

## 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: 31.08.2022

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

| Catalogue of Requirements Prostate | Version N1.1 | 31.08.2022 |
|------------------------------------|--------------|------------|
| Indicator Sheet Prostate           | Version N1.1 | 31.08.2022 |



#### **Overview of FAQs**

#### Catalogue of Requirements

| Section CR                                   |       | Requirement                     | Last update |
|--|-------|---------------------------------|-------------|
| 1.2 Interdisciplinary cooperation            | 1.2.1 | Number of cases in a Centre     | 29.09.2017  |
|  | 1.2.5 | Tumor board                     | 14.07.2016  |
|  | 1.2.8 | Morbidity/mortality conference  | 29.10.2018  |
| 1.4 Psycho-oncology                          | 1.4.1 | Psycho-oncology – Qualifikation | 20.08.2018  |
|  | 1.4.8 | Documentation and evaluation    | 21.07.2016  |
| 1.8 Nursing care                             | 1.8.2 | Responsibilities / Tasks        | 30.05.2018  |
| 2.2 Diagnostics procedures                   | 2.2.9 | Biopsy                          | 12.04.2016  |
|  | 5.2.8 | Prostate surgeons               | 30.05.2018  |
| 6.2 Organ-specific oncologic pharmacotherapy | 6.2.1 | Specialist's qualification      | 18.06.2019  |
| 7 Radio-oncology                             | 7.3   | Radiation Therapy Expertise     | 26.04.2017  |
|  | 7.11  | Expertise Brachytherapy         | 14.07.2016  |
| 8 Pathology                                  | 8.11  | Report of findings punch biopsy | 29.09.2017  |

#### 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 10.

| Indicator                 |   | Las update |
|---------------------------|---|------------|
| 10                        | Procedure for exceeding the target value          | 18.06.2019 |
| Matrix outcome<br>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: <u>http://www.xml-oncobox.de/de/Zentren/ProstataZentren</u>



#### FAQs - Catalogue of Requirements Prostate Centres

#### 1.2 Interdisciplinary cooperation

| Section | Requirements  |  |
|---------|---|--|
| 1.2.1   | <ul> <li>Number of cases in a Centre Definition of "Centre case": <ul> <li>All patients with a primary diagnosis, <ul> <li>localised and/or metastatic or recurrence or</li> <li>metastasis, who are presented in the Centre</li> <li>or at the tumour board and receive essential</li> <li>elements of the treatment there (surgery,</li> <li>radiotherapy, systemic therapy, watchful</li> <li>waiting active surveillance, etc.)</li> </ul> </li> <li>Patients and not stays or surgical <ul> <li>procedures</li> <li>A patient as a "Centre case" can only be</li> <li>counted for 1 Centre</li> </ul> </li> <li>Patients, who are only presented for the <ul> <li>purposes of seeking a second opinion or for</li> <li>the purposes of consultation, are not</li> <li>counted.</li> </ul> </li> <li>Interdisciplinary therapy plan must be <ul> <li>available</li> </ul> </li> <li>Time of counting is the (first) presentation in</li> <li>the Centre</li> <li>Histology report must be available.</li> <li>Complete recording in the tumour</li> <li>documentation system</li> </ul> </li> <li>Definition primary case (subset Centre case): <ul> <li>Patient with initial disease (incl. primary M1)</li> </ul> </li> </ul> | FAQ (14.07.2016)Are patients who were not presented at eitherthe pretherapeutic or postoperative tumorconference primary cases (lack ofinterdisciplinary treatment plan)?Answer:These are to be counted as primary cases, butthis may cause a discrepancy in the tumorconference metrics.FAQ (29.09.2017)Can pat. who do not receive guideline-guidedtherapy (e.g., HIFU pat.) be counted as aprimary case?Answer:To the extent that this is done in the context ofinterventional studies, the patients may becounted. |
| 1.2.5   | Tumour board:   | FAQ (05.06.2018)   |
| a)      | <ul> <li>The tumour conference must be held once a month on the specialist level for the purposes of therapy planning.</li> <li>The responsibilities for preparation, conduct and follow-up are to be laid down.</li> <li>Participation rate of specialties &gt; 95 %</li> </ul>  | Does the tumor board always have to take<br>place in the mentioned rotation or can it be<br>cancelled sometimes?<br>Answer:<br>If no patients are registered for the tumor board,<br>it can be omitted.  |



#### 1.2 Interdisziplinäre Zusammenarbeit

| Section | Requirements  |  |
|---------|---|--|
|         | <ul> <li>Participants:</li> <li>Urology</li> <li>radiotherapy)</li> <li>Haematology/internal oncology</li> <li>If the haematologist-oncologist cannot take part in the conference, s/he can be represented by the urologist responsible for chemotherapy (qualification in line with Section 6.2).</li> <li>Pathology</li> </ul>  | FAQ (14.07.2016)Are patients with recurrence or distant<br>metastasis who did not receive their primary<br>treatment at the center also to be presented?Response:<br>Yes (see definition of center cases).   |
|         | <ul> <li>Patients to be discussed:</li> <li>All primary cases with a histology requiring discussion (&gt;pT3a, R1, pN+); generally, no binding obligation for other patients primarily receiving radiotherapy or who underwent curative surgical interventions</li> <li>All recurrences or metastatic patients</li> <li>At least 10 patients with castration-resistant prostate cancer per year</li> </ul>          |  |
| 1.2.8   | <ul> <li>Morbidity/mortality conference</li> <li>The participants in the tumour board are<br/>the invited participants.</li> <li>The conference can be staged on the same<br/>date as the pre-therapeutic</li> </ul>  | FAQ (29.10.2018)<br>How should the requirement "Patients who died<br>postoperatively/interventionally must be<br>discussed in every case" be interpreted? What<br>is the time period here?   |
|         | <ul> <li>conference/tumour conference.</li> <li>A list of participants must be kept.</li> <li>M&amp;M conferences are to be held at least twice a year.</li> <li>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.</li> <li>Minutes must be taken of the M&amp;M conferences.</li> </ul> | Answer:<br>The corresponding patients are to be discussed<br>in the next<br>M&M conference. Since the M&M conference<br>has to take place twice a year, the key figure<br>year can usually be well covered.<br>All patients who died<br>postoperatively/interventionally within the<br>calendar year (audit year before) must be<br>discussed. |



#### FAQs Catalogue of Requirements - Prostate

#### 1.4 Psycho-oncology

| Section | Requirements   | Explanatory remarks of the Prostate Cancer<br>Centre   |
|---------|--|--|
| 1.4.1   | <ul> <li>Psycho-oncology – Qualification</li> <li>qualified psychologists, qualified to perform a scientifically recognised psychotherapy or</li> <li>physicians,</li> <li>degree/master in social education, qualified to perform a scientifically recognised psychotherapy</li> <li>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)</li> <li>Licensing: At least 1 person from the network's psychotherapist)</li> <li>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.</li> </ul> | 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   | <b>Psycho-oncology – Availability and access</b><br>Every patient must have prompt access in the<br>vicinity to psycho-oncological counselling (must<br>be documented). The threshold to these services<br>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<br>necessary to perform a standardized screening<br>on psychological stress (see S3 guideline<br>Psychooncology: e.g. Distress Thermometer o.<br>HADS) and to document the result. |



#### 1.8 Nursing Care

| Section | Requirements  |  |
|---------|---|--|
| 1.8.2   | Responsibilities / Tasks  | FAQ (30.05.2018)                                 |
|         | Patient related tasks:  | Are 12 nursing rounds required per certified     |
|         | Conduct and evaluation of nursing and   | center/module?                                   |
|         | therapeutic measures  |  |
|         | • Identification of individual patient-based need   | Answer:  |
|         | for counselling.  | The required 12 nursing rounds apply to the      |
|         | • The need for specialist counselling is to be  | entire uro-oncology center, i.e. nursing rounds  |
|         | defined already in the nursing concept of the   | from all modules can be considered collectively. |
|         | 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   |  |
|         | taken into account in the Prostate Cancer   |  |
|         | Centre.   |  |
|         | <ul> <li>Drawing up of specialist in-house standards</li> </ul>                                       |  |
|         | based (if possible) on evidence-based   |  |
|         | guidelines (e.g. S3-LL Supportive)  |  |
|         | <ul> <li>Offer of consultation/supervision by</li> </ul>  |  |
|         | colleagues  |  |
|         | <ul> <li>Networking between oncology nurses in a</li> </ul>   |  |
|         | joint quality circle and participation in a   |  |
|         | quality circle in the Prostate Cancer Centre.   |  |
|         | <ul> <li>Interdisciplinary exchange with all</li> </ul>   |  |
|         | <ul> <li>Interdisciplinary exchange with all<br/>professional groups involved in treatment</li> </ul> |  |
|         |   |  |
|         | Responsibility for implementing the     requirements for the encodelist nurse who                     |  |
|         | requirements for the specialist nurse who   |  |
|         | administers chemotherapy (see Section   |  |
|         | 6.2.2)  |  |



#### 2.2 Diagnostics

| Section | Requirements  | Explanatory remarks of the Prostate Cancer<br>Centre  |  |
|---------|---|---|--|
| 2.2.10  | <ul> <li>Biopsy<br/>The correct indication for TRUS biopsy of the<br/>prostate must be shown.</li> <li>At least 20% of the patients with punch<br/>biopsies must test positive.</li> <li>At least 10 punch biopsy cylinders at least 1<br/>cm in length must be taken.</li> <li>An evaluation must be submitted.</li> </ul> | FAQ (12.04.2016)What about when multiple punch biopsies are<br>taken from the region because none were 1 cm<br>long. But together they add up to 1.0 cm? Does<br>that count as a punch over 1cm in length?Answer:<br>Yes, counts. |  |

#### 5 Surgical Oncology

| Section | Requirements   |   |  |
|---------|--|---|--|
| 5.2.8   | <ul> <li>Prostate surgeons Description of the prostate surgeons' specific qualifications (training) via curricula. <ul> <li>Radical prostatectomy (retropubic, perineal or laparoscopic)</li> <li>Nerve-sparing radical prostatectomy</li> <li>Removal of the pelvic lymph nodes (including extended-field lymphadenectomy)</li> <li>Transurethral palliative therapy of prostate carcinoma (in particular transurethral resection of the prostate) <ul> <li>Monitoring of complications after surgery</li> <li>Metastatic surgery</li> <li>At least 1 dedicated prostate training event for each surgeon each year (length &gt; 0.5 day)</li> </ul> Name of surgeons in table Prostate surgeons (at the end of the chapter)</li></ul></li></ul> | FAQ (30.05.2018)<br>If a designated prostate surgeon performs a<br>Radical Cystoprostatectomy for prostate cancer,<br>can this surgery also count for surgical expertise<br>of the urinary bladder?<br>Answer:<br>If a surgeon is designated for both modules,<br>performing cystoprostatectomy may be counted<br>for both prostate (prostatectomy) and urinary<br>bladder (cystectomy) surgical expertise. |  |

#### 6.2 Organ-specific oncologic pharmacotherapy

| Section | Requirements | Explanatory remarks of the Prostate Cancer<br>Centre |  |
|---------|--------------|--|--|
|---------|--------------|--|--|



| 6.2.1 | Specialist's qualifications:   | FAQ (18.06.2019)  |  |
|-------|--|---|--|
|       | <ul> <li>Specialist's qualifications:</li> <li>Specialist in internal medicine, haematology and oncology or specialist in radiotherapy or specialist in urology</li> <li>Requirements for urology specialist</li> <li>Further qualification in medical tumour therapy; alternative: participation in the "Oncology Agreement", Annex 7 to the Federal Collective Agreements, regional implementation and</li> <li>5 years' experience in medical tumour therapy of prostate carcinoma (documentation)</li> <li>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.</li> </ul> | Does the urology specialist still need to fulfill the<br>requirement for the additional designation of drug<br>tumor therapy?<br>Answer:<br>In accordance with the 2018 Model Advanced<br>Training Regulations, the Medicinal Tumor<br>Therapy qualification will in future already be an<br>integral part of the advanced training in urology.<br>In this respect, physicians who are trained<br>according to the new model further training<br>regulations (2018) will no longer be required to<br>acquire the additional designation Medicinal<br>Tumor Therapy. |  |
|       |  |   |  |

#### 7 Radio-oncology

| Section | Requirements   |  |  |
|---------|--|--|--|
| 7.3     | <ul> <li>Expertise Radiotherapy Prostate Cancer <ul> <li>Definitive or postoperative (adjuvant or salvage) radiotherapy: at least 50</li> <li>cases/year;</li> <li>For 25-49 cases/year: at least 75 definitive or postoperative radiotherapy cases in the last 5 years before the audit.</li> <li>Prerequisite: Recommendation in the audit report for granting/maintaining the certificate without restriction.</li> </ul> </li> <li>Network structure see section "7.4 Network".</li> </ul> | <ul> <li><u>FAQ (26.04.2017)</u><br/>How is salvage radiotherapy differentiated from adjuvant radiotherapy?</li> <li><u>Response:</u><br/>Radiation therapy is salvage therapy,</li> <li>When radiation therapy is given for a persistent PSA level, or</li> <li>if the radiotherapy is given after a diagnosis of biochemical recurrence or</li> <li>if the radiotherapy is performed &gt; 6 months after surgery.</li> </ul> |  |
| 7.11    | <ul> <li>Expertise Brachytherapy (optional)</li> <li>LDR brachytherapy (permanent seedim-<br/>plantation)</li> <li>HDR brachytherapy</li> </ul> Expertise LDR/HDR must be proven according to<br>the G-BA decision of 18.06.2015 (guideline value<br>without consideration of special regulations is a<br>single proof of at least 100 therapies performed<br>within the last 5 years).  | <ul> <li><u>FAQ (14.07.2016)</u></li> <li>Performing brachytherapy is optional - why is it necessary to formulate an expertise?</li> <li><u>Response:</u></li> <li>When brachytherapy is offered, the appropriate expertise must also be provided.</li> </ul>  |  |



| Kap. | Anforderungen  |  |
|------|--|--|
| 8.11 | <ul> <li>Findings report punch biopsy:</li> <li>The result of the preoperative histology is available within 5 working days.</li> <li>Positions must be labeled according to clinical indications.</li> <li>Processing with retention of position labeling.</li> <li>Number u. Localization of carcinomapositive tissue samples.</li> <li>Estimation of percentage of total carcinoma area/total punch area.</li> <li>Gleason grading according to the modifications consented by ISUP 2005. Indication for each tumor-affected stanza separately.</li> <li>Lymphatic (L) and venous (V) invasion (L0 or L1, V0 or V1).</li> <li>Perineural infiltration (Pn0 or Pn1), o if assessable, capsular infiltration, cross-capsular growth, and seminal vesicle infiltration should be indicated.</li> </ul> | 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<br>resections for pT2 c /<br>pN0 or Nx M0 | Numerator    | Operations of the denominator with R1                     | FAQ (18.06.2019):<br>How will an overrun of the target be<br>handled?   |
|----|--|--------------|---|---|
|    |  | Denominator  | Operations on primary<br>cases with pT2 c/pN0 or<br>Nx M0 | Answer:<br>- Centers exceeding the target have to   |
|    |  | Target value | ≥ 15%   | present their R1 cases differentiated by<br>width (≤ / > 3 mm) and occurrence<br>(unifocal / multifocal) of R1 positive<br>incision margins for the audit.<br>- Centers with a <u>majority of R1 cases with</u><br><u>positive incision margins &gt; 3 mm and/or a</u><br><u>majority of multifocal R1 cases will receive</u><br><u>a deviation of the target.</u><br>and<br>- If the <u>majority of R1 cases are multifocal</u><br>the auditor will decide on the further<br>procedure depending on the situation on<br>site (e.g. measures taken, patient<br>collective of the center, etc.). |

| 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).   |