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COMMENTARY

Call for the use of the ILAE terminology for seizures and epilepsies by health care professionals and regulatory agencies to benefit patients and caregivers

Stéphane Auvin[1,2,3] | **Alexis Arzimanoglou**[4] | **Isabella Brambilla**[5] | **Jacqueline French**[6] | **Kelly G. Knupp**[7,8] | **Lieven Lagae**[9] | **Emilio Perucca**[10,11] | **Eugen Trinka**[12,13,14] | **Dennis Dlugos**[15,16]

Correspondence
Stéphane Auvin, Service de Neurologie Pédiatrique, CHU Hôpital Robert Debré, 48, boulevard Sérurier, 75935 Paris Cedex 19, France.
Email: stephane.auvin@aphp.fr

Abstract

The International League Against Epilepsy (ILAE) introduced a classification for seizure types in 2017 and updated the classification for epilepsy syndromes in 2022. These classifications aim to improve communication among healthcare professionals and help patients better describe their condition. So far, regulatory agencies have used different terminology. This paper stresses the crucial need for consistently adopting ILAE terminology in both regulatory processes and clinical practice. It highlights how language plays a significant role in healthcare communication and how standardized terminology can enhance patient comprehension. The ongoing review of guidelines by regulatory bodies offers a timely opportunity. Aligning regulatory terminologies holds the potential to facilitate discussions on future drug development and harmonize practices across diverse regions, ultimately fostering improved care and research outcomes in epilepsy treatment.

KEYWORDS

caregivers, epilepsy, seizure, terminology

In 2017, the International League Against Epilepsy (ILAE) published a position paper on the operational classification of seizure types.[1] The seizure type classification is important for several reasons.[1] First, it serves as a tool for communicating a refined terminology to professionals involved in the care of individuals with epilepsy. Second, it also provides appropriate words for patients to describe the manifestations of their disease. Third, it allows the grouping of patients for research on topics such as mechanisms underlying seizures, the link between seizure type and specific etiologies or syndromic diagnosis, and the relationship between seizure type and response to treatment. At the regulatory level, agencies generally approve drugs or devices for use in a specific seizure type. Homogenization across terminology used in clinical practice and in clinical trials is essential to avoid misinterpretations that lead to errors in clinical trial inclusion and clinical care application. Such discrepancies also impact the future use of licensed antiseizure medications (ASMs).

In 2022, the ILAE updated the definition and classification of epilepsy syndromes. An epilepsy syndrome is herein defined as "a characteristic cluster of clinical and

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electroencephalographic features, often supported by specific etiological findings." Usually, the diagnosis of a syndrome carries prognostic and treatment implications.[2]

Approvals of new ASMs or new seizure-related indications by both the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) after 2017 have not used the updated seizure terminology. In some cases, the terminology used by regulators to designate a seizure follows neither the 2017[1] nor the preceding (1981) ILAE classification.[3] Terms such as "primary generalized seizure," "partial onset seizure," and "drop seizure" are still used in the Summary of Product Characteristics provided to health professionals, patients, and caregivers. Regulatory agencies need to begin implementing the syndrome names designated by the ILAE in 2022[2] in the approval label. Indifferent use of terms such as "absence seizures" and "absence epilepsy," the latter corresponding to a syndromic diagnosis, also need to be avoided.

This paper is a call to action for a consistent use of the ILAE terminology in protocols of studies aimed at regulatory approval, as well as in the labeling of ASM products. This call is timely because at the time of writing, the EMA is currently in the process of revising the "Guideline on Clinical Investigation of Medicinal Products in the Treatment of Epileptic Disorders."[4]

Language holds immense power. Words are not just symbols[5]; they carry the ability to shape how we comprehend, feel, interact, and decide. Within health care, effective communication, whether written or verbal, forms the strength of the connection between health care professionals and patients.[6] Several justifications exist for the utilization of a common terminology to describe the different seizure types (Table 1). Sometimes, medical terminology can be difficult for people without medical or scientific background, but the multiplicity of different terms used interchangeably can increase confusion and lead to misunderstanding and misdiagnosis.[7] This can even occur among health care professionals.[8] Lexical simplification, which involves substituting complex terms with simpler ones, and lexical clarification are especially important in medical terminology. Studies have demonstrated that reducing the use of technical language and offering explanations within medical records can enhance understanding.[9]

Uniform and consistent terminology is essential to ensure communication that is both clear and exact. When individuals employ identical language to articulate symptoms, the potential for confusion or misrepresentation diminishes significantly. The ILAE terminology is the reference standard used by health care professionals worldwide. For clinical trials, use of ILAE terminology will reduce confusion and errors in defining seizure types, which can be a source of population heterogeneity. In addition, with the advent of participatory medicine and emphasis on patient-related outcomes, the shared use of specific terminology becomes imperative. Shared use of terminology empowers patients and fosters mutual understanding between health care practitioners and individuals seeking care. For researchers and regulatory bodies, standardized terminology is a prerequisite for collecting and analyzing data. Consistency in language facilitates comparison of data from diverse sources and plays a critical role in comprehending disease patterns, assessing drug effectiveness, and ensuring safety measures.

The draft "Guideline on Clinical Investigation of Medicinal Products in the Treatment of Epileptic Disorders" released by the EMA is open for comments until the end of January 2024.[4] The ILAE Regulatory Affairs Task Force considers this a unique opportunity to advocate for the adoption of a unified terminology (Table 2) in the regulatory process and in clinical practice. The use of the terminology in the development plan of the next compounds entering discussions with the FDA for the treatment of epilepsy presents a promising chance to harmonize regulatory terminologies across both sides of the Atlantic.

TABLE 1 Reasons for use of ILAE terminology by regulatory agencies.

Ensure clarity and precision
Align regulatory language with terminology used by researchers and by health care professionals
Avoid misunderstanding in communication between health care professionals and individuals seeking care
Reduce the risk of inadequate inclusions in clinical trials
Promote participatory medicine
Facilitate research

TABLE 2 Examples of current ILAE terminology and older names still used in regulatory processes and in product labeling.

Current ILAE terms, 2017	Terms used by regulatory agencies
Generalized tonic–clonic seizure	Primary generalized tonic–clonic seizures
Focal onset seizure	Partial seizure
Focal to bilateral tonic–clonic	Partial seizure secondarily generalized tonic clonic
Myoclonic–atonic Epilepsy	Doose syndrome
(Developmental) epileptic encephalopathy with spike-waves activation in sleep	Epileptic encephalopathy with continuous spike-waves in slow sleep
Infantile epileptic spasms syndrome	West syndrome

AFFILIATIONS

[1]INSERM NeuroDiderot, Université Paris Cité, Paris, France
[2]Pediatric Neurology Department, APHP, CRMR Epilepsies Rares, member of European Reference Network EpiCARE, Robert Debré University Hospital, Paris, France
[3]Institut Universitaire de France, Paris, France
[4]Coordinating Member of the European Reference Network EpiCARE, Children's University Hospital San Juan de Dios, Barcelona, Spain
[5]Coordinator, EPAG Patient Group, European Reference Network EpiCARE, Dravet Italia Onlus, Verona, Italy
[6]Department of Neurology, NYU Grossman School of Medicine, New York, New York, USA
[7]Department of Pediatrics, University of Colorado Anschutz Medical Campus, Aurora, Colorado, USA
[8]Department of Neurology, University of Colorado Anschutz Medical Campus, Aurora, Colorado, USA
[9]Member of the European Reference Network EPICARE, Paediatric Neurology Section, Department of Development and Regeneration, University Hospitals KU Leuven, Leuven, Belgium
[10]Department of Medicine (Austin Health), University of Melbourne, Mebourne, Victoria, Australia
[11]Department of Neuroscience, Central Clinical School, Monash University, Melbourne, Victoria, Australia
[12]Member of European Reference Network EpiCARE, Department of Neurology, Center for Cognitive Neuroscience, Christian Doppler University Hospital, Paracelsus Medical University, Salzburg, Austria
[13]Neuroscience Institute, Center for Cognitive Neuroscience, Christian Doppler University Hospital, Paracelsus Medical University, Salzburg, Austria
[14]Institute of Public Health, Medical Decision Making and Health Technology Assessment, University for Health Sciences, Medical Informatics, and Technology, Hall in Tyrol, Austria
[15]Pediatric Epilepsy Program, Division of Neurology, Department of Neurology, Children's Hospital of Philadelphia, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania, USA
[16]Pediatric Epilepsy Program, Division of Neurology, Department of Pediatrics, Children's Hospital of Philadelphia, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania, USA

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CONFLICT OF INTEREST STATEMENT

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ORCID

Stéphane Auvin https://orcid.org/0000-0003-3874-9749
Alexis Arzimanoglou https://orcid.org/0000-0002-7233-2771
Isabella Brambilla https://orcid.org/0000-0002-9860-8246
Jacqueline French https://orcid.org/0000-0003-2242-8027
Kelly G. Knupp https://orcid.org/0000-0002-1967-0827
Lieven Lagae https://orcid.org/0000-0002-7118-0139
Emilio Perucca https://orcid.org/0000-0001-8703-223X
Eugen Trinka https://orcid.org/0000-0002-5950-2692

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