

Creation of an FND Classification System: Governance and Project Plan

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1. Background

Functional neurological disorder (FND) and its subtypes are currently poorly defined. There is no consensus on diagnostic criteria across the neurologic and psychiatric literature, and different terms are used to describe FND and its subtypes (e.g. “conversion disorder”, “psychogenic non-epileptic seizures”, “functional movement disorder”, etc.). This causes confusion amongst healthcare professionals and patients, hampers the quality monitoring of clinical care and complicates research. Different professional organizations, including the Functional Neurological Disorder Society (FNDS), International League Against Epilepsy (ILAE) and Movement Disorders Society (MDS), have made efforts to address these issues. The FNDS recently established a Classification Committee (FNDS CC) with the aim of coordinating these efforts, by organizing and supervising the development of an FND Classification System that will include a new definition and diagnostic criteria of FND and its most common subtypes, and to reach a consensus on the nomenclature used for these disorders.

This document describes the governance and process that the FNDS CC intends to follow in order to reach the aims listed below.

2. Aims

The aims of the FNDS CC are as follows:

- To develop a new, overarching definition of FND that will be acceptable to relevant professional and patient organizations.
- To reach a consensus on the preferred nomenclature for FND and its subtypes, beginning with the two most common ones, namely functional/dissociative seizures and functional motor disorders (including functional movement disorders and functional weakness), with others to follow.
- To formulate diagnostic criteria, including descriptions of symptoms, signs, and supporting neurophysiological tests (as applicable) for positive clinical diagnosis of FND and its subtypes.
- To implement and disseminate the new definitions, nomenclature and diagnostic criteria for FND and its subtypes.

The FNDS CC is aware that there is a need for revision of nomenclature and diagnostic criteria for other subtypes of FND. However, it has decided to begin with an overarching definition of FND and its most common subtypes, i.e. functional/dissociative seizures and functional motor disorder.

Of note, in this document we use ‘functional motor disorders’ and ‘functional/dissociative seizures’, but these terms should be considered as ‘working names’. One of the tasks of the work groups is to reach consensus on the preferred nomenclature, so the terminology used by the work groups may change over time.

The FNDS aims to begin its classification efforts by publishing three documents:

- 1) **An overarching definition of FND and preferred nomenclature for symptoms and signs of FND**
This document will include an introduction of the disorder, mentioning previously used terms, and a definition of the disorder with diagnostic criteria that are applicable to all subtypes of FND, acknowledging significant heterogeneity in severity, symptom overlap and comorbidities.
- 2) **Diagnostic definition of FND characterized by functional/dissociative seizures.**
This document will include operational diagnostic criteria for functional/dissociative seizures, including descriptions of symptoms, positive clinical signs and ancillary test results. The document will also provide guidance for applying the diagnostic criteria to establish a diagnosis of FND characterized by functional/dissociative seizures versus a single event of a functional/dissociative seizure, and the differentiation with functional/dissociative seizures in the context of another disorder. Moreover, the differentiation of functional/dissociative seizures from their main differential diagnoses and from commonly co-existing conditions will be discussed. We anticipate this work being done in collaboration with the existing ILAE Functional/Dissociative Seizure Task Force.
- 3) **Diagnostic definition of FND characterized by functional motor disorder.**
This document will include operational diagnostic criteria for functional motor disorder, including a description of symptoms, positive clinical signs and ancillary test results, where relevant. It will also provide guidance for applying the diagnostic criteria to establish a diagnosis of FND characterized by functional motor disorder, and the differentiation with single episodes of functional movements, or movement disorders that arise in the context of another condition. Moreover, main differential diagnoses and commonly co-existing conditions will be discussed. Of note, treatment options will not be included in these documents. We anticipate this work being done in collaboration with the existing Movement Disorder Society FMD Study Group.

3. Organization of the FNDS Classification Committee (FNDS CC)

The FNDS CC will consist of two parts, a Classification Oversight Committee (COSC) and chairs of workgroups that are actively engaged in creating or revising content for the FND Classification System.

- A. The COSC shall have 4 standing members, 2 Co-Chairs, a Liaison Officer, and a Publication Officer. The COSC will charter workgroups as described in section 4.1 and will provide these workgroups with the infrastructure and guidance needed to reach their aims.

- 1) The Co-Chairs shall be appointed by the FNDS Board to lead the COSC. They shall oversee the creation, maintenance, and dissemination of the FND Classification System as well as its future revisions, collaborating with external organizations where that may be beneficial to advance the purpose of the FND Classification System.
 - 2) The Liaison Officer shall be appointed by the FNDS Board on nomination of the COSC Co-Chairs. The Liaison Officer shall be responsible for developing and maintaining relationships between the COSC and leaders of professional, governmental, regulatory, commercial, and patient advocacy organizations that may have a specific interest in FND and its classification.
 - 3) The Publication Officer shall be appointed by the FNDS Board on nomination of the COSC Co-Chairs. The Publication Officer shall be responsible for the publication and dissemination of the FND Classification System in all media, including maintenance of up-to-date copies of all FND Classification System products on the FNDS website in readily downloadable formats.
- B. Chairs of all workgroups that are actively creating or revising content for the FND Classification System will constitute the remaining members of the FNDS CC. This will ensure close collaboration among the workgroups and between workgroups and the COSC.
- 1) Chairs of workgroups will become members of the FNDS CC immediately on their appointment by the COSC.
 - 2) They will serve on the FNDS CC until their workgroup completes its appointed tasks.

The founding Co-Chairs of the FNDS CC shall serve in their roles until the FND Classification System is established as determined by the FNDS Board. Until the positions of Liaison Officer and Publication Officer are filled, the founding Co-Chairs shall assume their responsibilities. Thereafter, the FNDS Board shall establish regular terms of office for the Co-Chairs, Publication Officer, and Liaison Officer. Ideally, these four positions will have overlapping terms so that the COSC always has at least two experienced members.

4. Methodology for Creating the FND Classification System

To create (and subsequently revise) the definition, diagnostic criteria, and nomenclature of FND and its most common subtypes, the FNDS CC will use a methodology that is partly based on the achievements of the Rome Foundation in their classification of functional gastrointestinal disorders and the Barany Society in developing for the International Classification of Vestibular Disorders. The deadline for the work groups to deliver their end products will be set at two years (renewable), and work groups will be expected to submit semiannual progress reports to the FND CC.

To create the FND Classification System, the following steps will be followed:

1. Workgroups will be formed as needed and charged by the COSC with preparing specific contributions to the FND Classification System. These are expected to include a definition, diagnostic criteria, and nomenclature for FND and its subtypes as well as any supporting

documents, position papers, and other materials needed to advance the purpose of the FND Classification System.

2. Chairs will be appointed by the COSC when the FNDS CC determines that a new workgroup is needed to advance its mission. The Chair will then organize the workgroup and select its members in accordance with Section 4.1.
3. Workgroups will utilize a standardized method to review scientific evidence within the scope of their assigned tasks.
4. Workgroups will utilize a consistent procedure to obtain consensus on the content of products that they produce within the scope of their assigned tasks.
5. Workgroups will work under the purview of COSC and in collaboration with any external organizations authorized by the Liaison Officer to collect feedback on their work and complete all internal and external, where applicable, reviews required to finalize their products.

Each step will be described in more detail below, including an outline of general principles the FNDS aims to follow during the creation and review process, as a guidance for the workgroups involved.

4.1 Formation of workgroups

The COSC will delegate the work to reach the initial aims described above to three workgroups, each chaired by a member of the FNDS. The COSC will provide the workgroups with guidelines for the process and specific charges regarding the scope of their work and expected products. To ensure broad support, relevant professional and patient organizations will be involved in different stages of the process, as described in section 4.5. This process will be extended to more workgroups in the future to address additional subtypes of FND.

The initial workgroups will include:

1. A Overarching Definition and Diagnostic Criteria, chaired by Dr. S. Rutten
2. A Functional/Dissociative Seizures Workgroup, chaired by Dr. M. Reuber, which we anticipate will establish a formal collaboration with the ILAE functional /dissociative seizure Task Force.
3. A Functional Movement Disorder Workgroup, co-chaired by Dr. T. Serranova and prof. M. Edwards, which we anticipate will establish a formal collaboration with the Classification Task Force from the MDS Study group on functional movement disorders.

Each chair will compose his/her own workgroup according to the following guidelines:

1. Each workgroup will consist of 5 - 7 active clinicians and researchers and at least 1 patient representative.
2. Each workgroup will include at least two neurologists and two psychiatrists or psychologists, including subspecialists within these groups. Individuals with other relevant expertise (e.g., clinical neurophysiologists, physiotherapists) will be included as needed.
3. Workgroups must include members from a minimum of three different continents to ensure that sociocultural/linguistic factors are considered.

4. Prospective candidates must be members of the FNDS (or a collaborating external organization when joint ventures are undertaken). The FNDS will advertise the position for workgroup membership on its website. Each prospective candidate must send an application to the COSC for review, including a brief CV focusing on relevant experience for the project, and a declaration of potential conflicts of interest. Members will be appointed by the COSC.
5. Input from each member of a workgroup should be sufficient to qualify for authorship of any publications or other products, i.e. all workgroup members must contribute to conceptualization, literature reviews/data collection, analysis, derivation of consensus, and preparation of workgroup products.
6. To create the first overarching definition of FND, the inaugural Definition and Nomenclature Workgroup will include representatives from the other two inaugural workgroups.

Workgroups will be dissolved after they complete their assigned tasks (i.e., after publication of the final definitions, diagnostic criteria, preferred nomenclature, and any other products that they will be charged with producing). All members of workgroups who contribute satisfactorily to the final product(s) will be eligible to apply for membership in future workgroups.

4.2 Review of scientific evidence

Each workgroup will review and synthesize publications relevant to definitions, nomenclature, and diagnostic criteria for FND and its subtypes. Workgroups should synthesize and itemize the literature according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) standards which are relevant to their topic, and may gather additional input from other sources as needed to complete their work. The results of the review will be shared with all panel members who take part in the consensus procedure, as described in the section below.

4.3 Consensus procedure

Workgroups may use various techniques to collect information to inform their drafting of definitions, diagnostic criteria, nomenclature and other components of the FND Classification System FND within their charge. Methods must be scientifically sound and chosen to balance the strengths and limitations of various processes. For example, an online Delphi survey would allow the workgroup to gather input from a large number of individuals whereas using a nominal group technique, facilitating 'face-to-face' discussions amongst workgroup members, would likely be more effective for managing details and compromises necessary to reach consensus on the final products. Workgroups may choose their own (combination of) consensus procedures. A consensus will be reached when 80% or more of the panel members agree on relevant aspects of their final products. Workgroups will be expected to describe substantive minority opinions and other areas of uncertainty to highlight topics in need of focused research.

4.4 Review, Collection of Feedback, Revision, and Approval

The products of each workgroup will be revised according to the following steps, before final approval by the FNDS Board.

1. Completed drafts of the products produced by each workgroup (e.g., documents containing proposed definition(s), diagnostic criteria, and nomenclature) will be reviewed first by the FNDS CC to ensure consistency with style and format of the FNDS Classification System and responsiveness to the charge given to the workgroup. Any revisions deemed necessary by the FNDS CC will be referred back to the workgroup.
2. After draft products acceptable to the FNDS CC are completed, they will be made available for internal review by members of the FNDS for a period of two months. In order to do so, the Publication Officer will post the products on a dedicated page on the FNDS website, only accessible to FNDS members. FNDS members will be alerted via an electronic mailing when new products are available for review and can post comments online only visible to the Publication Officer and editor of the FNDS website.
3. At the end of the two-month member review period, the Publication Officer will consolidate all feedback and send it anonymously to the workgroup for consideration and revision of the draft products, if needed. Workgroups will not reply directly to members' feedback.
4. Products revised in response to member's feedback will be forwarded to the FNDS CC along with copies of the consolidated feedback. The FNDS CC will ensure that all substantive aspects of members' feedback have been addressed adequately.
5. The products of the workgroup will then be presented to collaborating organizations for input, as described in section 4.5, by the Liaison Officer. The Liaison Officer will consolidate all feedback from the collaborating organizations and send it to the workgroup for consideration and revision of the draft products if needed. The workgroups will produce a revised version of their product, as well as respond to major points of feedback from the collaborating organizations.
6. The revised products of the work groups will be made publicly available for review for a period of one month. In order to do so, the Publication Officer will post the products on a dedicated, publicly accessible page on the FNDS website, and advertise the possibility to review products via various social media. Interested individuals can post comments online only visible to the Publication Officer and editor of the FNDS website. At the end of the one-month review period, the Publication Officer will consolidate all feedback and send it anonymously to the workgroup for consideration and revision of the draft products, if needed. Workgroups will not reply directly to feedback.
7. The FNDS CC will review the products of the workgroup, as revised in response to all internal and external feedback, and will forward all products given provisional approval to the FNDS Board for final approval. If products were prepared as Joint Ventures or with Input and Endorsement agreements with external organizations (see section 4.5), the FNDS Board also will request

approval (for Joint Ventures) or endorsement (for Input and Endorsement agreements) from the external organizations.

4.5 Collaboration with other organizations

The FNDS CC will endeavor to create an FND Classification System that has the widest possible acceptability to clinicians, investigators, patients, and other interested parties worldwide while retaining ownership and responsibility for its products. For each workgroup that it charters, the Liaison Officer, assisted by the FNDS CC, will identify professional societies, patient organizations, and other established groups that may have a particular interest in the topic charged to the workgroup and consider benefits of collaborating with external groups to create the workgroup's products. The FNDS CC, at its discretion and with approval from the FNDS Board, may invite selected external groups to collaborate in one of the following ways:

- A. Joint Venture – This process will be a full partnership in which the workgroup will be comprised equally of members from FNDS appointed as above and members of the collaborating organization appointed at its discretion. The final products of the joint workgroup will be authored by all of its members, approved by both organizations and disseminated jointly.
- B. Input and Endorsement – This process will remain solely under the governance of the FNDS following the procedures outlined herein. The collaborating organization will be invited to review draft documents iteratively with the goal of creating final products that can be formally endorsed by the collaborating organization. Final products will be authored only by members of the FNDS workgroup (individual representatives from the collaborating organization may be acknowledged as liaisons) and disseminated by the FNDS with a statement of endorsement by the collaborating organization.
- C. Input only – This process will remain solely under the governance of the FNDS following the procedures outlined herein. The collaborating organization will be invited to provide input to the FNDS workgroup, but otherwise will not participate in its activities. Final products will be authored only by members of the FNDS workgroup (input from the collaborating organization may be acknowledged if substantive) and disseminated by the FNDS.

5. Dissemination and implementation

After all final approvals and endorsements, when applicable, are obtained, the Publication Officer will post final versions of workgroup products on the FNDS website and ensure that readily downloadable versions are made available free of charge.

The workgroups will prepare a manuscript describing the methodology and results of their work, i.e. the final definitions, diagnostic criteria, and preferred nomenclature, that will be submitted for publication in a scientific journal.



The FNDS CC will endeavor to collaborate and positively influence the work of other organizations worldwide that develop classification systems or diagnostic criteria of interest to members of the FNDS, with the overarching goal of harmonizing nomenclature and diagnostic systems to advance patient care, education, and research in fields intersecting with FND.