators receive all relevant instruments and documents for the participating PPC practices in their country from IGFo. Country coordinators are instructed in written form by the IGFo and, if needed, can receive further information from the study coordinator. The country coordinators recruit PPC practices in accordance with the pre-defined criteria, collect filled questionnaires and send the documents in an anonymised form to IGFo. They also collect all questions of PPC practices related to the survey questionnaires' contents.

All survey instruments and documents are developed by IGFo. The study coordinator pre-tests these documents in a number of international practices. After possible changes or adjustments the survey documents are sent to the country coordinators. Country coordinators receive documents for 15 PPC practices to ensure, that the minimum number of participants will be reached. Country coordinators distribute the survey documents among the participating practices in their country. On the basis of 10 randomly selected patient records each participating paediatrician collects data needed for each COSI-QI and estimates feasibility and effort. PPC practices shall fill in the questionnaire within 4 weeks; 2 weeks after document distribution the country coordinators kindly remind non-responding practices. At least six weeks after distribution the country coordinators have to send all filled questionnaires to IGFo in an anonymous form. IGFo then performs data analysis and produces the report and the short country-specific outcome descriptions.

6.4.Data Analysis

Data analysis is performed separately for each country using IBM SPSS Statistics programme. Qualitative and descriptive analysis of structural practice features and feasibility/ effort QI data comprises all common measures of location/ dispersion and graphics, where appropriate. Structural features, each QI as a whole and - if necessary - each QI nominator and denominator are analysed. Thus, descriptive analysis of all structural features and every feasibility criteria studied (applicability, availability, feasibility, effort, relevance, reliability and acceptance) is provided.

Providing electronic patients records in PPC practices may increase feasibility ratings of COSI-QI. Therefore, correlation analysis of structural features and feasibility ratings is also performed for each country. However, due to low sample size this analysis is only hypothesis-generating.

Conducive and hindering factor will be described qualitatively.

6.5.Data Management

All data sent to IGFo by the country coordinators shall not include any personal or identifying information of the respective paediatrician. Therefore, all descriptions and analyses are provided, distributed and published in anonymous form by IGFo. IGFo guarantees to comply to relevant data protection rules. According to German law ethical approval is not necessary for analysing the kind of anonymous data that is produced within this study.

7. Timetable

Task	Time Frame	Responsibilities
Assuring sufficient funds for the study budget	November 2014	Study coordinator, IGFo
Development of survey instruments and documents	November 2014	IGFo, study coordinator
Pre-test of survey instruments and documents	December 2014	study coordinator
Data collection in PPC practices	January 2015	country coordinators, study coordinator
Data analysis, report	February – March 2015	IGFo

8. Signatures

date and place

Prof Dr Max Geraedts

date and place

Dr Gottfried Huss