EBNI

The European Board of Neurointerventions

Guidelines and qualification process for Industry Initiated Educational Activities in Neurointerventions

Prepared by the Board of EBNI
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1 Preamble

Neurointerventional therapy involves treatment of a broad spectrum of cerebral/spinal diseases, primarily vascular pathologies. Because of its multidisciplinary nature, safe and successful practice of this specialty requires thorough knowledge in a multitude of disciplines, including clinical neurosciences, neuroimaging as well as image guided interventional techniques.

Relevant scientific organizations, such as the UEMS Section of Neuroradiology, produced detailed guidelines for training in neurointerventions, endorsed by both the World Federation of Therapeutic and Interventional Neuroradiology (WFITN) and the European Society of Minimally Invasive Neurological Therapy (ESMINT) (http://www.ejmint.org/original-article/1212000052) [1]. More recently, specific guidelines have been produced by multiple global organizations to set standards of training for the neurointerventional treatment of ischemic stroke [2]. Considering the changing environment and the fast growing need for trained personnel in the field of Acute Ischemic Stroke (AISI), the European Board of Neurointerventions (EBNI) provided its guidelines for training both in the field of Endovascular Neurointerventions (ENI) as well as in AISI (www.ebni.eu) in Europe.

According to those standards, clinical training is provided by accredited training centers, as described by relevant recommendations [3] (www.ebni.eu). For the theoretical backgrounds, in Europe, ESMINT provides a formal structured training course and a diploma in neurointerventions (ECMINT, http://www.esmint.eu/ecmint).

Considering the quickly changing arsenal of neurointerventional treatment technologies and devices, besides of clinical and theoretical education, there is a need for practical skill training in certain treatment methods. In such training, the industry that develops and provides those techniques, may serve a key role.

EBNI is an international multidisciplinary organization that promotes harmonization of training and medical practice of neurointerventions to the highest level and aims to defend the professional interests of physicians performing neurointerventions in Europe.

With the following document, EBNI aims to set standards for Industry Initiated Educational Activities (IIEA) in the field of neurointerventions.

2 Goal of Industry Initiated Educational Activities in neurointerventions

As described in the preamble, physicians working in the demanding field of neurointerventions should be trained both clinically and theoretically by highly qualified clinicians, researchers and teachers, in properly equipped clinical and teaching facilities. However, safe application of sophisticated interventional methods, and particularly newly introduced techniques require thorough understanding of the technique and devices, as well as special manual skills. Proper training in these territories needs knowledge, material and equipment (such as models, simulators, etc.) that may not be available at the clinical training centers, but might be provided by the specific company that developed such techniques. Further, it is the specific responsibility of the medical device companies to provide sufficient skill training for any new devices that they introduce into the medical market.

Subsequently, the goal of IIEA include providing the following:

- Thorough understanding of certain interventional technologies including its
    - Design, materials used, goals, results, limitations
- Thorough understanding of the special clinical and pathological aspects of the disease relevant to the particular treatment method(s)
- Understanding of proper patient selection for the particular technique(s)
- Knowledge of available alternative treatment methods, including both interventional and surgical/medical techniques
- Knowledge of complications and handling of those
- Thorough understanding of any medical treatment that might become necessary in association with application of the relevant interventional technique(s)
- Practical skills for the safe and successful application of the relevant technique(s)

IIEA must not intend to be, and should not be considered as a replacement either completely or in part of the theoretical and clinical training recommended by the relevant professional organizations as described in the Preamble.

3 Teaching methods and techniques applied for industry sponsored training in neurointerventions

To achieve the above goals, IIEA may use any or all of the following teaching methods:

3.1 Live case training

This may include either attending live case(s) performed by the trainer (Live Case Demonstration, LCD), or live case(s) performed by the trainee supervised by the trainer (proctoring). In either case, all relevant local and international rules and regulations must be observed, with particular attention to the

- proper medical licensing of both trainer and trainee according to the local laws
- confidentiality of patient data
- informed consent (including procedure and observation!) by the patient or relatives according to local rules

3.2 Recorded case(s) presentation

Using pre-recorded cases may serve as good substitutes for live cases. These case presentations may even have a higher teaching value if properly edited and demonstrated. Confidentiality of patient data must be strictly observed in these cases as well.

3.3 Flow model training

Using mechanical flow models for skill training has a high teaching value as it provides good understanding of the device behavior, its potential advantages and drawbacks, without the stress of live cases. Real case specific vascular models are ideal, however, for teaching of certain elements of a procedure, simple flow models can be successfully applied. Using flow models under a video camera generally provides an experience inferior to X-ray mediated realistic imaging under fluoroscopy and therefore the later is preferred.

3.4 Animal lab training

Animal models can be used to mimic some vascular pathologies and for hands on training for the application of certain devices or techniques. Such trainings must be

performed in accredited animal laboratories and with proper animal ethics committee approval. The rules of Good Laboratory Practice must be observed at all time. In case of using X-ray, radiation safety must be ensured. The facility might be chosen by the course director, however course director and sponsor should have shared responsibility for the safety of the trainees. Having other options available, such as flow models, simulators, etc, the usage of animal for teaching purposes should be minimized as much as possible.

3.5 Radiation safety

Considering the above, radiation safety is a key element of such training courses. Providing the necessary radiation protection devices and ensuring the safe operation of the X-ray equipment is the primary responsibility of the training facility, however, the organizing company must guarantee to select sites that is capable of providing those protective measures.

3.6 Computer assisted simulators

Computer Assisted Simulators (CAS) are increasingly used in teaching and training medical technologies particularly including vascular interventional methods. In general, CAS are easy to apply, do not need X-ray and relevant protective devices and can simulate real cases instead of theoretical pathologies/morphologies.
On the other hand, the selection of available cases is generally limited, the application of the available instruments is complex and requires a certain learning curve to properly use the simulator itself. Besides, for the student, they may create a false impression of being able to treat a case just after a few runs on a simulator.
Subsequently the use of CAS is recommended to teach certain elements of a procedure only, rather than trying to simulate a full operation for treatment of a certain pathology.

4 Quality requirements for industry sponsored training in neurointerventions

4.1 Content

The content of IIEA must include theoretical and practical elements to serve the goals listed in # 2 of this document. Subsequently, IIEA should consist of the following:

- Didactic course focusing on the
    - Pathology, epidemiology, clinical course of the particular disease
    - Goals, results and complications of the relevant interventional technique(s)
    - Design, materials, instructions for use of the device(s)
    - Patient selection for the relevant technique(s)
    - Tips and tricks for the application of the technique(s)
    - Complications and handling.
    - Clinical results based on broad based literature
    - Alternative technologies and their indication in lieu of the technique(s) in focus.
- Case demonstrations using either:
    - Live case demonstration
    - Pre-recorded cases demonstration
    - Didactic case presentations
- Interactive sessions allowing the attendees to actively discuss their questions, personal experiences and problems in the field. Ideally, the attendees should be encouraged to bring their own cases for such discussion.
- Skill training using either:
    - Flow models preferably under fluoroscopy
    - Computer assisted simulators

  following the recommendations as detailed in # 3. of this document.

4.2 Format

IIEA should be preferably organized in small groups, as skill training requires close attention of the trainer(s) that cannot be provided in a large crowd of students.

Training sessions should include didactic lectures, group discussions and skill trainings.

4.3 Faculty

The Sponsoring Company (SC) should select the Course Director (CD). The CD should be a nationally/internationally accepted expert of the field, either recognised as an established neurointerventionist by EBNI (www.ebni.eu) or acknowledged by an ECMINT diploma and having at least 10 years of experience in the field of Neurointerventions.

The faculty should include physicians and trainers representing the SC. Members of the medical faculty are chosen by the CD in agreement with the SC. A multidisciplinary faculty is encouraged. Including nurses and radiographers in the program may improve the quality of the program. Industry trainers are delegated by the SC.

4.4 Attendees

Attendees are selected by the SC. In the selection process, the SC must ensure that the selected trainees

- Have an appropriate level of basic training in the field of neurointerventions
- Are practicing in a department or unit primarily treating neurovascular disease

Providing training for physicians without basic knowledge in the required disciplines (clinical neurosciences, neuroimaging and neurointerventions) and working outside of a neurointerventional unit. (as described by the Standards of Practice in Interventional Neuroradiology [3], the multisociety recommendations on the Standards of Practice in Acute Ischemic Stroke Interventions [4] and the Standards of Practice in Acute Ischemic Stroke Interventions by EBNI (www.ebni.eu) is strictly discouraged and not acceptable by EBNI.

The list of attendees should be shared and discussed with the CD prior to each courses. Attendees should have a similar level of clinical experience and training.

4.5 Facility and training material

The training facility is selected by the SC. LCD-s must be performed in a clinical facility conforming to the Standards of Practice as listed above [3, 4] (www.ebni.eu). Skill training can be provided in either a properly equipped clinical site or in a

teaching/experimental facility. Household rules for both clinical and teaching facilities should be prepared and shared with both faculty members and attendees prior to each course. These should guarantee patient safety, personal data security, undisturbed workflow and hygiene of the clinical facility (if applicable) as well as the safety of the attendees including but not limited to radiation protection and infection prevention.

All endovascular materials used for skill training should be provided by and used under the full responsibility of the SC.

5 Academic background

In order to provide a high standard of teaching, the CD should have an academic background (ie. university appointment, university affiliated institute).

6 Legal aspects

IIEA should be provided in a legally safe environment. Such environment must be guaranteed by a legal agreement between the SC and the facility and/or the CD and members of the faculty. Remuneration for the courses should be regulated in a transparent manner that excludes any direct commercial interest of the SC in selecting either the site or the faculty. Contracts should clearly clarify the responsibilities of the site and the SC in order to guarantee the security of the training personnel.

7 Qualification process and EBNI endorsement

EBNI, as a multidisciplinary organization that promotes harmonization of training and medical practice of neurointerventions is prepared and capable of evaluating the program of IIEA-s. For the qualification process, an applications should be submitted by the SC using EBNI's website (www.ebni.eu) including

- The goal of the course
- List of faculty
- Teaching site
- Detailed program
- Number of attendees

- A statement by the SC and the CD on the conformance of the course to all of the above requirements with special attention to the selection of attendees and lack of direct commercial interests as set forth by # 4.4 and # 6.

Applications will be scrutinized by *by an IIEA* Review Board appointed by the Board of EBNI. For those that qualify, an approval of EBNI endorsement will be issued that allow the organizers to use the EBNI logo for their courses. EBNI will charge a qualification fee, the amount being dependent on the extent of the course as well as on the number of attendees. For courses repeated multiple times a year, the endorsement should be valid for 1 year.

References

1. Specialists, E.U.o.M., *UEMS recommendations for acquiring "Particular qualification" in Endovascular Interventional Neuroradiology - INR.* EJMINT, 2012.
2. Lavine, S.D., K. Cockroft, B. Hoh, et al., *Training Guidelines for Endovascular Ischemic Stroke Intervention: An International Multi-Society Consensus Document.* AJNR Am J Neuroradiol, 2016.
3. Jansen, O., I. Szikora, F. Causin, et al., *Standards of practice in interventional neuroradiology.* Neuroradiology, 2017. **59**(6): p. 541-544.
4. Pierot, L., M. Yayaraman, I. Szikora, et al., *Standards of Practice in Acute Ischemic Stroke Intervention: International Recommendations. An International Multi-Society Consensus Document.* J.Neurointervent Surg, 2018. 10, 1121-1126.