

F A Q ' s to the

Catalogue of Requirements for Head and Neck Cancer Centres Module in the Oncology Centre

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Within the framework of the certification procedure, questions regularly crop up which require an explanation of the Technical and Medical Requirements. This document contains answers to the questions which the centres can refer to when implementing, and the experts can refer to when assessing the Technical and Medical Requirements.

Version FAQ and Catalogue of Requirements

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The FAQs listed in this document are continuously checked to ensure that they are up to date and adapted in the event of changes to the Technical and Medical Requirements.

Overview of FAQ's

Catalogue of Requirements

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1.2 Interdisciplinary cooperation	1.2.1 a	Number of primary cases	03.06.2019
	1.2.2	Interdisciplinary pretherapeutic* and therapeutic tumour board	14.07.2016
1.4 Psycho-oncology	1.4.2	Documentation and Evaluation	21.09.2023
	1.4.3	Psycho-oncology resources	14.07.2016
1.7 Study management	1.7.3 a	Proportion of study patients	21.09.2023
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1.6. Patient involvement	1.61.1	-----	29.08.2024
1.7. Study management	1.7.3a	Proportion study patients	21.09.2023
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1.9 General care areas (pharmacy, nutritional counselling, speech therapy, ...)	1.9.1	Phoniatrics	02.03.2022
2.1 Consulting hours	2.1.4	Services/ Procedures consulting hours	14.07.2016
	2.1.5	Quality-determining procedures	19.07.2018
5. Surgical oncology	5.2	Surgical unit	14.01.2021

Indicator Sheet

Indicator		Last update
2a	Pretherapeutic tumour board	27.08.2020
9	Imaging of oral cavity cancer to determine N category	19.07.2018
10	Thorax CT to rule out pulmonary filiae in the case of oral cavity cancer	14.07.2016
11	Complete diagnostic report for oral cavity cancer	14.07.2016
12	Neck dissection in case of oral cavity cancer	19.07.2018
13	Radiotherapy to treat oral cavity cancer	24.08.2020
14	Post-operative radiotherapy or radio-chemotherapy for oral cavity cancer	09.10.2017
15	Dental examination prior to radiotherapy or radio-chemotherapy for oral cavity cancer	07.07.2020
18	Panendoscopy for laryngeal cancer	07.07.2020
20	Counselling by speech therapist/ speech scientists for laryngeal cancer	07.07.2020

FAQ's - Head and neck survey form

1.2 Interdisciplinary cooperation

Section.	Requirements	
1.2.1 a	<p>Number of primary cases</p> <ul style="list-style-type: none"> • 75 primary cases (= invasive neoplasms and in situ carcinomas of the upper aerodigestive tract (main nasal cavity and paranasal sinuses, oral cavity, pharynx and larynx, salivary glands) not including oesophagus ICD 10 list in the Data Sheet 	<p><u>FAQ (14.07.2016)</u> To which cancers do the cancers at the base of the tongue belong?</p> <p>Answer: The base of the tongue belongs to the oropharyngeal cancers, the anterior 2/3 of the tongue to the oral cavity cancer</p>
1.2.2	<p>Interdisciplinary pretherapeutic* and therapeutic tumour board</p> <p>A tumour board must be held at least once a week.</p> <p>Participants: Surgeon**, diagnostic radiologist, pathologist, radio-oncologist, haematologist, and oncologist</p> <p>Depending on the indication, other participants (nuclear medicine specialist, plastic surgeons, etc.) are to be invited.</p> <p>If the haematologist/oncologist is unable to attend the conference, he/she may be represented by the chemotherapy specialist who fills out/meets the requirements set out in section 6.2).</p> <p>*: after staging has been performed **: the case reviews for the ENT and OMS specialties are done together.</p>	<p><u>FAQ (14.07.2016)</u> Deviation in case of falling short of the participation quota of 80% per specialty</p>

1.4 Psycho-oncology

Section	Requirements	
1.4.2	<p>Documentation and Evaluation</p> <p>To identify the need for treatment, it is necessary to carry out a screening for psychological stress (see indicator "Psycho-oncological distress screening") and to document the result. The proportion of patients with excessive stress in the distress screening should be presented.</p> <p>Psycho-oncological counselling Psycho-oncological care, especially for patients with high distress scores in the distress screening, should be presented.</p>	<p><u>FAQ (21.09.2023)</u> How should the proportion of patients with excessive distress in distress screening and further psycho-oncological care be presented?</p> <p>Answer: The number of screened patients who have shown an excessive test should be described.</p> <p>The processes of psycho-oncological care should be described; the number of counselling sessions carried out should be recorded.</p> <p>See separate FAQ document on psycho-oncology.</p>

1.4 Psycho-oncology

Section	Requirements	
1.4.3	Psycho-oncology resources In line with demand at least 1 psycho-oncologist with the specified qualifications is available to the Centre (name to be provided). Human resources can be made available centrally; an organisation plan must be available.	FAQ (14.07.2016) Psycho-oncological care can be initiated or provided by all cooperation partners (incl. e.g. radiotherapy)

1.6.. Patient involvement

Section.	Requirements	
1.6.	If patient events are (co-)financed by industry, this fact including potential conflicts of interest of the speakers must be disclosed. The centre must rule out any direct influence on patients by industry representatives.	FAQ (29.08.2024) How can the Centre prove the exclusion of direct influence by industry representatives? Answer: Proof can be provided e.g. via internal compliance rules or alternatively via a self-disclosure by the centre. In this, the centre should provide information on free access to the event, excluding the industry exhibition/information stands and remarks on contact between industry representatives and patrons.

1.7 Study management

Section.	Requirements	
1.7.3 a	Proportion study patients Initial certification: patients must have been included in studies. after one year: at least 5% of primary cases	FAQ (31.08.2022) Can negatively screened study patients be counted?
1.7.3 b	Only the inclusion of patients in studies with an ethical vote counts as study participation (also non-interventional/diagnostic studies and prevention studies, healthcare research are recognised, biobank collections are excluded.	Answer Patients who have signed a informed consent form for screening for study participation can be counted for the numerator of the respective study indicator, even if the results of screening examinations performed with special diagnostics (no routine diagnostics) do not allow the patients to participate in the study.
1.7.3 c	All study patients can be taken into account when calculating the study rate (share study patients based on the Centre's primary case number). General preconditions for the definition of the study quota: <ul style="list-style-type: none"> • Patients can be counted 1x per study, time: Date of patient's informed consent. (Exception Patients CPM (=Centres for Personalised Medicine) see FAQ document). • Patients in a palliative and adjuvant situation can be counted, no limitations regarding stage of disease. • Patients who are taking part in several studies simultaneously can be counted several times. 	FAQ (21.09.2023) Can patients referred to a Centre for Personalised Medicine (CPM) for the purpose of complex diagnostics, interdisciplinary consultation and individual therapy recommendations who participate in a study there be counted towards the study quota of the sending centre? Answer: Yes, in this case the study inclusion can be counted by both the sending centre and the CPM. The other requirements for study inclusion according to the survey form will apply.

1.7 Study management

	<p>Information about ongoing studies is available at: https://www.krebsgesellschaft.de/deutsche-krebsgesellschaft-wtrl/deutsche-krebsgesellschaft/ueberuns/organisation/sektion-b-arbeitsgemeinschaften/iag-kht.html</p> <ul style="list-style-type: none"> • Study patients can be counted for 2 centres, provided that the sending centre itself conducts at least one study for patients of the haematological neoplasms centre. If this counting method is chosen (optional), the centre must show how many patients are included in studies at their own centre, sent to other centres/clinics to participate in studies and taken from other centres/clinics to participate in studies – see also Excel template Data Sheet. 	<p><u>FAQ (28.08.2023)</u> Can patients referred to a Centre for Personalized Medicine (CPM) for the purpose of complex diagnostics, interdisciplinary consultation and individual therapy recommendations who participate in a study there be counted for the study quota of the sending centre?</p> <p>Answer: Yes, in this case the study inclusion can be counted by both the sending centre and the CPM. The other requirements for study inclusion according to the Catalogue of Requirement apply.</p>
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1.9 General care areas (pharmacy, nutrition counselling, speech therapy, ...)

Section.	Requirements	
1.9.1	<p>Phoniatrics</p> <ul style="list-style-type: none"> • The diagnosis and treatment of speech, voice and swallowing disorders should be undertaken in cooperation with a phoniatrics department or a practice-based phoniatrician. • Details of any cooperation between phoniatrics, ENT/OMS and speech therapy must be provided. • In the clinics with a phoniatrics specialty, cooperation is mandatory. 	<p><u>FAQ (02.03.2022)</u> Does the additional title "Voice and Speech Disorders" fulfil the requirement for the qualification "Phoniatrics"?</p> <p>Answer: The requirement can also be fulfilled by medical specialists with the additional title "Voice and Speech Disorders" (WBO 1992) or medical specialists with the specialist title "Speech, Voice and Childhood Hearing Disorders" (WBO 2003).</p>

2.1 Consulting hours

Section.	Requirements	
2.1.4	<p>From the appointment during consulting hours, the following services/procedures are to be ensured:</p> <ul style="list-style-type: none"> • Consultative presentation of patients to OMS and/or ENT if possible on the same day; • B-mode and colour Doppler sonography, ≥5 MHz: Requirements for conduct: the requirements of the ultrasound agreement "criteria for assessing dignity" are to be met:(LINK); • Panendoscopy: Appointment scheduling <2 weeks; requirement for conduct: see section 5. • For ENT: <ul style="list-style-type: none"> • Magnifying laryngoscope; • Rigid laryngoscopy from different angles (e.g. 25°, 70°); • Flexible nasopharyngolaryngoscope. <p>For OMS: Orthopantomograph.</p>	<p>FAQ (14.07.2016) Is it compulsory for every patient to have a panendoscopy?</p> <p>Answer: No.</p>
2.1.5	<p>The following quality-determining procedures are to be described including details of responsibilities:</p> <ul style="list-style-type: none"> • Organisation/conduct ENT mirror examination/ panendoscopy (In line with the S3 Guidelines): <ol style="list-style-type: none"> a) a) Oral cavity cancer: "To rule out synchronous second tumours, an ear-nose-and-throat mirror examination (based on the findings using mirrors or radiological findings) where appropriate an endoscopy, is to be conducted as part of the primary diagnosis of oral cavity cancer. b) Laryngeal cancer: "The panendoscopy should be performed on patients with laryngeal cancer." c) Oropharyngeal/Hypopharyngeal cancer: "Panendoscopy should be performed as part of the primary diagnostic work-up for oropharyngeal and hypopharyngeal cancers. It is a central component of the primary diagnostic work-up for more precise staging of the primary tumour and for the detection of secondaries cancer. • Preparation of patients for the tumour board; • Inpatient admission for ENT und OMS; • Coordination of rehabilitation of chewing function. <p>Sufficient resources must be available to conduct the procedures.</p>	<p>FAQ (19.07.2018) Who performs the panendoscopy?</p> <p>Answer: Panendoscopy is performed by the ENT specialists.</p> <p>FAQ (19.07.2018) What are the definitions of ENT medical examination and panendoscopy?</p> <p>Answer: ENT medical examination (= mirror examination). Panendoscopy (pharynx, larynx, trachea, oesophagus) is under anaesthesia with a rigid/flexible endoscope).</p>

5. Surgical oncology

Section.	Requirements	
5.2	<p>Surgical unit If a unit (ENT and/or OMS) is involved in surgical care, at least 20 resections/year (removal of an invasive tumour/in situ tumour, primary cases/recurrences; biopsies are not included) must be documented.</p>	<p><u>FAQ (14.01.2021)</u> How are interventions that are performed jointly by ENT and OMS are performed together?</p> <p>Answer: Procedures performed in cooperation can be counted for both main surgeons. Furthermore, this surgery can be counted for the surgical expertise of both units (ENT and OMS).</p> <p><u>FAQ (07.07.2020)</u> Can panendoscopies be counted as a surgical expertise procedure?</p> <p>Asnwer: No, panendoscopies do not count.</p> <p><u>FAQ (30.04.2020)</u> Would a panendoscopy also count as a procedure to prove surgical expertise, especially if an OPS with "5-xxx" was used here?</p> <p>Answer:: No, panendoscopies do not count as surgical expertise.</p>

FAQ's – Indicator Sheet Head and Neck

2a	Pretherapeutic tumour board	Numerator	Primary cases of the denominator presented in the pre-therapeutic tumour board	<p><u>FAQ (27.08.2020)</u> Are primary cases with salivary gland tumours to be presented at the pre-therapeutic tumour board and counted for the index number?</p> <p>Answer: No, primary cases with salivary gland tumours do not have to be presented in the pre-therapeutic tumour board and are not included in the denominator of indicator 2a. Primary cases with a malignant salivary gland must be considered in indicator 2b.</p>
		Denominator	Primary cases without salivary gland tumours	
		Target value	≥ 95%	
9	Imaging of oral cavity cancer to determine N category	Numerator	Primary cases of the denominator with examination of the region from base of skull up to upper thoracic aperture with CT or MRI to determine the N category	<p><u>FAQ (19.07.2018)</u> Is sonography sufficient as an alternative to CT/MRI for observation of the N category in patients with oral cavity cancer?</p> <p>Answer: No, according to the guidelines of the S3 GL on oral cavity cancer, CT or MRI is required for lymph node diagnostics, and sonography alone is not sufficient. Only patients with lymph node staging by CT or MRI are to be considered for the indicators.</p>
		Denominator	Primary cases oral cavity cancer	
		Target value	≥ 90%	
10	Thorax CT to rule out pulmonary filiae in the case of oral cavity cancer	Numerator	Primary cases of the denominator with thorax CT to rule out pulmonary tumour (filiae, second cancer)	<p><u>FAQ (14.07.2016)</u> What is the correct counting method for the numerator of this indicator?</p> <p>Answer: Number of patients who received a thorax CT.</p>
		Denominator	Primary cases oral cavity cancer stages III + IV	
		Target value	≥ 90%	

FAQ's – Indicator Sheet Head and Neck

11	Complete diagnostic report for oral cavity cancer	Numerator	Primary cases of the denominator in which the histopathological diagnostic report is documented as follows: Tumour localisation, macroscopic tumour size, histological tumour type according to WHO, histological tumour grade, depth of invasion, lymph node invasion, blood vessel invasion and perineural invasion, local infiltrated structures, pT classification, indication of affected areas and infiltrated structures, R status, minimum safety margins in mm, pN classification extracapsular growth LN yes/no	<p><u>FAQ (14.07.2016)</u> How must this information be provided?</p> <p>Answer: As a collective statement. The submission of the pathology report must contain the information in full.</p> <p><u>FAQ (14.07.2016)</u> In the case of in situ cancer, L, V, Pn, depth of invasion, lymphatic vessel invasion, blood vessel invasion and perineural invasion as well as locally infiltrated structures cannot be specified because they do not exist. Are the pathological findings complete for in situ cancer even without this information?</p> <p>Answer: Yes, since this cannot be stated, the report is complete even without this information at the in situ and the in situ patient can appear in the numerator!</p>
		Denominator	Surgical primary cases oral cavity cancer	
		Target value	≥ 90%	

FAQ's – Indicator Sheet Head and Neck

12	Neck dissection in case of oral cavity cancer	Numerator	Primary cases of the denominator with no interruption of radiotherapy	<p><u>FAQ (19.07.2018)</u> How many lymph nodes are required for an elective neck dissection?</p> <p>Answer: According to the S3 guideline for oral cavity cancer, no minimum number of lymph nodes to be resected is defined. Resection should be performed according to the lymph node stations/levels defined in the guideline.</p> <p><u>FAQ (02.03.2022)</u> How are primary cases of the denominator with negative sentinel lymphnode to be considered?</p> <p>Answer: Surgical Primary cases with negative findings in the SLN biopsy are evaluated as patients with elective neck dissection and are included in the numerator.</p>
		Denominator	Primary cases oral cavity cancer and radiotherapy	
		Target value	No target value	

FAQ's – Indicator Sheet Head and Neck

13	Radiotherapy to treat oral cavity cancer	Numerator	Primary cases of the denominator with no interruption of radiotherapy	<p><u>FAQ (10/09/2019)</u> How is "without interruption of radiotherapy" defined?</p> <p>Answer: A non-interrupted radiation therapy is to be assumed if the actual radiation duration does not exceed the planned radiation duration by more than 1 calendar week.</p> <p><u>FAQ (24.08.2020)</u> Should the denominator also include patients who started radiotherapy and then discontinued it?</p> <p>Answer: No. Only those patients are included in the denominator who have received the planned radiation series.</p>
		Denominator	Primary cases oral cavity cancer and radiotherapy	
		Target value	≥ 80%	
14	Post-operative radiotherapy or radio-chemotherapy for oral cavity cancer	Numerator	Primary cases of the denominator with post-operative radiotherapy or radio-chemotherapy	<p><u>FAQ (09.10.2017)</u> Do in situ cancers with a narrow resection margin also count here?</p> <p>Answer: The indicators refer to invasive oral cavity cancer, which excludes in situ cancers.</p> <p><u>FAQ (09.10.2017)</u> What does "LN", nodal status (pN+) or lymphangiosis (L1) mean?</p> <p>Answer: In the certification system, LN always means lymph nodes.</p>
		Denominator	'Primary cases oral cavity cancer - T3/T4 category and/or - minimal (≤ 3mm) or positive resection margins - and/or perineural or vessel invasion - and/or positive LN	
		Target value	Target value ≥ 60%	

FAQ's – Indicator Sheet Head and Neck

15	Dental examination prior to radiotherapy or radio-chemotherapy for oral cavity cancer	Numerator	Primary cases of the denominator with dental examination prior to commencement of radiotherapy or radio-chemotherapy	<p><u>FAQ (07.07.2020)</u> Do patients without their own teeth also have to be seen by a dentist?</p> <p>Answer: Yes. Patients who supposedly no longer have their own teeth sometimes still have tooth remnants in their jaws.</p>
		Denominator	Primary cases oral cavity cancer and radiotherapy or radio-chemotherapy	
		Target value	≥ 95%	
18	Panendoscopy for laryngeal cancer	Numerator	Primary cases of the denominator with panendoscopy	<p><u>FAQ (07.07.2020)</u> Are primary cases with in situ laryngeal cancer also to be assigned to the denominator?</p> <p>Answer: Yes.</p>
		Denominator	Primary cases laryngeal cancer	
		Target value	Target value ≥ 90%	
20	Counselling by speech therapist/ speech scientists for laryngeal cancer	Numerator	Primary cases of the denominator with counselling by speech therapists/speech scientists for laryngeal cancer	<p><u>FAQ (08.09.2021)</u> Does the consultation have to be attended before the tumour resection in order to be counted in the counter?</p> <p>Answer: Nein</p>
		Denominator	Primary cases laryngeal cancer and therapy	
		Target value	90%	