ORIGINAL ARTICLE



Quality assessment in prostate cancer centers certified by the German Cancer Society

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Abstract

Purpose In 2008, the German Cancer Society certification program for prostate cancer centers (PCCs) was introduced, fostering multidisciplinary and interprofessional cooperation. Since then, 97 PCCs have been certified. This paper describes the PCC certification program, quality indicators (QI) that are reported during certification, as well as changes over time and correlates of QI fulfillment.

Methods Observational data from 70,683 primary prostate cancer (PCa) cases treated between 2010 and 2013 in certified PCC sites are analyzed using descriptive and correlation analyses.

Results Fulfillment of the requirements is high with over 80 % of the sites fulfilling the requirements for most of the presented QIs with defined target values. Fulfillment increased slightly over time, with significant improvements in conducting multidisciplinary tumor conferences (increasing proportion of cases presented pre- and post-treatment, increasing participation of specialists),

psycho-oncologic care, social service counseling and research participation. Bivariate associations between hospital characteristics and QIs observed were most distinct for time since first certification.

Conclusions Results suggest that the PCC certification program presented contributes to establishing multidisciplinary teams over time and assures the provision of high-quality PCa care. However, differences in fulfillment of the requirements exist with regard to hospital characteristics beyond the scope of the certification system.

Keywords Multidisciplinarity · Quality indicators · Prostate cancer · Certification

Introduction

Prostate cancer (PCa) is the most common cancer among men in Western countries with an estimated 65,830 newly

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diagnosed patients in 2010 in Germany (lung: 35,040 men; colon: 33,800 men). 12,676 patients die of the disease per year in Germany [1], while the PCa death rate decreases in the USA, in Germany, and in Europe overall [2, 3]. The many different treatment options as well as specific sideeffects and benefits call for treatment and counseling by multidisciplinary and interprofessional teams [4–6]. To our knowledge, the first multidisciplinary clinic for the treatment of PCa has been founded as early as 1996 in the USA [5, 7, 8], and since then, quite a number of countries have introduced national efforts and established multidisciplinary PCa units [9]. In Germany, the introduction of prostate cancer centers (PCCs) was driven by efforts of the medical societies, patient advocacy groups, as well as the federal government. PCCs in Germany are certified by the German Cancer Society, the association of medical oncologic societies. The centers are multidisciplinary in that they require the collaboration of the relevant medical disciplines. They are at the same time interprofessional, in that the relevant non-medical professional groups, like social workers and psycho-oncologists, are involved in patient care and also take part in the tumor boards, the heart of multidisciplinary and interprofessional cancer care, and in that patient advocacy group provide additional on-site support.

Since 2008, the certification program of the German Cancer Society includes PCCs, making them the third specific cancer center type to be recognized, after breast (2003) and colorectal (2006) cancer centers. As of 2014, about a third of all German newly diagnosed PCa patients were treated in a certified center. The basis of the certification program for PCCs is the catalogue of requirements a center needs to fulfill in order to be awarded the certificate. The requirements are developed by the certification commission, which consists of 35 experts from the professions and disciplines specialized in the field of PCa, as well as patient advocacy groups [10]. Among these requirements are quality indicators (QIs) that are reported to the public annually in structured reports [11]. These QIs are classified into (1) QIs that refer to interdisciplinary collaboration and (2) PCa specific QIs (guideline-based [12] and specialist expertise). Thus, QIs are based on expert opinion and on the clinical guidelines. This allows for including QIs for all disciplines that refer to treatment procedures and structures, and also to specialist expertise that has been shown to impact outcomes, such as patient volume [13]. Prospectively, these QIs will be supplemented by guideline derived QIs that are developed following a formalized methodology that has been described in more detail for melanoma [14]. QIs are reevaluated regularly by the certification commission based on the centers' results and guideline updates. Based on these discussions, QIs may be omitted, added,

re-defined or their thresholds may be modified. For example, the research study target value was recently lowered from 10 to 5 %.

This report analyzes a selection of 15 quality indicators collected during the certification process for PCCs and shows the development over time from 2010 to 2013. As yet, attempts to link fulfillment of accreditation/certification criteria to hospital characteristics are rare although they may give valuable insights into what facilitates or hinders the implementation of such programs [15]. Thus, ultimately, we exploratorily investigate how requirement fulfillment relates to hospital characteristics that are beyond the scope of the certification system itself.

Patients and methods

Data collection

Hospitals that intend to be (re-)certified as a PCC have to document the fulfillment of the requirements and report these to OnkoZert, the certification institute that organizes the auditing procedure on behalf of the German Cancer Society. After collecting the data from the operating sites, these are edited and tested for plausibility. Most indicators have plausibility thresholds and, if these are not reached, the centers have to report on the deviations. Subsequent to the reporting year, hospitals are audited by trained oncologic medical experts who check the reported data before the audit and have insight into patient files to verify the data onsite. Data are published for comparison between sites in the year after the auditing. For example, 2013 data are audited during 2014, and published during 2015, thus, the most recent data presented here are based on the 2013 patient cohort. Data presented are limited to those from the 2010 patient cohort onwards after the method of collecting and quality assurance was fully established. Data are only available for centers that were certified throughout the year and had no change in the documentation system. Table 1 presents a description of PCCs certified between 2010 and 2013, and Fig. 1 presents an overview over the most recent patient cohort treated in these centers, the distribution of cancer stages, and treatments. We present 15 QIs that are collected during certification [11] to give an overview of indicators referring to interdisciplinary cooperation (11), and QIs that are PCa specific, guideline-based, or refer to the specialist expertise (4). The indicators are listed in Table 2. All indicators presented relate to primary cases except for QIs 3-6, which relate to participation of specialists, and QI 8 as well as QI 15, which relate to patients with recurrences or distant metastases and all radical prostatectomies, respectively.



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Table 1 Development of site structure 2010–2013 and patients treated

	As of 31 December 2014 (primary cases 2013) ^a	As of 31 December 2013 (primary cases 2012)	As of 31 December 2012 (primary cases 2011)	As of 31 December 2011 (primary cases 2010)
Certified centers	94	94	91	80
Certified sites ^b	95	95	92	81
Primary cases with PCa treated in PCCs ^c	20,682	21,605	21,115	18,160
Median primary cases per PCC	155	163	163	171
Certified sites with data available ^d	91	88	79	62
Primary cases from sites with data available	18,288	19,558	17,425	15,412

^a 2013 patient data are audited during 2014, and published in 2015; i.e., the most recent data presented are based on primary cases treated in 2013

^d Data not available for the sites that were certified for the first time in the respective year

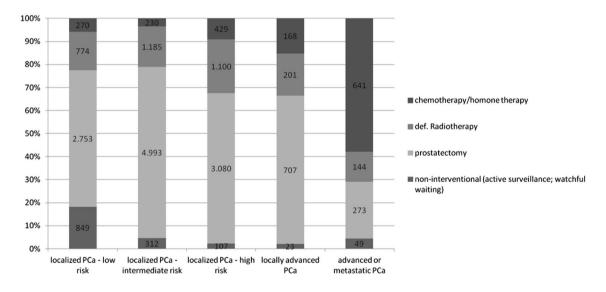


Fig. 1 Primary cases treated in 2013: stage and treatment regimen, N = 18,288; every patient is counted once; chemotherapy/hormone therapy is only reported if neither prostatectomy nor definitive radiotherapy were primary treatment

Statistical analyses

We present absolute patient numbers and proportions of patients receiving a specific procedure for all years when applicable, and the proportion of sites fulfilling the target values in 2013. Trends over time are analyzed using two-sided Cochran–Armitage tests with Monte Carlo method when QIs are fractions. We analyzed associations between the QIs and select hospital characteristics: the "conventional set" [15] ownership status (charitable, for-profit, public), teaching

status (yes, no), and volume (primary cases, continuous); urbanity of hospital location [small town (pop. <20,000), medium sized town/city (20,000-100,000), large city (>100,000)]; and time since first certification in years (continuous). Spearman's r was calculated for associations between QIs and volume and time since first certification; t tests for associations with teaching status; and Kruskal–Wallis tests with pairwise comparisons for associations with ownership status and urbanity. Descriptive analyses are done using the Data-WhiteBox; Cochran–Armitage tests were calculated



^b Certified centers usually consist of one certified site, but in rare cases can consist of two sites

^c Defined as patients with a primary diagnosis of PCa (localized or metastasized) presented in the center/the tumor conference and that received substantial parts of the treatment in the center (e.g., surgery, radiotherapy, systemic therapy, active surveillance, watchful waiting), each patient can only be counted once and in one site

 Table 2
 Selected quality indicators 2010–2013 and bivariate correlations between quality indicator fulfillment 2013 and hospital characteristics (N = 91)

Quality indicators	Site median, ab	Site median, absolute number of patients, proportions, C-A test, target value, and fulfillment	tients, proportions	; C-A test, target v	alue, and fi	ılfıllment		Correlations with	Correlations with site characteristics			
	2010: PCC median; absolute number of patients; proportion (%)	2011: PCC median; absolute number of patients; propor- tion (%)	2012: PCC median; absolute number of patients; proportion (%)	2013: PCC median; absolute number of patients; proportion (%)	C-A test	C-A test Target value	Sites with target fulfilled 2013	Academic/ teaching (t test)	Ownership (Kruskal-Wallis test)	Urbanity (Kruskal–Wal- lis test)	Time since 1st certification (years) (Spearman's r)	Number of primary PCa cases (Spearman's r)
Interdisciplinary collaboration 1. Case pres 99.3 % entation in 11,303 pretreatment 95.2 % conference— through urology	aboration 99.3 % 11,303/11,873 95.2 %	99.8 % 13,003/13,775 94.4 %	99.3 % 14,661/15,053 97.4 %	98.4 % 14,206/15,099 94.1 %	0.506	>95 %	81.3 %		Adj. $P = 0.030$ Charitable: 97 % Public: 94 %			
(primary cases) 2. Case presentation in pretreatment conference— through radio-therapy (primary cases)	100 % 2762/2885 95.7 %	100 % 3635/3953 92.0 %	100 % 3273/3400 96.3 %	100 % 2971/3071 96.7 %	<0.001	>95 %	% 8.68					-0.269 $P = 0.011$
3. Participation of core disciplines in post-therapy conferences—urology (diagnostic + surgical)	100 % 1366/1381 98.9 %	100 % 1844/1850 99.7 %	100 % 2124/2128 99.8 %	100 % 2318/2321 99.9 %	<0.001	% 56%	200 %					
4. Participation of core disciplines in post-therapy conferences—radiotherapy	100 % 1363/1380 98.8 %	100 % 1836/1853 99.1 %	100 % 2106/2133 98.7 %	100 % 2294/2321 98.8 %	0.825	>95%	94.5 %					0.214 $P = 0.042$
5. Participation of core disciplines in post-therapy conferences—urologist or medical oncologist	100 % 1350/1390 97.1 %	100 % 1787/1853 96.4 %	100 % 2045/2099 97.4 %	100 % 2309/2321 99.5 %	<0.001	% \$6<	% L'96				0.275 $P = 0.008$	
6. Participation of core disciplines in post-therapy conferences—pathology	100 % 1325/1390 95.3 %	100 % 1757/1853 94.8 %	100 % 2053/2150 95.5 %	100 % 2235/2321 96.3 %	0.060	>95%	87.9 %					



Table 2 continued

					-							
Quanty indicators	Site median, a	Site median, absolute number of patients, proportions, C.–A test, target value, and furnilment	atients, proportions	s, C-A test, target	value, and n	IIIIIIIment	:	Correlations with	Correlations with site characteristics		·	
	2010: PCC median; absolute number of patients; proportion (%)	2011: PCC median; absolute number of patients; propor- tion (%)	2012: PCC median; absolute number of patients; proportion (%)	2013: PCC median; absolute number of patients; proportion (%)	C–A test	C-A test Target value	Sites with target fulfilled 2013	Academic/teaching (t test)	Ownership (Kruskal-Wallis test)	Urbanity (Kruskal-Wal- lis test)	Time since 1st certification (years) (Spearman's r)	Number of primary PCa cases (Spear- man's r)
7. Presentation at post-therapy conference— primary cases >pT3a and/or R1 and/or pN	100 % 2837/2974 95.4 %	100 % 3151/3355 93.9 %	100 % 4122/4165 99.0 %	100 % 3688/3738 98.7 %	<0.001	% 001	84.6 %					
8. Presentation at post-therapy conference— all patients with initial manifestation of a recurrence and/or distant metastasis	100 % 1351/1501 90.0 %	100 % 1705/1848 92.3 %	100 % 1952/2062 94.7 %	100 % 2099/2369 88.6 %	0.127	% 001	70.8 %	<i>P</i> < 0.001 Teaching: 87 % Non-teaching: 100 %	Adj. <i>P</i> = 0.035 For-profit: 100 % Public: 83 %			
9. Psycho-oncologic care (>30 min) (primary cases)	8.2 % 2857/14,412 19.8 %	12.1 % 3258/16,972 19.2 %	17.2 % 4634/19,558 23.7 %	17.1 % 4264/18,288 23.3 %	<0.001	-/-	n.a.				0.209 $P = 0.046$	
10. Social service counseling (primary cases)	62.3 % 8159/13,714 59.5 %	57.1 % 10,168/16,941 60.0 %	59.5 % 11,573/19,413 59.6 %	58.4 % 11,359/18,288 62.1 %	<0.001	-	п. а.					
 Participation in research study PCa specific QIs (gui) 	2.0 % 2212/13,991 15.8 % ideline-based and	11. Participation 2.0 % 1.3 % in research study 2212/13,991 1373/17,302 15.8 % 7.9 % PCa specific QIs (guideline-based and specialist expertise)	4.8 % 2350/19,357 12.1 %	2.9 % 2727/18,288 14.9 %	<0.001	Initial: >1; after 1 year: ≥5 %	41.8 %					
12. Hormone ablative therapy in addition to percutaneous radio-therapy	Revised in 2012	Revised in 2012	27.3 % 1168/4505 25.9 %	22.7 % 999/4716 21.2 %	<0.001	+	n. a.					
in high-risk patients (PSA > 20 ng/ml or Gleason												



 Table 2
 continued

Quality indicators	Site median, al	Site median, absolute number of patients, proportions, C	atients, proportions	s, C-A test, target value, and fulfillment	alue, and fu	Ifillment		Correlations with	Correlations with site characteristics			
	2010: PCC median; abso- lute number of patients; proportion (%)	median; abso-median; absolute median; absolute number of number of patients; propor-of patients; proportion tion (%) proportion (%)	2012: PCC median; absolute number of patients; proportion (%)	2013: PCC median; absolute number of patients; proportion (%)	C-A test	C-A test Target value	Sites with target fulfilled 2013	Academic/teaching (t test)	Academic/ Ownership Urbanity Time since 1st teaching (t test) (Kruskal–Wallis (Kruskal–Wal- certification test) lis test) (years) (Spearman's r)	Urbanity (Kruskal-Wal- lis test)	Time since 1st Number of certification primary PC (years) (Spear cases (Speaman's r) man's r)	Number of primary PCa cases (Spearman's r)
13. Record of R1 resections with pT2 c/pN0 or Nx M0	8.4 % 552/6580 8.4 %	8.9 % 681/6735 10.1 %	8.9 % 765/8191 9.3 %	9.1 % 634/6973 9.1 %	0.419	<u><10 %</u>	57.1%					
14. Number of primary cases of prostate cancer	Median: 182.5 N: 15,412	Median: 182.5 Median: 169 N: 15,412 N: 17425	Median: 159 N: 19,558	Median: 149 N: 18288	n. a.	>100	97.8 %				0.224 $P = 0.033$	
15. Postoperative wound infection	1.2 % 143/9639 1.5 %	0.9 % 123/11,127 1.1 %	1.4 % 189/13,230 1.4 %	1.5 % 149/12,229 1.2 %	0.397	~5 %	% 1.96					-0.212 $P = 0.044$

indicators are fractions: proportion of patients eligible for a specific treatment who receive the treatment, except "primary cases PCa" (14): number of cases; C-A test, Cochran-Armitage test or trend; n.a., not applicable; empty table elements indicate non-sig. associations in the five columns on the right using XLSTAT Version 2015.3.01. Bivariate correlations were calculated using SPSS 23.

Results

The number of certified sites increased steadily from 2010 to 2012 and remained stable in 2013. The number of patients treated in these centers increased until 2012 and slightly decreased in 2013 (Table 1). In 2013, 20,682 primary cases were treated in 94 certified PCCs. Of these, two centers serve an extraordinarily high number of patients, with one treating 2124 primary cases alone. Data were available from 91 centers that treated 18,288 primary cases (Table 1). The vast majority of these patients were treated with an intervention (16,948; Fig. 1). Of the 1340 patients treated with watchful waiting (WW) or active surveillance (AS), 849 had a localized PCa with low risk.

Table 2 presents results for the QIs over time. Fulfillment is high with over 80 % of the sites fulfilling the recommendations for all but three of the presented QIs with defined target values. Over time, fulfillment of seven requirements increased significantly, specifically with regard to conducting multidisciplinary tumor conferences (increasing proportion of cases presented pre- and post-treatment, increasing participation of specialists), psycho-oncologic care, social service counseling and research participation (QIs 2, 3, 5, 7, 9, 10, 11). Fulfillment of the QI for which data were only available for 2 years decreased (12) with p < 0.001.

The bivariate analyses (Table 2: columns on the right) identified statistically significant associations between patient volume and case presentation in pre-therapy conference through radiotherapy (r = -0.269, p = 0.011), participation of radiotherapists in pre-therapy conferences (r = 0.214, p = 0.042), and postoperative wound infection (r = -0.212, p = 0.044); between time since first certification and participation of urologists/medical oncologists in pre-therapy conferences (r = 0.275, p = 0.008), psychooncologic care (r = 0.209, p = 0.046), and the number of primary cases (r = 0.224, p = 0.033); between charitable (compared to public) ownership and case presentation in pre-treatment conference through urology (adj. p = 0.030); between private (compared to public) ownership and presentation rates of recurrence/distant metastasis patients at the post-therapy conferences (adj. p = 0.035); and higher presentation rates of recurrence/distant metastasis patients at the post-therapy conferences in non-teaching units (p < 0.001).

Discussion

This article for the first time provides nationwide treatment data for the E.U.'s most populous country's PCa



center certification system. Fulfillment of the requirements was initially high and improved slightly overall. Only few bivariate analyses with hospital characteristics yielded statistically significant results, with the most uniform pattern identified with regard to time since first certification: higher implementation of requirements was associated with longer time since first certification. These cross-sectional analyses, however, do not allow for causal inference: The "time since first certification effect" may, e.g., be both due to learning or because better implementing centers applied for certification earlier. Similar limitations apply for the ownership and teaching status variables (i.e., no adjustment for time since a possible status change). Also, individual-level case mix adjustment is not possible, since the data are reported aggregated on center level for certification. These exploratory results based on a huge database call for analyses based on individual data linked with hospital characteristics as has been done for other cancers [16]. Such data, however, are not available for PCa centers in Germany yet.

Prostatectomy was the most common treatment regimen for localized and locally advanced PCa in the certified centers, especially when comparing with data from other countries. It must be kept in mind, however, that AS or WW patients may not always be seen by PCCs but treated by office-based urologists who are often not part of a certified network. Because the centers that were certified early on tended to be larger university centers and those that were certified recently tended to be smaller units, the median of patients per center decreased slightly over time.

PCCs differ from other certified center types for two reasons inherent in the disease. First, there is a wider range of therapy options, and there are various ways to combine them. These options/combinations are performed either through hospital or office-based urologists, or hospital or office-based radiotherapists. As a result, interdisciplinary discussion during the pre- and post-therapeutic tumor boards is essential to balance preferences of one discipline that may exist in local contexts. Second, the dual infrastructure for medical specialists in Germany—that is, due to the two sectors of secondary care (hospitals, office-based physicians) results in a substantial number of patients being seen by only one specialist without a connection to other experienced colleagues or to a certified PCC. The objective of the certification system is—among other issues—to provide a network of qualified partners that represents the entire chain of health care specialists for as many patients as possible and to evaluate the patients' disease and treatments in a multidisciplinary manner [17, 18]. This does not mean that office-based colleagues shall refer their patients to hospitals, but that they become part of the network while keeping their role as the patient's gate keeper. The interdisciplinary collaboration in certified prostate cancer networks is mainly focusing on the multidisciplinary tumor board that is controlled by the number of patients discussed in the pre- and post-therapeutic conferences, and the participation of core disciplines. The pretreatment multidisciplinary conference is chaired by the urologist and the radio-oncologist. The two related QIs reflect the number of patients who are presented in the tumor board out of the total number of primary cases from urology (QI 1) and radiotherapy (QI 2). Both indicators show a very good fulfillment of the target values.

The requirements explicitly include the provision of social service and psycho-oncologic counseling, i.e., elements of care that do not refer to the quality of technical/medical but to interpersonal care [19]. Comparison with other center types that have the same criteria show that implementation is higher in breast and colorectal cancer centers [20, 21], which may be due to gender-specific patient preferences.

The target value for the recording of R1 resections with pT2 c/pN0 or Nx Mo, however, is fulfilled by only 57.1 % of the PCCs (<10 %), and the range varies between 0.0 and 26.9 % (ranges not reported). The reasons given by the PCCs for this wide range are diverse—learning curves after implementation of the new technique of laparoscopic or robot-assisted RPE in combination with too restricted apical resection and missing color coding of the specimens. In addition, the histopathological assessment of the specimens differs considerably between centers, despite formal standard operation procedures depicted in the national guidelines. The PCCs have agreed on various measures within the audits: surgical advanced education, color coding of the specimens, and uropathology conferences to reflect the R1 cases.

Comparable research has shown that having compliance rates of 100 % for a whole set of indicators is unlikely to be achieved [22], and also, is not the ultimate aim of such a program. Instead, using the data and the resulting benchmark to initiate processes of reflection and the development of care, quality improvement strategies are encouraged. Not fulfilling the requirements without giving appropriate reasons and without credibly showing the intent of improving care, however, will ultimately result in the denial of the certificate. Studies that relate structure and process QIs to clinically relevant outcomes were able to show clear associations [23], but deeper insight is still needed [24]. Future challenges include the incorporation of patient reported outcome measures, like it is done in other certification programs [25], a careful analysis of the impact of the certification system on long-term survival, and the identification of potential disparities between social groups [26].

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Authors' contribution Kowalski involved in data analysis and wrote and edited the manuscript. Ferencz involved in data collection and management, data analysis and wrote and edited the manuscript. Albers involved in protocol/project development and wrote and edited the manuscript. Fichtner involved in protocol/project development and wrote and edited the manuscript. Wiegel involved in protocol/project development and wrote and edited the manuscript. Feick involved in protocol/project development and wrote and edited the manuscript. Wesselmann involved in protocol/project development and wrote and edited the manuscript.

Compliance with ethical standards

Conflict of interest C.K., S.W., and J.F. are employees of the two institutions in charge of the certification system. P.A., J.F., T.W., and G.F. are chairs/members of the German Cancer Society certification commission on PCCs.

Ethical standard Research presented here is based on routinely collected data, and as such not subject to the declaration of Helsinki. For this type of study formal consent is not required.

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