EUROSPINE Task Force Surgical Spine Centre of Excellence (SSCoE)

Guidelines

Table of Contents

INTRO	DUCTION	2
GUIDE	LINES	3
1.	EUROSPINE Surgical Spine Centre of Excellence (SSCoE)	3
2.	Centres to be certified	3
3.	Definition of pathology groups for the concept of certification	4
4.	Definition of quality criteria	5
5.	Audit and course of certification	10
APPEN	DIX	11

INTRODUCTION

The EUROSPINE Task Force Surgical Spine Centre of Excellence (SSCoE) has developed a European certification process for surgical spine centres. The Task Force is a collaboration of the German Spine Society (DWG), EUROSPINE and the EUROSPINE Foundation (ESF).

The initial step was to develop internal rules, guidelines and criteria to be used as a basis for an independent certification system. For this European exercise, a Delphi process has been done to build consensus on the internal rules, guidelines and criteria and thus eventually buy-in of all involved stakeholders.

GUIDELINES

EUROSPINE Surgical Spine Centre of Excellence (SSCoE)

Defined by the EUROSPINE Task Force (TF) Surgical Spine Centre of Excellence (SSCoE)

1. EUROSPINE Surgical Spine Centre of Excellence (SSCoE)

1.1. Only individual persons can apply in the name of their institution for receiving a certificate as a EUROSPINE Surgical Spine Centre of Excellence.

1.2. A EUROSPINE Surgical Spine Centre of Excellence is certified for one or more specific pathologies. The pathologies that can be certified are listed in chapter 3.

1.3. A concept was established giving minimal numbers and minimal complexity of surgeries (listed in chapter 4) for becoming a EUROSPINE Surgical Spine Centre of Excellence.

2. Centres to be certified

2.1. This concept of certification was developed for centres which are focused on spine surgery.

2.2. The term "centre" basically characterises a highly specialised institution. A "centre" is usually supposed to have exceptional equipment, highly qualified personnel, experience and competence on its field. Its significance must be beyond normal organisation units and has to be - based on national juridical measures and common sense - of high relevance beyond its region.

2.3. Suitable "hospitals" hosting the centres should provide 24/7 care with the possibility to perform emergency surgeries on the spine at any time. 24/7 indicates availability over 24 hours, 7 days a week including weekends and holidays.

2.4. The term "hospital" and the necessity to provide in-patient treatment indicates the availability of services "on hospital ground" (campus) or in direct neighbourhood to each other and on an every-day basis.

2.5. Centres that perform conservative treatment only, such as pain clinics or rehabilitation clinics, are not intended to be certified under those parameters. It is planned to establish a certification process for EUROSPINE Conservative Spine Centre of Excellence (CSCOE) in the future.

2.6. Only one certificate for each hospital or centre will be granted. However, the EUROSPINE Surgical Spine Centre of Excellence at one hospital can be represented by multiple clinical departments or facilities "under the same roof" or with the same clinical management structure, proven interdisiplinary cooperation and common trainees. The goal of this regulation is to foster interdisciplinary collaboration. An association between several

hospitals or facilities of different location is not suitable. The guiding principle for this EUROSPINE Surgical Spine Centre of Excellence certificate is to provide all necessary services "under the same roof".

2.7. Therefore, it is necessary to clarify in the application process which departments treating spinal pathologies are available in the hospital and which will represent the EUROSPINE Surgical Spine Centre of Excellence. This is to prevent several clinical departments applying for this certificate and excluding other departments of the same hospital. If several spine surgical departments in the hospital - that applies for a certificate - are not involved in a EUROSPINE Surgical Spine Centre of Excellence application, a statement is mandatory that the non-participating departments are informed about the application. If a EUROSPINE Surgical Spine Centre of Excellence is represented by more than one department a written agreement must be presented regulating the interdisciplinary collaboration between the departments.

3. Definition of pathology groups for the concept of certification

3.1. Spine surgery covers different pathology groups. Only few centres cover the whole spectrum of spine surgery.

3.2. Five pathology groups are identified. Any centre can have competence for the treatment of one or several of these:

- A. degenerative diseases
- B. tumour (including intradural pathologies
- C. infectious, inflammatory and metabolic diseases
- D. injuries
- E. deformities (including congenital spine diseases)

3.3. A very accurate differentiation between the pathology groups can often not be achieved but it is indispensable for the concept of certification.

An example: A patient with an osteoporotic vertebral body compression fracture (group D) of metabolic origin (group C) might develop a painful kyphotic deformity (group E) superimposed by a degenerative disc disease (group A) contributing to the clinical symptoms. In these cases, the centre decides in which pathology group the case should be listed. Each case can only be listed in one pathology group.

3.4. If the Centre wants to be certified for a certain pathology it has to fulfil all quality criteria for that specific pathology. It is possible that a centre is certified for just one specific pathology. The pathology group for which the EUROSPINE Surgical Spine Centre of Excellence has been certified for must be listed in the title of the centre. *For example: "EUROSPINE Surgical Spine Centre of Excellence for degenerative diseases"*

4. Definition of quality criteria

4.1. Characteristics of equipment, diagnostic, therapeutic and interdisciplinary facilities.

4.1.1. For all pathology groups:

4.1.1.1. The following diagnostically and therapeutically facilities have to be **permanently** (24/7) available "**in-house**":

- X-ray
- CT
- MRI
- Image Intensifier in the OR

4.1.1.2. The following diagnostically and therapeutically facilities have to be available "**in-house**":

- ICU with ventilation capacities (continuous availability "24/7" is mandatory for a high volume EUROSPINE Surgical Spine Centre of Excellence)

- postoperative monitoring according to severity of intervention

- dept. for neurology (also as consultant service)

- pain therapy with specialisation in "special pain therapy" (also as consultant service)

- dept. for physiotherapy

4.1.1.3. The following diagnostically and therapeutically facilities have to be **permanently** (24/7) available "**in-house**" or have to be assured **by external cooperation** (24/7):

- blood bank
- laboratory
- dept. for vascular surgery

4.1.1.4. The following diagnostically and therapeutically facilities have to be available "**in-house**" or have to be assured by **external cooperation**:

- dept. for internal medicine
- dept. for visceral surgery
- institute for hygiene, bacteriology, microbiology

- institute for pathology

- centre for paraplegic patients

- dept. for rehabilitation- dept. for psychology and psychosomatic medicine

4.1.2. Additional for group **A pathologies** (degenerative diseases) the following diagnostically and therapeutically facilities have to be available "**in-house**":

- "injection room" with image intensifier or X-ray for image-guided injection
- possibility of CT-guided injection (for example: periradicular or epidural

injection)

4.1.3. Additional for group B pathologies (tumour diseases)

4.1.3.1. The following diagnostically and therapeutically facilities have to be available "**in-house**":

- interventional radiologist department with angiography (angio-CT) and possibility of embolization

- possibility for CT-guided biopsy

- neuro monitoring in the OR provided intradural pathologies are operated

4.1.3.2. Further, the following diagnostically and therapeutically facilities have to be available "**in-house**" or have to be assured by external cooperation:

- scintigraphy or PET-CT
- department for oncology
- department of radiotherapy
- tumour board

4.1.4. Additional for group **C pathologies** (infectious, inflammatory, metabolic diseases) the following diagnostically and therapeutically facilities have to be available "**in-house**" or have to be assured by **external cooperation**:

- scintigraphy or PET-CT
- possibility for CT-guided biopsy

4.1.5. Additional for group **D pathologies** (injuries) the following diagnostically and therapeutically facilities have to be available "**in-house**":

- interventional radiology
- angiography
- Angio-CT

4.1.6. Additional for group **E pathologies** (deformities) the following diagnostically and therapeutically facilities have to be available "**in-house**":

- neuro monitoring in the OR
- whole-spine X-ray

4.2. Staff and qualification

4.2.1. Personal EUROSPINE certificates

4.2.1.1. In a certified EUROSPINE Surgical Spine Centre of Excellence at least one physician has to hold a EUROSPINE Diploma or a comparable educational certificate starting on January 1st 2023.

4.2.2. Number of personnel

4.2.2.1. In a certified EUROSPINE Surgical Spine Centre of Excellence at least four physicians have to be employed in full time positions. At least two of

them have to have a board certificate in neurosurgery, trauma surgery or orthopaedic surgery.

4.3. On-call duty and on-duty emergency

4.3.1. In a EUROSPINE Surgical Spine Centre of Excellence a spine specialist has to be permanently available on-call (24/7).

4.3.2. In a EUROSPINE Surgical Spine Centre of Excellence the possibility for emergency surgery on the spine including decompression and stabilisation is provided permanently (24/7).

4.4. Consultation hours for spine pathologies

4.4.1. At least twice a week a specialised outpatient clinic for spine diseases is offered, allowing pre-operative evaluation and post-operative follow-up care.

4.5. Frequency and complexity of surgeries

4.5.1. Number of surgical cases (see table 1)

A overall minimum number of 300 cases have to be treated surgically in a EUROSPINE Surgical Spine Centre of Excellence. If the Centre of Excellence wants to be certified for a certain pathology, it has to fulfil the "treatment numbers" of this specific pathology. For the calculation of cases solely the numbers of performed surgeries are considered, not the amount of performed and coded parts of procedures or interventions. One surgery can only be counted for one specific pathology group.

4.5.2. Complexity of surgeries

4.5.2.1. "Complex" spine surgeries differ explicitly in effort and necessary expertise in comparison to "minor" spine surgeries. In addition to the case numbers it seems reasonable to establish a classification which measures the "complexity" of a surgery.

4.5.2.2. The following point-based system shall allow an easy classification of complexity of surgeries (for details of complexity grades see appendix Table 1):

1 point	"minor" spine surgery
3 points	"medium" spine surgery
6 points	"complex" spine surgery

4.5.2.3. The minimum necessary overall points that a EUROSPINE Surgical Spine Centre of Excellence has to reach are 500. The minimum necessary points per each pathology group that should be reached are calculated with

regards to this point-based system as a ratio of 60% "minor", 30% "medium" and 10% "complex" spine surgeries.

This does **not** mean that the centre has to perform 10% large surgeries, but it means that it has to acquire the minimal calculated number of points with the performed surgeries for that specific pathology group, it wants to be certified for.

For an example, that would mean for a **EUROSPINE Surgical Spine Centre of Excellence** that wants to be certified as Centre for **degenerative pathologies** that it has to achieve the following points:

120 cases (60% of 200 cases) of minor surgeries = 120 x 1 point = 120 points; plus 60 cases (30% of 200 cases) of medium surgeries = 60 x 3 points = 180 points; plus 20 cases (10% of 200 cases) of complex surgeries = 20 x 6 points = 120 points resulting in **overall 420 points**.

This minimum amount of points might also be acquired by 110 medium (330 points) and 90 small (90 points) surgeries (overall 420 points).

If the same Centre wants to be certified also as a **EUROSPINE Surgical Spine Centre of Excellence** for **deformities** it has to achieve the following additional points:

18 cases (60% of 30 cases) of minor surgeries = 18 x 1 point = 18 points; plus 9 cases (30% of 30 cases) of medium surgeries = 9 x 3 points = 27 points; plus 3 cases (10% of 30 cases) of complex surgeries = 3 x 6 points = 18 points resulting in overall **53 points**.

This minimum amount of points might also be acquired by 12 medium (36 points) and 18 small (18 points) surgeries (overall 54 points).

If the Centre is successfully certified it will be named: EUROSPINE Surgical Spine Centre of Excellence for degenerative diseases and deformities

Table 1 shows the number of cases and the minimum points required to be certified for a specific pathology as a EUROSPINE Surgical Spine Centre of Excellence.

Pathology group	A degenerative	B tumour	C inflammatory	D injuries	E deformities
SSCoE (regular volume) Number of cases	200	20	15	70	30
Minimum points	420	42	32	147	53

4.6. Quality Management

4.6.1. Use of quality control systems

The certified EUROSPINE Surgical Spine Centre of Excellence has to take part in the hospital infection surveillance system (for example KISS). Further a critical incidence reporting system (for example CIRS) is mandatory. The WHO checklist has to be used regularly before surgery. A quality management system has to be established, especially evaluating risk, complaint and failure management.

4.6.2. Survey of complications

In a EUROSPINE Surgical Spine Centre of Excellence a continuous survey and documentation of complication has to be proven. All patients with spine diseases who were operated on must be included in this data collection. The documentation of complications preferable takes place in the spine registry of EUROSPINE (Spine Tango).

4.6.3. Quality circle

A regular analysis and review of observed and / or treated complications (M&M conference) must be performed in a EUROSPINE Surgical Spine Centre of Excellence, at least once a quarter. Protocols of M&M conferences have to be available.

4.6.4. Spine registry of EUROSPINE (Spine Tango)

A participation in the spine registry of EUROSPINE (Spine Tango) <u>is recommended</u> for all EUROSPINE Surgical Spine Centre of Excellence. If the Centre participates in the registry of EUROSPINE (Spine Tango) a cost-reduction for the re-audit of the EUROSPINE Surgical Spine Centre of Excellence will be granted. If the Centre participates in the spine registry of EUROSPINE (Spine Tango) the documentation of the so called "minimal-data-set" from patients admitted to the centre for the first time and treated surgically is obligatory. Preferably the used implants are registered as well. Documentation of additional data is optional, for example clinical scores, outcome parametrs, subsequent treatment and follow-up data or documentation of data of non-surgically treated patients.

The Spine Tango Task Force of EUROSPINE ensures continuous quality control, consistency and plausibility for the obligatory participation in the spine-registry. Every certified spine centre will receive an annual analysis of data.

4.6.5. SOPs

In a certified EUROSPINE Surgical Spine Centre of Excellence standardized diagnostic and therapeutic algorithms have to be applied. For frequent disease patterns and treatment courses, written "standard operating procedures (SOP)" are to be defined for surgical and conservative treatments. Nursing and physiotherapy have to be respected in the SOPs. The SOPs have to be presented on request during the audit.

4.6.6. Conservative treatment

Non-surgical conservative treatment has to be available in a EUROSPINE Surgical Spine Centre of Excellence. The amount of conservatively treated patients has to be indicated. Documented conservative treatment courses will be checked randomly during the audit 4.7. Accreditation for a surgical training programme

4.7.1. The training of surgeons with transfer of knowledge and skills is a valuable criteria and precondition for certification.

4.7.2. For a EUROSPINE Surgical Spine Centre of Excellence a full accreditation by national authorities for a surgical training program in neurosurgery or trauma / orthopaedic surgery is necessary. The accreditation for a training program can also be provided in a network of several hospitals.

4.8. Research and teaching plus training, advanced training and further education

4.8.1. A EUROSPINE Surgical Spine Centre of Excellence has to participate actively in advancement of spine surgery and/or transfer of knowledge and skills.

4.8.2. Written publications for books or journals, lectures, presentations at congresses, arrangement of courses or congresses are defined as adequate contributions to achieve these goals. Internal educational events cannot be counted in this context.

4.8.3. A EUROSPINE Surgical Spine Centre of Excellence has to prove 5 of the abovementioned contributions per year.

5. Audit and course of certification

5.1. The audit and the course of certification will be defined by the actually valid rules and regulations of the Task Force EUROSPINE Surgical Spine Centre of Excellence.

APPENDIX

1 point	"small" spine surgery			
	removal of implant			
	sequestrectomy, discectomy (disc surgery,			
	non-instrumented)			
	noin surgical intervention on spine with			
	pain surgical intervention on spine with permanent implants (f. e. SCS-pump)			
	permanent implants (1. e. 5C5-pump)			
	percutaneous cement augmentation of			
	vertebrae			
	non-instrumented dorsal decompressions			
	biopsy on spine			
	application of inter spinous implants			
3 points	"medium" spine surgery			
	Surgery on cervical, thoracic, lumbar spine			
	and sacrum which are not mentioned under			
	small (1 point) and large (6 points) spine			
	surgery			
6 points	"large"spine surgery			
	en-bloc spondylectomy with reconstruction			
	and stabilization			
	correction interventions due to deformity ≥			
	6 segments			
	o segments			
	resection interventions due to intra			
	medulla tumors			
	revision surgery with implant removal and			
	complete re-instrumentation ≥ 6 segments			
	combined dorso ventral interventions due			
	to spine injury over separate approaches			
	with vertebral (partial) replacement			
	combined interventions with multiple			
	change of approach (dorsal ventral dorsal			
	or ventral dorsal ventral)			

Table of severity of intervention (point-based system)