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Current perspective

The requirements of a specialist Prostate Cancer Unit: A discussion paper from the European School of Oncology

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ARTICLE INFO

Article history:

Received 30 September 2010

Received in revised form 26 October 2010

Accepted 29 October 2010

Available online 1 December 2010

Keywords:

Prostate cancer

Multidisciplinary communication

Patient care team

Interdisciplinary health team

Patient care management

Patient-centred care

Organizational structure

Cancer care units

Criteria

Holistic health

ABSTRACT

The widely recognised benefits of a multidisciplinary approach to treating cancer may be particularly important in prostate cancer, where there are so many treatment options to choose from. It offers patients the best chance of receiving high-quality medical procedures administered by a team of specialists in prostate disease, which is able to tailor treatment and observational strategies to their needs, and ensure access to specialist counselling, supportive care and rehabilitation. This article proposes Prostate Cancer Units as the most suitable structures for organising specialist multidisciplinary care for patients at all stages, from newly diagnosed to advanced disease, including preventing and managing the main complications, whether physical, emotional or psychological, arising from the disease and its treatment. Following the German example with prostate cancer, the British example with urological malignancies and the European breast cancer units, this article proposes general recommendations and mandatory requirements for Prostate Cancer Units, with a view to laying the basis for a network of certified units across Europe. Such a network could help improve standards of care throughout the region, providing patients, practitioners and health authorities with a means of identifying high-quality units and providing a system of quality control and audit. The article is intended as a contribution to the debate within the European uro-oncologic community on the best way to organise prostate cancer care.

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doi:10.1016/j.ejca.2010.10.029

1. Introduction and background

The incidence of prostate cancer has been steadily rising in Europe¹, and it is now the most common cancer diagnosed in men, with around 382,000 new cases and around 89,000 deaths every year.²

The multidisciplinary management of patients with cancer has become almost universally accepted in recent years as offering the best chance of optimising the experience and outcome for patients, enabling a team of specialists to plan, optimise and provide care tailored to each patient's needs.^{3–8}

The concept has a particular relevance in prostate cancer^{9–17} because of the availability of multiple treatment options – including surgery, radiotherapy (combined or not with hormonal therapy) and brachytherapy, – which all appear to have a specific place and indication but may cause different side-effect profiles.^{18–20}

Moreover, recently, observational strategies such as active surveillance and watchful waiting have been proposed.^{2,21–26}

Active surveillance aims to provide observation to indolent and clinically insignificant cancers, reserving invasive treatment to those who show progression. On the other hand, watchful waiting delays palliative treatment until symptoms require it.^{21–26}

A well-defined multidisciplinary management of patients with prostate cancer, including disease recurrence and metastatic stages, can help ensure the applied medical procedures, are of high quality and administered by a team that treats adequate numbers of similar patients.^{27–31} It can also ensure that patients get access to specialist counselling, supportive care and rehabilitation, all of which are very important in the care of this malignancy.

A Prostate Cancer Unit – a place where men with prostate cancer can be cared for by specialists in prostate disease working together within a multiprofessional team – offers the most suitable organisational structure for caring for prostate cancer patients at all stages, from newly diagnosed to advanced disease, including prevention and treatment of the main complications of the malignancy and its treatments.

Moreover, a Prostate Cancer Unit, beyond facilitating access to care, could help patients recognise and express emotional needs that might not otherwise be addressed. Men are less likely than women to recognise the need for help and to look for advice and support³² because of cultural and social barriers.^{33,34}

Sexual issues, which are particularly relevant in prostate disease, are often the most difficult to confront and are usually not verbalised. Prostate Cancer Unit specialists may elicit the discussion of sexual issues, helping patients overcome shyness, shame and embarrassment.³⁵

In recent years, some countries have started to manage prostate cancer multiprofessionally and reorganise the delivery of services in line with the concept of a Prostate Cancer Unit. The German Oncology Society, Deutsche Krebsgesellschaft, for instance, has launched an initiative to set up a network of Prostate Cancer Units that are responsible for the diagnosis, staging, and management of prostate cancer patients (http://www.krebsgesellschaft.de/wub_zertifizierte_prostatakarzinomzentren_karte,120895.html). In the United

Kingdom (UK), the National Institute for Health and Clinical Excellence (NICE) has drawn up guidance on improving cancer services in urological cancers (http://www.nice.org.uk/nicemedia/pdf/Urological_Manual.pdf), which is enforced through regular peer audits and penalties for hospitals that fail to comply. The Institute has argued that urology has tended to lag behind other fields of cancer in adopting a 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 whom should be members of a multidisciplinary team, their roles and training and how the team should organise its work.

To improve standards of management, reorganising prostate care delivery around a network of Prostate Cancer Units has the potential to significantly improve standards of care throughout Europe. Establishing a European certification process for Prostate Cancer Units would provide patients, practitioners and health authorities the means of identifying high-quality units. It would also provide an important means of quality control and audit.

This model is already being successfully implemented in breast care, in line with a policy adopted in 2003 by the European Parliament, which called on Member States to establish a network of certified multidisciplinary breast units that would cover the entire population. Certification was to be based on the fulfilment of a set of criteria modelled on requirements set out by EUSOMA (the European Society of Breast Cancer Specialists) and first described in an article in this journal.³⁶

Many Member States have now undergone a substantial reorganisation of their breast cancer services in line with these requirements,^{37,38} and the move has been strongly influenced by breast cancer patient advocacy groups such as Europa Donna – the European Breast Cancer Coalition (www.europadonna.org).

This paper aims to contribute to the debate on the requirements for European Prostate Cancer Units. It is hoped that prostate cancer advocates, like Europa Uomo – the European Prostate Cancer Coalition (www.europa-uomo.org) – can have comparable success in securing political action on implementing a European policy on Prostate Cancer Units.

2. General recommendations

2.1. Certification of a Prostate Cancer Unit must be based on a minimum set of agreed requirements.

2.2. A European certification process for Prostate Cancer Units that is based on the fulfilment of agreed mandatory requirements should be established. A standard database should be developed to collect demographic and clinical data, in obedience to the laws on privacy in force in the different countries, and ensure consistency and uniformity in data collection. An independent European body that is accredited by the European Commission needs to be appointed to assess and certify eligible Prostate Cancer Units.

2.3. Prostate Cancer Units should be able to provide care for patients with prostate cancer at all its stages – from newly diagnosed through to advanced disease.

2.4. Research is an essential part of training of specialists. As part of the Unit's audit the numbers of patients entered into clinical trials and details of all other on-going research must be recorded. Units should be encouraged to provide research opportunities and this must be taken into account when assessing units for their suitability for accepting trainees. The Unit should aim to enrol at least 10% of all patients into innovative clinical trials.

2.5. The Unit should provide teaching, either for junior staff or for students on a national or international basis. A number of Units will be recognised as teaching centres, nationally or internationally. They may be recognised for teaching overall prostate disorder management or special aspects (e.g. prostate cancer biopsy and pathology, prostate cancer treatment in different modalities, physical or psychological rehabilitation).

2.6. Prostate Cancer Units should manage their own budget, covering all the work of the Unit. The Unit's budgets must include provision for ongoing education of all core team members.

3. Mandatory requirements

3.1. Critical mass

3.1.1. To ensure a sufficiently large caseload to run regular clinics and make it practical and cost-effective for the specialists in the core team to spend an agreed amount of time working on prostate cancer, there has to be a minimum size for a Prostate Cancer Unit. Such Units need not necessarily be a geographically single entity, although the separate buildings must be within reasonable proximity to provide a stable structure for teams of specialists to work together. In case of distant locations, Prostate Cancer Units should be adequately organised to offer prostate cancer patients top quality services, care and assistance on a regular basis, with the participation of core team members and associated services and non-core personnel. If two hospitals are close together it is more practical for only one of them to establish a functional prostate unit serving both hospitals, i.e. the prostate team works at both centres. If Prostate Cancer Units are organised as multiple entities in separate buildings, patients must be managed and followed-up by a single multidisciplinary team.

3.1.2. Prostate Cancer Units will most often be established in large or medium-sized hospitals; they should cover a population of at least 300,000 people. Some highly specialised units will be larger and considerably engaged in clinical research activity.

3.1.3. A Unit must be of sufficient size to have more than 100 newly diagnosed cases of prostate cancer coming under its care (for treatment and observation) each year. Patients may have been diagnosed elsewhere but if they have received any prior treatment and have been transferred, for example, to receive radiotherapy, they should not be counted as new cases.

3.1.4. All treatments and observational strategy protocols must be carried out under the guidance of the Unit's multidisciplinary team. Surgery, radiation therapy and brachytherapy must be delivered within the Prostate Cancer Unit; however,

adjuvant and palliative therapies as well as psychological support may be delivered in other settings but under the direction of the Prostate Cancer Unit; patients on active surveillance and watchful waiting may be followed up by the Prostate Cancer Unit's multidisciplinary team or in other settings but under the direction of the Prostate Cancer Unit. Patients' follow-up care and rehabilitation should be guided by the Prostate Cancer Unit.

3.2. Documentation/audit

3.2.1. Prostate Cancer Units must record basic data on diagnosis, pathology, surgical treatments, radiotherapy, brachytherapy, adjuvant treatments, observational strategies, palliative treatments, clinical outcomes and follow up, including side-effects and complications. The data must be available for audit and the Unit must achieve the minimum outcome for mandatory quality indicators (QI) as established by Accredited Audit Teams. Performance and audit figures must be produced yearly and set alongside defined quality objectives and outcome measures.

3.2.2. The Unit team must hold an audit meeting at least once a year to review QI and amend protocols as necessary. A formal record of these meetings must be kept.

3.2.3. Prostate Cancer Units must have written protocols for diagnosis and for the management of prostate disease and cancer at all stages. All protocols must be agreed upon by the core team members. New protocols and protocol amendments should be discussed by the core team at the audit meetings.

3.2.4. All relevant data should be collected, recorded and available for analysis, evaluation and audit.

3.3. Core team

Prostate Cancer Units must have a core team whose members have specialist training in prostate disorders, spend an agreed amount of their time working with prostate cancer, and undertake continuing professional education on a regular basis. All core team members must attend multidisciplinary meetings for case management and audit purposes. Core team members include:

3.3.1. Clinical Director

An identified Clinical Director of the Prostate Cancer Unit – preferably a MD or PhD from any specialty of the core team – who is responsible for the coordination of the Unit.

3.3.2. Uro-pathologists

One or more uro-pathologists specialising in prostate disease will be responsible for all prostate pathology. Pathologists carrying out these roles must have contractual sessions to attend team case management and audit meetings. They must be familiar with national and/or European performance quality standards and guidelines. They must take part in available European, National and Regional quality assurance protocols. A uro-pathologist must spend approximately 30% of his/her working time in prostate disease. All specialist uro-pathologists reporting on prostate cancer should see at least 150 sets of prostate biopsies per year.

3.3.3. Urologists

Two or more urologists specially trained in prostate disease diagnosis and treatment will be a part of the unit. Each should carry out at least 25 radical prostatectomies per year for a total of 50 radical prostatectomies per year per unit and should attend at least one prostate clinic per week. To be prostate dedicated a urologist should spend approximately 50% or more of his/her working time in prostate disease.

3.3.4. Radiation oncologists

Two or more radiation oncologists specially trained in prostate cancer radiotherapy will be a part of the Unit. Each should carry out external radiotherapy (radical or adjuvant) on at least 25 prostate cancers per year for a total of 50 treatments per year per unit, or be specially trained in prostate cancer brachytherapy (HDR or LDR) and carry out on at least 15 prostate cancer HDR or LDR brachytherapy procedures per year. To be prostate dedicated a radiation oncologist should spend approximately 50% or more of his/her working time in prostate disease.

3.3.5. Medical oncologists

One or more specialised medical oncologists should be specially trained in the treatment of prostate cancer. Each medical oncologist should see at least 30 prostate cancer patients per year. To be prostate dedicated a medical oncologist should spend approximately 30% or more of his/her working time in prostate disease.

3.3.6. Nurse specialist in prostate care

There should be at least one nurse specialist in prostate care with special training in providing care for patients at different stages of disease who can act as the key contact person for patients and their significant others. Specialist nursing support should be available to patients at the time of diagnosis as well as other important milestones in the patient journey (e.g. recurrence).

3.3.7. Data managers

One or more dedicated data managers should be responsible for entering data on diagnosis, treatment, pathology and clinical outcomes and for ensuring that all relevant data are collected, recorded and analysed. Reasonably, one 0.5 full time position could be allocated for up to 200 newly diagnosed cases and an additional 0.1 full time position for 200 aftercare cases.

3.3.8. Documentation representative

One documentation representative who is responsible for the documentation system should be identified within the Prostate Cancer Unit core personnel. He/She should monitor the complete and correct compilation of patient data, support staff active in data compilation and schedule regular evaluations.

3.4. Associated services and non-core personnel

In addition to the core team, Prostate Cancer Units must have access to a variety of additional professional services that

might be available in the various European countries under different professional headings:

3.4.1. Radiologists

One or more nominated radiologists fully trained and with continuing experience in all aspects of prostate disease imaging (MRI, PET/CT, TRUS, Nuclear Medicine). To be associated with a Prostate Cancer Unit, a radiologist must spend approximately 20–30% of his/her working time in prostate disease.

3.4.2. Medical physicists

One or more nominated medical physicists specially trained in prostate cancer external radiotherapy and brachytherapy. Each must personally carry out treatment planning on at least 40 prostate cancer radiotherapy and brachytherapy treatments.

3.4.3. Radiation therapy technologists

Two or more radiation therapy technologists specially trained in prostate cancer external radiotherapy. Each must personally carry out simulation and treatment on 25 prostate cancer radiotherapy treatments.

3.4.4. Physiotherapists

One or more physiotherapists specially trained to use interventions that can minimise postoperative complications and promote rehabilitation following prostate cancer treatments.

3.4.5. Palliative care specialists

One or more palliative care specialists dedicated to prostate cancer, responsible for all palliative treatments and supportive care. Palliative care specialists carrying out these roles should have contractual sessions to attend team case management and audit meetings.

3.4.6. Professionals offering psychological support

If the patient is in need of psychological support after the diagnosis or in the decision making phase or is experiencing psychological morbidity that cannot be dealt with effectively by members of the Unit, he should be referred to a clinical psychologist with experience in seeing prostate patients and with whom there are particular arrangements to see prostate patients for the Prostate Cancer Unit. Regular support (advice, counselling, psychological help) is given by nurses specialists in prostate care in some countries and by persons professionally trained to give psychological support and with expertise in prostate cancer in others.

3.4.7. Sexologist/andrologist

Support from a sexologist or andrologist should be available for prostate patients who require counselling about changes in their sexual function. Ideally, access to a certified sperm preservation unit on a national level should be available.

3.4.8. Geriatrician

One geriatrician specially trained in the care of the elderly with prostate cancer should be available.

3.4.9. Clinical trials coordinators

One or more clinical trials coordinators, who can be either a medical figure or a research nurse, should be responsible for all clinical trials and research protocols.

3.4.10. Patient advocates and advocacy group

Patient advocates or advocacy group members like Europa Uomo should be an integral part of the liaison/communication network of the Prostate Unit. Patients should have access to the cooperating support group in all phases of treatment. They will help improve the quality of care offered to patients, be the contact person to offer patients information on the disease, treatment and observational strategies, side-effects and complications, and follow up procedures, thus favoring a better understanding and hopefully a better compliance. They should also collaborate with Prostate Cancer Unit personnel to evaluate innovative studies with respect to the impact on patients' quality of life and risk/benefit issues.

4. Organisation of Prostate Cancer Unit

4.1. Multidisciplinary case management

All members of the Prostate Cancer Unit core team must attend the multidisciplinary meeting (MDM), which must be held at least weekly. Records must be maintained of the colleagues who attended the meeting and of the patients who were discussed and reviewed. If possible/on demand, the psychologist amongst other non-core professionals should attend the MDM or provide the core team with written notes on the prostate patients examined in the multidisciplinary clinic or drawn to her/his attention by the Prostate Cancer Unit. At least 90% of all the cases referring to the Prostate Cancer Unit must be discussed. This figure includes the following:

- cases in which the diagnosis is as yet uncertain;
- cases in whom the diagnosis of cancer is confirmed and who may be considered for radical therapy or observational strategies;
- all cases following surgery on receipt of the histopathology for discussion of further care; and
- cases in follow-up after radical treatment or in the observational setting or who recently have undergone diagnostic investigations for possible symptoms/signs of recurrent or advanced disease.

There should be audit data from the multidisciplinary case management to ensure compliance with 90% cases discussed and for external verification. Decisions from the MDM will be documented in patient charts as a permanent and confirmatory evidence of compliance and as a multidisciplinary team (MDT) case review.

The MDT proposes the appropriate management options in light of the biopsy or histopathologic report, the clinical and biochemical assessment and the risk benefit evaluation; the final decision is made by patients.

4.2. Availability of different services and treatment/observational options

4.2.1. All the following options must be available: radical prostatectomy, external radiotherapy, brachytherapy, observational strategies, hormonal therapy, chemotherapy, palliative care and psychological support. In the case of operated patients, pathology of the surgical specimen should be taken into consideration in deciding on adjuvant therapies. Innovative protocols should be also offered to prostate cancer patients.

4.2.2. The patients' right to information and self-determination should be respected. Men must be offered clear and easy-to-understand written and oral information regarding their diagnosis and/or treatment/observational options. The Prostate Cancer Unit should also provide patients with written information about local patient groups and other potential sources of support.

4.2.3. The diagnosis on biopsy or following transurethral resection of the prostate (TURP) should be communicated to the patient by a urologist member of the core team. It is advisable that any of the professionals offering psychological support be present, where available. A suitable room with sufficient privacy must be available. A diagnosis should not be given to a patient by letter or on the telephone, unless at the specific request of the patient given adequate and full informed choice. The urologist will refer the patient to the multidisciplinary clinic where he will receive advice for treatment or observational strategies.

4.2.4. Patients following surgery should be offered pelvic floor physiotherapy to promote early continence. Patients following any therapy should be offered specialist support (andrologic) and psychological counselling to cope with treatment-induced morbidities.

4.2.5. People with a strong family history of prostate cancer should be offered the opportunity to see a clinical geneticist.

4.2.6. The pathology service should refer to internationally accepted guidelines with regard to workup of the specimen, items included in the report and nomenclature. It is recommended to show histology at MDM, preferably directly projected from slides. The laboratory should keep slides archived for at least 10 years (2 years on site) and report for 25 years minimum or following the relevant national protocols if available.

4.2.7. The radiology service should refer to internationally accepted guidelines.

4.3. Treatment and observational setting

Every patient should be provided with a clear, exhaustive and detailed written record of the treatment and follow-up plan as decided in the MDM. Centralised pathologic review of diagnostic biopsies carried out elsewhere should be performed on a regular basis before radical treatment or active surveillance is suggested.

4.3.1. Surgery should be carried out within the Prostate Cancer Unit. If this is not possible, and patients have to travel to a urology unit in another hospital, the core team urologist should be able to supervise the surgical technique and procedure and the core team uro-pathologist should be responsible for the prostate pathology.

4.3.2. External radiotherapy or brachytherapy may be delivered within the same hospital or patients may have to travel to a radiotherapy unit in another hospital. In the latter case, the core team radiation oncologist should be able to supervise treatment planning and quality assurance.

4.3.3. If management by active surveillance according to protocols stating inclusion and discontinuing criteria is agreed, the patient should be followed up in the Prostate Cancer Unit or at a local hospital under the guidance of the Prostate Cancer Unit MDT. If management by watchful waiting is agreed, the patient could be followed up in the Prostate Cancer Unit or at a local hospital under the supervision of the Prostate Cancer Unit MDT or by general practitioners, depending on national guidelines.

4.3.4. Hormonal therapy will be prescribed by the MDT and can be administered by general practitioners in the most appropriate context (eg. in the community) under the supervision of the MDT.

4.3.5. Chemotherapy with cytotoxic drugs or immunological therapies should be prescribed by an accredited medical oncologist, a specialist in internal medicine with focus on haematology/oncology or a urologist specially trained on and certified for the use of drugs with prostate cancer patients (members of the core team). Chemotherapy and immunological therapies should be administered in the Unit or at a local hospital that has proper facilities. In the latter case the treatment should be administered under the supervision of the core team medical oncologist.

4.3.6. A specialist palliative care service must be available or easily accessed for the referral of patients with metastatic prostate cancer. A close working relationship must be established between members of the Prostate Cancer Unit core team (especially the nurse specialist in prostate care) and the palliative care service to ensure that breakdowns in continuity of care do not occur. Palliative care should be delivered in the most appropriate setting for the patient.

4.4. Clinics

4.4.1. Prostate Clinic

Consultations for patients with prostate disease should be held separately, i.e. not as part of a general urology clinic. New prostate cancer diagnoses will be communicated here.

4.4.2. Multidisciplinary clinics for newly referred prostate cancer patients

At least one clinic per week should be available for newly-referred prostate cancer patients. These patients should be offered an appointment within 10 working days of receipt of the referral and, depending on their risk class, they should meet with an urologist, a radiation oncologist and a medical oncologist, synchronously or in rapid succession. If possible, a psychologist should be present in the clinic.

4.4.3. Follow-up of prostate cancer patients

All prostate cancer patients should be followed-up at a clinic directly supervised by one of the Prostate Cancer Unit core team members who was responsible for the initial treatment (urologist, radiation oncologist and medical oncologist). The skills of the diagnostic prostate team should be available for the detec-

tion and investigation of a possible recurrence. Although the patient may have to visit a different hospital to receive radiotherapy or chemotherapy, the treatment and follow-up decisions should be made by the Prostate Cancer Unit's MDT.

4.4.4. Recurrent/advanced prostate cancer

A clinic dedicated to recurrent and advanced prostate cancer should be held at least every 2 weeks. This should be separate from the general oncology clinics. Treatment decisions should be made by the Prostate Cancer Unit's MDT (urologist, radiation oncologist and medical oncologist; if possible, a psychologist should be present), synchronously or in rapid succession; however, palliative treatment can be administered at a hospital closer to the patient's home, under the supervision of the Prostate Cancer Unit. Patients should be referred to palliative care specialists as appropriate.

5. Equipment

5.1. The Unit must be in possession of or have easy direct access to all necessary radiology equipment for complete and adequate imaging of prostate disease: conventional radiology, TRUS, bone scan, MRI, CT, PET-CT.

5.2. The minimum equipment in a Prostate Cancer Unit radiotherapy department must be two megavoltage units, a brachytherapy unit, a simulator and a computerised planning system. The department must have a radiotherapeutic quality control programme for prostate cases. 5.3. The Unit must also have a quality control programme and perform verification of the linear accelerator output.

5.3. The Unit must be equipped with appropriate pathology equipment: processors, microtomes, staining machines and immunostainers.

5.4. It is recommended that all equipment should be no more than 10-years-old and should be well maintained

6. Conclusions

Establishing a Prostate Cancer Unit may often require some reorganisation of an institution's current prostate cancer services. Services will need to be reconfigured in order to provide sufficient staff for the Prostate Cancer Units. Some specialists will have to focus more on prostate disease, while other specialists will no longer be able to treat patients with prostate cancer. Such reorganisation would mirror changes that are already occurring within many medical disciplines, for example the move away from general surgery to surgical specialities that deal with different clinical problems or organ sites. The establishment of Prostate Cancer Units could provide financial savings and avoid multiple consultations, inappropriate treatments and secondary therapies. Prostate Cancer Units can deliver high-quality care to patients with prostate disease and provide for a holistic, multi-layer, multiprofessional management of the disease, due to the continuous interchange among different specialists and care providers. European countries should consider the certification of Prostate Cancer Units as a necessary way forward to ensure that men with prostate cancer receive optimal treatment and care.

Conflict of interest statement

None declared.

Acknowledgements

There was no funding source to this paper.

The authors wish to thank Anna Wagstaff, Assistant Editor of ESO's Cancer World magazine, for her expert and meticulous assistance in writing and editing the manuscript and ESO's Prostate Programme Secretary Rita De Martini for organisational and coordination activities.

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