

## Basic Data Prostate

Reg. No.	Not listed <span style="color: green;">i</span>	(Template certificate) <span style="color: green;">i</span>
Centre		
Location		
Contact		Date recorded <span style="color: green;">i</span>
		Date of initial certification <span style="color: green;">i</span>
		Indicator year <span style="color: green;">i</span>
		----- <span style="color: green;">i</span>
		2021 <span style="color: green;">i</span>

Country	
Tumour documentation system	XML-OncoBox Prostate <span style="color: green;">i</span>
	Yes

Centre patient with prostate carcinoma <sup>1)</sup>	non-interventional <sup>2)</sup>		interventional <sup>2)</sup>								systemic treatment only <sup>4)</sup>	other treatment <sup>5)</sup>	Total
	Active Surveillance	Watchful Waiting	local treatment of prostate										
			radical prostatectomy (RPE)	radical cystoprostatectomy (RCE) due to PCa	Incidental finding after RCE	Definitive percutaneous radiotherapy	LDR brachytherapy	HDR brachytherapy	other local therapy <sup>3)</sup>				

a) Primary cases - patients <sup>1)</sup>													
locally confined (T1/2-N0-M0)	low risk <sup>6)</sup>	<span style="color: green;">i</span>											<span style="color: green;">i</span>
	intermediate risk <sup>6)</sup>												<span style="color: green;">i</span>
	high risk <sup>6)</sup>												<span style="color: green;">i</span>
locally advanced (T3/4-N0-M0)													
advanced (N1, M0)													
advanced (N0/1, M1)													
non classifiable <sup>7)</sup>													
<b>Total primary cases</b>													<span style="color: green;">i</span>
proportion of pat. with "AS/WW"													

b) Patients with new recurrence and / or distant metastasis in calendar year <sup>1)</sup>													
patient with new recurrence													<span style="color: green;">i</span>
patient with new distant metastasis													<span style="color: green;">i</span>
<b>Total pat. (no multiple counting)</b>													
proportion of pat. with concurrent status of primary case													

<b>Total centre patients</b> (row 40 + 47 - 49)													
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<b>Surgical expertise</b> (basis for CR 5.2.1)	RPE (sum of F40 + F47)												<span style="color: green;">i</span>
	RCE due to Pca (sum of G40 + G47)												
	Incidental finding after RCE (sum from H40 + H47)												

The TNM classification of malignant tumours, 8th edition 2017, the ICD classification ICD-10-GM 2021 (DIMI) and the OPS classification OPS 2022 (DIMI) are the basis for this Catalogue of Requirements.

**Processing instructions:**

1) Patients can be counted as a primary case (section a) only once per calendar year. Patients with "recurrence and / or distant metastasis" are counted in section b) - if applicable, patients can be counted in row 45 AND 46 each. If a primary case patient also received the diagnosis "recurrence and / or distant metastasis", he can be counted under a) and b). The definition of centre patient and primary case can be found under 1.2.1 in the catalogue of requirements. The counting time point is the first visit at the centre.

2) Each patient can only be assigned to one therapy category per calendar year. The patient is assigned to the main therapy. For instance:  
- The patient receives a percutaneous radiotherapy and in addition a hormonal therapy, then the patient is counted in column I (definitive percutaneous radiotherapy)  
- In January, the patient is treated according to AS / WW and in October the patient receives a RPE on his own demand. This patient is to be registered only in column F (RPE).

3) i.e. HIFU,....

4) i.e. only hormone therapy, chemotherapy

5) Other treatment; i.e. palliative radiotherapy of bone metastasis, Best Supportive Care

6) Classification of primary cases according to the clinical tumour status:

Risk classification: low risk: PSA  $\leq$  10ng/ml and Gleason score 6 and cT-category <2a; intermediate risk: PSA>10-20 ng/ml or Gleason score 7 or cT 2b; high risk: PSA >20ng/ml or Gleason score  $\geq$  8 or cT 2c

If allocation of patients to multiple groups is possible, the following rules apply:

If one condition for high risk applies ("or" connection): classify as high risk

If all conditions of low risk apply ("and" connection): classify as low risk

7) only applicable in exceptional cases; i.e. long term hormonal therapy before first diagnosis, incidental diagnosis after radical cystectomy

Legend:

RPE – radical prostatectomy

RCE – radical cystoprostatectomy

LDR – low-dose rate

HDR – high dose rate

Pca – prostate carcinoma

AS – active surveillance

WW – watchful waiting

The fields are inter-dependent. Each line should, therefore, be completely processed from left to right and continuously from top to bottom.

Grey fields must be processed.

The processing of the Excel template should be done with Microsoft Office 2010 or one of the later versions.

Microsoft Office 2007 can be used with some constraints (e.g. information buttons are not displayed).

Earlier versions of Microsoft Office 2007 are not suitable for processing the Excel template.

All numbers and texts must be entered manually (not using copy / paste function; with exception of data imported from OncoBox).

Each change to the basic data leads to a change in the Data Sheet.

The document "Specifications Data Quality" sets out the basic principles for data assessment as part of the audit process.

In particular details are given of how to deal with Indicators where the target value is not met (download from [www.onkozert.de](http://www.onkozert.de); section Remarks).

## Data Sheet Prostate

Centre

Reg. No.  Date recorded

IN	CR/ GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausibility unclear	Target value	Plausibility unclear	Current value	Data quality
1 a)	1.2.1	Number of primary cases of prostate carcinoma	See target value	Primary cases	----		≥ 100		Number 0	Incomplete
1 b)	1	Distribution of primary cases with locally confined prostate carcinoma and low risk	----	Primary cases with locally confined PCa and low risk (PSA ≤ 10ng/ml and Gleason score 6 and cT category ≤ 2a)	----		No target value		Number 0	Incomplete
	2	Distribution of primary cases with locally confined prostate carcinoma and intermediate risk	----	Primary cases with locally confined Pca and intermediate risk (PSA > 10-20 ng/ml or Gleason score 7 or cT 2b)	----		No target value		Number 0	Incomplete
	3	Distribution of primary cases with locally confined prostate carcinoma and high risk	----	Primary cases with locally confined Pca and high risk (PSA > 20 ng/ml or Gleason score ≥ 8 or cT2c)	----		No target value		Number 0	Incomplete
1c)		Patients with new recurrence and/or distant metastasis	----	Patients with new recurrence and/or distant metastasis	----		No target value		Number 0	Incomplete

IN	CR/GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausibility unclear	Target value	Plausibility unclear	Current value		Data quality	
2	1.2.4	Presentation at the weekly pre-therapeutic tumour board	Presentation of as many patients as possible in the pretherapeutic tumour board (via urology)	All patients of the denominator presented in the pre-therapeutic tumour board	All patients who present urology or radiotherapy (e.g. via referral) and have been diagnosed as primary cases in line with CR 1.2.1 (without primary M1, without incidental findings according to RZE)		≥ 95%		Numerator		Incomplete	
									Denominator			
									%	n.d.		
			Presentation of as many patients as possible in the pretherapeutic tumour board (via radiotherapy)						Numerator			Incomplete
									Denominator			
									%	n.d.		
3	1.2.5	Presentation in the monthly tumour board	Presentation of as many patients as possible in the tumour board	All patients of the denominator presented in the tumour board (post OP: operated primary cases and pre-therapeutic: primary M1, recurrence / distant metastasis)	Primary cases > pT3a and / or R1 and / or pN+		100%		Numerator		Incomplete	
									Denominator			
									%	n.d.		
			Presentation of as many patients as possible in the tumour board (primary cases) as possible in the tumour board						Numerator		Incomplete	
									Denominator			
									%	n.d.		
			Presentation of as many patients as possible in the tumour board (primary cases) as possible in the tumour board						Numerator		Incomplete	
									Denominator	0		
			Patients with new recurrence and/or distant metastasis (=Indicator 1c)						Numerator		Incomplete	
Denominator	0											

IN	CR/ GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausibility unclear	Target value	Plausibility unclear	Current value		Data quality
									%	n.d.	
4	GL QI	Active surveillance (AS)	Adequate rate of patients under AS	Primary cases of the denominator under AS	Primary cases with locally confined PCa and low risk (PSA ≤ 10ng/ml and Gleason score 6 and cT category ≤ 2a)	< 0,01%	No target value	> 90%	Numerator	0	Incomplete
									Denominator	0	
									%	n.d.	
5	GL QI	Percutaneous radiotherapy with hormone ablation therapy for locally confined PCa with high risk	As high a percentage as possible of patients with a high risk profile and percutaneous radiation + hormonal therapy	Primary cases of the denominator with additional neo- and / or adjuvant hormone ablation therapy	Primary cases with prostate carcinoma T1/2, N0, M0 with high risk (PSA >20ng/ml or Gleason score ≥ 8 or cT category 2c) and percutaneous radiotherapy	< 90%	No target value		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
6	1.4.4	Psychooncologic care (consultation ≥ 25 min.)	Appropriate rate of psycho-oncological counselling	Patients of the denominator who received psycho-oncologic care (in- or outpatient setting) (duration of consultation ≥ 25 min)	Primary cases (= Indicator 1a) and patients with new recurrence and/or distant metastasis (= Indicator 1c)	< 4%	No target value	> 80%	Numerator		Incomplete
									Denominator	0	
									%	n.d.	
7	1.5.2	Counselling social service	Adequate rate of counselling by social services	Patients of the denominator who received social service counselling (in- or outpatient setting)	Primary cases (= Indicator 1a) and patients with new recurrence and/or distant metastasis (= Indicator 1c)	< 50%	No target value		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
8	1.7.5	Share of study patients	Inclusion of as many patients as possible in studies	Patients who were included in a study with an ethical vote	Primary cases (= Indicator 1a)				Numerator		Incomplete
									Denominator	0	
									%	n.d.	

IN	CR/ GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausibility unclear	Target value	Plausibility unclear	Current value		Data quality
9	5.2.1	Number of prostatectomies at the centre	See target value	Total number of radical prostatectomies / cystoprostatectomies (see basic data)	-----		≥ 50		Number	0	Incomplete
10		Record of R1 resections for (y)pT2 c / pN0 or Nx M0	Max. 15% rate of R1 for (y)pT2 c/pN0 or Nx M0	Operations of the denominator with R1	Operations on primary cases with (y)pT2 c/pN0 or Nx M0		≤ 15%		Numerator		Incomplete
									Denominator		
									%	n.d.	
11		Definitive radiotherapy	Information on primary cases with definitive radiotherapy	Primary cases of the denominator with definitive radiotherapy	Primary cases (= Indicator 1a)	< 10%	No target value	> 90%	Numerator	0	Incomplete
									Denominator	0	
									%	n.d.	
12		Permanent seed implantation – D 90 > 130 Gy  * Implementation of this therapy is voluntary!	D 90 > 130 Gy at ≥ 90% should be achieved in case of permanent seed implantation	Primary cases of the denominator for whom D 90 > 130 Gy was achieved	Primary cases with LDR monotherapy		≥ 90%		Numerator		Incomplete
									Denominator		
									%	n.d.	
13		HDR brachytherapy  * Implementation of this therapy is voluntary!	Number of patients with HDR brachytherapy	Primary cases of the denominator with HDR brachytherapy	Primary cases (= Indicator 1a)		No target value		Numerator	0	Incomplete
									Denominator	0	
									%	n.d.	

IN	CR/ GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausibility unclear	Target value	Plausibility unclear	Current value	Data quality		
14	GL QI	Diagnostic report - punch biopsy	As many complete diagnostic reports as possible	Primary cases of the denominator with report of findings indicating: - Localization and number of carcinoma-positive tissue samples in relation to the number of punches taken. - Semiquantitative estimate of tumor extent per punch (in percent and/or mm). - Gleason score according to ISUP 2014 and WHO 2016	Primary cases with punch biopsy		≥ 80%		Numerator Denominator %	n.d. n.d. n.d.	Incomplete	
15	GL QI	Diagnostic report - lymph nodes	As many complete diagnostic reports as possible	Primary cases of the denominator with diagnostic reports stating: - pN category - number of affected lymph nodes in relation to resected lymph nodes	Primary cases with lymphadenectomy		≥ 80%		Numerator Denominator %	n.d. n.d. n.d.	Incomplete	
16	GL QI	Beginning of Salvage-radiotherapy for recurrent prostate cancer	As many patients as possible with early started Salvage-radiotherapy	Patients of the denominator who have started Salvage-radiotherapy at PSA <0.5 ng/ml	Patients after RPE and PSA recurrence and Salvage-radiotherapy		≥ 70%		Numerator Denominator %	n.d. n.d. n.d.	Incomplete	
17		Radiotherapy per time	If possible, frequent recommendation of bisphosphonate or denosumab therapy	Not mandatory for the audit year 2022. Cross-organ definition is currently being prepared for this indicator. The mandatory depiction of this indicator in audit year 2022 is not envisaged independently of the discussions conducted.						Numerator Denominator %	n.d. n.d. n.d.	

IN	CR/ GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi- bility unclear	Target value	Plausi- bility unclear	Current value		Data quality
18	GL QI	Postoperative complications after radical prostatectomy	As few complications as possible after RPE	Primary cases of the denominator with complications Clavien-Dindo grade III or IV within the first 6 months after RPE	Primary cases p T1/2, N0, M0 and RPE (from the previous Indicator year)		≤ 15%		Numerator		Incomplete
									Denominator		
									%	n.d.	
19	GL QI	Adverse effects after radiotherapy	As low occurrence as possible of adverse effects after radiotherapy	Primary cases of the denominator with adverse effects CTCAE grade III or IV within the first 6 months after radiotherapy	Primary cases with definitive radiotherapy (from the previous Indicator year)		≤ 3,5%		Numerator		Incomplete
									Denominator		
									%	n.d.	
20	GL QI	Dental examination prior to commencement of bisphosphonate or denosumab therapy	As frequent as possible recommendation of dental examination prior to commencement of bisphosphonate or denosumab treatment	Pat. of the denominator with a recommended dental examination prior to commencement of bisphosphonate or denosumab therapy	Pat. of bisphosphonate or denosumab therapy		≥ 90%		Numerator		Incomplete
									Denominator		
									%	n.d.	
21	GL QI	No hormone ablation therapy in the case of locally advanced prostate carcinoma with radical prostatectomy	No adjuvant hormone ablation therapy in the case of locally advanced prostate carcinoma and radical prostatectomy (RPE)	Primary cases of the denominator with adjuvant hormone ablation therapy	Primary cases pT3-4 pN0 M0 and RPE		< 0,1%		Numerator		Incomplete
									Denominator		
									%	n.d.	
22 specifica- tion- optional	GL QI	Focal therapy for locally advanced prostate carcinoma	No focal therapy for locally advanced prostate carcinoma	Primary cases of the denominator who received focal therapy	Primary cases with locally advanced prostate carcinoma		No target value	> 0,01%	Numerator		optional - incomplete
									Denominator		
									%	n.d.	



IN	CR/ GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi- bility unclear	Target value	Plausi- bility unclear	Current value	Data quality
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### Data quality indicators

OK	Plausible	0,00% (0)	0,00% (0)	Processing quality
	Plausibility unclear	0,00% (0)		
Target value not met			0,00% (0)	0,00% (0)
Erroneous	Incorrect	0,00% (0)	100,00% (27)	
	Incomplete	100,00% (27)		

### Processing remarks:

The respective entry or change of "Number / Numerator / Population" (dotted fields) can only be made in the spreadsheet "Basic Data", the data are then automatically transferred.  
The numerator is always a subset of the denominator (exception: Indicator 8 - Share of study patients).

#### 1) Plausibility unclear

In comparison to other centres, the Indicator value provided/obtained is an unusual value. The classification "plausibility unclear" does not automatically mean a negative assessment. The Indicator value is to be checked for correctness because of its unusual character. In individual cases a positive Indicator value, when viewed in detail, may also present a negative care situation (e.g. oversupply). The result of this check is to be explained in more detail by the Centre in the Catalogue of Requirements in the column "Reasons/Cause" . Where appropriate, specific actions should be defined and carried out in line with the procedure "Failure to meet the target value" for the purpose of improvement.

#### 2) Target value not met

The relevant Indicators are to be analysed. The result is to be documented in the data sheet "Indicators". The document "Specifications Data Quality" contains more detailed information about this.

3) Incomplete  
If any Indicators have the status "incomplete", then they are to be provided at a later stage or a clear statement is to be made about the possibility of presenting missing data in the future ("incomplete Indicators" always constitute a potential deviation).

### Note:

For reasons of easy readability, the term "patient" expressly covers all gender attributions (female, male, other).