# Revised version of quality guidelines for presurgical epilepsy evaluation and surgical epilepsy therapy issued by the Austrian, German, and Swiss working group on presurgical epilepsy diagnosis and operative epilepsy treatment

<sup>1,2</sup>Felix Rosenow, <sup>3</sup>Thomas Bast, <sup>4</sup>Thomas Czech, <sup>5</sup>Martha Feucht, <sup>6</sup>Volkmar H. Hans, <sup>7</sup>Christoph Helmstaedter, <sup>8</sup>Hans-Jürgen Huppertz, <sup>9</sup>Soheyl Noachtar, <sup>10</sup>Frank Oltmanns, <sup>11</sup>Tilman Polster, <sup>12</sup>Margitta Seeck, <sup>13,14</sup>Eugen Trinka, <sup>15</sup>Kathrin Wagner, and <sup>1,2</sup>Adam Strzelczyk

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Felix Rosenow is director of Epilepsy Center Frankfurt Rhine-Main and acting secretary of the working group on presurgical epilepsy diagnosis and operative epilepsy treatment.

# **SUMMARY**

The definition of minimal standards remains pivotal as a basis for a high standard of care and as a basis for staff allocation or reimbursement. Only limited publications are available regarding the required staffing or methodologic expertise in epilepsy centers. The executive board of the working group (WG) on presurgical epilepsy diagnosis and operative epilepsy treatment published the first guidelines in 2000 for Austria, Germany, and Switzerland. In 2014, revised guidelines were published and the WG decided to publish an unaltered English translation in this report. Because epilepsy surgery is an elective procedure, quality standards are particularly high. As detailed in the first edition of these guidelines, quality control relates to seven different domains: (I) establishing centers with a sufficient number of sufficiently and specifically trained personnel, (2) minimum technical standards and equipment, (3) continuous medical education of employees, (4) surveillance by trained personnel during video electroencephalography (EEG) monitoring (VEM), (5) systematic acquisition of clinical and outcome data, (6) the minimum number of preoperative evaluations and epilepsy surgery procedures, and (7) the cooperation of epilepsy centers. These standards required the certification of the different professions involved and minimum numbers of procedures. In the subsequent decade, quite a number of colleagues were certified by the trinational WG; therefore, the executive board of the WG decided in 2013 to make these standards obligatory. This revised version is particularly relevant given that the German procedure classification explicitly refers to the guidelines of the WG

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¹Epilepsy Center Frankfurt Rhine-Main, Goethe University, Frankfurt, Germany; ²Epilepsy Center Hessen, Philipps-University, Marburg, Germany; ³Epilepsy Center Kork, Kehl, Germany; ⁴Department of Neurosurgery, MUW/AKH, Vienna, Austria; ⁵Department of Pediatrics and Adolescence Medicine, MUW/AKH, Vienna, Austria; ⁶Division of Neuropathology, Institute of Pathology, Ruhr University, Bochum, Germany; ¹Department of Epileptology, University of Bonn, Bonn, Germany; ⁵Swiss Epilepsy Center, Zürich, Switzerland; ⁰Epilepsy Center Munich, Ludwig-Maximilians-University, Munich, Germany; ¹¹Epilepsy Center Bethel, Bielefeld, Germany; ¹¹EgG and Epilepsy Unit, Geneva University Hospital, Geneva, Switzerland; ¹³Department of Neurology, Christian Doppler Medical Centre, Paracelsus Medical University, Salzburg, Austria; ¹⁴Centre for Cognitive Neuroscience, Salzburg, Austria; and ¹⁵Epilepsy Center Freiburg, Albert-Ludwigs-University, Freiburg, Germany

Address correspondence to Felix Rosenow, Department of Neurology, Epilepsy Center Frankfurt Rhine-Main, Goethe-University Frankfurt, Schleusenweg 2-16, 60528 Frankfurt am Main, Germany. E-mail: rosenow@med.uni-frankfurt.de

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with regard to noninvasive/invasive preoperative video-EEG monitoring and invasive intraoperative diagnostics in epilepsy.

KEY WORDS: Guidelines, Epilepsy surgery.

# **KEY POINTS**

- Definition of standards is essential for high standard of care and adequate staff allocation or reimbursement
- Limited publications are available regarding the required staffing or methodologic expertise in epilepsy centers
- The working group published the first guidelines in 2000 for Austria, Germany, and Switzerland
- We present the revised quality guidelines of 2014 for presurgical evaluation and surgical therapy
- German procedure classification refers to these guidelines regarding preoperative and intraoperative diagnostics

# BACKGROUND

In patients with drug-resistant epilepsy, preoperative epilepsy evaluation and subsequent surgical therapy lead to a significant improvement in seizure control, the proportion of seizure-free patients, quality of life, and social participation. <sup>1–3</sup> The aims of presurgical epilepsy evaluation are to define the chance of complete seizure freedom and the likelyhood of inducing new neurologic deficits in a given patient. Because epilepsy surgery is an elective procedure, quality standards are particularly high.

The definition of minimal standards for diagnostic procedures and therapies remains pivotal as a basis for a high standard of care for patients and for payers as a basis for staff allocation or reimbursement. So far, there are only limited publications regarding required staffing or methodologic expertise in epilepsy centers. The Executive Board of the Working Group (WG) on presurgical epilepsy diagnosis and operative epilepsy treatment (Arbeitsgemeinschaft für prächirurgische Epilepsiediagnostik und operative Epilepsietherapie; http://www.ag-epilepsiechirurgie.de/) published German-language guidelines for Austria, Germany, and Switzerland in 2000<sup>4</sup> and 2014.<sup>5</sup> In 2000, the WG also defined certificates for presurgical epilepsy diagnosis and surgical treatment. 6 The guideline resulted from an interdisciplinary consensus development panel comprising the Executive Board of the WG. The participants reflected the full range of professionals (i.e., adult and pediatric epileptologists, neurosurgeons, neuropathologists, and neuropsychologists) to which the guidelines apply. The participants also represented the three involved countries (i.e., Austria,

Germany, and Switzerland). The guidelines were then finalized by agreement (consensus) by the WG. Due to the limited evidence of what is currently practiced, and due to the aim of the guideline to provide a basis for the definition of minimal requirements for reimbursement, the guidelines abstained from providing formal grades of evidence for each recommendation. Given that different centers and other countries have a range of views and approaches, these guidelines should not be considered as proscriptive or mandatory, particularly as our guideline relates to unique local factors around funding and access to particular investigative modalities in Austria, Germany, and Switzerland. However, due to continuous, also international, interest and as a basis for further guideline development, the WG decided to publish the following, unaltered English translation of the first revised guidelines from 2014.<sup>5</sup>

# Guidelines for Presurgical Epilepsy Evaluation and Surgical Epilepsy Therapy, First Revised Version

### Introductory remarks

In 2000, the Executive Board of the WG published the first version of the now-revised quality guidelines for presurgical epilepsy evaluation and surgical epilepsy therapy. At that time, the introduction of certificates was recommended, which were issued by the WG. Furthermore, it was stipulated that a minimal, uniform, and therefore comparable, preoperative and postoperative data sets should be captured at each center. In the meantime, the WG has created guidelines for the acquisition of certificates<sup>6</sup> for physicians and other professionals from the following disciplines:

- 1 Epileptology (neurologist and pediatric neurologist)
- 2 Neurosurgery
- **3** Neuropsychology
- 4 Neuroradiology
- 5 Medical technical staff (comparable to EEG technicians)
- 6 Nursing staff

The WG established a database with minimum standards to allow for the collection of comparable data among different epilepsy centers.<sup>7</sup> In the past, different epilepsy centers in Germany, Austria, and Switzerland used a variety of tests for neuropsychological assessment that made the comparison of results very difficult.<sup>8,9</sup> On June 29, 2012, the Executive Board of the WG decided to

redefine the quality guidelines for presurgical epilepsy evaluation and surgical epilepsy therapy on the basis of the publication from 2000. This new version is particularly relevant for the implementation and reimbursement of the German OPS 1-210 ("Operationen- und Prozedurenschlüssel" German procedure classification for nonpreoperative video electroencephalography [EEG] – intensive diagnostics in epilepsy). The definition of OPS 1-210 decidedly refers to the quality standards of the WG. The same applies to OPS 1-211 (German procedure classification for preoperative invasive video-EEG intensive diagnostics in epilepsy) and OPS 1-212 (German procedure classification for invasive intraoperative epilepsy diagnostics). The analogue procedures in Switzerland (CHOP, Swiss operation classification) are currently Z89.19.10 (noninvasive preoperative video-EEG intensive diagnostics) and Z89.19.20 (invasive preoperative video-EEG intensive diagnostics in epilepsy) or on the DRG level B01Z (several step complex operating room (OR) procedures in diseases and disorders of the nervous system or epilepsy surgery with invasive preoperative video-EEG; SwissDRG 2.0 - Catalog Version 2010/2013).

# Setting up or availability of an epilepsy center with sufficient staffing of qualified personnel

The presence of following disciplines is mandatory: epileptology (neurology/pediatric neurology), surgery, neuropsychology, and neuroradiology or a consultant with additional training in magnetic resonance imaging (for Austria and Switzerland: Radiology with a 2-year training in the field of neuroradiology). Per center, two epileptologists should be present that substitute each other (totaling no <120% activity equal to 1.2 full-time employees). A specialist in psychiatry and, if possible, a specialist in child and adolescent psychiatry should be available. In case of need, patients should have access to psychosocial care from personnel experienced in epileptology. A pediatric neurologist must be integrated for presurgical evaluations in children. Medical technical staff must be available for the video-EEG monitoring unit with a professional degree: in Germany, medical technical assistants for functional diagnostics (MTA-F); in Austria, medical technical function assistants (MTF), MTA, graduate nurses, or skilled graduates in medical and technical diagnostics; in Switzerland, function assistant in neurophysiologic diagnosis (FND). Alternatively, other professionals with at least 3 years of experience in presurgical video-EEG monitoring may be employed.

Furthermore, an intensive care unit for the treatment of emergencies (e.g., status epilepticus after a reduction in anticonvulsant drugs, complications of intracranial electrodes) should be available, that, in close cooperation, can take further care of such patients. The relevant institutions do not have to be represented at the same hospital, but within the same region, and should be accessible within

30 min. For epilepsy centers performing surgery, cooperation with a section of neuropathology with experience in areas relevant to epilepsy surgery differential diagnosis is required. The cooperation of relevant departments has to be documented by regular, joint case conferences, taking place at least four times a year, in which all the aforementioned professional groups have to participate.

# **Technical equipment**

The technical minimum equipment of a video-EEG monitoring (VEM) unit should include ≥64-channel EEG recording stations, a 1.5-Tesla MRI, and at least two other methods of epilepsy-specific imaging (e.g., single-photon emission computed tomography [SPECT], positron emission tomography [PET], functional MRI [fMRI], MRI postprocessing, magnetoencephalography [MEG], and 64-256-channel EEG with source imaging [ESI]).

# Training of staff working in the center

The availability of staff of the two first-mentioned disciplines (neurology or pediatric neurology and neurosurgery) with the certificate of the Working Group (WG) is mandatory. To make it possible to acquire missing certificates, this requirement has been demanded from January 1, 2015.

The relevant requirements for the acquisition of the certificate of WG can be found on the website of the WG (http://www.ag-epilepsiechirurgie.de) (Note: an English translation of the requirements is provided in Table 1.) As a rule, a certain period of training at an epilepsy center is required and an examination in the form of a collegial expert talk has to take place with a certified counterpart of the respective professional group. Because only few people in the areas of neuroradiology, the medical-technical staff (see above), and a few nurses to date have acquired a certificate or epileptologic training, such a certificate is not currently required for these professions. However, it is desirable that one employee of the relevant professional groups per center acquire such a certificate in the future.

# Monitoring during the intensive monitoring/video-EEG monitoring evaluation

In patients whose anticonvulsant medication was reduced as part of the presurgical evaluation, a 24-h continuous supervision during VEM is required. On the one hand, this allows the immediate recognition of emergency situations, and on the other hand, this ensures that in case of seizures, testing to define seizure semiology can be performed without delay. Because intensive monitoring with the reduction of medication is an elective procedure with increased risk, <sup>10</sup> the presence of suitably trained medical technical staff (see above) with appropriate qualifications is recommended and must be guaranteed at least during one shift on working days. Alternatively, specifically trained staff may be employed. These personnel must supervise exclusively the patients in the VEM unit.

|                                     | :   | (as of November 2005; v   | (as of November 2005; www.ag-epilepsiechirurgie.de)   |   | -  |
|-------------------------------------|---|---|---|---|--|
| Profession                          | Epileptology  | Neuropsychology   | Neurosurgery  | Neuroradiology  | Medical technical staff  |
| Required training                   | Specialist training as neurologist <sup>o</sup> , psychiatrist or pediatrician (with additional qualification in neuropediatrics <sup>b</sup> or I year of expertise) | Psychologist specializing in neuropsychology with 6 months of training in an epilepsy center offering all presurgical diagnostics and operative epilepsy treatment (grade IV center or comparable)  Nonspecialized psychologists should have 2 years of training in neuropsychology | Specialist trained as a neurosurgeon with at least 2 years of operative work after board exam 10 implantations of intracranial electrodes Conducted 20 epilepsy surgeries as assistant and 25 as the lead surgeon 6 months training in an epilepsy center offering all presurgical diagnostics and operative epilepsy treatment (grade IV center or comparable) | Specialist training in<br>neuroradiology<br>Austria: Specialist in<br>radiology diagnostics with<br>at least 2 years of training<br>in the field of<br>neuroradiology | Professional degree as medical technicians for functional diagnostics (MTA-F) or medical technical function assistants (MTA) Alternatively, several years of experience in a EEG department certified by the Austrian, German, or Świss society for clinical neurophysiology |
| EEG certificate                     | Membership of the Austrian,<br>German, or Swiss society for<br>clinical neurophysiology with<br>EEG certificate   |   |   |   |  |
| ILAE membership                     | Membership of the Austrian,<br>German, or Swiss ILAE<br>chapter with certificate  |   |   |   |  |
| Membership of<br>working group      | Membership of working group on presurgical epilepsy diagnosis and operative epilepsy treatment  | Membership of working group on presurgical epilepsy diagnosis and operative epilepsy treatment  | Membership of working group on<br>presurgical epilepsy diagnosis<br>and operative epilepsy<br>treatment   | Membership of working group on presurgical epilepsy diagnosis and operative epilepsy treatment  |  |
| Examination                         | Examination in the form of a collegial expert talk (discussing three surgical cases)  | Examination based on the clinical investigation of three patients   | Examination in the form of a collegial expert talk (discussing three surgical cases)  | Examination in the form of a collegial expert talk (discussing three surgical cases)  | Examination concerning noninvasive and invasive longterm recordings, electrocorticography, care of patients and archiving of recordings <sup>c</sup>   |
| Working in an epilepsy center Other | Working in an epilepsy center<br>(>25 cases/year) for 2 years   | Working in an epilepsy center<br>(>25 cases/year) for 2 years   | Working in an epilepsy center<br>(>25 cases/year) for 2 years   | Working in an epilepsy center<br>(grade IV or comparable) for<br>6 months   | Additional training in an epilepsy center (grade IV or comparable) for 12 months Resuscitation training  |
| - 6                                 |   |   |   |   |  |

alroluding "Nervenarzt."
 blncluding "Kinder- und Jugendneuropsychiatrie" in Austria.
 clncluding handling of electrodes, handling of recording equipment, reporting and evaluation of the long-term registrations, ictal testing, recording the seizure phenomena, dressings, and emergency measures.

# Follow-up, quality assurance, and data acquisition

Quality assurance is possible only with appropriate minimum data capture for the individual patient. In addition to high-quality preoperative diagnostics with recording of the relevant data, postoperative data have to be collected at regular intervals in the same center so that an individual patient's course is documented in a uniform way. A follow-up must take place at least twice, one of them after about 1 year, to allow for the comparison of results. In children and adolescents in whom developmental aspects play a role, more follow-up visits are required. To facilitate complete documentation, especially in children and adolescents, in patients with a long travel time (>1 h) and in patients with disabilities, hospitalization is regularly required. In patients who do not notice or remember the majority of their seizures, postoperative VEM is recommended.

For follow-up documentation, the WG has conducted a minimum dataset conference, and on the basis of the agreed minimum data-set, an epilepsy surgery database (EpiSurge-Dat) was programmed and established.<sup>7</sup> The database is accessible through the website of the WG. It contributes to the necessary standardization of recorded data and is a specifically adapted tool for recording preoperative data and postoperative follow-up. At the same time, this database meets strict data protection rules, which are necessary for web-based data entry and retrieval. The WG recommends the use of this database to document the presurgically recorded data and the postoperative follow-up data. The use of the database for quality assurance is not yet mandatory. However, the WG recommends that practitioners start using this database now. Its use is free: the webhosting is currently funded by the WG.

# Annual numbers of investigations and interventions

Epilepsy surgery with an appropriate standard is only possible if regular implementation is ensured. A newly established epilepsy surgical center is expected to reach a minimum of 25 therapeutic procedures per year within 3 years and then must perform at least 25 procedures per year in order to gain and maintain sufficient experience (according to International League Against Epilepsy [ILAE] recommendations<sup>11</sup>). However, national circumstances have to be considered. Due to language barriers, smaller catchment areas are present in Switzerland, so that only 20 therapeutic interventions are expected per year for a surgical epilepsy center. For cooperative epilepsy centers bound by contractual agreement, the joint annual number of cases of therapeutic interventions is considered. However, at least 100 OPS 1-210 or 700 treatment days have to be provided in the VEM unit per year. 11

# Cooperation

Not all epilepsy centers will be able to deal adequately with "the most complex epilepsy surgical cases," as selected patients present with different complexity levels. To ensure high-quality care for these patients, close and collegial contact with leading institutions will help to determine the optimal method of treatment and the optimal treatment site. As a rule, the case conferences of such centers are always available for external case presentations and case discussions. Centers with specific expertise can be obtained from the secretary of the WG. Complex cases may be presented in appropriate case conferences.

### Note

The comments of the Executive Board of the German Society of Epileptology (DGfE, German chapter of ILAE) and Austrian Society of Epileptology (ÖGfE, Austrian Chapter of the ILAE) on the manuscript were taken into account.

# CONCLUDING REMARKS

Efforts to provide treatment according to guidelines and a high level of care are not only in the interest of the patient, but also support demands for appropriate staff and financial resources. These revised guidelines<sup>5</sup> serve as a basis for further improvement in quality of care and help to maintain patient safety in video-EEG monitoring units as seizure-associated morbidity and mortality comes more into focus. <sup>10,12,13</sup>

# CONFLICT OF INTEREST

All authors are members (term of office 2013-14 or 2015-16) of the executive board of the working group on presurgical epilepsy diagnosis and operative epilepsy treatment. Dr. Rosenow reports grants and personal fees from Eisai GmbH, UCB Pharma, Desitin Pharma, Novartis Pharma, Medtronic, Cerbomed, ViroPharma,, and Shire, and grants from the European Union (EU) and Deutsche Forschungsgemeinschaft, outside the submitted work. Dr. Bast reports personal fees for advisory boards from Eisai, UCB Pharma, Desitin Pharma, and Shire. Dr. Feucht reports scientific grants, speaker and advisory board honoraria, as well as travel cost refunding from Biocodex, Cyberonics, Eisai, Novartis Pharma, Shire, and UCB, and EU grants (EPISTOP, EDIBLE) not related to this article. Dr. Hans reports personal fees from Medac and Novocure for participation in lectures, outside the topic of the submitted work. Dr. Helmstaedter reports grants and personal fees from Eisai, UCB, Desitin Pharma, and a grant from the EU outside the submitted work. Dr. Huppertz reports personal fees from Novartis Pharma for taking part in an advisory board, outside the topic of the submitted work. Dr. Noachtar reports speakers and consultancy fees and educational and research grants from Eisai, UCB Pharma, Desitin Pharma, Novartis Pharma, Pfizer, Janssen-Cilag, Aventis, Johnson & Johnson, and grants from Deutsche Forschungsgemeinschaft and Hertha-Riehr-Stiftung, outside the submitted work. Dr. Polster reports personal fees from Desitin, Novartis Pharma, Shire, and UCB for participation in advisory boards or lectures, outside the topic of the submitted work. Dr. Seeck reports consulting fees from Eisai and UCB Pharma, Dr. Trinka has acted as a paid consultant to Eisai, Ever Neuropharma, Biogen Idec, Medtronics, Bial, Shire, and UCB and has received speakers' honoraria from Bial, Eisai, GL Lannacher, GlaxoSmithKline, Boehringer, Viropharma, Actavis, Teva, Newbridge,, and UCB Pharma. Dr. Trinka has also received research funding from UCB Pharma, Biogen-Idec, Red Bull, Merck, the European Union, FWF Österreichischer Fond zur Wissenschaftsförderung, and Bundesministerium für Wissenschaft, und Forschung. Dr. Wagner reports personal fees from Eisai and UCB Pharma, outside the submitted work. Dr. Strzelczyk reports grants and personal fees from Bayer HealthCare,

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