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Platinum Priority – Prostate Cancer

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The European Prostate Cancer Centres of Excellence: A Novel Proposal from the European Association of Urology Prostate Cancer Centre Consensus Meeting

Manfred Wirth[a], *Nicola Fossati*[b,*], *Peter Albers*[c], *Chris Bangma*[d], *Maurizio Brausi*[e], *Eva Comperat*[f], *Sara Faithfull*[g], *Silke Gillessen*[h], *Barbara Alicja Jereczek-Fossa*[i], *Ken Mastris*[j], *Nicolas Mottet*[k], *Stefan C Müller*[l], *Bradley Pieters*[m], *Maria J Ribal*[n], *Vijay Sangar*[o], *Ivo G Schoots*[p], *Vitaly Smelov*[q], *Luzia Travado*[r], *Riccardo Valdagni*[s], *Simone Wesselmann*[t], *Thomas Wiegel*[u], *Hendrik van Poppel*[v]

[a] *European Association of Urology (EAU), Department of Urology, University Hospital Carl Gustav Carus, Technical University of Dresden, Dresden, Germany;* [b] *European Association of Urology (EAU), Division of Oncology / Unit of Urology; IRCCS Ospedale San Raffaele, Milan, Italy;* [c] *European Association of Urology (EAU), Department of Urology, University Hospital Düsseldorf, Heinrich-Heine University Medical Faculty, Düsseldorf, Germany;* [d] *European Association of Urology (EAU), Department of Urology, Erasmus University Medical Centre, Rotterdam, The Netherlands;* [e] *EAU Section of Oncological Urology (ESOU) Department of Urology, B. Ramazzini Hospital, Carpi-Modena, Italy;* [f] *Service d'anatomie et cytologie pathologiques, hôpital Tenon, HUEP, Sorbonne université, Paris, France;* [g] *European Association of Urology Nurses (EAUN), School of Health Sciences, Faculty of Health & Medical Sciences, Duke of Kent Building, University of Surrey,Surrey, UK;* [h] *European Organisation for Research and Treatment of Cancer (EORTC), Manchester Cancer Research Centre, Manchester, UK;* [i] *European Society for Radiotherapy and Oncology (ESTRO), Department of Oncology and Hemato-oncology, University of Milan, Division of Radiotherapy, IEO European Institute of Oncology, IRCCS, Milan, Italy;* [j] *Europa Uomo (EUomo);* [k] *European Association of Urology (EAU), Department of Urology, University Hospital, St. Etienne, France;* [l] *European Board of Urology (EBU), Arnhem, The Netherlands;* [m] *European Society for Radiotherapy and Oncology (ESTRO), Amsterdam University Medical Centers / University of Amsterdam, Amsterdam, The Netherlands;* [n] *European Urological Scholarship Programme (EUSP), Uro-Oncology Unit. Hospital Clínic. University of Barcelona, Spain;* [o] *European Association of Urology (EAU), The Christie NHS Foundation Trust & Manchester University Hospital NHS Foundation Trust, Manchester, UK;* [p] *European Society of Uro Radiology (ESUR), Department of Radiology and Nuclear Medicine, Erasmus University Medical Center, Rotterdam, The Netherlands;* [q] *Prevention and Implementation Group, Section of Early Detection and Prevention, International Agency for Research on Cancer (IARC), World Health Organization (WHO);* [r] *International Psycho-Oncology Society (IPOS), Psycho-oncology, Champalimaud Clinical and Research Center, Champalimaud Foundation, Lisbon, Portugal;* [s] *European School of Oncology (ESO), University of Milan, Department of Oncology and Hemato-oncology, Fondazione IRCCS Istituto Nazionale dei Tumori, Prostate Cancer Program, Fondazione IRCCS Istituto Nazionale dei Tumori, Radiation Oncology, Milano, Italy;* [t] *German Cancer Society (DKG), Berlin, Germany;* [u] *European Society for Radiotherapy and Oncology (ESTRO) Milan, Italy;* [v] *European Association of Urology (EAU), Dept Urology, University Hospital KU Leuven, Belgium*

[*] Corresponding author. Division of Oncology/Unit of Urology, IRCCS Ospedale San Raffaele, Via Olgettina, 60, Milan 20132, Italy. Tel. +39 022 6437286, +39 022 6433321; Fax: +39 022 6437298.
E-mail addresses: Manfred.Wirth@uniklinikum-dresden.de (M. Wirth), fossati.nicola@hsr.it (N. Fossati), Peter.Albers@med.uni-duesseldorf.de (P. Albers), c.h.bangma@erasmusmc.nl (C. Bangma), m.brausi@ausl.mo.it (M. Brausi), eva.comperat@aphp.fr (E. Comperat), s.faithfull@surrey.ac.uk (S. Faithfull), silke.gillessen@kssg.ch (S. Gillessen), barbara.jereczek@ieo.it (B.A. Jereczek-Fossa), ken.mastris@btinternet.com (K. Mastris), nicolas.mottet@chu-st-etienne.fr (N. Mottet), stefan.mueller@ukb.uni-bonn.de (S.C. Müller), b.r.pieters@amc.uva.nl (B. Pieters), mjribal@clinic.cat (M.J. Ribal), vpsangar@gmail.com, vijay.sangar@nhs.net (V. Sangar), i.schoots@erasmusmc.nl (I.G. Schoots), smelovV@iarc.fr (V. Smelov), luzia.travado@fundacaochampalimaud.pt (L. Travado), Riccardo.Valdagni@istitutotumori.mi.it (R. Valdagni), wesselmann@krebsgesellschaft.de (S. Wesselmann), Thomas.Wiegel@uniklinik-ulm.de (T. Wiegel), hendrik.vanpoppel@uzleuven.be (H. van Poppel).

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Abstract

Background: High-quality management of prostate cancer is needed in the fields of clinics, research, and education.
Objective: The objective of this project was to develop the concept of "European Prostate Cancer Centres of Excellence" (EPCCE), with the specific aim of identifying European centres characterised by high-quality cancer care, research, and education.
Design, setting, and participants: A task force of experts aimed at identifying the general criteria to define the EPCCE. Discussion took place in conference calls and by e-mail from March 2017 to November 2017, and the final consensus meeting named "European Association of Urology (EAU) Prostate Cancer Centre Consensus Meeting" was held in Barcelona on November 16, 2017.
Outcome measurements and statistical analysis: The required criteria were grouped into three main steps: (1) clinics, (2) research, and (3) education. A quality control approach for the three steps was defined.
Results and limitations: The definition of EPCCE consisted of the following steps: (1) clinical step—five items were identified and classified as core team, associated services, multidisciplinary approach, diagnostic pathway, and therapeutic pathway; (2) research step—internal monitoring of outcomes was required; clinical data had to be collected through a prespecified database, clinical outcomes had to be periodically assessed, and prospective trials had to be conducted; (3) educational step—it consists of structured fellowship programmes of 1 yr, including 6 mo of research and 6 mo of clinics; and (4) quality assurance and quality control procedures, related to the quality assessment of the previous three steps. A limitation of this project was that the definition of standards and items was mainly based on a consensus among experts rather than being an evidence-based process.
Conclusions: The EAU Prostate Cancer Centre Consensus Meeting defined the criteria for the identification of the EPCCE in the fields of clinics, research, and education. The inclusion of a quality control approach represents the novelty that supports the excellence of these centres.
Patient summary: A task force of experts defined the criteria for the identification of *European Prostate Cancer Centres of Excellence*, in order to certify the high-quality centres for prostate cancer management.

1. Introduction

Prostate cancer (PCa) is the first most commonly diagnosed cancer in men in 2018, accounting for 19% of all cancers diagnosed. Moreover, PCa is the second leading cause of death from cancer in men, with an estimated 29 430 deaths representing 9% of the total male cancer mortality in the USA [1]. A high prevalence and mortality of PCa are detected in European countries also [2].

However, the quality of the diagnostic and treatment pathways for PCa is still highly heterogeneous among different countries: a patient diagnosed with and treated for PCa may receive extremely different cancer care in terms of quality [3,4]. Several reasons stand behind this heterogeneity:

1. The multidisciplinary approach. PCa represents a disease that should be diagnosed and treated by a multidisciplinary team of physicians, including urologists, radiation oncologists, medical oncologists, radiologists, pathologists, nuclear medicine physicians, general practitioners, geriatricians, and specialised nurses [5]. The presence of all these professionals and their communication are fundamental to providing high-quality care. However, at the same time, optimal integration of this team may be challenging.
2. The level of evidence supporting decision making in PCa care. Nowadays, there are several important open questions in the field of PCa, despite relevant randomised trials that have been conducted. For instance, the impact of screening programmes for PCa [6,7], the best treatment option [8–11], and the best surgical route for a patient treated with radical prostatectomy [12] or best fractionation scheme for radiotherapy [13,14] are examples of relevant topics that are still under debate. Despite the availability of different PCa guidelines [15,16], the lack of clear answers to these important questions may lead to heterogeneous patient management, with possible implications on quality of care.
3. Hospital volume. There is evidence that radical prostatectomy outcomes and quality of care are strictly related to hospital volume, which is defined as the annual number of PCa-related procedures in each hospital [17–21]. However, a considerable number of PCa treatments are still performed within low-volume hospitals, with a significant risk of reducing the quality of care for patients [22,23].
4. Socioeconomic status. This factor may have a relevant impact on PCa survival inequality, also in European countries [24]. Education should incorporate training on communication skills.

In this context, there is an important need for standardisation and reproducibility of PCa care to guarantee high-quality treatments for PCa patients. Furthermore, education of young doctors and training for professions allied to medicine represent essential steps for providing and maintaining high-quality care. The Prostate Cancer Programme of the European School of Oncology developed the concept of specialised interdisciplinary and multiprofessional PCa care to be formalised in prostate cancer units (PCUs), to set standards for quality-comprehensive PCa care [25]. Moving beyond the standards of PCUs, the aim of this project was to create and develop the concept of "European Prostate Cancer Centres of Excellence" (EPCCE), with the specific primary objective of identifying European centres focused on high-quality cancer care, research, and education in the field of PCa.

2. Patients and methods

Creation of the EPCCE was a multidisciplinary project that consisted of different steps.

Initially, the European Association of Urology (EAU) representatives (M.W., H.V.P., and P.A.) organised a multiprofessional task force, where the representatives of the major international oncological societies and organisations were invited to participate and nominate their representatives. The invitation was accepted by the European School of Oncology (ESO), the European Organization for Research and Treatment of Cancer, the European Society for Radiotherapy and Oncology (ESTRO), Europa Uomo (EUomo), the German Cancer Society (Deutsche Krebsgesellschaft [DKG]), the International Agency for Research on Cancer, the Specialized Cancer Agency of the World Health Organization, the International Psycho-Oncology Society (IPOS), and the European Board of Urology (EBU). Furthermore, different sections of the EAU were involved in this project, including the EAU Guideline Office, the EAU Section of Oncological Urology (ESOU), the EAU Section of Uro-Pathology (ESUP), the EAU Section of Urological Research (ESUR), the European Urological Scholarship Programme Office (EUSP), and the EAU Nurses (EAUN). The multiprofessional task force was created in order to include representatives from all the different cancer specialities: urologists—N.F., C.B., N.M., M.B., M.R., and V.S.; radiation oncologists—R.V., T.W., B.A.J.F., and B.P.; medical oncologists—S.G. and S.W.; pathologists—E.C.; radiologists—I.G. S.; nurses—S.F.; psycho-oncologists—L.T.; and patient advocate organisations—K.M.

The task force aimed at identifying the standards to define the EPCCE. Specifically, the required criteria were grouped into three main topics: (1) clinics, (2) research, and (3) education. A fourth step related to the assessment of the quality of the three previous topics was defined.

Discussion took place in conference calls and by e-mail from March 2017 to November 2017, and the final consensus meeting named "EAU Prostate Cancer Centre Consensus Meeting" (EPCCCM) was held in Barcelona on November 16, 2017. The aim of the discussion was to evaluate the applicability of the criteria in routine clinical practice and in the different health contexts of all European countries. The task force experts reviewed, through an iterative process, comprehensive multidisciplinary guidelines and literature within the framework described, thereby leading to a consensus on the standards for excellence of PCa care.

3. Results

The EPCCCM identified the following four main steps for the definition of the EPCCE.

3.1. Clinical step

The first step consisted of the certification of the institution as a "European Prostate Cancer Clinical Centre of Excellence". The general requirements are summarised in Table 1. Briefly, five items were identified and classified as follows: core team, associated services, multidisciplinary approach, diagnostic pathway, and therapeutic pathway. Each item consisted of specific requirements for excellence.

3.2. Research step

The second step consisted of the certification of the institution as a "European Prostate Cancer Research Centre of Excellence". The general requirements are summarised in Table 2. In this step, internal monitoring of outcomes is required. Specifically, a data manager plays a central role for data collection of patients diagnosed with and treated for PCa. Clinical data must be collected through a prespecified database, including pathological outcomes (for patients surgically treated), perioperative outcomes (complications, toxicity profiles, and readmission), functional outcomes (urinary continence, erectile dysfunction, and early and late genitourinary and gastrointestinal toxicity), and oncological outcomes (cancer recurrence rate, distant metastasis rate, and cancer-specific and overall mortality). Moreover, scientific activity represents the second item of this step: a clinical trial unit should be present and should include at least one representative of each component of the clinical core team [5]. The centre should be involved in at least five prospective trials, with three of them recruiting patients. The number of scientific publications represents periodical monitoring of the scientific activity of the centre of excellence: at least three publications are required every year. Clinical, translational, and basic research are allowed.

3.3. Educational step

The third step consisted of certification of the institution as a "European Prostate Cancer Educational Centre of Excellence". The general requirements are summarised in Table 3. In this step, young doctors have a central role during specific fellowship programmes focused on PCa. In detail, a fellowship programme will have a duration of at least 1 yr, comprising at least 6 mo of clinical and/or translational and/or basic research, and at least 6 mo of clinical activities. During the research period, the fellow will be the principal investigator of, at least, one project on PCa. On the contrary, in the clinical period the fellow will work in collaboration with urologists, radiation oncologists, and medical oncologists, as well as with psycho-oncologists, with specific requirements that have to be satisfied. At the end of the year, the young uro-oncologist will be certified as "Fellow of the European Prostate Cancer Centre of Excellence". Training in specific communication skills (eg, psychosocial needs, sexual needs, and masculinity issues) with PCa patients will supplement the education.

Table 1 – General requirements for the clinical step (first step)

No.	Quantity criteria	Requirements
1	Core team	
	-Urologist	-Two or more urologists specially trained in prostate cancer diagnosis and treatment
	-Radiation oncologist	-Two or more specialised radiation oncologists specially trained in prostate cancer radiotherapy
	-Medical oncologist	-Two or more specialised medical oncologist trained in the treatment of prostate cancer
	-Pathologist	-One or more pathologists in charge of uropathology, responsible for prostate cancer
	-Radiologist	-One or more radiologists in charge of uroradiology, responsible for prostate MRI
	-Nuclear medicine physicians	-One or more nuclear medicine physicians, responsible for PET/CT scan
2	Associated services	
	-Nurse	-One or more nurses dedicated to or specialised in urology
	-Psychologist/psychiatrist	-One or more clinical psychologists, with experience in uro-oncology, with access to a psychiatrist with experience in uro-oncology for complex cases
	-Geriatrician	-One or more geriatricians specially trained in the care of the elderly with prostate cancer
	-Physiotherapist	-One or more physiotherapists, for patients who require counselling about urinary continence
	-Sexual therapist or urologist trained in andrological urology, or certified andrologist	-One or more sexual therapists or urologists trained in andrological urology or certified andrologists available for patients who require counselling about changes in their sexual function incorporating the needs of partners
	-Palliative care specialists	-Available for patients with advanced disease
3	Multidisciplinary approach	
	-Leader	-An identified director or leader from any speciality of the core team
	-Counselling	-Patients should be offered counselling with different specialists
	-Tumour board evaluation	-Periodical multidisciplinary meetings, at least one per month. All patients have to be at least reported or discussed
	-Morbidity and mortality meetings	-Periodical multidisciplinary meetings, at least one per month
4	Diagnostic pathway	
	-Consultations	-At least 500 consultations performed for prostate cancer per year; consultation is defined by a new treatment plan; follow-up consultations are excluded
	-Prostate biopsy	-At least 200 prostate biopsies performed per year
	-mpMRI	-At least 300 mpMRI scans performed per year
5	Therapeutic pathway	
	-Treatment	-At least 500 patients treated per year, regardless of treatment proposed (active surveillance, focal therapy, radical prostatectomy, radiation therapy, or systemic therapies)

CT = computed tomography; MRI = magnetic resonance imaging; mpMRI = multiparametric MRI; PET = positron emission tomography.

3.4. *Quality control*

A final step concerning quality control is considered. Quality criteria apply to all the three previous steps, with different requirements (Table 4). Specifically, for the "clinical step", the following criteria are requested: (1) a data system should be available for periodical quality control of pathological, oncological, functional, and patient-reported outcomes, and an internal audit every 6 mo and an external audit every year should be organised; (2) pathological report should be completed within 2-wk time; and (3) clearly defined follow-up protocols for active surveillance, and local and systemic treatments (based on the EAU-ESTRO-ESUR-SIOG guidelines) are required.

Specific quality criteria for the "research step" are also requested: (4) a data system should be available for periodical quality control of clinical data, especially regarding missing data, follow-up data, and correlation between tumour characteristics and oncological outcomes (double check system). As an example, prostate-specific antigen and Expanded Prostate Cancer Index Composite (EPIC) score should be available for 90% of the patients, with a periodical report of correlation between tumour characteristics and oncological outcomes; (5) there should be a

Table 2 – General requirements for the research step (second step)

No.	Criteria	Requirements
6	Internal monitoring of outcomes	
	-Database	-One internal database including patients diagnosed and treated for prostate cancer; the same prespecified database will be adopted by centres
	-Data manager	-At least one data manager to collect data
	-Evaluated outcomes	-Oncological outcomes, functional outcomes, toxicity and complications, patient-reported outcomes, and distress, to be periodically assessed
7	Scientific activity	
	-Clinical trial unit	-Unit composed by at least one representative of the clinical core team
	-Clinical trials ongoing	-Five prospective trials to be involved (three of them recruiting)
	-Number of publications	-At least three publications per year, focused on prostate cancer, in peer-reviewed journals
	-Type of research allowed	-Clinical/translational/basic

Table 3 – General requirements for the educational step (third step)

No.	Criteria	Requirements
8	Structured fellowship	
	-Fellowship	-At least one structured fellowship should be offered
	-Research period	-At least 6 mo of clinical/translational/basic research on prostate cancer
	-Clinical period	-At least 6 mo of clinics working with urologists, radiation oncologists, and medical oncologists during which time there should be participation in at least one communication skill training session
9	Research period	
	-Number of publications	-At least one publication per year, focused on prostate cancer, in peer-reviewed journals
10	Clinical period	
	-Urology	-At least 2 mo: consultations, treatment, and follow-up with urologists
	-Radiation oncology	-At least 2 mo: consultations, treatment, and follow-up with radiation oncologists
	-Medical oncology	-At least 2 mo: consultations, treatment, and follow-up with medical oncologists or clinical oncologists

Table 4 – Quality criteria

No.	Quality criteria	Requirements
1	Clinic	A—Data system available for periodical quality control of:
		-Pathological outcomes
		-Oncological outcomes
		-Functional outcomes
		-Patient-reported outcomes
		-Internal audit: every 3 mo
		-External audit: every 1 yr
		B—2 wk time for pathological report
		C—Clearly defined follow-up protocols for active surveillance, and radical and palliative treatments
2	Research	D—Data system available for periodical quality control of clinical data:
		-Missing data
		-Follow-up data
		-Correlation between tumour characteristics and oncological outcomes (double check system)
		E—Grants and funding: periodical report
		F—At least three publications, focused on prostate cancer, per year in peer-reviewed journals, where the institution represents the affiliation of the first or the senior author; sum of the impact factors of the journals of the three or more publications should be 5.0 or more
3	Education	G—Certified curricula
		H—FEBU examination

FEBU = Fellow of the European Board of Urology.

periodical report of grants and funding; and (6) there should be at least three publications per year focused on PCa in international peer-reviewed journals, where the institution represents the affiliation of the first or the senior author. The sum of the impact factors of the journals of the three or more publications should be 5.0 or more.

Finally, the following criteria are required for the "educational step": the fellow should successfully complete (7) a certified curriculum or (8) the Fellow of the European Board of Urology examination.

Once the institution successfully achieves all the steps, it will be certified as an EPCCE. The certification will be reviewed every 3 yr, whereas the list of the certified centres will be published on uroweb.org. The accreditation team will be prespecified, and it will be composed of seven members of the EPCCCM ([1] C.B., *EAU*; [2] E.C., *Pathologist*; [3] B.A.J.-F., *ESTRO*; [4] M.B., *ESOU*; [5] I.S., *ESUR*; [6] K.M., *EUomo*; and [7] S.W., *DKG*).

4. Discussion

The EPCCCM was aimed at defining the requirements of the EPCCE. Four main topics were identified, consisting of clinics, research, education, and quality control.

The clinical step evaluated all the figures and aspects involved in the clinical activities related to PCa. In particular, the core team of health care professionals was identified, their interaction in a multidisciplinary team was discussed, and the requirements within the diagnostic and therapeutic pathways were fixed to define a centre of excellence. The discussion within the EPCCCM took into consideration an important aspect of the clinical step, which consisted of life expectancy evaluation and geriatric assessment. With a median age at diagnosis of 68 yr, PCa is common in men aged >70 yr. However, in Europe and USA, the increase in men aged >65 yr being diagnosed will result in an estimated 70% increase in annual diagnosis of PCa by 2030 [26,27]. In localised disease, >10 yr of life expectancy is considered mandatory for any benefit from local treatment. However, comorbidity is more important than age in predicting overall mortality in localised PCa, and it is a major predictor of non–cancer-specific death in localised PCa treated with radical prostatectomy [28]. It was a general consensus that, at the time of diagnosis, geriatric assessment should be performed in a centre of excellence. However, it could be time and money consuming. Therefore, according to the EAU PCa guidelines [15], a systematic comorbidity profile assessment should be performed using

the Geriatric 8 (G8) health status screening tool. Patients with a G8 score of <14 should undergo complete geriatric assessment to evaluate reversibility of any impairments [29].

The second step was focused on research. In this field, clinical, translational, and basic research may coexist. However, a relevant role is played by outcome research with the presence of data collection and data analysis. This point represents the important link between the first clinical step and the second research step. On the one hand, outcome research leads to scientific activity and publications. On the other hand, it represents optimal monitoring of the quality of clinical activities in terms of pathological, oncological, and functional outcomes.

The third step was then represented by education. This is an important innovation in the field of accreditation of PCa centres. The general consensus was that education of young uro-oncologists was fundamental in a centre of excellence. In particular, for the first time, a structured fellowship programme was proposed for young doctors interested in PCa. The structure of the fellowship programme was the direct link with the two previous steps, clinics and research. Indeed, it consisted of two periods of 6 mo: a first research period, where the fellow has the opportunity to develop knowledge and competence in PCa research, and to contribute actively to the scientific activity of the centre; and a second clinical period, where the fellow works in collaboration with expert physicians and has access to communication skills training.

In the field of PCa, the concept of hospital certification has already been addressed. For example, the ESO in collaboration with EAU and supported also by EAUN, EBU, EONS, ESTRO, IPOS, and DKG developed the concept of a "PCU", which was based on minimal requirements and mandatory and suggested standards [5,25]. Differently from the EPCCE, the "PCU" was not aimed at identifying centres of excellence, but it was a general consensus about the minimal requirements that a hospital should achieve. Furthermore, the topics of research and education were not taken into consideration, with multidisciplinary clinical activity and the spread of the concept of multiprofessional care through a set of minimal requirements in the European countries being the main aims of the initiative. However, most importantly, quality control, representing the fourth step of the EPCCE, was not included in any standard and item. On the contrary, in the EPCCE, quality control represented the fourth step of the certification for a centre of excellence, with different requirements related to the three initial steps (clinics, research, and education).

This relevant difference applies also to the other two initiatives for European PCa centres. The DKG, for instance, has launched an initiative to set up a network of PCa centres that are responsible for the diagnosis, staging, and management of PCa patients [30–35]. The quality results of the 108 certified PCa centres in three European member states are summarised in annual reports (http://ecc-cert.org/fileadmin/user_upload/Annual_Report_Prostate_2016.pdf). The latest annual report displays the results of around 100 000 patients with the first diagnosis of PCa over the course of 5 yr. Furthermore, since 2016, patient-reported outcomes are collected with the EPIC within the PCO-CRV study. Till August 2017, 5500 pretreatment questionnaires were included in the study. With the predefined database (http://www.xml-oncobox.de/), clinical data and patient-reported outcomes could be combined, and used for quality control and improvement. On the contrary, in the UK, the National Institute for Health and Clinical Excellence (NICE) has drawn up guidance on improving cancer services in urological cancers, which is enforced through regular peer audits and penalties for hospitals that fail to comply. NICE has argued that urology has tended to lag behind other fields of cancer in adopting serious multidisciplinary management. In its guidance, it stipulates that urological cancer patients should be treated by specialist urology cancer teams, and sets out minimum requirements on who should be the members of a multidisciplinary team, their roles and training, and how the team should organise its work [36]. In addition, this guidance notes the importance of providing information and access to counselling in relation to decision making and medical comorbidities such as urinary symptoms or erectile dysfunction.

Implications of the EPCCE are strictly related to the quality of care provided by different hospitals. For example, PCa mortality trends range widely from country to country in the industrialised world. Mortality due to PCa has decreased in most Western countries, but the magnitude of the reduction varies between countries [37]. In this context, identification of centres of excellence has the objective to increase the quality of care, research, and education, reducing the gap that currently exists among different countries.

Despite its novelty and possible implication, the EPCCE may be affected by the following limitation: it is important to underline that the definition of standards and items was mainly based on a consensus among experts rather than being an evidence-based process. Therefore, a certain grade of arbitrariness affected the definition of the standards.

5. Conclusions

Under the auspices of the EAU, experts on PCa diagnosis and treatment defined a set of criteria within the categories of clinical care, research, and education, to identify the EPCCE. The inclusion of a quality control approach represents the critical principle that supports the excellence of these centres. The increased level of quality of care in Europe provided by the EPCCE will have to be assessed by future evaluations.

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Study concept and design: Wirth, Albers, van Poppel, Fossati.
Acquisition of data: Wirth, Fossati, Bangma, Valdagni, Gillessen, Mottet, Comperat, Wiegel, Jereczek-Fossa, Pieters, Brausi, Mastris, Ribal, Schoots, Faithfull, Wesselmann, Sangar, Smelov, Travado, Müller, Albers, van Poppel.

Analysis and interpretation of data: Wirth, Fossati, Bangma, Valdagni, Gillessen, Mottet, Comperat, Wiegel, Jereczek-Fossa, Pieters, Brausi, Mastris, Ribal, Schoots, Faithfull, Wesselmann, Sangar, Smelov, Travado, Müller, Albers, van Poppel.
Drafting of the manuscript: Wirth, Fossati, Bangma, Valdagni, Gillessen, Mottet, Comperat, Wiegel, Jereczek-Fossa, Pieters, Brausi, Mastris, Ribal, Schoots, Faithfull, Wesselmann, Sangar, Smelov, Travado, Müller, Albers, van Poppel.
Critical revision of the manuscript for important intellectual content: Wirth, Fossati, Bangma, Valdagni, Gillessen, Mottet, Comperat, Wiegel, Jereczek-Fossa, Pieters, Brausi, Mastris, Ribal, Schoots, Faithfull, Wesselmann, Sangar, Smelov, Travado, Müller, Albers, van Poppel.
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