EUROPEAN CANCER CENTRES

FAQs

Catalogue of Requirements for the Prostate Cancer Centres

of the German Cancer Society (*Deutschen Krebsgesellschaft* – DKG)

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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 (CR)

Version status FAQ: 14.12.2023

The FAQs in this document refer to the following documents which are now in force:

Catalogue of Requirements Prostate	Version O2	28.11.2023
Indicator Sheet Prostate	Version O1.2	14.12.2023

Overview of FAQs

Catalogue of Requirements

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	1.2.5	Tumor board	14.07.2016
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Indicator Sheet Prostate

If the R1 rate is exceeded for pT2 c/pN0 or Nx M0, a course of action was determined by the Certification Commission at the Prostate meeting on June 18, 2019: see page 12.

Indicator		Las update
10	Procedure for exceeding the target value	18.06.2019
Matrix outcome quality	Number of primary cases (post-therapy tumor-free)	27.04.2022

Further interpretations regarding the key figures prostate are not shown in this document, as the FAQs for this organ are stored in the specification document.
Download: http://www.xml-oncobox.de/de/Zentren/ProstataZentren

FAQs - Catalogue of Requirements Prostate Centres

1.2 Interdisciplinary cooperation

Section	Requirements		
1.2.1	**Number of cases in a Centre** Definition of "Centre case": • All patients with a primary diagnosis, localised and/or metastatic or recurrence or metastasis, who are presented in the Centre or at the tumour board and receive essential elements of the treatment there (surgery, radiotherapy, systemic therapy, watchful waiting active surveillance, etc.) • Patients and not stays or surgical procedures • A patient as a "Centre case" can only be counted for 1 Centre • Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not counted. • Interdisciplinary therapy plan must be available • Time of counting is the (first) presentation in the Centre • Histology report must be available. • Complete recording in the tumour documentation system Definition primary case (subset Centre case): • Patient with initial disease (incl. primary M1)	FAQ (14.07.2016) Are patients who were not presented at either the pretherapeutic or postoperative tumor conference primary cases (lack of interdisciplinary treatment plan)? Answer: These are to be counted as primary cases, but this may cause a discrepancy in the tumor conference metrics. FAQ (29.09.2017) Can pat. who do not receive guideline-guided therapy (e.g., HIFU pat.) be counted as a primary case? Answer: To the extent that this is done in the context of interventional studies, the patients may be counted.	
1.2.5	**Tumour board:** • The tumour board must be held weekly on the specialist level for the purposes of therapy planning. • The responsibilities for preparation, conduct and follow-up are to be laid down. • Participation rate of specialties > 95 %	FAQ (05.06.2018) Does the tumor board always have to take place in the mentioned rotation or can it be cancelled sometimes? Answer: If no patients are registered for the tumor board, it can be omitted.	
	Participants • Urology • radiotherapy) • Haematology/internal oncology • If the haematologist-oncologist cannot take part in the tumour board, s/he in exceptions can be represented by the urologist responsible for chemotherapy (qualification in line with Section 6.2). • Pathology • Radiology • Nuclear medicine Patients to be discussed:	FAQ (14.07.2016) Are patients with recurrence or distant metastasis who did not receive their primary treatment at the centre also to be presented? Answer: Yes (see definition of centre cases)	

	• All primary cases with a histology requiring discussion (≥pT3a, and/or R1 and/or pN+); generally, no binding obligation for other patients primarily receiving radiotherapy or who underwent curative surgical interventions • All recurrences or metastatic patients At least 10 patients with castration-resistant prostate cancer per year		
1.2.8	**Morbidity/mortality conference** • The participants in the tumour board are the invited participants. • The conference can be staged on the same date as the pre-therapeutic conference/tumour conference. • A list of participants must be kept. • M&M conferences are to be held at least twice a year. • Cases with a special history or a history that could be improved are to be discussed (e.g. grade 3 CTC). All patients who died after surgery/intervention must be discussed. • Minutes must be taken of the M&M conferences.	FAQ (29.10.2018) How should the requirement "Patients who died postoperatively/interventionally must be discussed in every case" be interpreted? What is the time period here? Answer: The corresponding patients are to be discussed in the next M&M conference. Since the M&M conference has to take place twice a year, the key figure year can usually be well covered. All patients who died postoperatively/interventionally within the calendar year (audit year before) must be discussed.	

1.4 Psycho-oncology

Section	Requirements		
1.4.1	**Psycho-oncology – Qualification** • qualified psychologists, qualified to perform a scientifically recognised psychotherapy or • physicians, • degree/master in social education, qualified to perform a scientifically recognised psychotherapy In each case with at least 1 additional training in psychotherapy: behavioural therapy, psychodynamic psychotherapy (analytical psychotherapy and depth psychology-based psychotherapy), systemic therapy, neuropsychological therapy (for psychological disorders caused by brain injuries), interpersonal therapy (IPT; for affective disorders and eating disorders), EMDR for the treatment of post-traumatic stress disorders, hypnotherapy for addictions and psychotherapeutic treatment for somatic disorders and specialty training in psycho-oncology (DKG recognized) Licensing: At least 1 person from the network´s psycho-oncological team (inpatient or outpatient) must be licensed (Psychological or medical psychotherapist) Currently recognised qualifications are upheld. Representatives of other psychosocial professions may be admitted if they can provide evidence of the above-mentioned additional qualifications. For this purpose an individual case examination is required.	FAQ (20.08.2018) Can the continuing education "Systemic Therapist" be recognized as psychotherapeutic continuing education? Answer: The continuing education "Systemic Therapy" can be recognized.	
1.4.2	**Psycho-oncology – Availability and access** Every patient must have prompt access in the vicinity to psycho-oncological counselling (must be documented). The threshold to these services must be low.	FAQ (21.07.2016) Can an on-site contact replace the screening? Answer: No. To identify the need for treatment, it is necessary to perform a standardized screening on psychological stress (see S3 guideline Psychooncology: e.g. Distress Thermometer o. HADS) and to document the result.	
1.4.4	**Scope of care provided** Psycho-oncological care, in particular for patients with excessive stress in the distress screening, must be presented.	FAQ (27.01.2023) How should the proportion of patients with excessive distress in distress screening and further psycho-oncological care be presented? Answer: The number of screened patients who have shown an excessive test should be described. The processes of psycho-oncological care should be described; the number of counselling sessions carried out should be recorded.	

		A separate FAQ document on psycho-oncology (Catalogue of Requirement and Indicators) is expected to be published in early 2024.	
	Frequency and length of counselling sessions must be recorded.		

1.6 Patient participation

Section	Requirements		
1.6.6	**Programmes for patients** At least once a year the Prostate Cancer Centre must hold scheduled events for patients and/or interested parties. If patient events are (co-)financed by industry, this fact, including potential conflicts of interest of the speakers, must be revealed. The Centre must exclude any direct influence on patients by industry representatives.	FAQ (27.09.2022) How can the centre prove the exclusion of direct influence by industry representatives? Answer: Proof can be provided, for example, 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 information on contact between industry representatives and patients.	

1.7 Study management

Section	Requirements		
1.7.5	Proportion of study patients Initial certification: at the time of initial certification ≥ 1 patient must already have been recruited for studies After 1 year: at least 5% of primary cases Only patients recruited for studies with a positive vote by the ethics committee are counted as study participants.	FAQ (16.08.2022) Can negatively screened study patients be counted? Answer Patients who have signed a informed consent form for the screening for study participation can be counted for the numerator of the respective study code, even if the patient's participation in the study is not possible due to the results of screening examinations carried out with special diagnostics (no routine diagnostics). FAQ (06.06.2023) 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:	
	In the event of non-compliance the Centre must meet the following requirements: The Centre must give the reason for non-compliance as well as any steps taken to promote participation in the studies. Only patients recruited for studies with a positive vote by the ethics committee count as participants (non-interventional/diagnostic studies are also recognised, biobank collections are excluded).		

	All study patients can be included when calculating the study rate (proportion of study patients in relation to all primary cases at the Centre). • Patients can be counted once per study; the relevant date is the date of patient consent (Exception Patients of CPM, see FAQ document). • Patients in palliative and adjuvant situations can be counted, no limitation on stages. • Patients who are recruited for a number of studies in parallel can be counted more than once.	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 data collection form apply FAQ (06.06.2023) Do the requirements “1 patient at initial certification” and “after 1 year: at least 5% of primary cases” also apply? Answer: If no patients are included in a study when a Penis Cancer Centre is certified (regardless of the audit phase), the centre must prove its activity for study inclusion. If there are no relevant studies, it must fulfil the study quota for the Prostate Cancer Centre.	

1.8 Nursing Care

Section	Requirements		
1.8.2	**Responsibilities / Tasks** Patient related tasks: • Conduct and evaluation of nursing and therapeutic measures • Identification of individual patient-based need for counselling. • The need for specialist counselling is to be defined already in the nursing concept of the Prostate Cancer Centre • Ongoing provision of information to and counselling of patients (and their family members) throughout the entire course of the disease and conduct, coordination and documentation of structured counselling sessions and instructions to patients and their family members. In line with the concept these activities may also be carried out by other long-serving specialist nurses with specialist oncological expertise. • Need-based participation in the tumour board (in line with Chapter 1.2) • Initiation of and participation in multi-professional case discussions/nursing visits. The objective is to find solutions in complex nursing situations. Criteria for the selection of patients are to be laid down. At least 12 case discussions/nursing visits are to be documented for each year and Centre Overarching activities: • A nursing concept is to be developed and implemented in which the organ-specific aspects of oncological nursing care are	FAQ (30.05.2018) Are 12 nursing rounds required per certified center/module? Answer: The required 12 nursing rounds apply to the entire uro-oncology center, i.e. nursing rounds from all modules can be considered collectively.	

	taken into account in the Prostate Cancer Centre. • Drawing up of specialist in-house standards based (if possible) on evidence-based guidelines (e.g. S3-LL Supportive) • Offer of consultation/supervision by colleagues • Networking between oncology nurses in a joint quality circle and participation in a quality circle in the Prostate Cancer Centre. • Interdisciplinary exchange with all professional groups involved in treatment • Responsibility for implementing the requirements for the specialist nurse who administers chemotherapy (see Section 6.2.2)		

2.2 Diagnostics

Section	Requirements		
2.2.9	Biopsy The correct indication for TRUS biopsy of the prostate must be shown. • At least 20% of the patients with punch biopsies must test positive. • At least 10 punch biopsy cylinders at least 1 cm in length must be taken. An evaluation must be submitted.	FAQ (12.04.2016) What about when multiple punch biopsies are taken from the region because none were 1 cm long. But together they add up to 1.0 cm? Does that count as a punch over 1cm in length? Answer: Yes, counts.	

5 Surgical Oncology

Section	Requirements		
5.2.1	**Surgical expertise** Number of prostatectomies during uro-oncology surgical procedures per year in the Centre (relative to primary cases and patients with new recurrence) • 50-74 prostatectomies: If only one surgeon is designated, a second surgeon needs to be designated by the next audit. (see CR Section 5.2.6) • ≥ 75 prostatectomies => designation of at least two surgeons Prostatectomies: • Radical prostatectomies (as primary intervention) • radical cystoprostatectomy with bladder cancer AND prostate carcinoma (primary intervention) • radical cystoprostatectomy with prostate carcinoma (primary intervention) • Radical prostatectomies (treatment of recurrences) - salvage prostatectomy Information on prostatectomies in basic data (Excel spreadsheet) • For 25-49 prostatectomies: individual case decision. The audit report must contain a recommendation for maintaining the certificate without any constraints (*inter alia* ≥ 100 primary cases). Designation of surgeons by name	FAQ (06.06.2023) Why can there be a discrepancy between the surgical expertise in the Data Sheet and in the Catalouge of Requirement? Answer: The surgical expertise in the Data Sheet refers to centre cases in the indicator year (primary cases counted = date of presentation at the centre); however, the information on surgeries in the Catalouge of Requirement provided by the named surgeons is generally based on the date of surgery. Discrepancies must be explained in the audit.	
5.2.8	**Prostate surgeons** Description of the prostate surgeons' specific qualifications (training) via curricula. • Radical prostatectomy (retropubic, perineal or laparoscopic) • Nerve-sparing radical prostatectomy • Removal of the pelvic lymph nodes (including extended-field lymphadenectomy)	FAQ (30.05.2018) If a designated prostate surgeon performs a Radical Cystoprostatectomy for prostate cancer, can this surgery also count for surgical expertise of the urinary bladder?	

	• Transurethral palliative therapy of prostate carcinoma (in particular transurethral resection of the prostate) • Monitoring of complications after surgery • Metastatic surgery At least 1 dedicated prostate training event for each surgeon each year (length > 0.5 day) Name of surgeons in table Prostate surgeons (at the end of the section)	Answer: If a surgeon is designated for both modules, performing cystoprostatectomy may be counted for both prostate (prostatectomy) and urinary bladder (cystectomy) surgical expertise.	

6.2 Organ-specific oncologic pharmacotherapy

Section	Requirements		
6.2.1	**Specialist's qualifications:** Specialist in internal medicine, haematology and oncology or specialist in radiotherapy or specialist in urology Requirements for urology specialist • Further qualification in medical tumour therapy; alternative: participation in the "Oncology Agreement", Annex 7 to the Federal Collective Agreements, regional implementation and • 5 years' experience in medical tumour therapy of prostate carcinoma (documentation) The specialists designated here must actively carry out the drug-based tumour therapy. Responsibility must not be delegated to physicians who do not have the above-mentioned qualification.	FAQ (18.06.2019) Does the urology specialist still need to fulfill the requirement for the additional designation of drug tumor therapy? Answer: In accordance with the 2018 Model Advanced Training Regulations, the Medicinal Tumor Therapy qualification will in future already be an integral part of the advanced training in urology. In this respect, physicians who are trained according to the new model further training regulations (2018) will no longer be required to acquire the additional designation Medicinal Tumor Therapy.	

7 Radio-oncology

Section	Requirements		
7.3	Expertise Radiotherapy Prostate Cancer • Definitive or postoperative (adjuvant or salvage) radiotherapy: at least 50 cases/year; For 25-49 cases/year: at least 75 definitive or postoperative radiotherapy cases in the last 5 years before the audit. • Prerequisite: Recommendation in the audit report for granting/maintaining the certificate without restriction. Network structure see section "7.4 Network".	FAQ (26.04.2017) How is salvage radiotherapy differentiated from adjuvant radiotherapy? Response: Radiation therapy is salvage therapy, • When radiation therapy is given for a persistent PSA level, or • if the radiotherapy is given after a diagnosis of biochemical recurrence or • if the radiotherapy is performed > 6 months after surgery. is performed.	

7.11	Expertise Brachytherapy (optional) • LDR brachytherapy (permanent seedim- • plantation) • HDR brachytherapy Expertise LDR/HDR must be proven according to the G-BA decision of 18.06.2015 (guideline value without consideration of special regulations is a single proof of at least 100 therapies performed within the last 5 years).	FAQ (14.07.2016) Performing brachytherapy is optional - why is it necessary to formulate an expertise? Response: When brachytherapy is offered, the appropriate expertise must also be provided.	

8 Pathology

Kap.	Anforderungen		
8.11	Findings report punch biopsy: • The result of the preoperative histology is available within 5 working days. • Positions must be labeled according to clinical indications. • Processing with retention of position labeling. • Number u. Localization of carcinoma-positive tissue samples. • **Estimation of percentage of total carcinoma area/total punch area**. • Gleason grading according to the modifications consented by ISUP 2005. Indication for each tumor-affected stanza separately. • Lymphatic (L) and venous (V) invasion (L0 or L1, V0 or V1). • Perineural infiltration (Pn0 or Pn1), • if assessable, capsular infiltration, cross-capsular growth, and seminal vesicle infiltration should be indicated.	FAQ 09/29/2017 To what does the percentage of total carcinoma area/total punch cylinder area refer: to all punch cylinders together or to the respective punch cylinder. Response: For the pathology report: it refers to the respective punch cylinder.	

FAQ – Indicator Sheet Prostate

10	Record of R1 resections for pT2 c / pN0 or Nx M0	Numerator	Operations of the denominator with R1	FAQ (18.06.2019): How will an overrun of the target be handled? Answer: - Centers exceeding the target have to present their R1 cases differentiated by width (≤ / > 3 mm) and occurrence (unifocal / multifocal) of R1 positive incision margins for the audit. - Centers with a majority of R1 cases with positive incision margins > 3 mm and/or a majority of multifocal R1 cases will receive a deviation of the target. and - If the majority of R1 cases are multifocal, the auditor will decide on the further procedure depending on the situation on site (e.g. measures taken, patient collective of the center, etc.).
		Denominator	Operations on primary cases with pT2 c/pN0 or Nx M0	
		Target value	≥ 15%	

Matrix	FAQ (27.04.2022): Question: Which primary cases are considered post-therapy tumour-free? Response: • Pat. with R0 resection after radical prostatectomy/cystoprostatectomy, without metastases. • Patients with R1 resection after radical prostatectomy/cystoprostatectomy and adjuvant radiotherapy and at least 1 follow-up in the year before the indicator year (= calendar year preceding the indicator year) without recurrence and without metastases. • Patients with definitive radiotherapy and at least 1 follow-up in the year before the indicator year (= calendar year preceding the indicator year) without recurrence and without metastases. A recurrence after definitive or adjuvant radiotherapy is present if the PSA value has increased by 2ng/ml in the course of the follow-up compared to the nadir (lowest value) (Phoenix definition).