



# Management of Spastic Paresis and Cervical Dystonia: Access to Therapeutic Innovations Through an International Program of Practical Courses

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## ABSTRACT

**Purpose:** Our purpose was to determine satisfaction and confidence of the Excellence Network training program on health care practitioners using botulinum toxin A (BoNT-A) for neurologic disorders, including spastic paresis and cervical dystonia.

**Methods:** The Excellence Network training program was designed by a scientific committee of 6 experts and then tested at centers in Europe, and Latin America. The training, provided by 16 experienced neurologists and rehabilitation specialists, consisted of theoretic and practical sessions that covered the different stages of the patient's journey from diagnosis to tailored treatment and rehabilitation. Trainees' feedback and the impact on participants' practice were evaluated by 2 individual questionnaires, at the end of the session (T0) and at 6 months (T6). Trainers' feedback was also collected through an individual questionnaire.

**Findings:** Between September 2012 and December 2017, 728 trained physicians participated in training programs with 48%, 23%, and 29% of attendees participating in training sessions dedicated to adult spastic paresis, child spastic paresis, and cervical dystonia, respectively. At T0, 93% of attendees thought that they had been given new information and 90% thought that the training would change their daily practice. This was confirmed at T6 by

93% of respondents. Trainees were highly satisfied with the program, in particular with the practical sessions. Trainers' expectations were met for attendees' level of expertise, motivation, language, and participation.

**Implications:** In this descriptive study, we show that the Excellence Network program represents a new educational approach to promote consistency in care practices and dissemination of expertise on the use of BoNT-A for neurologic disorders. (*Clin Ther.* 2019;41:2321–2330) © 2019 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

**Key Words:** Botulinum toxin, cerebral palsy, cervical dystonia, continuous medical education, patient management, spastic paresis.

## INTRODUCTION

Botulinum toxin A (BoNT-A) is a neuromuscular paralyzing agent produced by anaerobic bacterium

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*Clostridium botulinum*. It is used in the treatment of many neurologic movement disorders associated with muscle hyperactivity such as adult spastic paresis (SP) from stroke, multiple sclerosis, and traumatic brain or spinal cord injury, pediatric SP from cerebral palsy and adult cervical dystonia (CD).<sup>1–7</sup>

Proper administration of BoNT-A requires specific training and clinical experience that accumulates over the years of treating patients.<sup>8</sup> The UK national guidelines on the management of SP state that “botulinum toxin should only be injected by clinicians with in-depth knowledge, skills and practical experience in neurological rehabilitation.”<sup>9</sup> The effectiveness of BoNT-A treatment highly depends on clinicians' experience, and lack of appropriate anatomic knowledge may prevent clinicians from administering BoNT-A.<sup>1–8</sup> Physicians must identify the distribution of SP and/or CD pattern and determine the appropriate dose of BoNT-A required based on the individual patient's condition and therapeutic objectives.<sup>10</sup> In addition, large muscles may require multiple injections at several sites, and each cycle of BoNT-A treatment must be reassessed based on the individual response.<sup>8</sup>

Two studies that involved patients with CD reported misdiagnosis in 66% of cases, a 5-year delay for correct diagnosis in 25% of patients, and a delay before first BoNT-A injection superior at 6.8 years after symptom onset.<sup>11,12</sup> In addition, some guidelines, such as the European guidelines on the diagnosis and treatment of primary dystonia, describe the efficacy of BoNT-A but do not mention the injection techniques.<sup>13</sup> The Upper Limb International Spasticity study-II additionally reported variations in clinical practice with respect to muscle selection and injection technique in patients with SP.<sup>14</sup> Currently, there are no specific recommendations about injection techniques in different clinical situations, although differences in treatment outcome with the use of specific BoNT-A injection techniques in limb spasticity have been described.<sup>15</sup> These reports indicate that current medical practices in SP and CD might benefit from harmonization and improved dissemination of expertise among clinicians.

Few countries in Europe, including Austria and Germany, have developed a nationally recognized training certificate for clinicians.<sup>16,17</sup> The French Physical Medicine and Rehabilitation national curriculum provides an optional course dedicated to

SP management, including basic information on BoNT-A treatment.<sup>18</sup> However, in these countries, no professional bodies regulate the quality of training. Physicians looking for experience and additional expertise on BoNT-A treatment usually follow a mentoring approach with their peers under variable degrees of supervision.<sup>1</sup> There is a clear need for a structured training program for physicians worldwide on the use of BoNT-A to achieve the required skills and expertise.

The best training approach would be a combination of theoretic courses and practical training delivered at regular intervals. With this perspective, an international Excellence Network program was developed to provide physicians specialized in SP and CD with an opportunity to access best practices and clinical innovations in the treatment with BoNT-A.<sup>19</sup> Here, we present the design of this training program and report the results from trainees' and trainers' feedback.

## METHODS

### Scientific design of the program

The training program was designed in 2012 by a scientific committee that consisted of 6 international experts specialized in the management of SP and CD (see [Supplemental Table I](https://doi.org/10.1016/j.clinthera.2019.09.007) in the online version at <https://doi.org/10.1016/j.clinthera.2019.09.007>).<sup>19</sup> Initially launched at 6 European training centers (France, Portugal, Italy, United Kingdom, Germany, and Spain), the Excellence Network was extended to 9 centers in 2013, including 1 center in Russia, Brazil and Mexico respectively ([Table I](#)).

The role of the steering committee was to design the program, develop, and update core modules on spasticity and dystonia management; select appropriate centers and trainers; and define the contents of every training course. Training centers were selected based on the clinical expertise and innovative methods used at these centers. Trainers responsible for each course were board-certified neurologists or physical medicine and rehabilitation specialists in their own countries, having longstanding experience with specific skills relating to the use of BoNT-A treatment, and they were internationally recognized by professional societies (see [Supplemental Table II](https://doi.org/10.1016/j.clinthera.2019.09.007) in the online version at <https://doi.org/10.1016/j.clinthera.2019.09.007>). They were also involved in the development of major innovative methods in the management of SP or CD.

Table I. The nine Ixcellence Network training courses covering all aspects of the patient journey.

Country	Course Title	Stage in the Patient Journey
<b>Adult spastic paresis</b>		
Portugal	Goal setting and gait analysis: advanced methods for a patient-centered strategy	Diagnosis and assessment
France/Switzerland	Neuromuscular ultrasonography and ultrasound-guided BoNT-A injection	Pattern diagnosis and BoNT-A—targeted injection with ultrasound guidance
Russia	Comprehensive adult spastic paresis management	Rehabilitation, guided self-rehabilitation, and telerehabilitation
Brazil	How to use advanced technologies in spastic paresis to improve botulinum toxin treatment benefits	Rehabilitation
<b>Pediatric spastic paresis</b>		
Mexico	Psychosocial approach, patient-centered goals and specific injection procedures in management of children with spastic paresis	Diagnosis, assessment, and treatment
Spain	Complex situations in children with spastic paresis: how to set the optimal strategy	Diagnosis, assessment, and treatment
<b>Cervical dystonia</b>		
Germany	New approaches to differentiate and treat cervical dystonia	Pattern diagnosis and targeted injection with ultrasound
United Kingdom	BoNT-A injection with EMG guidance in complex cases of cervical dystonia	Complex cases diagnosis and targeted injection with EMG
Italy	The impact of motor relearning techniques on BoNT-A treatment in dystonia complex cases	Long-term management of cranial and cervical dystonia; EMG-guided injection and motor re-learning techniques

BoNT-A = botulinum toxin A; EMG = electromyography.

To be appointed center of the Ixcellence Network, an application form had to be submitted describing the expertise of the center (eg, specific BoNT-A injection technique, Gait Analysis, evaluation by means of Goal Setting), the number of patients treated, compliance with logistic requirements, training facilities, equipment, and the trainer(s) profile, including English-speaking skills, number of trainees in their department, and commitment to scientific societies. The training modules specifically addressed innovative methods and concepts about patients' diagnosis, clinical evaluation, muscle identification, tailored treatment administration, and rehabilitation methods. Techniques to optimize BoNT-A injection formed an important part of this educational

program. Each center delivered specific training on a particular aspect of management of adult and pediatric patients with SP and dystonia (Table I).

The steering committee designed a universal slide deck in line with the objectives of the program and published guidelines. This slide deck included an up-to-date literature review, offering the trainers a full state-of-the-art educational tool kit about management of patients with SP and CD. The steering committee was also responsible for making necessary adjustments in the program to precisely meet the expectations of the physicians and attendees based on their feedback. Each year, the steering committee meets with the trainers to discuss the program performance and to exchange experience

about training sessions and to find the best ways to improve them. It is also a good opportunity for the experts to share the latest scientific data in SP and CD management.

### Training format

Each training course consisted of theoretic and practical sessions. In the theoretic part, the trainers shared an up-to-date literature review of the relevant field with the audience. The practical sessions predominated the training course in terms of both time and content and included didactic patient videos, patient consultations, treatment with BoNT-A injections (in accordance with information contained in the spasticity/CD labels of BoNT-A products) and training sessions based on innovative approaches.

Each training course had a limited number of participants (average 6 trainees per session) to promote discussion and interaction and to share best clinical practices for each specialty. The physicians who participated in these courses were selected based on their experience in the management of SP, CD, and cerebral palsy, specifically selecting those with at least 2 years of practical experience with regular botulinum toxin clinics. Physicians were allowed to attend multiple training courses.

### Evaluation of outcomes

The committee applied for accreditation from the European Union of Medical Specialists (UEMS) to ensure that the training courses were in line with current medical education requirements. Evaluation procedures based on questionnaires for attendees' feedback were designed by the steering committee to verify the efficiency of the program and to allow further improvement. These questionnaires were given to each participating physician in paper format, on site, at the end of each session from July 2013 (questionnaire T0; see Supplemental Material in the online version at <https://doi.org/10.1016/j.clinthera.2019.09.007>).

A second questionnaire was sent to the attendees by email, using a standard survey software (LimeSurvey) 6 months after completion of training to gather information on the impact of the training on their daily practice (questionnaire T6; see Supplemental Material in the online version at <https://doi.org/10.1016/j.clinthera.2019.09.007>). Attendees were asked to complete this evaluation

within 2 weeks. Two reminders were sent by email, and participants who did not reply were contacted by phone. The trainers were also invited to respond to a questionnaire by email in 2015 to gather their opinions on the organization of the program and the level of the trainees who had participated in their training courses since the inception of the program.

Although respondents were asked to include their names in the questionnaires to identify those who wanted to attend other training courses or become local trainers, results were subsequently made anonymous before being shared with the trainers.

## RESULTS

### Attendee characteristics

From launch on September 2012 to December 2017, 728 attendees with expertise in the field participated in the training sessions, with an average of 136 attendees per year (between 117 and 155 trainees per year). Forty-eight percent attended sessions dedicated to adult SP, 23% attended pediatric SP, and 29% attended sessions dedicated to CD. Data on speciality was collected from 655 attendees (90%). Most practitioners selected were neurologists and rehabilitation specialists (86%; 628 participants). A few representatives from other categories of health care professionals (HCPs) (4%; 27 participants) such as orthopedic surgeons, physiotherapists, and nurses, also took part in these training courses. HCPs who participated in the training sessions between 2015 and 2017 had approximately 8 years of experience in BoNT-A injections.

HCPs from all over the world participated in the training sessions (Figure 1), with the greatest number of participants being from European countries (71.3%), because most sessions were conducted in Europe. The participants mainly attended 1 training session. Between September 2012 and December 2017, 49 trainees (7%) attended 2 sessions, 10 (1%) attended 3 sessions, and 4 (<1%) attended 4 sessions.

### Results from trainee questionnaires

At the end of the training sessions between July 2013 and December 2017, a total of 615 immediate response feedback forms were collected, representing a 100% response rate. An excellent level of

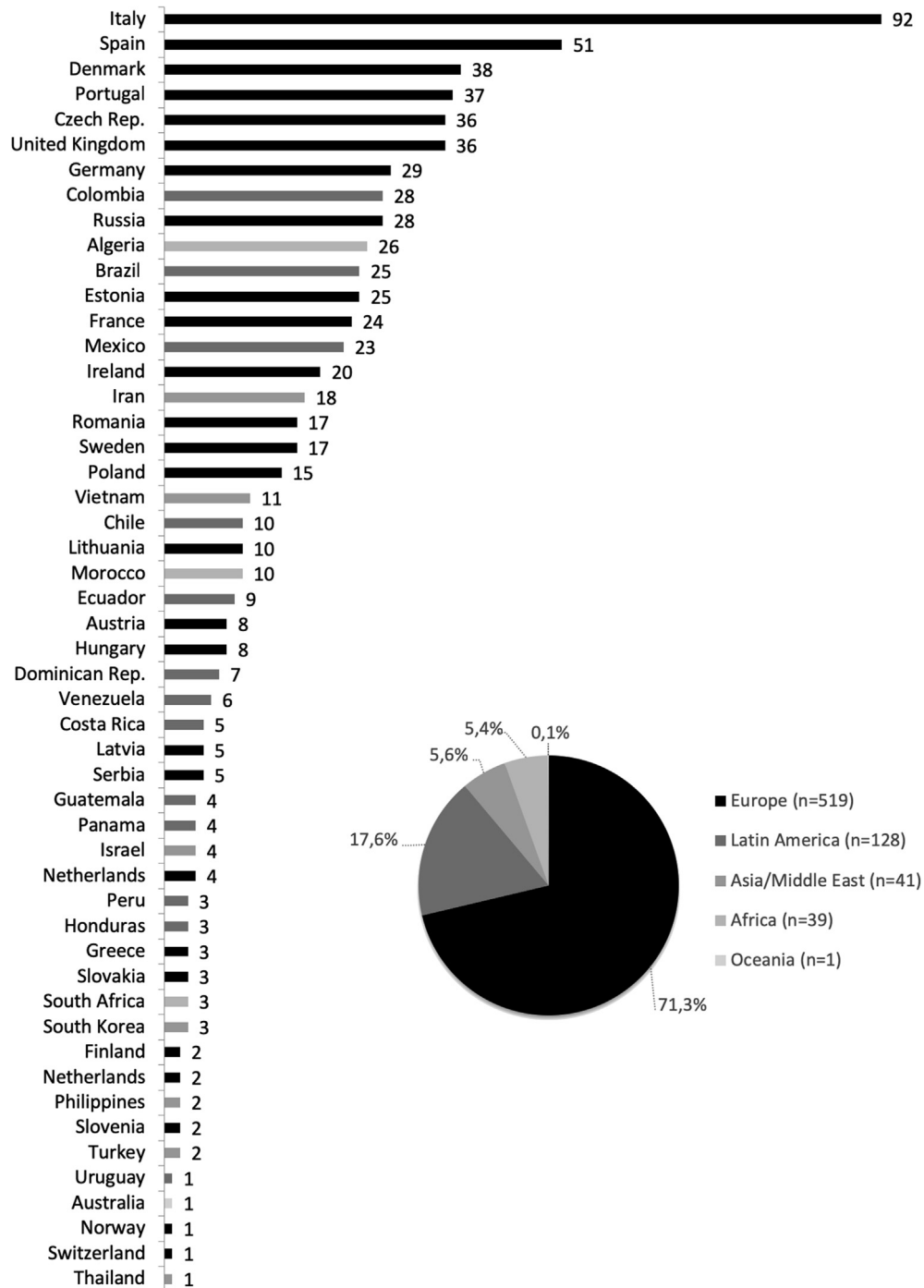


Figure 1. Trainees' geographic origin per country and continent (data available from September 2012 to December 2017).

satisfaction (a score of 5 on a scale of 1–5) was reported by 77% of participants; 93% stated that they received new information, 90% thought that the training will change their daily practice, 94% believed that the training course will benefit management of their patients in the long run, and 95% stated that the training helped them in achieving the personal objectives they had set for themselves.

From January 2013 to December 2017, 655 attendees received the questionnaire sent 6 months after the training course (T6) with a response rate of 41%. Of the trainees who responded to questionnaire T6, 92% confirmed that their medical practice had changed after their participation in the program (Figure 2) and 90% responded that the course had improved their professional self-confidence.

Ninety-seven percent of trainees gave the practical part of the training courses a satisfaction score of  $\geq 4$  (on a scale of 1–5) versus 92% for the theoretic part, which is consistent with the practical focus of the program (Figure 3).

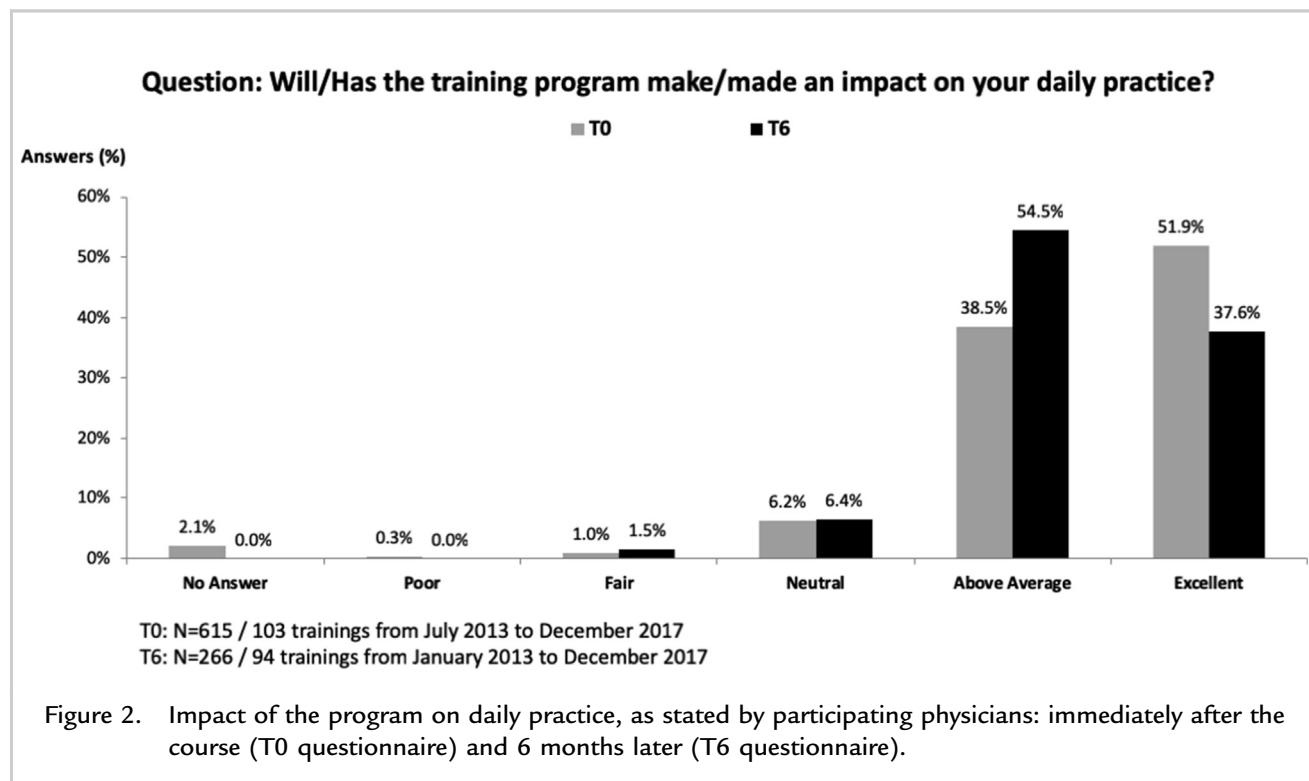
### Results from trainer questionnaires

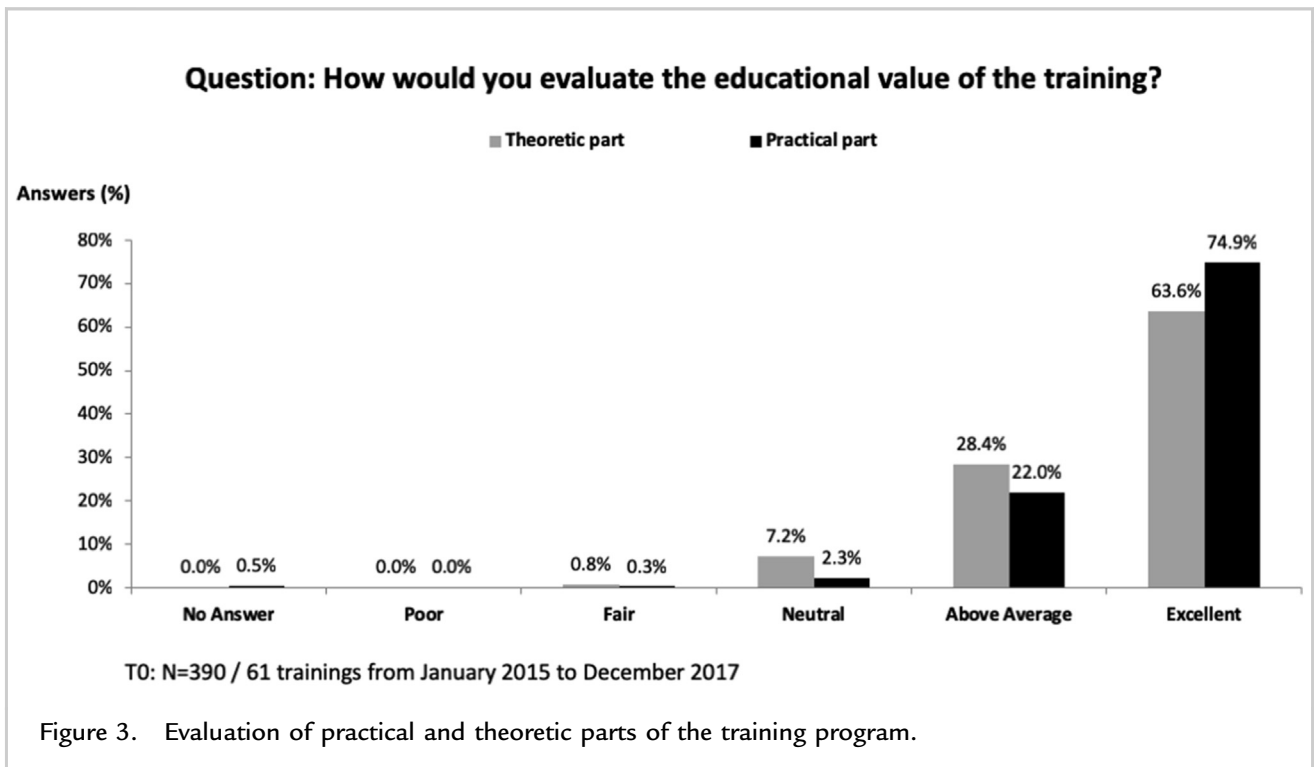
All trainers stated that the trainees' level of expertise met their expectations and most trainers also stated that the attendees' motivation, language, and participation level also met their expectations (10, 10, and 9 of 14, respectively). It was reported by 4 of 14 trainers (29%) that the groups' level of motivation exceeded their expectations, whereas 2 of 14 (14%) found that the trainees' participation level was lower than they had anticipated. Overall, groups were considered homogeneous by 13 of the 14 trainers (93%).

All trainers (n = 16) received the feedback questionnaire after the training sessions and 14 responded, of whom 82% were satisfied with the information and communications that had been provided to them before the training sessions.

### DISCUSSION

To our knowledge, this medical education program is the first of its kind, designed to train experienced physicians on the use of BoNT-A injections for the management of SP and CD. The educational





outcomes of the first 5 years of this Excellence Network program are encouraging from both quantitative and qualitative analyses. From September 2012 to December 2017, the program allowed 728 international physicians, physiotherapists, and nurses to gain expertise for the use of BoNT-A injections. Moreover, the annual number of participants in the program remained constant over the 5-year period (~140 trainees/y), suggesting that there is a constant need for this type of training program. Although more HCPs could attend the training, we have voluntarily chosen to limit the annual number of trainees to maintain the quality of the program by ensuring an adequate supervision by trainers.

The HCPs attending these sessions were selected through a process consistent with the proposed scope of the program, and the trainers acknowledged that participants had appropriate expertise required for these sessions. Furthermore, the qualitative outcomes recorded with the use of the feedback questionnaires also confirmed that the innovative and practical focus of the sessions was appreciated by the trainees in most cases.

Participants stated that their practice had improved and that their patients had benefitted after they participated in these sessions. The survey conducted 6 months after the training also confirmed the benefits of the training sessions in the long run.

Program participants were essentially new each year. Only 8.6% of them attended >1 course between September 2012 and December 2017. Indeed, the topics addressed in the program were highly specific, and HCPs attending the training choose the session that best suited the development of their skills. Having a large and renewed audience at these training sessions suggests that clinicians are trying to seek continuous medical education to improve their practice and to optimize patient management. Because the program has been designed to cover overall patient management, more physicians can benefit by using this program as a global curriculum and attending several training courses within the program by following a personalized educational curriculum. This personalized curriculum can be designed with the use of an algorithm that can guide each trainee to select multiple courses during

the sessions for CD or SP management, based on their expertise and personal needs.

Despite several benefits of the training sessions reported in the present study, there are also limitations that provide areas for improvement to enhance the educational impact of the program. First, the clinical benefits of the sessions as stated by the participants cannot be directly reported. The measurement of these parameters would need collection and assessment of patients' feedback before and after the training sessions, which is rarely feasible because of confidentiality and logistics issues. Furthermore, only declarative and qualitative feedback could be collected from patients; with this in mind, the study plans to obtain more detailed feedback from attendees after each session to accurately identify and characterize the impact of the program on their practice. This could help in documenting the improvement in standards of care and clinical practice for better management of patients with SP or CD. Another way to further evaluate the efficacy of the program would be to compare the Excellence Network content and delivery with those of the recognized trainings developed in some countries such as Austria, Germany, or France.

The present study was conducted to meet the applicable laws and regulations and the sponsor's industry codes to the highest ethical standards. The industry sponsor did not have any influence on the data or training content, and all course material was developed by the steering committee based on literature. Moreover, feedback from trainees indicated that they never felt any bias in the training course, and between 2012 and 2014, 62% of the training courses earned continuous medical education accreditation from UEMS. However, because few participants claimed their continuous medical education credits and the program was expanded outside of Europe with opening of new centers and growing participation of non-European HCPs, we did not apply for UEMS accreditation after 2014. Indeed, among the 728 trainees who participated in the Excellence Network program from 2012 to 2017, only 168 come from countries that signed agreements of recognition with UEMS (Austria, Finland, Greece, Hungary, Ireland, Norway, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, Turkey, and the United Kingdom). Finally, because this program was supported by an industry sponsor, this study aims to

further investigate how academic institutions could develop this kind of educational programs, and complementary exchanges of early career specialists and practical sessions associated with international congresses could be of interest.

## **CONCLUSIONS**

The Excellence Network program represents a new educational approach for neurologists and rehabilitation specialists and could be a starting point for the exchange of innovation and expertise among physicians around the globe in the treatment of SP and CD. The program can enhance the confidence of attendees in treating their patients, who could then help peers and colleagues in their home country, by providing them with educational tools. Overall, this "train the trainer" approach could help a wider community of experts by making them aware of the latest concepts and methods in the management of SP and CD.

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responsible for conceptualization, methodology, resources, writing review and editing, validation, and project administration. Therese Landreau was responsible for conceptualization, methodology, resources, funding acquisition, and writing review and editing. Luis Jorge Jacinto was responsible for conceptualization, methodology, resources, writing of original draft, writing review and editing, validation, and supervision.

Sponsor provided support in the collection of attendees' feedback questionnaires, the analysis (but not the interpretation) of data collected, and funding of the medical writer.

## DISCLOSURES

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grants and honoraria as a scientific advisor, lecturer, and peer trainer from Allergan and Merz. The authors have indicated that they have no other conflicts of interest regarding the content of this article.

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## SUPPLEMENTARY MATERIAL

Supplementary Table 1. Ixculture Network<sup>®</sup> Steering Committee.

Expert	Country	Affiliations
<b>Spastic paresis</b>		
Dr. Klemens Fhedoroff	Austria	<ul style="list-style-type: none"> <li>• Neurologist and first assistant medical director in the Department of Neurorehabilitation Gaital-Klinik, Hermagor</li> <li>• Member of World Federation for Neurorehabilitation (WFNR) and committed to the Special Interest Group Measurement, Assessment and Classification (SIG-MAC) and Robotics</li> </ul>
Dr. Luis Jorge Jacinto	Portugal	<ul style="list-style-type: none"> <li>• Director of the Adult rehabilitation department 3, Centro de Medicina de Reabilitação, Estoril</li> <li>• Member of International Society of Physical and Rehabilitation Medicine</li> </ul>
Prof. Tae Mo Chung	Brazil	<ul style="list-style-type: none"> <li>• Institute of Rehabilitation Medicine, Hospital das Clinas, University of Sao Paulo</li> <li>• Chairperson of the Latin American Botulinum Toxin (SymTox) group</li> </ul>
<b>Cervical dystonia</b>		
Prof. Kailash Bhatia	United Kingdom	<ul style="list-style-type: none"> <li>• Sobell Department of Movement Neuroscience at the Institute of Neurology, UCL, Queen Square</li> <li>• Honorary Consultant Neurologist at the affiliated National Hospital for Neurology London</li> <li>• Member of the European Federation of Neurological Societies Education Committee</li> </ul>
Prof. Carlo Colosimo	Italy	<ul style="list-style-type: none"> <li>• Chairman, Department of Neurology, Santa Maria University Hospital, Terni</li> <li>• Member of Executive Board of Movement Disorder Society, European Section; Co-editor in chief of Moving Along, official newsletter of the Movement Disorder Society</li> </ul>
Prof. Roongroj Bhidayasiri	Thailand	<ul style="list-style-type: none"> <li>• Director of the Chulalongkorn Center of Excellence for Parkinson's Disease &amp; Related Disorders, Chulalongkorn University Hospital</li> <li>• Member of the educational committee of the international Movement Disorder Society</li> <li>• Full voting member of the World Federation of Parkinsonism and Related Disorders</li> </ul>

Supplementary Table 2. Ixcellence Network<sup>®</sup> Trainers.

Country	Course Title	Trainers
<b>Adult Spastic Paresis</b>		
Portugal	Goal setting and gait analysis: advanced methods for a patient-centred strategy	Dr. Jorge Jacinto Dr. Luís Gonçalves
France/Switzerland	Neuromuscular ultrasonography and ultrasound guided BoNT-A injection	Dr. Serdar Koçer
Russia	Comprehensive adult spastic paresis management	Dr. Svetlana Khatkova Dr. Alexandra Botsina
Brazil	How to use advanced technologies in spastic paresis to improve botulinum toxin treatment benefits	Prof. Tae Mo Chung Dr. Arquimedes Ramos
<b>Pediatric Spastic Paresis</b>		
Mexico	Psychosocial approach, patient-centred goals and specific injection procedures in management of children with spastic paresis	Dr. Jose Javier Zorilla Sanchez
Spain	Complex situations in children with spastic paresis: how to set the optimal strategy	Prof. Samuel Ignacio Pascual Pascual Dr. Mercedes Martínez Moreno
<b>Cervical Dystonia</b>		
Germany	New approaches to differentiate and treat cervical dystonia	Prof. Wolfgang Jost
United Kingdom	BoNT-A injection with EMG guidance in complex cases of cervical dystonia	Dr. Santiago Catania Dr. Peter Misra
Italy	The impact of motor relearning techniques on BoNT-A treatment in dystonia complex cases	Prof. Alberto Albanese Dr. Anna Castagna

BoNT-A = botulinum toxin A; EMG = electromyography.



**QUESTIONNAIRE T6**

The questionnaire below was sent 6 months after the end of the training course using survey software.

**Ixcellence Network® Training – Long term satisfaction questionnaire**

First Name:

Last Name:

Country:

- |            |                   |
|------------|-------------------|
| 1. None    | 4. Important      |
| 2. Little  | 5. Very important |
| 3. Average |                   |

1. Overall, what impact did the training program make on your daily practice?
 

1	2	3	4	5
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2. Overall, what impact did the training program make on your self-confidence?
 

1	2	3	4	5
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3. On which of the following items did the training program make an impact in your practice?
 

<input type="checkbox"/> Disease diagnosis					
<i>Please, rate this impact</i>	1	2	3	4	5
<input type="checkbox"/> Patient evaluation					
<i>Please, rate this impact</i>	1	2	3	4	5
<input type="checkbox"/> Injection techniques & procedures					
<i>Please, rate this impact</i>	1	2	3	4	5
<input type="checkbox"/> Rehabilitation & relearning methods					
<i>Please, rate this impact</i>	1	2	3	4	5
<input type="checkbox"/> Goal-setting approach					
<i>Please, rate this impact</i>	1	2	3	4	5
<input type="checkbox"/> Specific practice in children spasticity					
<i>Please, rate this impact</i>	1	2	3	4	5
4. In your opinion, how did your patients benefit from your training?
  - I know my patients have experienced an important benefit.
  - I know my patients have felt some positive change.
  - I think some of my patients have noticed some improvements.
  - I do not think there have been real changes for my patients.
  - I cannot say.
5. Since this training, have you shared some of the information you learnt with one or several colleagues?
  - Yes, through daily practice.
  - Yes, by sharing documents.
  - Yes, by organising a meeting.
  - Yes, by another way. Please specify: \_\_\_\_\_
  - Not yet.
6. Would you be interested in another training topic?
  - Yes. Precise which topic: \_\_\_\_\_
  - No. Please, indicate why: \_\_\_\_\_