SFCNS Swiss Federation of Clinical Neuro-Societies

REPORT OF THE COMMISSION MANDATED BY THE SWISS FEDERATION OF CLINICAL NEURO-SOCIETIES (SFCNS)

ON

STEREOTACTIC FUNCTIONAL NEUROSURGERY

on adults and children in Switzerland

ON MANDATE OF THE PROJECT SECRETARY FOR HIGH SPECIALIZED MEDICINE (HSM)

Bern, 23 mai 2013

Content

0. Summary

Given the new indications in the field of DBS as well as new deep seated and cortical targets. Given. Different existing technologies and newer technologies for treating patients, the commmission proposes. Given that, in rare cases, pediatric population may also benefit from stereotactic functional procedures Given that new indications, new technologies, as well as treatment of pediatric population require at least the same multidisciplinary expertise and institutional infrastructure. The commission proposes to call the mandate stereotactic functional neurosurgery for adult and pediatric population and proposes an extension of this mandate to other indications, other surgical techniques/technologies.

Based on the respect of the decisions of the IVHSM on one side and the existing competences and infrastructures in Switzerland on the other side. The commission proposes 3 centers/poles of excellence for stereotactic/functional neurosurgery: USZ-KSSG, Inselspital Bern-USB, CHUV-HUG with a formal term of collaboration. The commission encourages also the collaboration with other network centers in terms of clinics, teaching and research.

Each center/pole has the responsibility of achieving tasks in the medical and surgical therapy of patients, as well as in teaching and research. The institutional and competence/expertise requisites for achieving these tasks are then defined.

As a consequence, a minimal number of 20 open operative procedures have to be performed in each center/pole, with a minimal number of 15 DBS and 5 other procedures including cortical stimulation and open lesioning).

Stereotactic functional neurosurgery is by essence a multidisciplinary field. Therefore, the stereotactic neurosurgery program is co-leaded by a neurosurgeon and a neurologist with the collaboration of several specialties.

Quality indices are proposed through a national register.

Certification criteria have been elaborated based on all these concepts.

I. Entscheid der Interkantonalen Vereinbarung für Hochspezialisierte Medizin (IVHSM) vom 21. Juni 2011

„zur Planung der hochspezialisierten Medizin (HSM) im Bereich der stereoktaktischen Chirurgie der anormalen/ungewollten Bewegungen und tiefe Hirnstimulation (Deep Brain Stimulation) beim Erwachsenen“

Die stereotaktische Chirurgie der anormalen / ungewollten Bewegungen und die tiefe Hirn Stimulation (DBS) beim Erwachsenen wird den folgenden Zentren zugewiesen:

- Centre Hospitalier Universitaire Vaudois
- Inselspital Bern
- Kantonspital St. Gallen
- Universitätsspital Zürich

Auflagen
Die vorgenannten Zentren haben bei der Erbringung der Leistung folgende Auflagen zu erfüllen:

a. Sie gewährleisten die Einhaltung der in der Anlage beschriebenen notwendigen Voraussetzungen (Struktur- und Prozessqualität).

b. Sämtliche notwendigen Spezialdisziplinen müssen an diesen Zentren vereint sein.

c. Jedes der vorgenannten Zentren hält eine Mindestfallzahl von 20 Eingriffen pro Jahr ein.

d. Sie arbeiten im Netzwerk mit Spezialkliniken zur Abklärung, Behandlung und Nachsorge der Patienten.

e. Sie führen ein Register. Das Register muss eine einheitliche, standardisierte und strukturierte Erfassung der Prozess- und Ergebnisqualität garantieren. Inhalt und Form des Registers müssen als Grundlage für eine Schweiz weit koordinierte klinische Versorgung und Forschungsaktivität genutzt werden können. Die Leistungserbringer unterbreiten dem HSM Fachorgan einen Vorschlag für das im Rahmen des Registers zu erhebende minimale Dataset sowie zur Form und Ausgestaltung Registers.

f. Die Leistungserbringer erstatten den IVHSM Organen zuhanden des Projektsekretariats jährlich Bericht über ihre Tätigkeiten. Die Berichterstattung umfasst die Offenlegung ihrer Fallzahlen, ihrer Tätigkeiten in Forschung und Lehre sowie der im Rahmen des Registers erhobenen Daten zur Prozess und Ergebnisqualität. Für die Berichterstattung zuhanden der IVHSM Organe bestimmen die vorgenannten Zentren ein Koordinationszentrum.

g. Das Universitätsspital Zürich und das Kantonsspital St. Gallen erarbeiten bis 12 Monate nach Inkrafttreten des Zuteilungsentscheids ein Konzept einer verstärkten Koordination in diesem Bereich, einschliesslich den Möglichkeiten der Konzentration der Aktivitäten entsprechend der Fallzahlen und der Entwicklung in einem Zentrum mit einem Zeithorizont von zwei bis drei Jahren

Begründung
Das Beschlussorgan hat an seiner Sitzung vom 3. März 2011 beschlossen, die zur Koordination der Konzentration vorgeschlagenen Bereiche der Neurochirurgie der hochspezialisierten Medizin zuzuweisen. Nach Prüfung der im Rahmen der Anhörung im Dezember 2010 vorgebrachten Argumente kommt das HSM Beschlussorgan zu folgenden Einschätzungen:

a. Die Zahl der betroffenen Patienten ist gering (rund 100 pro Jahr in der Schweiz).
b. Eine Konzentration ist sinnvoll aus Gründen der Fallzahlen, aber auch zur Sicherung der Versorgungsqualität, der notwendigen Subspezialisierung sowie angesichts der kostspieligen infrastrukturellen Voraussetzungen.
c. Es handelt sich um planbare Eingriffe.
d. Die Versorgungslage durch diese Zentren erscheint adäquat.
e. Die minimale Fallzahl pro Zentrum (20) pro Jahr sollte erreicht werden können.

f. Die Konzentration soll da erfolgen, wo schon ein Aufbau der Infrastruktur, beträchtliches Wissen und Kompetenz sowie die grössten Fallzahlen über die letzten Jahre vorhanden sind. Dementsprechend soll z.B. die Expertise des Kantonsspitals St. Gallen beachtet werden. Die im Bericht «Neurochirurgie in der Schweiz» vom 3. Mai 2011 unter Kapitel 8.1 auf Seite 16 aufgeführten Patientenzahlen pro Leistungserbringer stützen den Vorschlag der Zuweisung und diese Zentren verfügen über die fachlichen und strukturellen Voraussetzungen.

g. Im Übrigen wird auf den Bericht «Neurochirurgie in der Schweiz» vom 3. Mai 2011 verwiesen.

II. Mandat des Projektsekretariats für Hochspezialisierte Medizin (HSM) an die Swiss Federation of Clinical Neuro-Societies (SFCNS)

in Sachen

Definition der fachlichen Voraussetzungen zur prächirurgischen Abklärung und chirurgischen Behandlung der refraktären Epilepsie (Erwachsene und Kinder) sowie im Bereich der stereotaktischen funktionellen Neurochirurgie und Deep Brain Stimulation beim Erwachsenen in Ergänzung zu den Anlagen zu den Beschlüssen des HSM-Beschlussorgans vom 21. Juni 2011, namentlich

- der Definition von minimalen Fallzahlen pro Zentrum
- der Festlegungen der Anforderungen zur Strukturqualität (Infrastruktur, fachliches Knowhow, Weiter- und Fortbildung, Beteiligung an der klinischen Forschung)
- der Prozessqualität (Verfügbarkeit der Fachkräfte, Aufbau und Führung eines einheitlichen Registers einschliesslich Indikatoren zur Ergebnisqualität);

sowie der gemäss Beschluss vom 21. Juni 2011 innerhalb von 12 Monaten vorzunehmenden Koordination zwischen dem Universitätsspital Zürich und dem Kantonsspital St. Gallen;

im Rahmen der Planung der hochspezialisierten Medizin im Bereich der neurochirurgischen Behandlungen in der Schweiz (Entscheid des HSM-Beschlussorgans vom 21. Juni 2011).

1. Begründung

- Das IVHSM Beschlussorgan hat am 21.06.2011 die Leistungszuteilung in den HSM-

Bereichen der Epilepsie-Chirurgie sowie der Deep Brain Stimulation bei erwachsenen Patienten vorgenommen.

- Das IVHSM Beschlussorgan hat in seinen HSM Spitallistenentscheiden Auflagen und Qualitätsstandards für die ausgewählten Spitäler vorgegeben. Diese Auflagen tragen zur Qualitätssicherung bei der Betreuung der betroffenen Patientinnen und Patienten in der Schweiz bei.

2. Vereinbarungsinhalt und Aufgabe

- Die SFCNS übernimmt die Führungsrolle bei der Definition der fachlichen Voraussetzungen zur prächirurgischen Abklärung und chirurgischen Behandlung der refraktären Epilepsie beim Erwachsenen sowie im Bereich der stereotaktischen funktionellen Neurochirurgie und Deep Brain Stimulation beim Erwachsenen
- Sie bildet hierzu eine entsprechende Kommission, welche aus Mitgliedern der verschiedener unter dem Dach der SFCNS zusammengeschlossenen Fachgesellschaften besteht.
- Die SFCNS schlägt den IVHSM Organen die Zusammensetzung dieser Kommission vor.
- Das HSM Projektsekretariat beauftragt diese SFCNS-Kommission mit der Entwicklung einer fachlichen Definition der Auflagen und Bedingungen (u.a. Mindestfallzahlen, Infrastrukturvorgaben, Qualitätsindikatoren, Register)
- Das HSM-Projektsekretariat beauftragt die SFCNS, die betroffenen Spitäler bis Ende Oktober 2012 zum vorgesehenen Vorgehen zu informieren.

Meilensteine in der Umsetzung

Bis Ende Oktober 2012:

Die Spitäler werden über das Vorgehen informiert.

Bis Ende Dezember 2012: Die Organisation und das Vorgehen zur Falldokumentation inkl. Register sind beschrieben, die Indikatoren sind definiert und die Kriterien operationalisiert.

Bis Ende März 2013:

Alle schweizerischen neurochirurgischen Zentren mit einem Leistungsauftrag gem. den HSM-Beschlüssen zur präoperativen Abklärung und Epilepsie-Chirurgie sowie Deep Brain Stimulation haben die Struktur- und Prozessvorgaben umgesetzt.

Bis September 2013:

Alle in den oben bezeichneten HSM-Beschlüssen benannten Leistungserbringer sind von der SFCNS einer Evaluation unterzogen worden und die Ergebnisse sind den IVHSM-Organen kommuniziert.

Bis Juni 2014:

Alle in den oben bezeichneten HSM-Beschlüssen benannten Leistungserbringer sind von der SFCNS re-evaluiert worden und die Ergebnisse sind den IVHSM-Organen kommuniziert (die Zuteilungsentscheide der IVHSM zur hochspezialisierten Epilepsie-Chirurgie und Deep Brain Stimulation/Stereotakt. Neurochirurgie sind bis dann befristet und die Standorte müssen vor diesem Datum re-evaluiert werden.

III. Mandatsannahme durch die SFCNS und Zusammensetzung der DBS-Kommission

Sehr geehrter Herr Dr. von Below

Wir danken Ihnen für die Anpassungen am Mandatsschreiben vom 4 Mai 2012 bezüglich der prächirurgischen Abklärung und chirurgischen Behandlung der refraktären Epilepsie beim Erwachsenen sowie der Deep Brain Stimulation beim Erwachsenen. Die zuständige SFCNS Kommissionen haben dieses Schreiben anlässlich ihrer Sitzung vom 30. Mai 2012 (Epilepsie) und 26. Juni 2012 (DBS) besprochen. Wir freuen uns, Ihnen mitzuteilen, dass die SFCNS den im Mandat beschriebenen Auftrag gerne annimmt.

Gerne schlagen wir Ihnen folgende Experten aus der Neurochiurgie und Neurologie als Kommissionsmitglieder vor.

SFCNS DBS Kommission (Zertifizierungskommission):

- PD Dr. med. C. Pollo, Neurochirurgie, Inselspital Bern, Präsident
- PD Dr. C. Baumann, Neurologie, USZ Zürich, Vize-Präsident
- Prof. Dr. med. F. Vingerhoets, Neurologie, CHUV Lausanne

Mitglieder SFCNS DBS Kommission:

- Dr. med. R. Bauer, Neurochirurgie, KSSG St.Gallen
- PD Dr. med. J. Bloch, Neurochirurgie, CHUV Lausanne
- Prof. Dr. med. P. Fuhr, Neurologie, Unispital Basel
- Dr. med. S. Hägele-Link, Neurologie, KSSG St.Gallen
- PD Dr. med. A. Kaelin, Neurologie, Inselspital Bern
- Prof. H. Landolt, Neurochirurgie, KSA Aarau
- Dr. S. Momjian, Neurochirurgie, HUG Geneva
- Prof. Dr. med. P. Pollak, Neurologie, HUG Geneva
- Prof. Dr. med. U. Roelcke, Neurologie, KSA Aarau
- Dr. med. O. Sürücü, Neurochirurgie, USZ Zürich
- Dr. E. Taub, Neurochirurgie, Unispital Basel

Um allen Beteiligten gerecht zu werden, wünschen sich die Kommissionen eine Erweiterung des Mandats um beratende Mitglieder:

- DBS: je ein Vertreter aus der Neuropädiatrie, Neuropsychiatrie, Neuropsychologie und Neuroradiologie sowie ein Vertreter vom EOC in Lugano.

Zudem bitten wir Sie um Modifikation des Titels zu „stereotaktische funktionelle Neurochirurgie“ anstelle von „stereotaktischer Chirurgie der anormalen/ungewollten Bewegungen und tiefe Hirnstimulation (DBS) beim Erwachsenen“.

III.1 Enlargement of the SFCNS commission for stereotactic functional neurosurgery

One representative of the EOC Lugano as well as consultative members were suggested by the members of the commission for their expertise and input in the interdisciplinary approach of stereotactic functional neurosurgery for **movement disorders**, and **other indications** as well as stereotactic functional neurosurgery on pediatric population

Representative of the EOC Lugano

➔ Prof. JC Möller, Neurology, EOC, Lugano

Consultative members of the commission

➔ PD Dr. U Gschwandtner, Psychiatry, USB, Basel
➔ Dr. Santhein, Neurophysiology, USZ, Zürich
➔ Dr. MI Vargas Gomez, Neuroradiology, HUG,
➔ Prof. E Roulet, Neuropediatrics, CHUV, Lausanne
➔ Dr. A Gronchi, Neuropsychology, CHUV, Lausanne

It was decided that these members have **no right to vote**

III.2. Extension of the mandate of the IVHSM

Given that:

- DBS for movement disorders have been the pioneering indication for stereotactic functional surgical approaches. However, in the last years, other indications have emerged in the field of stereotactic functional neurosurgery like refractory pain, epilepsy, psychiatric disorders. In parallel, cortical targets have emerged and showed to be efficient in the treatment of these diseases. New indications and brain deep and cortical targets will emerge in the next future. These other indications, and consequently these new targets are so far less frequent than the ones used in DBS for movement disorders. Nevertheless, at least the same requirements or even additional expertise as those for movement disorders (institutional, personnel and equipment) are needed (a psychiatrist is represented in the commission).

- Movement disorders and other pathologies affect also children. In rare cases, they can benefit from stereotactic functional neurosurgical procedures (dystonia for example). Here also, at least the same requirements and even additional expertise as those for

adults (institutional, personnel and equipment) are needed. Finally they require neuropediatric competences (one neuropediatrician is represented in the commission)

- Classical stereotactic functional surgical techniques include Deep and Cortical brain stimulation, as well as brain lesionning with thermofrequency. More recently, other lesioning technologies (radiosurgery, MR focused ultrasound) are part of the stereotactic functional neurosurgery armentarium for the treatment of movement disorders and other indications in patients who are not good candidates for electrical brain stimulation

The commission proposes an extension of the mandate, which should be called:

STEREOTACTIC FUNCTIONAL NEUROSURGERY ON ADULTS AND CHILDREN

and include:

- **Indications :** movements dosorders**,** psychiatric disorders, pain, epilepsy, any other documented new indication

- **Surgical techniques :**
  Deep Brain Stimulation, Cortical Brain Stimulation, thermofrequency mediated Brain Lesion, radiosurgery, MR focused ultrasound, any new technology

- **Population:**
  Adult and Pediatric population

IV. Centers/Poles for stereotactic functional neurosurgery

IV.1. Definition of stereotactic functional neurosurgery center/pole

Based on international guidelines (German, French, European society for stereotactic and functional neurosurgery), a stereotactic functional neurosurgery center/pole is a **cantonal or intercantonal** competence center which provides the **expertise and infrastructure** for the neurosurgical management of ambulatory and hospitalized patients which suffer from pathologies, which include at least movement disorders, but also refractory pain syndromes, epilepsy syndromes, psychiatric syndromes and other diseases which involve a dysfunction of cortico-subcortical specific networks.

The basement for such centers/poles is a **qualified personal, interdisciplinary collaboration and infrastructure** dedicated to the **diagnosis, differential diagnosis and surgical therapy** of these diseases, as well as the professional recommendations to patients, parents and relatives.

Beside the management of the patients, the centers/poles have tasks and responsibilities in **teaching, pre- and postgraduate training**, research as well as the communication to the public in the field of these diseases and their surgical therapies.

University hospitals as well as **cantonal hospitals with neurology/neurosurgery departments defined class A** according to the FMH classification, with a defined collaboration with a university hospital can only be defined as competence centers/poles.

IV.2. Tasks for the stereotactic functional neurosurgery centers/poles

IV.2.1 Stereotactic functional neurosurgery for movement disorders

a. Diagnosis

Capability of diagnosis and differential diagnosis of diseases which present with movements disorders, such as Parkinson's disease, tremors, dystonias, choreo-athetosis, dyskinesias, according to international guidelines

Diagnosis and differential diagnosis of the neurological, neuropsychological, psychiatric and social aspects of stereotactic functional neurosurgery for movement disorders

b. Presurgical evaluation

Evaluation of the candidates eligible for stereotactic functional neurosurgery for movement disorders, including neurological, neuroradiological neuropsychological, psychiatric, and neurosurgical assessment

Parkinson's disease: Clinical and neurological examination including video-documented Levodopa challenge test, standardized neuropsychological examination, psychiatric examination, and magnetic resonance Imaging. If necessary, PET/SPECT should be performed.

The indication for stereotactic functional neurosurgery may be given if the following criteria are fulfilled:

- Idiopathic Parkinson's diseae
- Levodopa-responder
- Motor fluctuations including dyskinesien/wearing off AND/OR insufficient control of Parkinson tremor
- No dementia
- No significant depression or psychosis
- No surgical or medical contraindication against DBS

Tremor: Clinical and neurological examination, standardized neuropsychological examination, psychiatric examination, and magnetic resonance tomography. If necessary, PET/SPECT should be performed.

The indication for stereotactic functional neurosurgery may be given if the following criteria are fulfilled:

- Tremor
- No dementia
- No significant depression or psychosis
- No surgical or medical contraindication against DBS
- If tremor is secondary to a medical condition, it must be stable over at least 12 months

Dystonia: Clinical and neurological examination, standardized neuropsychological examination, psychiatric examination, and magnetic resonance tomography. If necessary, PET/SPECT should be performed.

The indication for DBS may be given if the following criteria are fulfilled:

- Segmental or generalized dystonia without prominent contractures and without sufficient response to medical treatment
- No dementia
- No significant depression or psychosis
- No surgical or medical contraindication against DBS

c. Available therapies

- Drug teatment for movement disorders and associated comorbidities
- Reeducational therapy for movement disorders and associated comorbidities
- Psychosocial/psychiatric therapies for movement disorders and associated comorbidities
- Patient education for the management of electrical stimulation (control of device energy, interval of therapy, on-off, dual programming, etc)
- Surgical therapy modalities include stereotactic operative procedures for brain electrical stimulation (DBS, cortical stimulation) and lesioning. (thermofrequency, **see IV.4.1**)

Except surgical therapies, the other can be performed on site or in network

d. Research, Teaching & Training

Clinical, fundamental and/or translational research related to the different aspects of movement disorders

Pre and postgraduate neurological and/or neurosurgical teaching and training program in the field of movement disorders for doctors, nurses, as well as non medical personal

IV.3. Requisites for stereotactic functional neurosurgery centers

IV.3.1. Requisites for stereotactic functional neurosurgery centers for movement disorders

a. **Institutional**

The following specialties are **mandatory** on site for the recognition of a stereotactic functional neurosurgery center and represented 24/24h:

- Neurosurgery
- Neurology (movement disorders outpatient and inpatient clinic)
- Neuroradiology
- Intensive care unit with neuro-specificity
- Interdisciplinary emergency unit, in which a patient can be managed by a neurologist/neurosurgeon at any time.
- Psychiatry

The following specialties are also **mandatory** on site but not necessarily represented 24/24h

- Neurophysiology
- Neuropsychology
- Neuro-anesthesiology
- Neuro-pediatrics
- Nurses
- Physiotherapists
- Social worker

The following specialties are also **mandatory** but not necessarily on site (in network)

- Neurorehabilitation
- Nuclear medicine (inside the hospital or network)

b. Personnel

Neurosurgery

The leading neurosurgeon fulfils the following criteria:

A board certified neurosurgeon (FMH neurosurgery or equivalent)

A. has been trained in the field of stereotactical neurosurgery (at least 1 year)
B. active membership in a national or international society dedicated to movement disorders (written criteria: participation, invited lectures, presentations, etc)
C. scientific work and/or teaching in the field of movement disorders
D. has been trained in a functional center and has actively participated in the treatment of at least 20 surgical patients (including selection, interdisciplinary assessment, preoperative diagnosis, perioperative and postoperative management)
E. Must perform at least 45 operative procedures, with at least 33 DBS, in the field of stereotactic functional neurosurgery over 3 years. A surgery outside the center (national or international) can be counted in this number
F. For the eligibility of training of other neurosurgeons, criteria in D must be doubled and there must be continuous activity in the stereotactic functional field over 3 years.
G. Is at least habilitated

Neurology

The leading neurologist fulfils the following criteria:

A board certified neurologist (FMH neurology or equivalent)

A. has been trained in movement disorders and has dedicated his interests to this field
B. active membership in a national or international society dedicated to movement disorders (written criteria: participation, invited lectures, presentations, etc)
C. scientific work and/or teaching in the field of movement disorders
D. has been trained in a movement disorders center and has actively participated in the treatment of at least 10 patients treated with a stereotactic functional procedure (including selection, interdisciplinary assessment, preoperative diagnosis, perioperative and postoperative management) and in the adjustment of stimulation parameters and medication after DBS in at least 20 patients.
E. For the eligibility of training of other neurologists, criteria in D must be doubled and there must be continuous activity in the field of stereotactic functional neurosurgery over 3 years.
F. Is at least habilitated

Remark: There is an **interdisciplinary medical lead** of the pole, which includes the leading neurologist and neurosurgeon. The leading neurologist and the leading neurosurgeon are both responsible for the **interdisciplinary assessment of indication for stereotactic functional procedure** center, under consideration of the findings of the collaborating specialists. The interdisciplinary assessment of indication for surgery must be made in a personal communication between the leading neurologist and the leading neurosurgeon, and the final decision must be made with the patients. Both are also responsible for the postoperative management. If necessary, interdisciplinary collaborators (neuroradiologist, neuropsychologist, psychiatrician) should be invited to join personally.

Neuroradiology

The leading neuroradiologist fulfils the following criteria:

Specialist of neuroradiology: A neuroradiologist (FMH neuroradiology or equivalent) who

A. has actively participated in the neuroradiological imaging of at least 10 surgical patients (including acquisition of preoperative and postoperative imaging and related procedures)
B. For the eligibility of training of other neuroradiologists, criteria in A must be doubled and there must be continuous activity in the field of stereotactic functional neurosurgery over 3 years.

Neurophysiology

The leading neurophysiologist fulfils the following criteria:

Specialist of neurophysiology: A neurologist (FMH neurology or equivalent) or any other specialist who

A. has been trained in a stereotactic functional center and has actively participated in 10 perioperative electrophysiological assessment.
B. For the eligibility of training of other neurophysiologists, criteria in A must be doubled and there must be continuous activity in the field of stereotactic functional neurosurgery over 3 years

Neuropsychology

The leading neuropsychologist fulfils the following criteria:

Specialist of neuropsychology (according to the Swiss society of neuropsychology) who

A. has been trained in a stereotactic functional center and has actively participated in the treatment of at least 10 operated patients (including selection, interdisciplinary assessment, preoperative diagnosis, and postoperative management)
B. For the eligibility of training of other neuropsychologists, criteria in A must be doubled and there must be continuous activity in the field of stereotactic functional neurosurgery over 3 years.

Psychiatry

The leading psychiatrist fulfils the following criteria:

Specialist of psychiatry: A psychiatrist (FMH psychiatry or equivalent) who

A. has been trained in a stereotactic functional center and/or has actively participated in the treatment of at least 10 operated patients (including selection, interdisciplinary assessment, preoperative diagnosis, and postoperative management)
B. For the eligibility of training of other psychiatrists, criteria in A must be doubled and there must be continuous activity in the field over 3 years.

The identified psychiatrist responsible for DBS has a central role in the decision and treatment of patients. He may require the collaboration of other specialised psychiatrists in the institution/pole

Other medical specialties

- Neuro-Anesthesiology,
- Neuropediatrics,
- Nuclear medicine

Certified according to FMH criteria or equivalent

c. Equipment and device

Neurosurgery

Stereotactic frame

Necessary: classic, and navigation-based device certified for human use (CE of FDA)

Optional: navigated systems, guidance devices for intraop imaging (still considered as experimental)

Micromanipulator

certified for human use (CE approved)

Planning software

Certified for human use (CE approved)

Intraoperative imaging:

Necessary: fluoroscopy with flat pannel

Optional: intraoperative 3D fluoroscopy, CT-scan or MRI

Lesionning device

Necessary: Thermofrequency stimulator device**;** Certified for human use (CE approved)

Optional: radiosurgery, focused ultrasound (still considered as experimental)

Implanted device (electrodes and IPG)

Certified for human use and indication (CE approved)

Postoperative assessment of electrode localisation

Postop (or intraop) CT and/or MRI and co-registration with pre-op imaging

Neurology

Video recording station, access to a ward for safe performance of

- preoperative clinical tests
- ability to perform electrophysiological assessment

Neuroradiology

Pre-op imaging: High definition MRI (3T or higher) : voxel size ≤1mm.

Stereotactic imaging: high resolution CT scan or MRI: voxel size ≤1mm

Postop imaging: high resolution CT or MRI: voxel size ≤1mm

Neurophysiology

- **Preoperative/postoperative**

  Necessary: equipment approved for human use (CE approved) for electrophysiological mapping SEP, MEP, EMG,

  Optional: TMS as a diagnostic (mapping) or non-invasive therapeutic tool

- **Intraoperative**

Intraoperative Recording/stimulation device (amplifier, Micro/macroelectrodes) for human use (CE approved). Intraoperative electrophysiological monitoring (SEP, MEP, EMG, EcoG): Thermolesion device approved for human use

IV.3.2. Requisites for stereotactic functional neurosurgery centers/poles for other indications

Each center/pole has the possibility to perform stereotactic functional neurosurgery for other indications (see III). Concerning neurosurgery, the infrastructure, personnel, equipment and device are strictly identical for the surgical management of other indications. Concerning other specialties, the leading neurologist responsible for functional neurosurgical therapies (see IV.3.1.b.) is still mandatory, as well as identified medical specialists of the pathology that is intended to treat (epilepsy, psychiatric disorders, etc). An interdisciplinary coordination remains mandatory for the optimal management of these pathologies

IV.3.3. Requisites for stereotactic functional neurosurgery centers/poles for pediatric population

Each center/pole has the possibility to perform stereotactic functional neurosurgery on pediatric population. Here again the infrastructure, personnel, equipment and device are strictly identical for the neurosurgical management of pediatric population. Concerning other specialties, the leading neurologist responsible for functional neurosurgical therapies (see IV.3.1.b.) is still mandatory. Moreover, at least one neuropediatrician is identified in every center/pole and collaborates with the leading neurologist.

IV.4. Specialisation as center/pole for stereotactic functional neurosurgery

IV.4.1. Definition of stereotactic functional neurosurgical procedures

Any stereotactic (framed or frameless) procedure performed **inside the brain at the level of** deep and cortical brain structures, which aims to change the function of a cortico-subcortical network, responsible for the clinical manifestation (or part of it) of a disease. This includes:

- Deep brain stimulation
- Cortical brain stimulation
- Brain lesionnig mediated by thermofrequency, radiosurgery, focused ultrasound

By definition, are not included in this category:

- Cranial and Peripheral nerve decompression or lesion or electrical stimulation
- spinal cord lesion or electrical stimulation

All the procedures aiming to revise and change stimulation systems are not considered in this category, although they must be performed in the same centers

IV.4.2. List of the stereotactic functional neurosurgical procedures

Brain lesions

Thermofrequency mediated Stereotactic thalamotomy, pallidotomy, subthalamotomy, capsulotomy, and any other procedure that makes a targeted lesion of brain structures

Electrical brain stimulation

Stereotactic electrical stimulation of cortical (motor cortex,Cg25 cortex, epileptogenic cortex, any other potential target) or deep brain structures (thalamus, pallidum, STN, PPN, Vc/Vs, internal capsule, Nucleus accumbens, PVG, hypothalamus, any other potential target)

Revision and/or replacement of implanted device

This includes, any revision or reimplantation of electrode(s), extension cable(s) and pulse generator(s). Reimplantation of a cerebral electrode is considered as a full implantation

IV.4.3 Special surgical prerequisite for centers/poles for stereotactic functional neurosurgery

a. Institutional

University Neurosurgery department or cantonal department defined class A according to FMH with a defined collaboration with a university department (neurology and neurosurgery)

The pole must perform a **minimum of 20 open operative** stereotactic functional procedures/year (mean over the last 2 years) including movement disorders and other indications. At least **15 DBS** and **5 other surgical techniques** including cortical brain stimulation and thermofrequency mediated brain lesion. This is mandatory to keep a high quality level of operations, as well as all a high level of interdisciplinary intraoperative management of pathologies needing stereotactic functional neurosurgical procedures. This is also mandatory to ensure a high quality teaching, as well as training

Patients with indications of stereotactic **non open operative** lesioning procedures with radiosurgery or other emerging new technologies (focused ultrasound, other) are collected in a dedicated research and development register (RDR). These technologies:

- May in the future be part of the certification criteria, depending on the numbers, results and complications,

- In case that these technologies are part of the future certification criteria, the same requisites will be needed for the center who provides the technology and/or performs the treatment, as described in IV.3.
- The leading surgeon (or member of the functional surgical team) of the center that provides the patient(s), participates to the planification and treatment of all the patients

b. Leading Persons

The stereotactic functional neurosurgery program of a center/pole is **co-leaded** by a **neurosurgeon** and **neurologist** fulfilling the criteria under IV.3.1.b.

Both are responsible for the **interdisciplinary assessment and indication for surgery** in the pole of excellence, under consideration of the findings of identified collaborating specialists The leading neurosurgeon and neurologist has a "Stellvertreter" = "remplaçant" in the center/pole which fulfils the same criteria except habilitation

Each **neurological stereotactic functional outpatient unit/clinic** of a center/pole is lead by a **leading neurologist**, fulfilling the criteria described under IV.3.I.b. .

Each **neurosurgical clinic/unit is led by one leader neurosurgeon for stereotactic functional patients.** He fulfils the criteria described under IV.3.I.b

Each leading neurosurgeon and neurologist has a "Stellvertreter" = "remplaçant" in the center/pole which fulfils the same criteria except habilitation

IV.5. Places of centers/poles for stereotactic functional neurosurgery

The IVHSM has proposed to concentrate the activity regarding stereotactic functional neurosurgery in USZ in collaboration with cantonal Hospital St-Gallen, Inselspital Bern und CHUV. Due to the already existing competences and infrastructures in Switzerland, the commission proposes to concentrate the stereotactic functional neurosurgical activity on 3 centers/poles of excellence:

- **USZ-KSSG**
- **Inselspital Bern-USB**
- **CHUV-HUG**

An internal agreement of collaboration has to be provided by each of the centers/poles and submitted to the commission.

The commission will support these 3 poles of excellence, as well as any University center and cantonal center defined class A according to FMH which fulfil the previous defined criteria for certification.

In the future, any center/pole may apply for full certification if they are a university neurology/neurosurgery department or neurology/neurosurgery department defined class A, if all criteria as given in IV are met and if they show that they are referring ≥ 20 operative

stereotactic functional cases (as defined in IV.4.3.a) in other centers (mean over the last 2 years)

On the other side, any certified center that do not fulfill anymore the criteria (mean over the last 3 years) will loose the certification

IV.5.1 Collaboration with other centers: network centers

The commission encourages the **creation of networks** between certified and other centers (which don't have the certification): the latters are named network centers. Each network center has the possibility to collaborate with one or more certified centers/poles and vice versa.

The prerequisite for the network center is to provide at least one certified neurologist who fulfils the following criteria:

· A board certified neurologist (FMH neurology or equivalent)
· has been trained in movement disorders and has dedicated his interests to this field including
· has been trained in a movement disorders center and has actively participated in the treatment of at least 10 patients treated with a stereotactic functional procedure (including selection, interdisciplinary assessment, preoperative diagnosis, perioperative and postoperative management) and in the adjustment of stimulation parameters and medication after DBS in at least 20 patients.

The terms of collaboration include that:

- The leading team of both centers meet at least once per month and discuss indications together
- The collaborative centers maintain a common database on their patients
- The two centers are involved in research and in teaching.
- The neurologist from the non-certified center has the opportunity to **participate** in the intra-op and/or **postop** management of the patient in collaboration with the university (particularly if he is part of the university clinic)

- The patients are **operated in the certified pole/center** with the possibility that an identified neurosurgeon from the network center can participate and be trained by the co-leading team of the certified center (see IV.3.1.b). A formal agreement between the chief of the neurosurgical department of the network center and the leading neurosurgeon of the certified pole/center has to be provided

V. Criteria for certification of centers for stereotactic functional neurosurgery

See annexed 1st draft. Has still to be accepted by the members of the commission

VI. List of Diagnostic and procedures (ICD 10, CHOP, DRG)

1. DBS-Relevante ICD10-Diagnosen

   G20 Parkinson's disease
   G21 Secondary parkinsonism
   G23 Other degenerative diseases of basal ganglia
   G24 Dystonia
   G25 Other extrapyramidal and movement disorders
   G26 Extrapyramidal and movement disorders in diseases classified elsewhere

2. Relevante Prozeduren im CHOP (Juli 2011)

01.32.20 Lobotomie et tractotomie, interruption stéréotaxique de systèmes de communication nerveuse
Coder aussi: Mise en place d'un cadre stéréotaxique

01.4 Opération du thalamus et du globus pallidum
01.41 Opération du thalamus
Chimiothalamectomie
Incision du thalamus *
Thalamotomie
EXCLUS *Par radiochirurgie stéréotaxique (92.30-92.39)*
01.42 Opération du globus pallidum
Incision du globus pallidum *
Pallidoansectomie
Pallidotomie
EXCLUS *Par radiochirurgie stéréotaxique (92.30-92.39)*

02.93 Implantation ou remplacement d'électrode(s) de neurostimulateur intracrânien
Implantation ou remplacement d'électrodes du trou ovale
Implantation ou remplacement d'électrodes en bandes
Implantation ou remplacement d'électrodes profondes
Implantation ou remplacement d'électrostimulateur intracrânien
Implantation ou remplacement de grilles sousdurales
Implantation ou remplacement de pointes épidurales
Implantation ou remplacement de récepteur électroencéphalographique
Implantation ou remplacement intracrânien de neuropacemaker
Coder aussi: Mise en place d'un cadre stéréotaxique (tête) (93.59)
Toute insertion de générateur d'impulsion de neurostimulateur (86.94-86.98)

02.93.0 Détail de la sous-catégorie 02.93
02.93.00 Implantation ou remplacement d'électrode(s) de neurostimulateur intracrânien, SAP

02.93.0 Détail de la sous-catégorie 02.93
02.93.00 Implantation ou remplacement d'électrode(s) de neurostimulateur intracrânien, SAP
02.93.10 Implantation ou remplacement de micro-électrode(s) temporaire(s) de dérivation et de stimulation monoloculaire
02.93.11 Implantation ou remplacement de micro-électrode(s) temporaire(s) de dérivation et de stimulation

multiloculaire
02.93.20 Implantation ou remplacement de micro-électrode(s) permanente(s) de dérivation et de stimulation
monoloculaire
02.93.21 Implantation ou remplacement de micro-électrode(s) permanente(s) de dérivation et de stimulation
multiloculaire
02.93.99 Implantation ou remplacement d'électrode(s) de neurostimulateur intracrânien, autre

02.99.70 Révision (sans remplacement) d'électrode(s) de neurostimulateur intracrânien, SAP
02.99.71 Révision (sans remplacement) d'électrode(s) de neurostimulateur intracrânien, stéréotaxique, système
permanent à une électrode pour stimulation permanente
02.99.72 Révision (sans remplacement) d'électrode(s) de neurostimulateur intracrânien, stéréotaxique, système
permanent à plusieurs électrodes pour stimulation permanente
02.99.79 Révision (sans remplacement) d'électrode(s) de neurostimulateur intracrânien, autre
02.99.90 Autre opération stéréotaxique du crâne, du cerveau et des méninges cérébrales
02.99.99 Autre opération du crâne, du cerveau et des méninges cérébrales, autre
86.94 Insertion ou remplacement de générateur d'impulsions de neurostimulateur, système à une électrode, non spécifié comme étant rechargeable
Générateur d'impulsions (circuit unique) pour neurostimulation intracrânienne, spinale et périphérique
Système à canal unique
Coder aussi: Toute implantation d'électrodes associée (02.93, 03.93, 04.92)
EXCLUS *Insertion ou remplacement de générateur d'impulsions de neurostimulateur, système à une électrode, rechargeable (86.97)*
86.94.0 Détail de la sous-catégorie 86.94
86.94.00 Insertion ou remplacement de générateur d'impulsions de neurostimulateur, système à une électrode, non spécifié comme étant rechargeable, SAP
86.94.10 Insertion de générateur d'impulsions de neurostimulateur intracrânien, système à une électrode, non rechargeable
86.94.11 Insertion de générateur d'impulsions de neurostimulateur épidural, système à une électrode, non rechargeable
86.94.12 Insertion de générateur d'impulsions de neurostimulateur périphérique, système à une électrode, non rechargeable
86.94.20 Remplacement de générateur d'impulsions de neurostimulateur intracrânien, système à une électrode, non rechargeable
86.94.99 Insertion ou remplacement de générateur d'impulsions de neurostimulateur, système à une électrode, non spécifié comme étant rechargeable, autre
86.95 Insertion ou remplacement de générateur d'impulsions de neurostimulateur, système à plusieurs électrodes, non spécifié comme étant rechargeable
Générateur d'impulsions (circuit double) pour neurostimulation intracrânienne, spinale et périphérique
Système à canax multiples
Coder aussi: Toute implantation d'électrodes associée (02.93, 03.93, 04.92)
EXCLUS *Insertion ou remplacement de générateur d'impulsions de neurostimulateur, système à plusieurs électrodes, rechargeable (86.98)*
86.95.0 Détail de la sous-catégorie 86.95
86.95.00 Insertion ou remplacement de
générateur d'impulsions de neurostimulateur, système à plusieurs électrodes, non

spécifié comme étant
rechargeable, SAP
86.95.10 Insertion de générateur d'impulsions de neurostimulateur intracrânien, système à plusieurs électrodes, non
rechargeable
86.95.20 Remplacement de générateur d'impulsions de neurostimulateur intracrânien, système à plusieurs
électrodes, non rechargeable

86.97 Insertion ou remplacement de générateur d'impulsions de neurostimulateur, système à une électrode, rechargeable
Générateur d'impulsions (circuit unique) pour neurostimulateur intracrânien, vertébral et périphérique
Coder aussi: Toute implantation d'électrodes associées (02.93, 03.93, 04.92)
86.98 Insertion ou remplacement de générateur d'impulsions de neurostimulateur, système à plusieurs électrodes, rechargeable
Générateur d'impulsions (circuit double) pour neurostimulateur intracrânien, vertébral et périphérique
Coder aussi: Toute implantation d'électrodes associées (02.93, 03.93, 04.92)
86.98.0 Détail de la sous-catégorie 86.98
86.98.00 Insertion ou remplacement de générateur d'impulsions de neurostimulateur, système à plusieurs électrodes, rechargeable, SAP
86.98.10 Insertion de générateur d'impulsions de neurostimulateur intracrânien, système à plusieurs électrodes, rechargeable
86.98.20 Remplacement de générateur d'impulsions de neurostimulateur intracrânien, système à plusieurs électrodes, rechargeable
86.98.99 Insertion ou remplacement de générateur d'impulsions de neurostimulateur, système à plusieurs électrodes, autre

86.99.10 Révision (sans remplacement) de générateur d'impulsions de neurostimulateur intracrânien

00.94 Monitoring neurophysiologique peropératoire
Contrôle neurophysiologique peropératoire
Monitoring neurologique
Monitoring peropératoire
Neuromonitoring
INCLUS Contrôle peropératoire des nerfs crâniens, des nerfs périphériques et de la moelle épinière
EXCLUS *Monitoring de l'oxygénation intracrânienne (01.16), Monitoring de la pression intracrânienne (01.10), Monitoring de la température cérébrale (01.17), Pléthysmogramme (89.58)*
00.94.0 Détail de la sous-catégorie 00.94
00.94.00 Monitoring neurophysiologique peropératoire, SAP 00.94.1 Monitoring neurophysiologique peropératoire
INCLUS Monitoring électrophysiologique; monitorage par communication vocale lors d'interventions chez le patient éveillé, application d'électrodes de stimulation sur un nerf cérébral, périphérique ou spinal; et/ou mesure de potentiels évoqués; et/ou électrocorticographie avec des électrodes corticales. Coder aussi: Durée du monitorage (00.94.3 ss)

88.39.10 Radiographie peropératoire
Radiographie en conditions stériles

88.96 Autre imagerie par résonance magnétique peropératoire
Imagerie par résonance magnétique en temps réel
Imagerie par résonance magnétique [IRM] Peropératoire

89.15.60 Diagnostic neuropsychologique et psychosocial simple
89.15.61 Diagnostic neuropsychologique et psychosocial complexe

89.15.40 Examen neurologique lors de troubles moteurs, étude de la pharmacosensibilité avec tests quantitatifs
89.15.41 Examen de l'opérabilité de troubles moteurs
Le diagnostic par imagerie doit faire l'objet d'un codage séparé /
Caractéristiques minimales: - tests quantitatifs avec stimulation médicamenteuse (évent. multiple) -examen neuropsychologique et
psychiatrique; - examen aux niveaux de la structure, des fonctions, de l'activité, de la participation et du contexte social; - conseil relatif à une intervention de nature à changer la vie du patient

3. DBS-Relevante Swiss DRG

B 21 A Implantation d'un neurostimulateur pour stimulation cérébrale, système à plusieurs électrodes
B21 B Implantation d'un neurostimulateur pour stimulation cérébrale, système à une seule électrode

B 67 A Maladie de Parkinson avec CC extrêmement sévères ou diminution extrême
B 67 B Maladie de Parkinson sans CC extrêmement sévères, sans diminution extrême

VII. Register

The members of the commission propose a Minimal Register for stereotactic functional neurosurgery which should include the following data:

Patient	**preformatted field**	YYCCNN - year-center-number, e.g. 13SG03
Sex	**drop-down menu**	female - male
Age	**open text**	age at operation
Diagnosis	**drop-down menu**	PD (tremor) - PD (bradykinesia) - Essential tremor - Dystonia - Other
Date of indication	**preformatted field**	DDMMYY - day-month-year, e.g. 280113
Date of OP	**preformatted field**	DDMMYY - day-month-year, e.g. 280113
Target	**drop-down menu**	STN - GPi - Vim - PPN - other
Bilaterality	**drop-down menu**	bilateral - left side - right side
Impl. Device	**drop-down menu**	list of all current devices
Manufacturer	**drop-down menu**	list of all current manufacturers
Hemorrhage	**drop-down menu**	yes - no (note: only critical hemorrhages) - if yes: appearance of a **preformatted field** with a field for date of onset and of a **drop-down menu** remission yes-no)
related risks	**open text**	related risks for hemorrhage, e.g. anticoagulation, antiplatelets, coagulopathy etc
Infection	**drop-down menu**	yes - no (note: only critical infections) - if yes: appearance of a **preformatted field** with a field for date of onset and of a **drop-down menu** remission yes-no)
related risks	**open text**	related risks for infection e.g. immunosuppressants, immunodeficiency etc
Death	**drop-down menu**	yes - no - if yes: appearance of a **preformatted field** with a field for date of onset
related risks	**open text**	related risks for death e.g. very old age etc
6 months F-up	**drop-down menu**	List of outcomes CGI (1, very much improved; 2,

		much improved; 3, minimally improved; 4, no change; 5, minimally worse; 6, much worse; or 7, very much worse.)
Reimplant	**drop-down menu**	yes - no - if yes: appearance of a **preformatted field** with a field for date of onset
Remarks	**open text**	Space for additional remarks

The data will be incorporated in an excel sheet

Bern, 23.5.2013
For the SFCNS stereotactic functional neurosurgery commission

PD Dr med C. Pollo
President of the SFCNS commission