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# Development of evidence-based quality indicators for deep brain stimulation in patients with Parkinson's disease and first year experience of implementation of a nation-wide registry

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ABSTRACT

*Introduction:* Deep Brain Stimulation (DBS) is a complex, invasive and cost-intensive therapy that requires a high level of expertise. To date, data on quality of DBS in clinical routine in the German health care system are lacking.

*Methods:* The development of evidence-based QIs for DBS in PD patients was performed following a standardized process by a multidisciplinary board between 2014 and 2016. The process was initiated by the German Parkinson Society and followed international recommendations for developing QIs including: a systematic literature search; an appraisal of the published evidence; a consensus-based selection of the QI set; and a pilot study to assess the feasibility in implementing the QIs in clinical routine.

*Results:* A set of 28 QIs for determining the quality of DBS in PD was established by the board covering different dimensions of health care quality (structure, process, and outcome) in different treatment phases of DBS care (pre-operative, peri-operative, and post-operative).

Implementation in clinical practice was tested in a pilot study comprising three hospitals delivering DBS care. The feasibility of the QI set was evaluated positively by the participating physicians and hospitals. Mean time to

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document one patient was 25 min. The German-wide implementation of the defined indicator set within a dedicated quality registry (QualiPa) started in June 2016.
*Conclusion:* QIs are a necessary requirement to monitor hospital performance in DBS care. The evidence-based approach to develop the proposed indicator set is expected to assure transparency, acceptance and long-term applicability of the QI set in Germany.

## 1. Introduction

Parkinson disease (PD) is a frequent neurodegenerative disorder affecting between 797 and 961 per 100,000 individuals in Germany [1]. Deep Brain Stimulation (DBS) is a complex, invasive and cost-intensive treatment option for motor complications of levodopa or severe tremor in PD requiring a high level of expertise [2–4]. DBS is an approved therapy for severe tremor and motor fluctuations in PD with Class I evidence level from several randomized-controlled clinical trials [5–9]. In careful selected candidates DBS seems to be superior to the best medical treatment of PD [10]. However, outcomes are highly variable and related to factors as surgeon's experience, an interprofessional team and patient selection [2]. A case series of 41 patients complaining about suboptimal outcomes revealed that poor outcome was in 51% related to insufficient management of DBS surgery [10]. Currently, data on DBS in routine clinical in Germany are lacking and no established quality assurance programs for this therapy exist. Quality indicators (QIs) are an accepted tool for measuring performance of hospitals in clinical routine [11]. QIs reflect the standard care and should be developed in an evidence-based, standardized way [11,12]. QIs can monitor the performance of a single facility over time, compare treatment quality between various health care providers, and finally evaluate and feed the results back to indicate areas where improvement is necessary [13]. Therefore, in 2014, the German Parkinson Association initiated a project to develop the methodology of quality assurance programs of invasive and device-aided procedures (deep brain stimulation, continuous apomorphine, or intestinal levodopa infusion) in the treatment of PD patients in Germany ('Quality Assurance of innovative invasive Procedures in the Treatment of Patients with Parkinson's Disease in Clinical Routine in Germany' - QualiPa). In addition, we aim to expand the project to develop and implement QIs also for other invasive PD therapies, such as continuous apomorphine or levodopa infusion. The process of developing QI and implementing the registry is currently underway and will be completed within the next year.

The following report summarizes the results of this initiative on the development and implementation of performance measures of DBS therapy in PD. First we describe the methodological background, followed by a description of the approach implementing the registry physically and the presentation of first results of the registry.

## 2. Methods

### 2.1. Constitution of the quality indicator board

The process was initiated by the German Parkinson Association, a member society of the German Neurological Association ("Deutsche Gesellschaft für Neurologie"), and supported by the Working Group Deep Brain Stimulation ("Arbeitsgemeinschaft Tiefe Hirnstimulation") within the German Neurological Association (DGN) and German Society for Neurosurgery (DGNC). Selected experts from high-volume DBS centers across Germany were invited to join the QI Board for the development of evidence-based QIs. A complete list of all participating members is provided in the Supplement (eTable 1).

### 2.2. Methodological approach

The standardized process for the development of QIs was adapted from the recommendations of the First Scientific Forum on Assessment of Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke of the American Heart Association [11] and the obligations for clinical performance measures in the German Healthcare system [14] that were also used for previous development of quality indicators in acute and rehabilitation stroke care [15,16]. The chosen approach consisted of a standardized Delphi process, literature search, and a critical appraisal of published evidence [15,16].

### 2.3. Definition of the term quality indicator

To define the term QI we applied the following specification which was also used for the development of QIs in acute stroke care [15,16]: QIs reflect the standard of care in clinical routine for all appropriate patients; in addition, QIs should include criteria for the selection of patients suitable for the specific indicator; evidence-based guidelines can support the development of Qis [11,14].

### 2.4. Methodological requirements of quality indicators

The QI board agreed on the following methodological requirements for QIs based on previous recommendations [11,14]: the QI should represent a meaningful outcome for the patient or society or it should be closely linked to those outcomes; a QI should be valid and reliable to ensure a useful measure of healthcare quality; performance measures should be adjustable for patient variability to acertain that observed differences are related to performance differences of the participating institutions rather than disparities in patient characteristics; the collection of data on QIs should be feasible for healthcare providers in clinical routine; QIs should be adjustable to changes in healthcare processes to encourage healthcare providers to improve their services.

### 2.5. Healthcare dimensions to be covered

The working committee chose to follow the Donabedian concept as theoretical framework, which assesses information on health care quality from three categories: structure, process, and outcome [17]. For a better reflection of different dimensions of health care of DBS therapy in PD, the different treatment phases pre-operative, peri-operative and post-operative were added to the three categories of the Donabedian concept. Overall, 9 components set the structure for the selection of clinical performance measures. The board aimed to propose at least one QI in each of the defined health care dimensions if applicable.

### 2.6. Evaluating the quality of scientific evidence

To identify already existing QIs for DBS, a systematic search of the literature in MEDLINE (via PubMed), in the Cochrane Library and in BMJ was performed and guideline databases and websites of neurological associations were reviewed for existing guidelines on DBS in patients with PD prior to the selection of potential QIs by the working group.

For each of the QIs proposed by the working group, a dedicated literature search was performed in MEDLINE (via PubMed), in the Cochrane Library and in BMJ. The identified evidence was prioritized by its level of evidence and its methodological quality. In the case that there was no scientific evidence available consensus recommendations or expert statements were considered.

### 2.7. Specification and rating of the quality indicators

In a next step, all potential indicators were rated regarding relevance and practicability by the members of the working committee using a 5-point Likert scale from 1 (definitely not applicable) to 5 (definitely applicable) considering the scientific evidence, the methodological quality and the a priori defined methodological criteria. To be eligible for the final set, the QI needed to score on average a minimum 4 of 5 points.

### 2.8. Ethics

The methodology of the registry was approved by the ethics committee of the University Hospital Würzburg (Nr. 235/15). The data management concept for the patient to participate in the registry was accepted by the corresponding data protection officer (DS-117.605-04/16). Participants gave their written informed consent to participate in the registry. The registry is registered within the German Clinical Trials Register (DRKS): DRKS-ID DRKS00011709.

## 3. Results

### 3.1. Development of a preliminary set of quality indicators

The whole process to define QIs for DBS in PD took place in one face-to-face workshop, one phone conference and working group activities between December 2014 and April 2015. A detailed timetable of the process is presented in the supplemental eTable 2. The systematic search for evidence on DBS and QI is listed in supplemental eTable 3. Different variations of the search terms 'Deep Brain Stimulation' and 'quality indicator' were combined with Boolean operators. A total of n = 1,185 results were identified. After removing n = 144 duplicates, the abstracts of the remaining n = 1,041 articles were screened to determine if the publication fulfilled the inclusion criteria and was relevant for DBS. Thereby, another n = 996 were excluded. Of the remaining n = 45 publications the full text was used to assess the relevance of the articles. Overall, n = 40 remained in the final pool and were assigned to potential QIs. Our search did not identify any published QIs for DBS.

From the initial pool of 43 proposed QIs, 28 were selected by the board based on the published evidence and the defined criteria. The initial set along with the finally selected QIs are provided in supplemental eTable 4. Five of the 28 indicators were classified as structural QIs of the institution, 18 as process and 5 as outcome QIs. Overall, 2 questionnaires were developed to measure the quality of care in a longitudinal manner from baseline up to 6–15 months after the intervention. The supplementary material contains the 2 questionnaires (baseline and follow-up) and the structural questionaire eFig. 1 to eFig. 4.

### 3.2. Pilot study

A pilot study to assess the feasibility of documenting the defined set of QIs in routine clinical care was carried out at three voluntary hospitals. A manual of operation with a detailed description of the questionnaire items was provided to the participating institutions. Consecutively admitted patients with diagnosis PD (ICD-10: G20.-) who underwent DBS surgery in 2015 or 2016 were eligible for the study. Overall, n = 28 patients were included and followed until the first follow-up visit 6–15 months after DBS. The mean time to document the mandatory information on each patient was about 25 min. A benchmark report was prepared and handed out to the participating facilities for comments. The feedback referred mainly to the presentation of the results or description of the questionnaire items.

### 3.3. Implementation of the nationalwide QualiPa registry

According to the results of the pilot study, the questionnaire, benchmark report and the data management concept were readjusted. In the first draft it was intended to collect the data completely anonymous but it turned out that it was necessary to obtain informed consent from the participants due to data protection regulations allowing to trace participants through different institutions. Standardized performance reports were developed to inform the participating hospitals annually. These reports were intended to allow the individual hospital to compare its performance on DBS to the aggregated performance information of all participating hospitals. To compile the questionnaire a pragmatic approach was choosen by capturing the most commonly and for the patient less stressful assessed conditions "med off/stim on" and "med on/stim on". We also used a workable definition to determine the „OFF"-phase – the patient has to be 10–12h without antiparkinsonian medication or at least without medication overnight. The participation is voluntary and no financial reimbursement will be offered. After five years of operation, the registry will be evaluated regarding the improvement of quality of care among the contributing sites. The implementation of the registry started in June 2016, and 15 high-volume DBS centers are voluntarily participating by December 2017, representing an estimated 42% of all German hospitals offering DBS (Table 1). Based on routine administrative data from the German Federal Statistical Office (Statistisches Bundesamt) DBS for different disease entities was performed in 1,693 patients in 2015 in Germany [18]. For PD, routine data from the Institute for the Hospital Remuneration System (InEK, Institut für das Entgeltsystem im Krankenhaus) states the number of patients undergoing DBS in Germany in 2014 ranged between 588 and 720 [18]. Furthermore, to ensure our QI-set reflects the current state of art in DBS and PD a regular update every three years is planned.

### 3.4. Results of the QualiPa registry from 2016

Based on data of recruiting DBS centers a standardized benchmark report for the year 2016 was prepared: All PD patients undergoing DBS in 2016 were asked to take part in the registry when they came for routine after care. A total of 59 patients were documented for baseline and of those n = 59 also had a follow-up assesment between 6 and 15 months after DBS surgery in the first 5 initiated and actively recruiting hospitals. The mean age of the participants was 62 years and n = 40 (67.8%) were male. Overall the percentage fulfilled for process indicators was high compared withoutcome quality indicators "complications" (Table 2), where the fulfillment was low. The largest variation between hospitals occurred for the process indicator 'documentation of long-term complications' and 'assessment of motoric function' by a validated scale range 0–100% (Table 2 and Fig. 1) and the smallest for the process indicator 'pre-operative brain imaging (MRI)' range

**Table 1**
Fifteen initial participating hospital by October 2017.

| |
|---|
| Hospital of the Philipps-University, Marburg |
| Paracelsus-Elena-Clinic Kassel |
| Schön Clinic Munich-Schwabing |
| University Hospitals Schleswig-Holstein, Campus Kiel |
| University Hospital Leipzig |
| Medical School Hannover |
| University Hospital Magdeburg |
| University Hospital Regensburg |
| University Hospital Rostock |
| University Hospital Tuebingen |
| University Hospital Wuerzburg |
| Central Hospital Augsburg |
| University Medicine Mainz |
| Charité – University Medicine Berlin |
| Movement Disorders Clinic – Beelitz-Heilstaetten |

**Table 2**
Performance of participating hospitals from 2016: Indicators Related to Processes and Outcome.

| Process indicators | | Fullfillment of quality aim overall score 2016 (%) | Range (min – max(%)) |
|---|---|---|---|
| pre | Documentation of disease duration and L-dopa responsiveness | 96.1 | 92.3–100.0 |
| | Assessment of motor function by (MDS-)UPDRS II + III | 70.3 | 0.0–100.0 |
| | Documentation of long-term complications by (MDS-)UPDRS IV | 69.4 | 0.0–100.0 |
| | Assessment of cognitive functions | 100.0 | |
| | Screening for depression | 100.0 | |
| | Pre-operative brain imaging (MRI) | 97.6 | 95.2–100.0 |
| | Pre-operative anesthesiological assessment | 100.0 | |
| peri | Frame-based stereotactic surgery | 100.0 | |
| | Peri-operative prophylactic antibiotic treatment | 98.5 | 92.3–100.0 |
| | Electrophysiological and clinical target verification | 90.7 | 69.2–100.0 |
| | Monopolar review (assessment of the stimulation effects post-operative) | 99.8 | 50.0–100.0 |
| | MRI-based stereotactic planning | 100.0 | |
| | Post-operative CT/MRI control (lead placement) | 99.8 | 50.0–100.0 |
| post | Delivering patient remote control and training of the patient | 99.8 | 50.0–100.0 |
| | Standardized discharge letter | 98.5 | 92.3–100.0 |
| | Standardized consultation for patient and its relatives at discharge | 100.0 | |
| | Post-operative control of stimulation parameters and medication | 92.3 | 80.0–100.0 |
| | Assessment of neurological and cognitive function at follow-up | 88.6 | 0.0–94.1 |
| Outcome indicators | | | |
| peri | Peri-operative complications until discharge from the hospital/30 days after surgery | 21.5 | 0.0–30.8 |
| post | Transient complications up to routine follow-up (6–15 m post-OP) | 98.3 | 92.3–100.0 |
| | Persistent complications up to routine follow-up (6–15 m post-OP) | 100.0 | |
| | Assessment of activities of daily living (UPDRS II) (6–15mo post-OP) | 80.3 | 42.9–100.0 |
| | Assessment of motor symptoms severity (UPDRS III) - med on/stim on; med off/stim on (6–15 m post-OP) | 89.6 | 0.0–93.8 |
| Structural indicators | | | |
| pre | Expertise in DBS (e.g. number of procedures per year) | | 5–270 |
| | Experience in PD treatment (e.g. number of PD patients treated per year) | | 60–1704 (inpatient)<br>49–967 (outpatient) |
| | Multi-disciplinary team | 8/10 | |
| post | Post-operative intensive care unit | 9/10 | |
| | Regular morbidity and mortality board for PD | 8/10 | |

95.2–100% (Table 2). Seven QIs showed 100% fulfillment (i.e. no variation between hospitals) like 'assessment of cognitive functions'. The most prevalent complications up to 30 days after surgery were 'delirium' (n = 3 (5.1%)) and 'falls' (n = 4 (5.2%)). 'Dyskinesia' was the most frequent transient (n = 10 (16.9%)) one at follow-up care (i.e. between 6 and 15 months after surgery) (Table 3). The most common persistent complications of DBS were 'incitement disorders (i.e. apathy)' and 'falls' (each n = 7 (11.9%)). 'Lead revision' and 'apraxia of eyelid opening' (n = 1 (1.7%)) rarely occurred in patients undergoing DBS within the QualiPa registry. The DBS therapy can be considered as a significant achievement as most of the patients (89.6%) showed a good to moderate improvement in UPDRS-III based on the individual levodopa response, the pre-operative levodopa response is given by the UPDRS III score difference between medication OFF and ON state and this value is compared to the difference between postoperative UPDRS III score in med off/stim on. The ratio of the two differences should be > 0.5, if the stimulation on/medication off state improves motor symptoms by at least 50% compared to levodopa alone. Similar improvements were obtained related to impairment in daily life: 80.3% of the patients showed a better performance compared to baseline. Two pages of the benchmark-report are depicted exemplarily in Fig. 1 and eFig. 5 representing a process indicator and an outcome indicator. The information provided as figure are the performance of the site compared to other sites and, separately stated in a box the patients not fulfilling the QI.

## 4. Discussion

This report describes the development of evidence-based QIs for DBS in PD in Germany and its implementation within a nation-wide registry. The working committee established a series of 28 QIs according to process (18 indicators), structure (5 indicators) and outcome (5 indicators). This set of QIs fulfills the predefined methodological requirements for QIs. Additionally, a systematic literature search to identify and appraise published evidence was performed. Furthermore, the feasibility of implementing the indicators in clinical routine care was tested in a pilot study. The implementation of the nation-wide QualiPa registry started in 2016 and first evaluations showed that the chosen quality indicators are suitable to measure the performance of DBS. Some indicators did not show variations (i.e. had 100% fulfillment of the quality aim) which might be due to the small numbers of patients with complete follow-up data set or the limited number of centers participating in the first year.

Due to a considerable socioeconomic burden of PD [19,20] and estimated worldwide increasing absolute numbers of patients with PD by 2030 [21] the importance of evidence-based approaches to measure and evaluate the quality of PD care in clinical practice will increase in the next decades. However, to date only few initiatives for the development and even less for the implementation of performance measures for PD exist with no initiatives specifically focusing on DBS care. The recently updated evidence-based QI-set developed by the American Academy for Neurology (AAN) comprises 11 indicators which address areas of basic care and surveillance of PD patients like annual review of diagnosis, query about sleep disturbances or advanced care planning [22]. Another initiative from the Netherlands developed and implemented 16 QIs concerning the quality of physiotherapy for PD patients [23,24].

Oral dopaminergic pharmacotherapy is considered as the mainstay treatment of PD, but due to its side effects like motor fluctuations, dyskinesias or behavioral dysregulation invasive treatments are considered effective alternatives in PD patients with motor complication [5–9]. Several guidelines recommend DBS therapy for PD in selected patients [5–9,25–27]. However, published data on the frequency and outcome of DBS performed in PD patients in clinical routine care are

**Quality Assurance of Innovative, Invasive Procedures in the Treatment of Patients with Parkinson's disease (QualiPa-DBS)**

**"Hospital Name" 2016**

## Quality Indicators

### Documentation of long-term complications

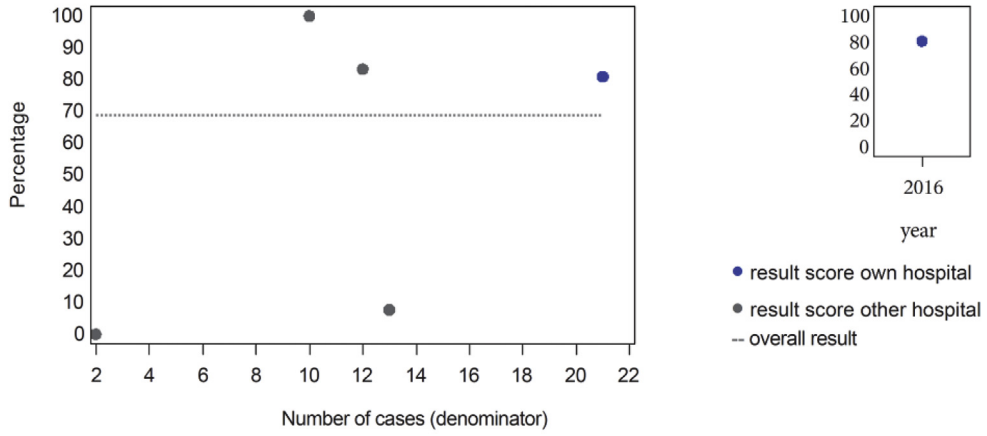
**Index:** THS-QI-14

**Aim:** Assessment of eligible patients (i.e. with idiopathic Parkinson's Syndrome), which will undergo DBS and which have a documentation of motor long-term complications by UPDRS IV (or MDS-UPDRS IV) for success monitoring.

**Hospital score:** (current year) 81.0 %
(previous year) . %

**Numerator:** all DBS patients with assessment of long-term complications with a validated and in clinical practice used score (UPDRS IV or MDS-UPDRS IV)

**Denominator:** all patients undergoing DBS




Following cases are suggested for a hospital-intern analysis (the pseudonym of the patient allows a reidentification of all documented patients in the registry):
A, F, G, L

**Fig. 1.** Presentation of process quality indicator on 'documentation of long-term complications' to participating hospitals in 2016.

limited. In addition, there is general consensus that DBS requires specialized skills since, for example, the experience of the surgical team plays an evident role in the proper placement of electrodes and the reduction of operative complications [2], whereas neurological expertise is required for patient selection and proper postoperative management of medication and stimulation. The quality of UPDRS improvement after DBS was judge based on the individual levodopa response. The stimulation induced motor benefit will ideally match the best medical ON induced by a suprathreshold levodopa challenge, if the electrode is properly placed and stimulation is well adjusted [28]. Therefore, we proposed to the best of our knowledge the first initiative of developing and implementing a quality assurance initiative for DBS treatment in patients with PD.

Our set of QIs covers a wide range of health care dimension in different treatment phases of PD patients, including neuropsychiatric screening, repeated assessment of motor and non-motor symptoms of PD, standardized discharge processes and documentation of the patient's life quality regarding the activity of daily living. The extension of the Donabedian concept by the three phases pre-, peri- and postoperative added a longitudinal and temporally more detailed

**Table 3**
Documented complications at follow-up care (between 6 and 15 months after DBS surgery): results from QualiPa in 2016.

| Complications | Yes, transient | Documented between 6 and 15 months after DBS surgery overall n (%) | | |
|---|---|---|---|---|
| | | Yes, persistent | No | Not available |
| Infection in the area around the implant | | 1 (1.7) | 54 (91.5) | 4 (6.8) |
| Pain in the area around the implant | | | 54 (91.5) | 4 (6.8) |
| Defect electrodes, cable or neurostimulator | | | 54 (91.5) | 4 (6.8) |
| Speech disorder | 6 (10.2) | 6 (10.2) | 42 (71.2) | 5 (8.5) |
| Impaired vision | 1 (1.7) | | 53 (89.8) | 6 (10.3) |
| Muscular cramp | 4 (6.8) | 1 (1.7) | 49 (83.1) | 5 (8.5) |
| Affective disorder (e.g. depression) | 8 (13.8) | 4 (6.8) | 42 (71.2) | 5 (8.5) |
| Suicid/suicidal tendency | | | 54 (91.5) | 5 (8.5) |
| Incitement disorders (e.g. apathy) | 5 (8.5) | 7 (11.9) | 42 (71.2) | 5 (8.5) |
| Gait disorder | 8 (13.8) | 5 (8.5) | 41 (69.5) | 5 (8.5) |
| Falls/vestibular disorders | 6 (10.2) | 7 (11.9) | 41 (69.5) | 5 (8.5) |
| Dyskinesia/dystonia | 10 (16.9) | 1 (1.7) | 43 (72.9) | 5 (8.5) |
| Apraxia of eyelid opening | | 1 (1.7) | 53 (89.8) | 5 (8.5) |
| Persistent off-symptoms | 4 (6.8) | | 50 (84.7) | 5 (8.5) |
| Lead revision | / | 1 (1.7) | 53 (89.8) | 5 (8.5) |
| Death | / | | 54 (91.5) | 5 (8.5) |

itemization of the quality of care. In addition, provision of written informed consent of patients allows to link those data longitudinally, which is important especially if the patient undergoes surgery and follow-up care in different hospitals. Thus, changes in the quality of DBS in PD patients can be measured and evaluated in a longitudinal manner.

Most of our indicators assess processes of care. Process indicators are expected to translate into patient outcomes [29]. The measurement of process indicators that are closely related to important patient outcomes is often preferable compared to outcome indicators for two reasons. First, process indicators are easily accepted by health care providers since they indicate where improvement in performance is possible. Second, outcome indicators ought to be risk adjusted for patient variability between the participating hospitals. However, often relevant confounders are not measurable in routine clinical care or are unknown and, therefore, render a valid comparison of many outcome QIs between hospitals unreasonable [29].

Our developed indicator set facilitates the monitoring of translating evidence derived from clinical trials into clinical routine care for DBS. As a first step the focus lies on implementing and evaluating the established QI-set in a registry of voluntary hospitals all over Germany. Constant feedback of the participation hospitals on the feasibility and practicability are also part of this update to ensure an accepted and sustainable project. Furthermore, the current state of research will be ensured by regular updates on the QIs set every three years. The project might also serve as an example for international quality assurance programs. In addition, we aim to expand the project to develop and implement QIs also for other invasive PD therapies, such as continuous apomorphine or levodopa infusion [30,31].

There are limitations of our study. First, the participation in the registry is voluntary for the sites as well as for the patients. Both might reduce the completeness of the registry. In addition, a selection bias towards better performing sites participating in the registry might have occurred, which should be considered when interpreting the results of DBS performance. Secondly, the evidence base for the QIs varies due to a lack of published high level evidence studies. Therefore, the evidence ranges from clinical guidelines or systematic reviews to extrapolation from similar research findings to expert opinions. This is the case for most of the structural indicators, such as postoperative surveillance on an intensive care unit in case of emergency or management of DBS patients by a multidisciplinary team. Likewise, for post-operative target verification or standardized education of the patient and his or her relatives at discharge no evidence from DBS studies could be identified. Those indicators reflect the state of evidence and current standard of care and the need for further trials on these issues of DBS in patients with PD. We did not include the experience of psychiatrists or specially trained PD nurses in our development approach. Therefore, it is possible that our indicator set might underrepresent processes involving PD nurses (a novel and yet rare PD support profession in Germany) or psychiatrists.

## 5. Conclusion

The development of QIs for DBS is an essential step towards a standardized tool for performance measurement of DBS in PD patients. An evidence-based approach helps to guarantee transparency, acceptance and sustainability of QIs in Germany, and a registry is readily attainable. Finally, the implementation and evaluation of a nation-wide registry may assure quality of DBS in routine care in Germany. Our project may serve as an example for initiating national and international initiatives for measuring and improving quality of PD treatment.

## Author contributions

Peter Heuschmann, obtaining funding, conceptualization of the study, interpretation of the data, review of the manuscript.

Jens Volkmann, conceptualization of the study, interpretation of the data, review of the manuscript.

Kirsten Haas, literature search, interpretation of the data, draft of the original manuscript.

Stephanie Stangl, draft of the original manuscript.

All other authors, interpretation of data and review of the manuscript.

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## Appendix A. Supplementary data

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