



## Accreditation of endocrine surgery units

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### Abstract

**Background/purpose** A key measure to maintain and improve the quality of healthcare is the formal accreditation of provider units. The European Society of Endocrine Surgeons (ESES) therefore proposes a system of accreditation for endocrine surgical centers in Europe to supplement existing measures that promote high standards in the practice in endocrine surgery.

**Methods** A working group analyzed the current healthcare situation in the field of endocrine surgery in Europe. Two surveys were distributed to ESES members to acquire information about the structure, staffing, caseload, specifications, and technology available to endocrine surgery units. Further data were sought on tracer diagnoses for quality standards, training provision, and research activity. Existing accreditation models related to endocrine surgery were included in the analysis.

**Results** The analysis of existing accreditation models, available evidence, and survey results suggests that a majority of ESES members aspire to a two-level model (termed competence and reference centers), sub-divided into those providing neck endocrine surgery and those providing endocrine surgery. Criteria for minimum caseload, number and certification of staff, unit structure, on-site collaborating disciplines, research activities, and training capacity for competence center accreditation are proposed. Lastly, quality indicators for distinct tracer diagnoses are defined.

**Conclusions** Differing healthcare structures, existing accreditation models, training models, and varied case volumes across Europe are barriers to the conception and implementation of a pan-European accreditation model. However, there is consensus on accepted standards required for accrediting an ESES competence center. These will serve as a basis for first-stage accreditation of endocrine surgery units.

**Keywords** Accreditation · Endocrine surgery · Quality control

### Introduction

The principal objective of the European Society of Endocrine Surgeons (ESES) is “the promotion and maintenance of high standards in the clinical practice of endocrine surgery and the promotion of education and research in this field.” In order to

achieve this goal, the Society has already implemented examinations for neck endocrine surgery and endocrine surgery within the European Union of Medical Specialists (UEMS) Section of Surgery and the European Board of Surgery, Division of Endocrine Surgery. Furthermore, the Society continues to develop and publish evidence-based recommendations

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and guidelines on the surgical management of endocrine disease and has established a pan-European registry for endocrine surgery (Eurocrine®). The latter serves as a tool for benchmarking and quality assurance as well as a basis for clinical studies and retrospective analysis of current clinical practice.

In order to complement these measures, ESES proposes to implement an accreditation system for endocrine surgery units in Europe. Although the effectiveness of accreditation in medicine has not been demonstrated in studies to date, it is generally accepted as one of a suite of measures that can maintain and improve the quality of patient care and surgical outcomes. A general definition of accreditation is outlined in the European Norm ISO 9001:2015, which specifies generic requirements for a quality management system that are applicable to any organization regardless of its type or size, or the products and services it provides. The norm is useful for organizations that (a) need to demonstrate their ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements and (b) aim to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customers and applicable statutory and regulatory requirements. It is hoped that ESES accreditation will permit patients and physicians to identify high-quality endocrine surgery centers more easily, and that in their efforts to comply with the requirements for ESES accreditation, centers for endocrine surgery will improve the quality of care that they deliver.

Pan-European accreditation is a significant challenge because the overarching goal of ensuring a minimum quality standard based on scientific guidance and clinical experience that is achievable and that can be maintained has to be adapted to diverse regional and national healthcare structures and clinic resources. Putative quality indicators and standards of endocrine surgery include aspects such as volume–outcome relationships, adherence to national and international surgical guidelines, continuous postgraduate education, training opportunities for residents and fellows, and research activities and outputs from a given center. In addition, in certain European countries, accreditation of endocrine surgery centers has already been implemented (e.g., Italy and Germany) or is currently being defined (Spain). Therefore, any proposed model should take account of these systems. Other disease-specific (but not surgical specialty-specific) European accreditation systems in the field of endocrinology are the certification of centers for neuroendocrine tumors by the European Neuroendocrine Tumor Society (ENETS) and the recently established European Reference Network that focuses on the treatment of rare diseases and includes a section for endocrinology and endocrine tumors.

## Methods

In preparation for the 8th ESES in Granada in May 2019, a working group was established with the task of developing a model for the accreditation of endocrine surgery centers. In order to develop an encompassing picture of the organization, resources, and staffing of endocrine surgery units in Europe, the necessary information was sought from the surgical literature, ESES membership, and existing national and international accreditation systems according to Tables 1, 2, and 3.

Requirements and procedures of existing national and European accreditation systems were translated into the English language and summarized in a synopsis in order to evaluate national differences.

In addition, two surveys were generated and distributed to ESES members. The surveys were displayed via the internet platform SurveyMonkey® and a login sent by e-mail to all members who had previously agreed to receive e-mail communication from the ESES. The first survey (survey A) was open between 14 and 31 January 2019 and included 23 questions and a comment field, and was sent out to 355 ESES members. If two or more responses were registered from the same site, only one answer was included.

The second ESES survey (survey B) was open between April 25 and May 5 and was sent to the ESES members according to the 295 ESES members identified from survey A. It comprised 13 questions that focused on the preference for distinct aspects of structure and requirements of the accreditation.

Survey results were transferred to Microsoft Excel® and analyzed. Analysis formed the basis of a preliminary proposal for accreditation that was presented at the 8th ESES international conference in Granada and discussed with the membership. The results of the panel discussion in Granada, as well as the results of other working groups evaluating the current evidence for volume–outcome relations in endocrine surgery and training in endocrine surgery, were acknowledged in the final preparation of this manuscript.

## Results

### Responses of surveys A and B

For survey A, a total of 105 replies were counted (response rate 29.6%). Three responses were deleted due to duplicate entries resulting in 102 unique responders representing centers that host 424 endocrine surgeons. Four (3.9%) responses related to primary-level hospitals (district or rural institutions), 7 (6.7%) were entered by secondary-level hospitals (regional or provincial centers), and 91 (89.2%) were from tertiary-level hospitals (highly specialized academic health institutions). Just fewer than 80% ( $n = 81$ ) of the respondents confirmed that they actively participated in the creation of national or

**Table 1** Synopsis of existing accreditation models

Items	Country	Italy	Spain	Belgium
	Germany	Italy	Spain	Belgium
Standards	DIN EN 15224 and DIN EN ISO/IEC 17021	Not defined	Pending	Not defined
Objects	<ul style="list-style-type: none"> <li>• Single surgical department</li> <li>• Association of several surgical units or departments, if they have a single director</li> <li>• Contractually bound cooperation with their leaders between a clinic and outpatient organizations (e.g., private practices)</li> </ul>	<ul style="list-style-type: none"> <li>• Single surgical center with interest in ES:</li> <li>• Department of Surgery</li> <li>• Division of General or Endocrine Surgery</li> <li>• Unit of Endocrine Surgery</li> <li>• Section of ES</li> </ul>	<ul style="list-style-type: none"> <li>• Competence</li> <li>• Reference</li> </ul>	<ul style="list-style-type: none"> <li>• Single clinics</li> <li>• Shared model (including 1 reference center and peripheral hospitals)</li> </ul>
<i>Hierarchy</i>	<ul style="list-style-type: none"> <li>• Competence</li> <li>• Reference</li> <li>• Excellence</li> </ul>	<ul style="list-style-type: none"> <li>• Reference</li> <li>• National reference</li> </ul>	<ul style="list-style-type: none"> <li>• Competence</li> <li>• Reference</li> </ul>	<ul style="list-style-type: none"> <li>• Reference</li> </ul>
Types	Thyroid/parathyroid Endocrine	Thyroid	Thyroid/parathyroid	Rare complex cancer covering ACC, parathyroid carcinoma, malignant pheo, pituitary, pancreatic NET MEN 1 and 2
Duration	3 years	2 years (1 + 1) subject to re-evaluation annually (audit)	2 years	3–5 years
Application and assessment	DGAV Board, CAEK Board, and auditor	Commission of the SIUEC, designed by the Society Board	Not defined: still pending	KCE
<i>Fees</i>	Yes	Yes	Not defined: still pending	Not defined
Staff	Documentation officer Competence: 2 accredited surgeons Reference/excellence: 3 accredited surgeons	2 “competent” endocrine surgeons	Competence: 2 surgeons	Endocrinologists with experience in endocrine and neuroendocrine tumors
Curriculum of surgeons in charge	Qualified “special visceral surgeon” (includes 20 thyroidectomies) or EBSQ qualification Exception for thyroid/parathyroid centers: 250 procedures performed DGAV/CAEK	Adequate training (no number) Certification of the specific thyroid surgical activity by the hospital director	Competence 3 years of exp., > 100 thyroidectomies, > 20 parathyroid	Not defined
Membership		SIUEC	> 2 surgeons members of endocrine surgery section of the AEC	Not defined
Equipment	Ultrasound IONM Postoperative laryngoscopy Reference center Intraop. ultrasound Minimally invasive adrenal surgery	Not mandatory (see variable merits)	Not mandatory: Surgical sealants IONM IOPH	Advanced imaging techniques Gamma knife, cyber knife FNA Laboratory for pathology Radiology/interventional Radiofrequency ablation Radiotherapy Medical oncology unit Molecular genetic testing Electronic medical record Facilities for videoconference

**Table 1** (continued)

Items	Country	Italy	Spain	Belgium
Infrastructure/cooperation	Germany In hospital or cooperation based on contracts: • Internal medicine • Endocrinology • Nuclear medicine • ENT • Oncology • Radiology • Radiotherapy • Laboratory medicine • Pathology	Italy In hospital: • Anesthetist on site 24 h • Radiology (standard-ultrasonography) • Laboratory for analysis open 24 h or on call In hospital or regional network: • Cardiologist on site 24 h or on call • Intensive care unit • Pathology unit able to satisfy quality standards and allowing cytological, pathological (also frozen section examination), immunohistochemistry evaluation • Radiology CT, MRI • Endocrinology • ENT unit • Speech therapy service • Nuclear medicine service for diagnosis and therapy • Transfusion service open 24 h for both elective and emergency procedures • Consultation of thoracic, vascular, and cardiac surgery • Medical services Not defined Not defined	Spain Competence: • Endocrinology • Pathology • ENT • Laboratory, incl. hormone tests • Intraoperative frozen section	Belgium Endocrinologist with specific competence in endocrine oncology Nuclear medicine specialist dedicated to radio-isotope therapy Oncologist Surgeon (ORL-head-neck, thoracic, liver, pancreas, urologist, neurosurgeon) Chemotherapist Radiotherapist Radiologist Interventional imaging specialist Neuroradiologist Pathologist Care coordinator Gastroenterologist Clinical genetics specialist
Genetic counseling Boards	Not defined Tumor board weekly	Not defined. Still pending. Competence: monthly endocrinology, nuclear medicine (if present in the hospital), pathology, surgery		Mandatory Not defined
Further training (self)	16 education credit points/surgeon/year Each of the accredited surgeons has to attend annual CAEK Meeting	2 national or international congresses/meetings or 2 courses or 2 endocrine surgery workshops during the accreditation period		Not defined
Organization of training for third parties	Reference center: 6 credit points Excellence center: 12 credit points (internal hospital training excluded) Reference and excellence centers must offer regular hospitalizations	Not defined: 6.2: not mandatory. Postgraduate training, clinical tutor for medical students, 15 h of teaching in 2 years		Involved in training and continuous education programs Organization/communication in international and national scientific congresses
Publications	Excellence: 3 papers/year in peer-reviewed journals	2 presentations in congresses or meetings, or author/co-authoring 2 papers during the accreditation period		Case report publication Clinical research in the endocrine oncology field
Patient care	SOPs not mandatory	SOP for postoperative treatment and complications		SIUEC SOP mandatory for patient management [47] < 15 days waiting time

**Table 1** (continued)

Items	Country	Spain	Italy	Belgium
Register quality control	Germany	Mandatory StuDoQ (DGAV) or Eurocrine® database	Endocrine surgery section of the AEC database	24 h specialized stuff 7 days/week
Minimum numbers	See Tables 2 and 3	Thyroid: 26 patients/year/surgeon Parathyroid: 20/team/year	Reference > 50 thyroid proc./year Nat. reference > 500 thyroid proc. year	Cancer registry Capacity to propose quality indicators Involvement in quality initiatives, annual reports Not defined
Complications	<ul style="list-style-type: none"> <li>&lt; 5% (NAR) for the recurrent nerve palsy at the time of hospital discharge following primary resection of benign goiter (mandatory laryngoscopy)</li> <li>50% decrease following 6 months</li> <li>Proportion of revision for bleeding &lt; 2%</li> </ul>	<ul style="list-style-type: none"> <li>Goiter (TT/HT): &lt; 2% (NAR) perm. paresis</li> <li>Bilateral paresis: &lt; 0.5% (no mandatory laryngoscopy)</li> <li>Bleeding &lt; 2.5%</li> <li>Perm. HPT (TT): ≤ 4% (central dissection, completion excluded)</li> <li>pHPT:               <ul style="list-style-type: none"> <li>- Localized pHPT: cure &gt; 95%</li> <li>- pHPT not localized: cure &gt; 90%</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Perm. unilateral ILN injury 1.3% (range 0.4–4.6%)</li> <li>(No mandatory laryngoscopy)</li> <li>Perm. hypoparathyroidism 2.2% (range 0.2–7.2%)</li> <li>Postoperative bleeding 1.6% (range 0.5–4.0%)</li> <li>Surgical site infection 0.4%</li> </ul>	Not defined Not defined
Publications	Excellence: 3 papers/year in peer-reviewed journals	2 presentations in congresses or meetings, or author/co-authoring 2 papers during the accreditation period	Suggested implementation but not specified	Case report publication Clinical research in the endocrine oncology field
Research	Reference: participation in 1 clinical trial with evidence level 1–3 in 3 years Excellence: participation in 1 clinical trial (level 1–2) in 2 years, include > 20 patients and heading 1 prospective registered clinical study Exceptions possible	Competence: at least 2 communications related to endocrine surgery in congresses or meetings, or participation in tables or papers (6.1.2) Not mandatory (6.2): - At least 1 article published or accepted for publication during the evaluation period. - Principal researcher or PhD in the field of endocrine surgery - Participation in multicenter studies	Suggested, not defined/mandatory	Access to clinical trials Link with a tumor bank Participation in national and international networks Case report publication Clinical research in the endocrine oncology field
Variable merits	Not defined Compensation between categories not possible	8 mandatory 1. Surgical sealants 2. IONM 3. IOPTH 4. 2 credits during accreditation period 5. Accred training stay in other hospitals 6. Clinical and bibliographical sessions 7. Regular morbidity and mortality sessions 8. European Board of Neck Surgery/Endocrine Surgery	Not defined	Not defined

**Table 1** (continued)

Items	Country
	Germany
	Spain
	Italy
	Belgium

9. 15 h of teaching in 2 years
10. Postgraduate training
11. Clinical tutor for medical students
12. At least 1 article published or accepted for publication during the evaluation period
13. Principal researcher or PhD in the field of endocrine surgery
14. Participation in multicenter studies
15. Providing informative brochure for patients in paper or electronic support
16. Protocols of intrahospital clinical practice

international guidelines for endocrine surgery. The average number of surgeons per center who graduated in general surgery and performing endocrine surgery interventions was 4, whereas the average number of surgeons certified as specialists in endocrine surgery (e.g., EBSQ exam) was 1.5. In 90% of units participating in the survey, patients with endocrine malignancies were presented in an interdisciplinary tumor board. In more than 90% of cases, a surgeon that was qualified/certified in endocrine surgery was present during all endocrine surgery operations. For quality control, 31 units (30.4%) used Eurocrine<sup>®</sup> and 39 units (38.2%) alternative registries, while 39 (38.2%) did not register endocrine surgery operations. The frequency of reported endocrine surgery caseload per unit demonstrated the considerable variation (Fig. 1). Similarly, the frequency of reported postoperative vocal cord paralysis and postoperative bleeding requiring reintervention varied significantly and frequently exceeded the rates reported in the literature (Figs. 2 and 3). However, regression analysis showed no significant inverse correlation between a high case volume and rates of vocal cord palsy or bleeding. A majority of the units declared an interdisciplinary in-house collaboration with endocrinology, radiology, pathology, and otolaryngology specialists.

For survey B, 96 responses were received (response rate 32.5%). The majority of the respondents agreed that a two-level accreditation model could be proposed, defining competence centers that offer high-quality treatment according to guidelines plus advanced training for endocrine surgeons and scientific activities and reference centers, which represent leading institutions regarding clinical experience, human and material resources, and scientific work in endocrine surgery. Similarly, 83.3% of the respondents preferred a model separating neck endocrine surgery (focusing on thyroid and parathyroid diseases) and endocrine surgery (thyroid, parathyroid, adrenal, paraganglioma, and gastroenteropancreatic neuroendocrine neoplasms (GEP-NEN)). The desired caseload stated by respondents (median of the responses received) for each diagnosis for competence centers and reference centers is summarized in Tables 4, 5, and 6.

Passing the EBSQ exam for neck endocrine surgery or endocrine surgery (with evidence of the qualifying minimum numbers of operations performed) was generally accepted as a prerequisite qualification for lead endocrine surgeons in accredited units. However, since most national examinations for surgery do not include a minimum indicative caseload in endocrine surgery, only 6.2% of respondents agreed that possession of national examinations signifies specialized certification in endocrine surgery. However, acknowledging the fact that many experienced endocrine surgeons may not possess the EBSQ exam, proof of numbers of operations personally performed according to the minimum numbers required for the EBSQ exam was accepted as an alternative qualification by 34% of the respondents.

**Table 2** Minimum annual caseload numbers for thyroid/parathyroid centers in Germany

Type of intervention	Competence center	Reference center	Excellence center
A. Nodular goiter	120	120	–
B. Graves' disease	10	10	–
C. Reinterventions for benign goiter, thyroid carcinoma, or HPT	15	20	–
D. Thyroid malignancy	15	20	–
E. Lymph node dissection of lateral lymph nodes	0	5	–
F. Hyperparathyroidism	5	25	–
Total	165	200	–

Both surveys included questions concerning surgical training and research activities. In survey A, 49% agreed that an accredited department should organize national or international conferences within the specialty of endocrine surgery. A majority (78.4%) also responded that they participated in the executive councils for national or international associations in the field of endocrine surgery, but only 31.4% of the respondents participated in the EBSQ examination. Overall, there was agreement that all accredited centers should participate in training, but it was felt that, whereas certain undertakings such as organization of congresses, development of guidelines, and the hosting of visiting surgeons might be the principal domain of reference centers, participation of competence centers in these activities was not seen as a precondition (Table 7).

Concerning research activities, respondents declared a median of 3 articles published per clinic per year (mean 3.2). A majority of ongoing studies were retrospective studies (mean 3.1 per year; the total number of published studies were 261), followed by prospective studies (mean 1.6; a total of 129) and randomized studies (0.4; total 27). Studies using Eurocrine® as a data source accounted for only 0.3 studies per clinic per year

**Table 3** Minimum annual caseload numbers for endocrine surgery centers in Germany

Type of intervention	Competence center	Reference center	Excellence center
A. Nodular goiter	–	120	200
B. Graves' disease	–	10	20
C. Reinterventions for benign goiter, thyroid carcinoma, or HPT	–	20	25
D. Thyroid malignancy	–	20	40
E. Lymph node dissection of lateral lymph nodes	–	5	10
F. Hyperparathyroidism	–	25	40
G. Adrenal tumor or paraganglioma	–	10	20
H. GEP-NEN	–	5	20
Total	–	215	375

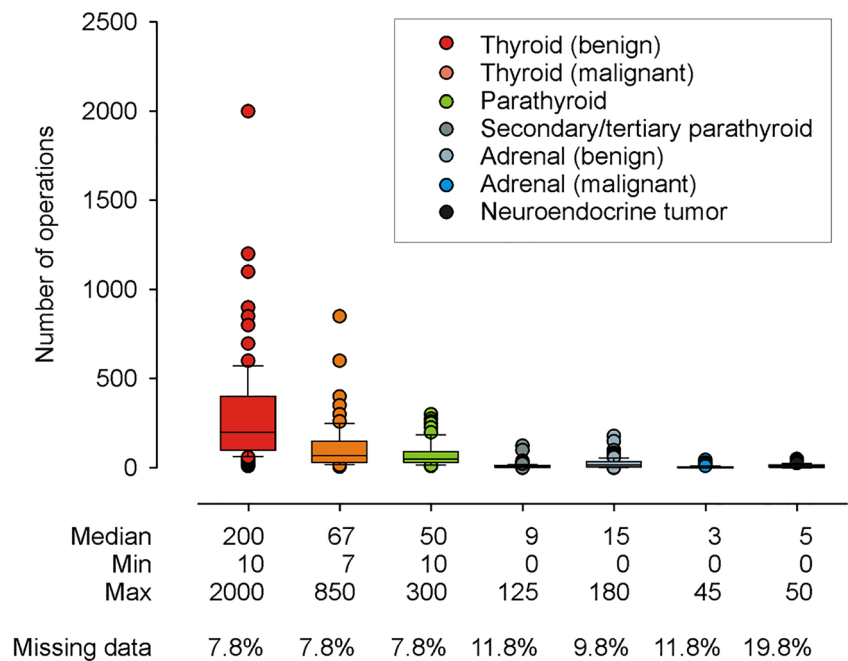
with a total number of published studies of 25. In the questionnaire survey, 12.6% responded that research should not be a precondition for competence centers, while for a reference center, that level was 4.2%. Just below 40% (38.9%), however, believed that a competence center should be able to compensate for the lack of research activity with other activities, while for reference centers, this figure halved (19.9%).

## Discussion

The ESES is focused on maintaining and improving the quality of care in the field of endocrine surgery. Consequently, accreditation of centers for endocrine surgery complements established measures such as the publication of treatment recommendations and guidelines, EBSQ examinations, and the pan-European Register for Endocrine Surgery (Eurocrine®). The process of quality improvement also encompasses aspects of structural quality (e.g., training/education, continuing professional development, clinic facilities, and organization), process quality (diagnostic algorithms, collaborations with other units, treatment protocols/guidelines), and quality of outcome (improvement or cure of diseases, patient satisfaction, complications, morbidity, and mortality). While not all endocrine surgery units will meet quality standards, units that are certified will gain national/European recognition. Therefore, the accreditation process has to be robust, defensible, unambiguous, and transparent.

The working group intensively analyzed the European healthcare situation in the field of endocrine surgery, examined details of existing and developing accreditation models in different European countries, and employed surveys in order to evaluate which model would be supported by the majority of ESES members. Although the results of the surveys and the analysis of existing accreditation models suggested that a model defining competence and reference centers for neck endocrine surgery and endocrine surgery might be a generally accepted solution, the discussion of various details of the model in the panel session revealed some differences of opinion regarding the required minimum caseload, tracer diagnoses and quality indicators, and qualification of endocrine surgeons. The results of these discussions were taken into account and integrated into the model described below. While the definition of competence and reference centers remains a final goal, it was decided to start with the implementation of competence centers in order to gather more information about the spectrum of endocrine surgery units and to use this information to improve the accreditation model as an evolving system. The embedding of reference centers is planned as the second stage. It was also decided that only ESES members can apply for the accreditation and that Eurocrine® should be used as a quality register by accredited centers to facilitate the validation of caseload and surgical outcomes.

**Fig. 1** Box-plot presentation of data from question 18 in survey A, investigated the numbers of procedures among endocrine surgical units in Europe



**Minimum number of interventions**

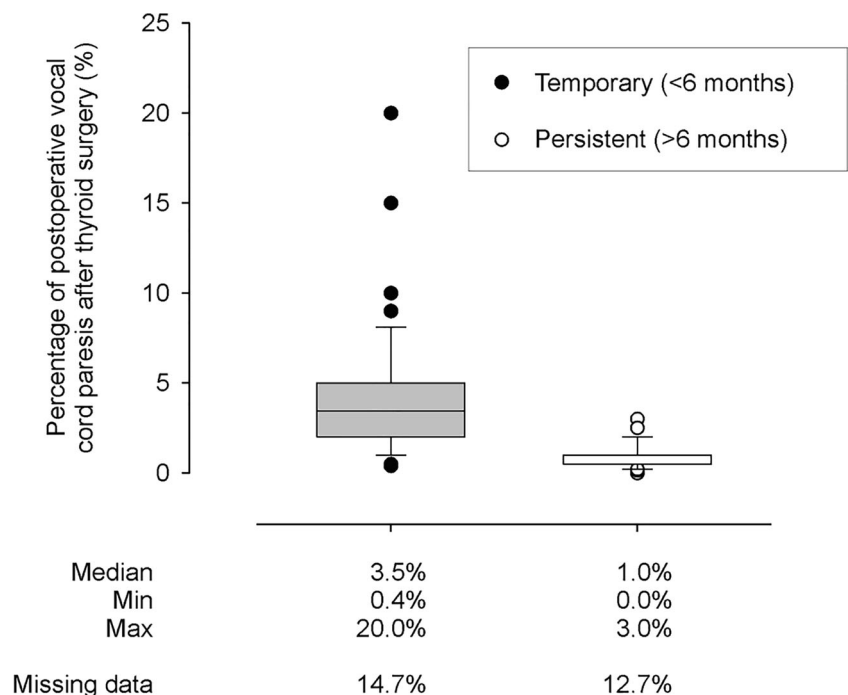
**Thyroid surgery**

The definition for low-volume thyroid surgeons ranges from < 10 to < 50 and for high-volume thyroid surgeons from > 23 to > 100 surgeries per year [1–8]. Surgeon volume and, to a lesser degree, hospital volume are inversely related to the prevalence of recurrent laryngeal nerve injury and

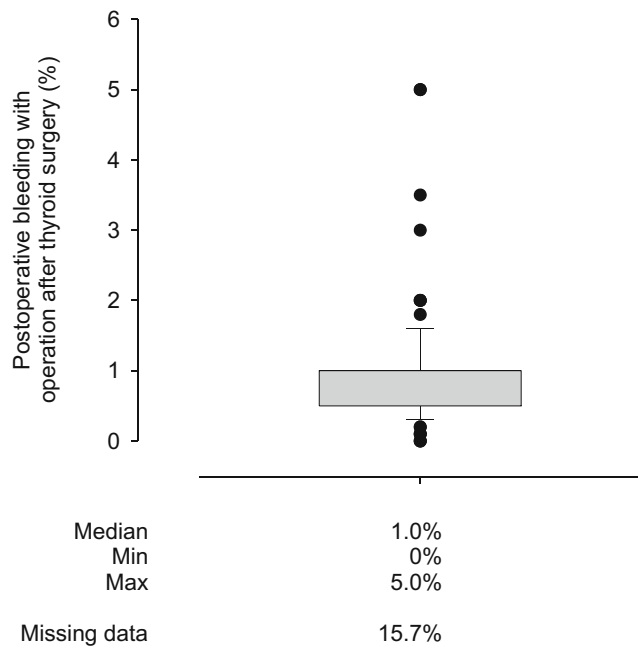
postoperative hypoparathyroidism. Different correlation analyses between surgeon [5, 7, 9–12] or hospital volume [9, 13–16] and postoperative bleeding have revealed conflicting results.

Surgery for thyroid cancer is a predictor of increased risk of recurrent laryngeal nerve injury and postoperative hypoparathyroidism and therefore should be performed by high-volume surgeons [2, 3, 8, 17]. Our survey among ESES members revealed a cutoff value for competence centers of 100

**Fig. 2** Self-reporting distribution on postoperative vocal cord palsy after thyroid surgery, grouped into temporary (< 6 months, left bar) and persistent (> 6 months, right bar). The data are presented as a box plot







**Fig. 3** The rate of postoperative bleeding after thyroid surgery requiring reintervention (i.e., reoperation). The data are presented as a box plot

annual thyroidectomies for benign disease, 25 annual thyroidectomies for thyroid cancer, and 10 systematic cervical lymph node dissections of the lateral lymph node compartment, which is in accordance with the existing literature (Table 4).

**Parathyroid surgery**

The definition for low-volume parathyroid surgeons ranges from <4 to <20 and for high-volume parathyroid surgeons from 20 to >100 surgeries per year [1, 15, 18–24]. The experience, and therefore the individual surgeon volume, seems to be more relevant than the hospital volume, especially in non-standard cases (multiglandular disease, hereditary primary hyperparathyroidism (PHPT), ectopic or unlocalized glands). A

**Table 5** Proposed minimum case volume for competence centers of neck endocrine and endocrine surgery

Type of intervention	Competence center
Benign goiter	100
Thyroid malignancy	25
Systematic cervical lymph node dissection of the lateral lymph node compartments (K2 right; K3 left)	10
Hyperparathyroidism	
pHPT	25
sHPT and hereditary HPT	5
Additional for endocrine surgery	
Adrenal or paraganglioma excision	10
GEP-NET	5

pHPT primary hyperparathyroidism, sHPT secondary hyperparathyroidism, GEP-NET gastroenteropancreatic neuroendocrine tumors

volume–outcome association was found with regard to higher cure rates [18, 23, 24], less persistent disease [18], fewer reoperations [25], and fewer avoidable reoperations [20, 26].

Surveys among ESES members revealed a cutoff value for competence centers of 25 operations per annum for primary HPT and 5 for secondary and/or hereditary HPT (bilateral cervical neck exploration), which is in accordance with the existing literature.

**Adrenal or paraganglioma surgery**

The definition for low-volume adrenal surgeons ranges from <3 to <6 surgeries per year [27–32]. A volume–outcome association was found with regard to lower morbidity and mortality rates, shorter length of hospital stay, and less overall costs.

Higher annual numbers of operations might be required for the treatment of adrenocortical carcinoma. Accordingly, we

**Table 4** Results from question 3 in ESES members’ second survey, regarding desired annual caseload of endocrine surgical procedures grouped by competence and reference centers, and sub-grouped in neck surgery (Thyr/Para) and neck-and-abdominal surgery (Endocrine)

Type of intervention	Competence center		Reference center	
	Thyr/Para	Endocrine	Thyr/Para	Endocrine
Thyroid benign	100	100	120	120
Thyroid malignant	25	25	50	50
Thyroid neck dissection	10	10	20	20
Thyroid reinterventions	10	10	20	20
Primary hyperparathyroidism	25	25	50	50
Secondary hyperparathyroidism	5	5	10	10
Adrenal tumor or paraganglioma	–	10	–	20
GEP-NEN	–	5	–	10
Total	175	190	365	300

**Table 6** Proposed minimum caseload for accreditation as a specialist surgeon in neck endocrine and endocrine surgery

Type of intervention	Surgeon
Benign goiter	50
Thyroid malignancy	15
Systematic cervical lymph node dissection of the lateral lymph node compartments (K2 right; K3 left)	5
Hyperparathyroidism	
pHPT	15
sHPT and hereditary HPT	3
Additional for endocrine surgery	
Adrenal or paraganglioma	5
GEP-NET	3

*pHPT* primary hyperparathyroidism, *sHPT* secondary hyperparathyroidism, *GEP-NET* gastroenteropancreatic neuroendocrine tumors

found a cutoff value of 10 adrenal or paraganglioma operations per annum for competence centers in the survey among ESES members.

### Gastroenteropancreatic neuroendocrine neoplasms

Due to the low incidence and broad range of different gastroenteropancreatic neuroendocrine tumors, a minimum annual caseload of gastroenteropancreatic neuroendocrine tumor (GEP-NET) operations is required for appropriate specialized knowledge in peri- and intraoperative management. Based on our survey among ESES members, we found a cutoff value of 5 annual GEP-NET resections for competence centers.

**Table 7** Question 10 in the survey B concerning different training activities required for competence and reference centers. The percentage that agreed with respective centers undertaking a given activity in order to be accredited

Training activities	Competence center (%)	Reference center (%)
Attending ESES congresses (at least once in accreditation period of 2–3 years)	73	91
Attending specialized endocrine surgery national or international congresses	84	95
Presentations at national and international endocrine surgery congresses	52	84
Graduating surgeons	51	78
Hosting visiting surgeons	25	83
Organization of endocrine surgery meetings	18	72
Participation in creating national or international guidelines	28	76

## Quality indicators

In order to assess and compare the quality of endocrine surgery centers, tracer diagnoses have to be selected that are performed in all hospitals with significant volume, include a relatively homogeneous group of patients, and are easy to evaluate during on-site audits. For the tracer diagnoses, there is a requirement for quality indicators that can be easily evaluated. The following three quality indicators were suggested by the majority of the ESES respondents.

### Thyroid surgery

1. Early postoperative unilateral recurrent laryngeal nerve paresis

Defined as vocal cord paresis within the first week after surgery, diagnosed by postoperative laryngoscopy, or documented by intraoperative neural monitoring following the International Standard Guideline Statement (clinical monitoring of voice quality is insufficient) [33, 34]. Early postoperative recurrent laryngeal nerve (RLN) injury occurs in 0.8% of patients with standard thyroidectomy [35] and 2.5% of patients with high-risk thyroidectomy (reoperation, thyroidectomy for malignancy, thyrotoxicosis, or retrosternal goiter) [36]. In accordance with the results of our survey, a cutoff value of RLN injury in standard thyroidectomy of < 5% per nerves at risk with a dropout rate of < 2% was defined for competence centers. The rate should be reduced by 50% after a follow-up of 6 months.

2. Postoperative hemorrhage requiring reintervention

Post-thyroidectomy hemorrhage occurs in 1.5% of patients [37]. A cutoff value of < 2% for postoperative bleeding requiring reintervention for competence centers was therefore proposed.

### Parathyroid surgery

1. Rate of normalized parathyroid function following resection of sporadic primary hyperparathyroidism

Defined as normalized or decreased PTH level on the first postoperative day [38]. Persistence or recurrence of pHPT occurs in 2.5–5% [39]. Based on a cutoff value of 25 annual operations for pHPT for competence centers, we defined a normalization rate of  $\geq 92\%$ .

## Requirements: equipment, staff, and multidisciplinary collaboration

The advantage for patients with endocrine pathology of being referred to an accredited unit is the possibility of obtaining a

customized and up-to-date treatment for their condition [40]. Endocrine diseases require a multiprofessional team that need access to specialist laboratory-based testing and imaging, combined with medical and surgical management [41]. Thyroid surgery should preferably be performed in centers with adequate quality, volume of procedures, structure, and technology standards [40, 41].

Unfortunately, the evidence base for this issue is almost non-existent. So, the following recommendations are a synthesis of the German [42] and Italian [43] accreditation systems, as well as the UK NHS requirements for Specialized Endocrine Units [41] and Training Requirements for Endocrine Surgery [44]. The figures take account of the results of surveys A and B.

## Structure

The accreditation models in Italy and Germany define that endocrine surgery, as a part of General Surgery Department, must have:

- Inpatient capacity: within the General Surgery Department
- Outpatient clinic: at least once a week [42, 44]
- Administrative and teaching rooms within the department
- Operating theater capacity to perform:
  - Competence centers:  $\geq 50$  [43] or  $\geq 165$  [42] thyroid surgeries/year
  - Reference centers:  $\geq 200$  [42] or  $\geq 500$  [43] thyroid surgeries/year

The figures determined by the accreditation systems consulted (Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie, 2016 no. 40; Società Italiana Unitaria di Endocrinochirurgia, no. 41) provide a very wide range of minimum volumes, which requires a consensus. The proposed figures are in keeping with those derived from ESES members and the determination of high-volume surgeons by an ESES working group. Thus, in competence centers for neck surgery, the required annual volume would total 135 thyroidectomies (including cancer, recurrences, and neck dissection) and 30 parathyroidectomies, adding 10 adrenalectomies and 5 neuroendocrine tumors, for accreditation in endocrine surgery (Table 5). The caseload for reference centers will depend on the results of the first stage of implementation of the accreditation model.

## Staff

The unit must have at least two accredited surgeons dedicated to endocrine surgery, who meet a number of requirements (specialist training, continued medical education, multidisciplinary links, demonstrable academic/professional skills) [42, 43] and are members of the ESES.

An accredited surgeon should be present as either lead surgeon or assistant for every operation [42]. Regarding the professional qualification, they must be specialized in general surgery plus a subject-specific EBSQ qualification or have performed at least 250 procedures in endocrine surgery during the last 5 years [42]. In reference centers, it is proposed that the number of accredited surgeons increases to a minimum of three [42].

Accredited surgeons require constant training and, consequently, they must demonstrate their attendance at both courses and related conferences (national or international), adding up to a total of at least 24 h (e.g., 3 days with 8 h per day).

## Equipment: diagnostic procedures

Within the hospital infrastructure, competence centers in neck endocrine surgery must have access to ultrasound and intraoperative neural monitoring [42]. Alongside this, the reference centers should be able to perform intraoperative determination of PTH [42].

Any reference center for endocrine surgery will also have access to intraoperative ultrasound, and minimally invasive techniques for adrenal surgery, in addition to the equipment previously mentioned [42].

All accredited centers must have the possibility of performing a pre- or postoperative laryngoscopy [42].

These recommendations are in accordance with the results of the working group surveys which consider as basic technical resources access to intraoperative PTH, frozen section pathology, neural monitoring, and laryngoscopy. In future reference centers, the required equipment will be more sophisticated and will include intraoperative ultrasound for open and laparoscopic surgery, expertise available to perform sternotomy, radio-iodine or radiopeptide treatment, local ablation (radiofrequency, HIFU, laser), interventional radiology for transarterial chemoembolization or selective internal radiotherapy, and external beam radiation treatment.

## Multidisciplinary collaboration

Due to the frequent complex clinical situations and necessary diagnostic procedures associated with optimal management and treatment of endocrine diseases, best practice requires a multidisciplinary team and cooperation between specialists. Collaborating disciplines should be preferably located in the same hospital but cooperation with selected outside units is also accepted, if formal service-level agreements with another provider exist. The list below summarizes the necessary team to provide high-quality service:

- Anesthesiology [40, 43]
- Intensive care unit (ICU) [40, 43]
- Cardiology [40, 43]

- Pathology [40–44]: cytology, histology, frozen section, immunohistochemical analysis
- Radiology [40–44]: CT, ultrasound, intraoperative ultrasound, MRI
- Interventional radiology [41]
- Endocrinology [40, 42–44]/internal medicine [42]
- ENT otolaryngology [40, 42, 43]
- Speech therapy [40, 43]
- Nuclear medicine [40–44]: scintigraphic diagnosis, investigation, and therapy
- Laboratory testing service [40, 42, 43]
- Blood transfusion service with blood and its products [40]
- Thoracic, vascular, or cardiovascular surgery [40, 43]
- Oncology [40, 42]
- Radiotherapy [40, 42]
- Clinical genetics [41]
- Endoscopic ultrasound (endocrine surgery centers) [41]
- Cryopreservation of oocytes/semen (not mandatory in the same unit)

ESES members agreed with this multidisciplinary approach and considered it necessary that malignant endocrine diseases are presented and discussed in interdisciplinary tumor board meetings in both reference and competence centers. Regarding the partner services, the following core services should be present in-house: pathology, otolaryngology, radiology, endocrinology, and ICU. Nuclear medicine, oncology, radiotherapy, psycho-oncology, and quality improvement units may apply for reference centers and will be defined in the future.

## Training and research

The scarcity of evidence in the literature regarding appropriate provision of training and research in accreditation means that any proposals are necessarily based upon existing guidelines, expert opinion, an attempt to be inclusive and pragmatic and, what is achievable within the various European healthcare systems.

### The trainee and training center

Although several countries (e.g., the Netherlands, UK, and the USA) are transitioning from a traditional time-based model of training to one that is competency-based [45], much of the literature on training is based upon observation of what residents and fellows achieve during a predetermined time (Gim et al. ESES working group submitted). Therefore, it may not be truly indicative of the number of procedures or duration of training required to gain operative competence. Furthermore, training involves other activities including accrual of non-technical and professional skills, evidence of research activity, and demonstration of knowledge. While the latter may be examined at the EBSQ or DES level, many of the other skills

are assumed rather than assessed. At present, the recommended minimum numbers as a main operator required for accreditation as a specialist are:

- Fifty thyroidectomies
- Two central neck dissections
- Two lateral neck dissections
- Fifteen parathyroidectomies (including 10 bilateral neck explorations)
- Two adrenalectomies
- Two GEP-NEN operations

Based upon these indicative numbers, there is a minimum caseload to which the trainee must be exposed, and this is likely to only be achievable in high-volume centers. There must also be opportunities for research, presentation to learned societies, and exposure to the broad range of surgical endocrine disease. Along with supervision and feedback from accredited surgical staff (see “Staff” above), competence centers provide a minimum caseload per annum as defined in Table 4.

The gradient (competence vs. procedure number) of learning curves for procedures in general surgery has been examined in general surgical procedures [46], and it may be that similar work in endocrine surgery will determine the true nature of skill acquisition for future endocrine surgery trainees. Therefore, the minimum indicative numbers required for training may change in light of evolving evidence.

## Research

Research drives innovation in patient care and is an integral part of surgical training. It is also an important component of continued professional development and a requirement for many European training programs. There was broad agreement among ESES respondents that both competence and future reference centers should participate in research activity to some degree. Following the panel discussion, it was proposed that competence centers should participate in the following research activities:

- Oral and poster communications to endocrine surgical conferences
- Local research

It is proposed that in the future, accredited reference centers should participate in the above and the following:

- Minimum of 1 peer-reviewed publication per annum
- Recruitment of patients to randomized or multicenter trials
- Registry (Eurocrine®) research
- Hosting of visiting surgeons

## Conclusions

Accreditation of clinics in Europe in the field of endocrine surgery should be implemented as one of several measures that aim to maintain and improve quality standards. Although local healthcare structures differ significantly, ESES members agree on a basic definition of high-quality care in endocrine surgery, necessary requirements, and evaluation procedures. The quality standards and requirements defined for the proposed accreditation model comply with detailed analysis of volume–outcome relations as well as training for endocrine surgery. The requirements for the application and the decision process must be unambiguous and transparent. However, in the process of implementing the proposed accreditation model, refinements will be necessary depending on results of audits performed in the initial round of accredited clinics. The implementation will therefore start with the accreditation of competence centers as a first stage. It is hoped that the criteria for reference centers will be agreed on and implemented as a second stage.

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## Compliance with Ethical Standards

**Conflict of Interest** The authors declare that they have no conflict of interest.

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