

Prostate Cancer Unit Initiative in Europe: a position paper by the European School of Oncology

Riccardo Valdagni^{1,2,3*}, Hendrik Van Poppel⁴, Michael Aitchinson⁵, Peter Albers⁶, Dominik Berthold⁷, Alberto Bossi⁸, Maurizio Brausi⁹, Louis Denis^{10,11}, Lawrence Drudge-Coates¹², Maria De Santis¹³, Gunther Feick^{10,14}, Chris Harrison¹⁵, Karin Haustermans¹⁶, Donal Hollywood^{17,a}, Morton Hoyer¹⁸, Henk Hummel¹⁹, Malcolm Mason²⁰, Vincenzo Mirone²¹, Stefan C. Müller²², Chris Parker²³, Mahasti Saghatchian²⁴, Cora N. Sternberg²⁵, Bertrand Tombal²⁶, Erik van Muilekom²⁷, Maggie Watson²⁸, Thomas Wiegel²⁹, Simone Wesselmann³⁰, Tiziana Magnani², Alberto Costa¹

¹ European School of Oncology, Milan, IT;

² Prostate Cancer Programme, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan (IT)

³ Radiation Oncology 1, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan (IT)

⁴ Dept. of Urology, University Hospital of the Katholieke Universiteit Leuven, Leuven (BE)

⁵ Renal Cancer Services, Royal Free Hospital, London (UK)

⁶ Dept. of Urology, Heinrich Heine University Hospital Düsseldorf, Dusseldorf (G)

⁷ Centre Polidisciplinaire d'Oncologie, Hospitalier Universitaire Vaudois, Lausanne (CH)

⁸ Dept. of Radiation Oncology, Institut Gustave Roussy, Villejuif (FR)

⁹ Dept. of Urology, Ausl Modena, Nuovo Ospedale Civile-S. Agostino Estense, Modena (IT)

¹⁰ Europa Uomo, Antwerp (BE)

¹¹ Oncological Centre, Antwerp (BE)

¹² King's College Hospital NHS Foundation Trust, London (UK)

¹³ Ludwig Boltzmann Institute for Applied Cancer Research (LBI-ACR Vienna) - LBCTO, 3rd Medical Department, Centre for Oncology and Haematology, Kaiser Franz Josef Hospital, Vienna (AT)

¹⁴ Bundesverband Prostatakrebs Selbsthilfe, Pohlheim (G)

¹⁵ Greater Manchester Strategic Health Authority, Manchester (UK)

¹⁶ Dept. of Radiation Oncology, Leuven Cancer Institute, University Hospitals Leuven, Leuven (BE)

¹⁷ Urologic and Radiation Oncology, Applied Radiation Therapy Trinity and Prostate Molecular Oncology Research Group, Discipline of Radiation Therapy and Institute of Molecular Medicine, Trinity College Dublin (IR)

¹⁸ Dept. of Oncology, Aarhus University Hospital, Aarhus (D)

¹⁹ Integraal Kankercentrum Nederland (IKNL), Comprehensive Cancer Centre Netherlands, Amsterdam (NL)

²⁰ Dept. of Oncology and Palliative Medicine, Cardiff University School of Medicine, Velindre Hospital, Cardiff (UK)

²¹ Dept. of Urology, University of Naples "Federico II, Naples (IT)

²² Dept. of Urology, Bonn University Hospital, Bonn (DE)

²³ Academic Urology Unit, The Royal Marsden NHS Foundation Trust, Sutton (UK)

²⁴ Breast Cancer Unit, Institut Gustave Roussy, Villejuif (FR)

²⁵ Dept. of Medical Oncology, San Camillo and Forlanini Hospitals Rome (IT)

²⁶ Dept. of Urology, Cliniques Universitaires Saint-Luc, Brussels (BE)

²⁷ Dept. of Urology, Netherlands Cancer Institute, Amsterdam (NL)

²⁸ Psychology Research Group, Royal Marsden NHS Foundation Trust, Sutton (UK)

²⁹ Dept. of Radiation Oncology, University Hospital Ulm, Ulm (DE)

³⁰ Deutsche Krebsgesellschaft, German Cancer Society, Berlin (DE)

^a *In memoriam* Prof. Donal Hollywood, President-Elect of the European Society for Radiotherapy & Oncology 2011–2013

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Abstract

The Prostate Cancer Programme of the European School of Oncology developed the concept of specialised interdisciplinary and multiprofessional prostate cancer care to be formalized in Prostate Cancer Units (PCU). After the publication in 2011 of the collaborative article “The Requirements of a Specialist Prostate Cancer Unit: A Discussion Paper From the European School of Oncology”, in 2012 the *PCU Initiative in Europe* was launched. A multiprofessional Task Force of internationally recognized opinion leaders, among whom representatives of scientific societies, and patient advocates gathered to set standards for quality comprehensive prostate cancer care and designate care pathways in PCUs. The result was a consensus on 40 mandatory and recommended standards and items, covering several macro-areas, from general requirements to personnel to organization and case management. This position paper describes the relevant, feasible and applicable core criteria for defining PCUs in most European countries delivered by *PCU Initiative in Europe* Task Force.

Key words

Prostate Cancer Unit, Multidisciplinary and multiprofessional approach, Minimal requirement, Prostate Cancer

* **Corresponding Author** at Prostate Cancer Programme and Radiation Oncology 1, Fondazione IRCCS Istituto Nazionale dei Tumori, via Venezian 1, 20133 Milan (IT); ph. 0039 02 23903034; fax 0039 02 23903015; e-mail: riccardo.valdagni@istitutotumori.mi.it

1. Introduction

Prostate cancer is the most common cancer diagnosed in men, with 417,000 new cases every year in Europe [1]. Multiple therapies and observational strategies are available for this malignancy. According to the patient's state of disease, surgery, external radiotherapy, brachytherapy, hormonal therapy, chemotherapy, radionuclide metabolic therapy as well as active surveillance, watchful waiting and supportive care can be considered [2-9]. As a result, several health care professionals play a significant role in the care of prostate cancer patients, including, non exhaustively, urologists, radiation oncologists, medical oncologists, pathologists, nuclear medicine physicians, imaging specialists, psychologists, nurses, sexual therapists, physiotherapists, geriatricians, and experts in palliative and supportive care potentially involved in specific disease settings [10].

Comprehensive multidisciplinary management of prostate cancer patients streamlines patients' access to care, rehabilitation and counseling delivered by a team of qualified experts [11-25]. The integration of care provision by multiple professionals is the best way to implement simultaneous care, thus enabling the coordination of care and facilitating patients' transition from curative to palliative treatments [26]. This is in line with the policy statement of the European Partnership for Action Against Cancer (EPAAC), which stresses a paradigm shift in cancer care from a disease-focused management to a patient-centered approach and highlights the importance of multidisciplinary teams for optimal coordination among professionals and communication with patients [27].

On the assumption that there is a critical need in Europe to provide prostate cancer patients with high quality, standardized and integrated care, the European School of Oncology (ESO) through its Prostate Cancer Programme developed the concept of specialised interdisciplinary and multiprofessional prostate cancer care to be formalized in Prostate Cancer Units (PCU). ESO initiated a discussion in the European uro-oncologic community and advocacy groups on the need and requirements for establishing PCU. The first step was the publication of the article "The Requirements of a Specialist Prostate Cancer Unit: A Discussion Paper From the European School of Oncology" in 2011 [10], which sought to open the debate in peer-reviewed journals [28,29,30] and within national and international scientific societies (i.e. European Association of Urology - EAU, European Society for Medical Oncology- ESMO, European Society for Therapeutic Radiation Oncology - ESTRO, Italian Society for Uro-Oncology - SIUrO), with dedicated sessions on the pros and cons of the multiprofessional management of prostate cancer patients.

At this point, in early 2012, the natural evolution of the project was considered the accreditation and certification of PCU in Europe. ESO (AC, RV) signed a collaboration agreement with the Organisation of European Cancer Institutes (OECI - MS), a non governmental organization running an accreditation and designation programme of Cancer Centres in Europe since 2008, and the Deutsche Krebsgesellschaft (DKG - SW), the German Cancer Society, which developed a certification system for prostate cancer centres in 2008, with 97 centres certified and quality-of-care indicators [31,32]. The agreement was aimed at setting standards for quality comprehensive prostate cancer care and designating care pathways in PCUs and the project was launched as *Prostate Cancer Unit Initiative in Europe*.

This paper (writing committee: TM, RV and AC) describes the achievements obtained thus far with the aim of reaching a broader consensus on the minimum criteria for defining and ultimately facilitating the process to accrediting PCUs in European countries.

2. Material and Methods

The first activity of the *PCU Initiative in Europe* was the creation of a multiprofessional Task Force with representatives from cancer specialties (urologists – MA, PA, MB, VM, SCM, BT, HVP; radiation oncologists – AB, KH, DH, MH, MM, CP, TW; medical oncologists – DB, MDS, MM, CNS), psychologists (MW), nurses (LDC, EVM), patient advocate organizations (Europa Uomo represented by LD, GF), cancer centre managers and quality experts (CH). The Task Force was chaired by the ESO Prostate Cancer Programme Coordinator (RV), and an OECI delegate (HH). The major international oncologic societies and organizations were invited to participate and nominate their representatives. The invitation was accepted by the EAU, the European Association of Urology Nurses (EAUN), the European Oncology Nursing Society (EONS), ESTRO, and **the International Psycho-Oncology Society (IPOS)** and, at a later stage, the European Board of Urology (EBU).

Discussion took place in face to face meetings, in conference calls and by e-mail, over a two year time frame (from November 2012 to September 2014). The Task Force analyzed the literature on the multidisciplinary and multiprofessional management of cancer patients in general and of prostate cancer patients in particular [28-30,33-36]. Task Force experts reviewed, through an iterative process, comprehensive multidisciplinary guidelines within the framework described, thereby leading to a consensus on the minimum standards for quality prostate cancer care.

The work of the Task Force allowed the re-evaluation of the previously described PCU requirements [10] and changes were introduced to make them adoptable at a European level.

Since the movement towards the establishment of PCUs was aimed to reach most European countries, the bar had to be set at a reasonably attainable medium level, at least in the first phase, and the feasibility of the criteria had to be thoroughly checked.

The focus was particularly on the ESO discussion paper [10] to confirm/redefine the minimal requirements. 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, to reach an agreement on them and to set up a system for the definition, development and organisation of PCUs based on OECI standards and methodology [37] showing medium-high quality system for cancer care.

Results

The work and dedication of the Task Force led to a consensus on 40 standards and items, distinguished as mandatory and recommended, for designing a PCU (Tables 1-6) and covering several macro-areas defined as standards: general requirements and critical mass, core team, non core team and associated services, clinics, organization and case management, different services, treatment and observational options, equipment.

Every standard contained one or more items, also known as measurable elements, which added specifics to the standards.

The standard 8 “PCU core team – Urologists” (Table 2), for example, defined one of the specialties of the PCU Core Team. More specifics were added by the items, which defined the number of urologists for a PCU, the amount of contractual time dedicated to prostate cancer, the number of procedures to be performed in the Unit per year and the activities they had to perform within the Prostate Cancer Unit (clinics, case management, etc).

Standards 25-27 (Tables 3 and 4) offered examples of the consensus reached among the Task Force experts. These standards described three possible clinical models for management of newly referred patients: (1) a monodisciplinary clinic performed by the urologist, the radiation oncologist or the medical oncologist; (2) a multidisciplinary clinic where the patient was seen by the urologist, the radiation oncologist and the medical oncologist in sequence; (3) a multidisciplinary clinic where the patient was seen synchronously by the urologist, the radiation oncologist and the medical oncologist. In the two multidisciplinary clinics, professionals able to offer psycho-social support were asked to participate if possible. In all the cases, the nurse had to be present to provide additional information and support as required and the patient had to be provided with written information on the therapeutic and

observational options. It is important to stress that all the cases were scheduled to be discussed in the Interdisciplinary and Multiprofessional Team Meeting, thus ensuring that a monodisciplinary approach was acceptable only if the clinical case is evaluated multidisciplinarily.

Consensus on standards and items for a PCU was reached in September 2014.

As a result of the discussion within the Task Force, several changes were introduced with respect to the requirements published in 2011 [10]. The following points are examples of the revisions:

- Professionals authorized to administer chemotherapy and immunological therapies were changed from only medical oncologists to medical oncologists plus specialists in internal medicine, hematology and oncology, specially trained in the treatment of prostate cancer plus certified specialists member of the core team trained on the use of drugs with prostate cancer patients;
- The working time of the prostate dedicated medical oncologists was increased from 30% to 50%;
- The working time of the uro-pathologists was increased from 30% to 50%;
- The number of mandatory biopsies to be seen by the uro-pathologists was cancelled;
- The requisites of the nurse were modified from being a specialist in prostate cancer to being dedicated to or specialized in urology and the contractual time for prostate cancer equal to 75% of one's working time care was added;
- Some professionals in the non-core team (i.e. the clinical trial coordinator, physiotherapist, sexual therapist, geriatrician) and some services (i.e. clinic dedicated to recurrent and advanced prostate cancer, physiotherapy, sexual rehabilitation, psychological counselling, centralized pathologic review of diagnostic biopsies carried out elsewhere before proposal of treatment and observational options) were considered recommended and no longer mandatory;
- It was added that advice, counseling and psychological help could be given by clinical nurse specialists in prostate cancer care in some countries and by persons professionally trained to give psychological support and with expertise in prostate cancer in others, with supervision from either a clinical psychologist, accredited counselor or liaison psychiatrist;
- It was added that sexual therapy could be offered by a sexual therapist as well as by a urologist trained in andrological urology or certified andrologist or clinical nurse specialist supervised by either a sexual therapist, clinical psychologist or urologist trained in andrological urology;

- At least in the first phase of implementation, a monodisciplinary clinic provided by the urologist or the radiation or the medical oncologist was considered to be acceptable as a third possible alternative to the multidisciplinary clinic. However, there was unanimous consensus that the discussion of clinical cases in the Interdisciplinary and Multiprofessional Team Meeting should be mandatory before starting any therapy or observational programs.

It must be underlined that the role of the patient and the partnership and alliance with patient advocates remained key elements for a PCU. Advocates or advocacy group members (e.g. Europa Uomo, local organizations) were confirmed as an integral to the liaison/communication network of the PCU, as was already proposed in the discussion paper. Furthermore, it was stated that PCUs had to provide patients with clear and easy-to-understand written and electronic information on diagnosis, treatment and observational options, follow up, rehabilitation programs, psychosocial care options, certified sperm preservation units on a regional level, patient groups and other potential sources of support.

3. Discussion

A detailed comprehensive 2 year long debate on the minimal requirements identified in the 2011 discussion paper [10] was undertaken by all members of the multidisciplinary Task Force of the *PCU Initiative in Europe*. Involvement of Europa Uomo representatives gave added value to the discussion and enabled consideration of the patient's perspectives on key issues such as the need for objectivity in the proposal of therapeutic and observational options, without the specialty driven bias, and for written and electronic information sheets on all the aspects of the disease and treatment phases.

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. Despite the extensive scientific output on the overall advantages of the multiprofessional management of cancer in general, there are few articles which provide evidence, in prostate cancer specifically, for figures and estimates of specialist workloads which could be used for the definition of PCUs [21,22,24,25,33-36]. For some standards, consensus was possible only by accepting a certain level of compromise. Some urologists, for example, wanted to increase the minimum practice standards required, in terms of number of radical prostatectomies per year, from 50 to 100, and to introduce a minimum number of procedures per surgeon (25/year). After a long discussion it was decided, at least for the initial phase of the implementation, to leave the

number as 50 in order to facilitate the introduction of PCUs for centers not particularly focused on prostate surgery. In addition, the evaluation of the case load of a PCU must pay particular attention to the number of patients on active surveillance, who should be considered as patients potentially undergoing radical treatments [33,38,39]. Another significant point of discussion was the mandatory participation of the uro-pathologists in the Interdisciplinary and Multiprofessional Team Meetings as member of the Core Team. Since this might not be routine in some centers, it was agreed to add that documented exceptions to the rule could be accepted.

The discussion within the Task Force highlighted the differences in healthcare resources between countries and these had to be taken into account to avoid potential problems, thus facilitating the spread of PCUs. As mentioned, it was decided that chemotherapy and immunological therapies could be administered by medical oncologists as well as specialists in internal medicine, hematology and oncology, specially trained in the systemic treatment of prostate cancer. It was also taken into account that in some countries urologists and radiation oncologists are also authorized to prescribe systemic therapies and for this reason it was added that drugs could be prescribed by a certified specialist member of the core team trained on the use of drugs with prostate cancer patients. Considering that in most European countries nurses are not specialized in prostate cancer, the definition was changed to “nurses dedicated to or specialized in urology”. Similarly, it was accepted that psychological support could be offered by psychologists as well as other professionals (nurses specialized in prostate care in some countries, persons professionally trained to give psychological support with expertise in prostate cancer) when supervised by either a clinical psychologist, accredited counselor or liaison psychiatrist. For the same reason, sexual therapy could be offered by a sexual therapist as well as by a urologist trained in andrological urology or certified andrologist or clinical nurse specialist supervised by either a sexual therapist, clinical psychologist or urologist trained in andrological urology.

Spanning almost two years, the work of the Task Force had to consider the impact of emerging technologies on the clinical practice and the professionals involved in the care of prostate cancer patients [40]. The most significant example is offered by the multiparametric Magnetic Resonance Imaging (mpMRI) in the prediagnostic [41] and observational settings [40]. The introduction of the exam into the clinical practice appears satisfactory in reducing the number of unnecessary biopsies and to support urologists by targeting biopsies to the suspected lesions [41]. This was the main rationale for cancelling the minimum number of prostate cancer biopsies equal to 150 defined as mandatory requirement in the discussion paper [10]. For the same reason, the Imaging Specialist became a key figure in the management of

prostate cancer patients. However, after long discussion, it was decided not to change the Imaging Specialist from the non core to the core team in the first release of the standards and items for the following reasons: the technology is utilized only in very limited centers in Europe and is completely absent in several countries; the exciting preliminary findings need to be further validated; randomized comparative trials to standard imaging are currently rare; not all centers equipped with the facility have qualified Imaging Specialists. It is quite conceivable that the Imaging Specialist could be moved to the core team in the first revision and update of the standards and items.

Similarly, active surveillance is proving a valid alternative to radical therapies in low and very low risk patients [9] (Bangma Eur Urol 2015). Centers systematically proposing active surveillance are experiencing a decrease in the number of prostatectomies and radiotherapy and brachytherapy [33,38,39] (Magnani, Aizer). This new scenario was considered when the number of radical procedures was decided as mandatory for the applying centers. It is for this reason that patients on active surveillance should be counted in the annual workload.

The aim of the *PCU Initiative in Europe* as launched by ESO, OECl and DKG was the definition of minimum standards and items for designing, accrediting and monitoring PCUs. In early 2014, however, OECl decided to focus their work on Comprehensive Cancer Centers rather than being involved in the accreditation of disease units. No new accrediting body was subsequently identified because the top priority was to complete the definition of standards and items for PCUs.

4. Conclusion and future activities

The *PCU Initiative in Europe* enabled the setting of standards and items for defining PCUs in Europe. Delivering core criteria which had relevance, feasibility and applicability was the most important point of the work of the multiprofessional Task Force in guaranteeing the acceptance and spread of PCUs in most European countries.

Given the importance of employing a workable methodology for prostate cancer care delivery and the emerging innovations in diagnosis and care, it is essential to schedule regular updates of standards and items. The first will take place mid 2016.

The participation of the scientific bodies in the *PCU Initiative in Europe*, the promotion of the concept of the PCUs and the cultural shift towards multidisciplinary working should win a broad consensus in the uro-oncologic community.

As well as the scientific societies, the efforts of patient advocacy groups in increasing patients' awareness about the importance of being treated and followed up in top quality centers are key elements for the success of the Initiative. Moreover, patient advocates could help the lobbying process and successfully approach European legislators.

Synergy among PCUs should be considered an added value for both professionals and patients and should be pursued by encouraging collaboration between centers.

Author contribution

All involved authors stated that they have read the manuscript, have agreed to the submission and have participated in the study to a sufficient extent to be named as authors.

Conflict of interest statement

The authors declare no conflict of interest.

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