THE FORGOTTEN 10,000:

GETTING IT RIGHT FOR MEN WITH PROSTATE CANCER

AN OVERVIEW OF THE DISCUSSIONS AND RECOMMENDATIONS OF THE PROSTATE CANCER EXPERT PANEL, FOLLOWING ITS INAUGURAL MEETING ON 30 JUNE 2011 AT THE ROYAL SOCIETY OF MEDICINE, LONDON

Prostate Cancer Support Federation
the voice of prostate cancer patients and their families
Reg. Charity No. 1123373

ORCHID
FIGHTING MALE CANCER

PROSTATE CANCER
RESEARCH CENTRE

DECLARATION OF INTEREST

This report, *The Forgotten 10,000: Getting it Right for Men with Prostate Cancer*, has been funded and produced in association with Sanofi, which also provided financial support for the Prostate Cancer Expert Panel meetings. However, the content of the report is entirely the responsibility of the Expert Panel. The initial selection of participating healthcare professionals and patient organisations was made via nominations from Sanofi, then further nominations were made by confirmed Expert Panel members. The agendas for the Prostate Cancer Expert Panel meetings were developed by Just:: Health PR and reviewed by all Expert Panel members before the meetings convened. Just:: Health PR also organised and facilitated the meetings, which involved the active participation of seven independent Expert Panel members, with one Sanofi representative in attendance. Some independent Expert Panel members were unable to attend the meetings, but participated subsequently in the production of this report.

FOREWORD

Around 10,000 men die of prostate cancer each year in the UK.[1] Yet, compared with many other common cancers, it does not attract a great deal of interest from policymakers—even in the past year, which has seen the launch of new treatments, and signs of further developments on the near horizon.

In view of the low profile for what is the most common male cancer in the UK,[2] and the ongoing developments in prostate cancer research, an Expert Panel of healthcare professionals and voluntary-sector workers met to consider the services currently received by men with the condition. Our discussions highlighted many key issues for patients with prostate cancer, for their families, and for healthcare professionals and the voluntary sector. The issues are set out in this document, along with the Expert Panel's recommendations, in the form of Calls to Action for Prostate Cancer.

We believe our Calls to Action could eventually form the core of a Bill of Rights—which we hope to see developed at a later date with the aim of ensuring that all men with prostate cancer—including "The Forgotten 10,000" who die each year from this poorly publicised condition—receive effective, well managed care.

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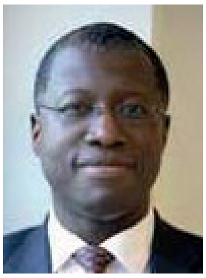

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CALLS TO ACTION FOR PROSTATE CANCER

- Given the prevalence of prostate cancer, the government must ensure it is a policy priority, with sufficient resources dedicated to it

- National guideline developers (such as National Institute for Health and Clinical Excellence [NICE]) must develop a clear, robust, integrated care pathway for prostate cancer across primary and secondary care, so that optimal interventions can be offered in a timely fashion

- There must be more emphasis on awareness of prostate health, and effective early recognition of prostate cancer symptoms, to minimise the number of men who have advanced disease at first diagnosis

- Every man with prostate cancer must be considered by a multidisciplinary team (MDT)—not just at diagnosis, but also if prostate cancer relapses or reaches a more advanced stage

- Every man with prostate cancer must have a named keyworker—ideally a clinical nurse specialist (CNS) with a workload dedicated entirely to prostate cancer

- Clear, impartial information on prostate cancer, its treatment (including likely side effects) and current clinical trials, must be readily available to patients and their families, and tailored to meet individual needs

- All patients with advanced prostate cancer must have access to a range of appropriate treatments to improve and extend their lives

- There must be equality of access UK-wide, regardless of a patient's age, to diagnosis, treatment and counselling for prostate cancer, based on evidence and without regional variation in the standard of care

- Every man with advanced prostate cancer must have access to palliative services and interventions provided as close as possible to his home

- Referral to support groups and other voluntary-sector activities needs to be improved, and must address the needs of families as well as patients

Terms highlighted in blue are defined in the Glossary

INTRODUCTION

2012 will be a significant year for men with prostate cancer, and for healthcare professionals and voluntary-sector workers involved in the provision and development of services for patients with the disease. New treatments have been licensed during the past year—and others are emerging—that extend survival for patients with advanced (metastatic) prostate cancer.[3]

This report considers the opportunities and challenges for the care of men with prostate cancer (in particular, advanced prostate cancer) in light of the new and forthcoming developments, and sets out the background to our Calls to Action.

MOST COMMON MALE CANCER

Prostate cancer is the most common cancer in men in the UK, accounting for about a quarter of all male cancers.[2] In 2008 (the most recent year for which Cancer Research UK has fully analysed data), around 37,000 new cases of prostate cancer were diagnosed (see Table 1)—i.e. around 100 men per day.[2] It is a disease largely of middle age and old age, with a potentially long-term effect on younger patients, i.e. those in their 50s, 60s and early 70s at diagnosis, whereas older men commonly die with rather than of prostate cancer.[2] Patients whose disease is detected at an early stage (when the cancer has not spread beyond the prostate) may be cured through active treatment, or they may not require immediate active intervention. Advanced disease requires a range of treatments to maximise patients' life expectancy and quality of life. (See Treatment strategies on the next page.)[4]

TABLE 1. Prostate cancer: key UK data[2,5]

New cases per year*	37,051
Lifetime risk	1 in 9
5-year survival rate†	77%
Deaths per year*	10,168
Age most commonly diagnosed	70–74 years

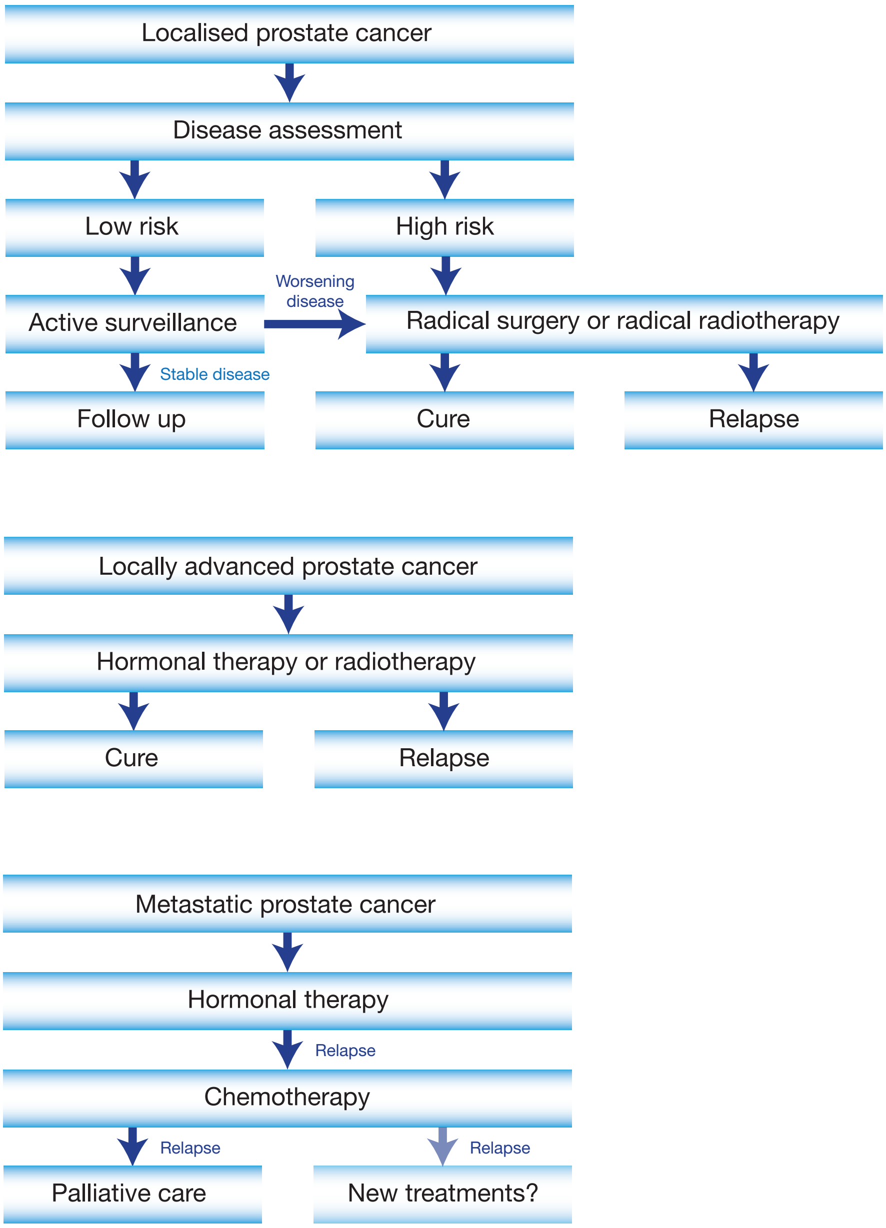
*2008 data
†Patients diagnosed between 2001–2006 in England

TREATMENT STRATEGIES:
SURVEILLANCE AND ACTIVE INTERVENTION

Treatment for prostate cancer (Figure 1) is ideally discussed and agreed by an MDT, and the patient's own preferences are a key factor in decisions on intervention.[4]

Prostate cancer is often curable if it is diagnosed at an early stage when it is confined to the prostate gland itself (known as localised disease).[6] However, the curative treatments can have significant side effects,[4] and active treatment is not always started immediately on diagnosis. The need for active treatment of localised disease is determined by the healthcare team based on various parameters, notably the risk category of the tumour (according to biopsy findings and other test results), the patient's underlying fitness, and estimated life expectancy.[4] Patients who are judged to have low-risk disease may have an initial period of active surveillance, i.e. regular follow up, with blood tests and biopsies, with a plan for radical therapy if the prostate cancer becomes higher risk.[4]

FIGURE 1. Prostate cancer management[4]



Those who are judged at high risk initially, or are considered to need active treatment after a period of surveillance, are offered radical prostatectomy (removal of the prostate) or radical radiotherapy (destruction of the prostatic tumour using targeted radiation).[4] If the localised prostate tumour is in a very high-risk category, men who receive radical radiotherapy are also offered additional hormonal therapy (directed at controlling the growth of the cancer by preventing production and activity of the male hormone testosterone).[4]

After radical treatment for localised prostate cancer, patients are followed up regularly by the hospital for at least 2 years,[4] and may be transferred to GP care once their symptoms and test results become stable.

Although the treatment for localised disease is often curative,[6] some patients will nevertheless go on to develop locally advanced prostate cancer (cancer that spreads to the structures near to the prostate, or is judged likely to do so based on the risk factors) or metastatic prostate cancer (advanced cancer that spreads to other parts of the body).[4] In addition, for some men, prostate cancer is already locally advanced or metastatic at the time of diagnosis.[7] The majority of men with locally advanced disease will require active therapy—usually with a combination of radical radiotherapy and hormonal treatment.[4]

For those men who have metastatic prostate cancer, the mainstay of treatment is hormonal.[4] Other treatments at this stage may be chosen specifically to reduce the patient's symptoms, e.g. pain from bone metastases may be reduced through local radiotherapy, drugs and/or orthopaedic interventions.[4]

While hormonal therapy is effective, it eventually fails, which means the cancer has reached a stage known as metastatic hormone-refractory prostate cancer.[7] Until the early 21st century, there was no survival-enhancing treatment for men with this advanced stage of prostate cancer. Palliative treatments were the only remaining options. However, the treatment strategy changed in 2006 when, for the first time, a chemotherapy agent was approved in the UK for use in men with metastatic hormone-refractory prostate cancer.[7] This chemotherapy was shown to extend the survival, in comparison with an unlicensed form of chemotherapy commonly delivered with palliative intent.[7]

This advance remained the only survival-enhancing option in advanced prostate cancer for a further 5 years. However, in 2011, two new treatments were granted European licences for use after initial chemotherapy and are currently awaiting health-economic appraisal, and various other promising treatments are emerging from research efforts across the world. The evidence base for these treatments suggests that they may extend patients' survival.[3] Hence, while metastatic prostate cancer is still not curable, there is a prospect for longer survival and improved tumour control with sequential therapies, despite the presence of the disease.

Note that an update to the clinical guidelines on prostate cancer is currently on the agenda of NICE, and a meeting on this topic was held in November 2011.

THERE IS A PROSPECT FOR LONGER SURVIVAL AND IMPROVED TUMOUR CONTROL WITH SEQUENTIAL THERAPIES.

PATIENT PERSPECTIVE

A diagnosis of any cancer is a frightening experience. In the case of prostate cancer, the disease may be curable if it is diagnosed at an early stage (i.e. localised prostate cancer), although the treatments may have significant side effects.[4,6] Once the disease is at an advanced (i.e. metastatic) stage, it cannot be cured.[8] However, patients may live for many years, and there are various different treatments now available—and in development—that can improve both the duration and the quality of the patient's life.

There are many challenges facing patients with advanced prostate cancer (and their partners/carers), for example:

- Understanding the information provided—often from a variety of healthcare professionals in different hospital departments, and not always tailored to the needs of the individual patient/family
- Using this information to make decisions on the treatment options, i.e. balancing the likely risks and benefits of the various interventions (it can be difficult and even distressing for patients to make these judgements)
- Coping with mental health problems such as depression and anxiety related to a diagnosis of cancer
- Coping with the side effects (including psychological effects) of surgery, radiotherapy, long-term hormonal treatment and other drug treatments
- Understanding when and where to seek advice on side effects or disease symptoms—importantly, many patients do not have access to a named keyworker
- Maintaining aspects of daily life, such as employment
- A perception that the different healthcare professionals involved in their care—in primary, secondary and palliative care—do not necessarily communicate with each other effectively
- Uncertainty over the final stages of life, e.g. will the patient be cared for at home or in hospital?

Voluntary organisations, ranging from large national organisations to small local support groups, provide a valuable source of information, advice and support, but not all patients are aware of the services available.

> THERE ARE SEVERAL DIFFERENT TREATMENTS NOW AVAILABLE—AND IN DEVELOPMENT—THAT CAN IMPROVE BOTH THE DURATION AND THE QUALITY OF THE PATIENT'S LIFE.

MEDICAL PERSPECTIVE

Prostate cancer, particularly the advanced stages of the disease, is currently the focus of a great deal of research. After many years with relatively little innovation, several new treatments are expected to reach the clinic in the near future. These medical advances have the potential to extend and/or improve the quality of life of patients with advanced prostate cancer.

In practice, access to new treatments can be affected either positively or negatively by national guidelines (e.g. from NICE, the Scottish Medicines Consortium, the All Wales Medicines Strategy Group and the Advisory Group for National Specialised Services), regional recommendations, local commissioning decisions, and the prescribing preferences of individual clinicians. In addition, it is unrealistic to think of prostate cancer alone when considering the allocation of NHS resources.

Currently, despite published guidelines on the management of prostate cancer,[4] there is variability in practice across the country. This variability has been highlighted by a survey conducted at five UK cancer centres, showing large differences in the way advanced prostate cancer is treated.[9] For example, current guidelines recommend that men with metastatic hormone-refractory prostate cancer are offered up to 10 cycles of chemotherapy, delivered at 3-week intervals.[7] In the survey, the average number of chemotherapy cycles given per patient at each centre ranged from 5 to 8 (Figure 2).[9] Although a second course of chemotherapy is not currently recommended in prostate cancer guidelines, the proportion of patients offered a second course ranged from 9% to 73% (Figure 3).[9]

Variation in access to treatment was one of the issues under consideration by the Prostate Cancer Charter for Action, a coalition of voluntary-sector and professional groups that was launched in 2003, which closed recently when funding was withdrawn.

FIGURE 2. Delivery of the recommended course of chemotherapy[7] for advanced prostate cancer across five UK centres[9]

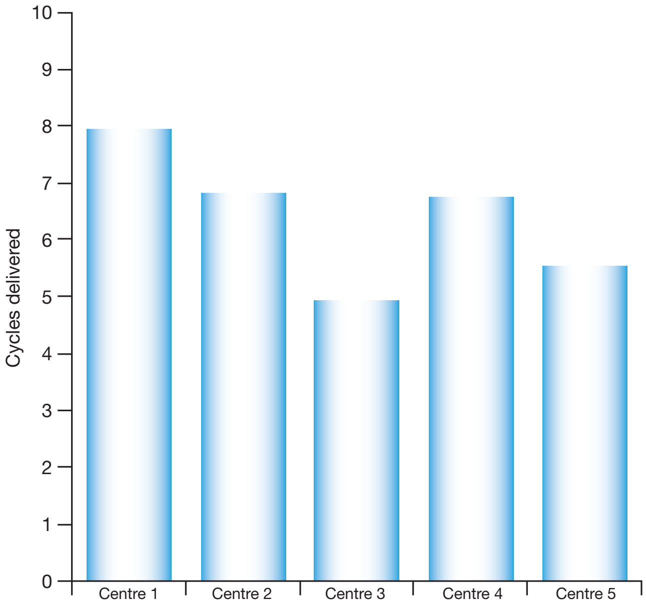
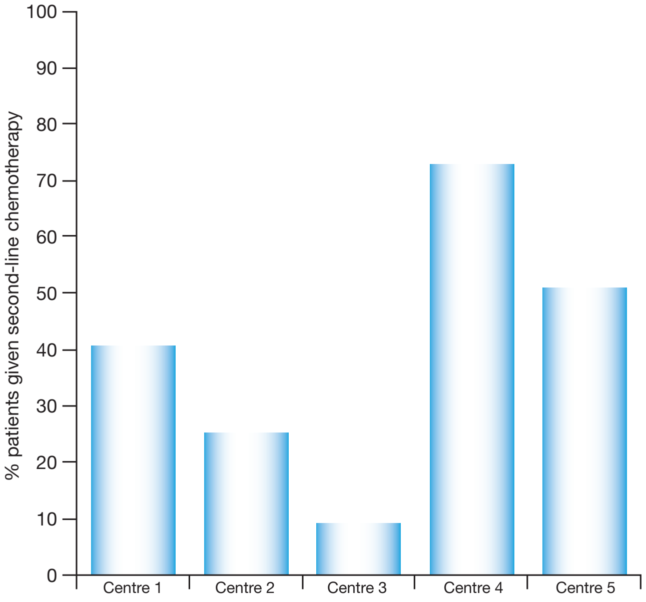


FIGURE 3. Second chemotherapy course (currently not recommended[7]): variation across five UK centres[9]



CARE DELIVERY PERSPECTIVE

Central to many of the issues in prostate cancer is the disjointed approach to care. As patients move between different services—e.g. urology, radiotherapy, chemotherapy, orthopaedic surgery, palliative care, general practice and research centres—there are often perceived gaps in information, and concern that the various specialties do not communicate effectively with each other. This fragmentation serves to increase anxiety at a time when patients are coping with their cancer diagnosis and, for some, the knowledge that they have an incurable disease.

The ideal patient pathway for prostate cancer centres on a named prostate-cancer-specific CNS, who acts as the patient's keyworker at every stage of the disease, across all services, and is readily accessible via telephone and email for advice and information.[10] The CNS/keyworker should be able to take a proactive approach, for example, getting in touch with patients at times when treatment side effects are expected. They should also be in the ideal position to tailor information provision to the patient's needs and preferences at each stage of the disease—men vary widely in the level of information they wish to receive, and a "one-size-fits-all" approach is inappropriate. Information Prescriptions (a government initiative to promote effective and appropriate provision of information) remains in an early form in prostate cancer, although some well designed materials have been developed by the prostate cancer charities.

The government has stated that cancer CNSs play a "critical role",[11] and the National Cancer Patient Experience Survey in 2010 found that patients with a CNS reported much more favourably on their care than those without.[12] A UK-wide survey conducted by The Prostate Cancer Charity found that patients preferred specialist nurses to other healthcare professionals for the provision of support around the time of prostate cancer diagnosis and when making decisions about their management.[10] There are no national data on the level of provision of CNS keyworkers in prostate cancer, but The Prostate Cancer Charity has found that only around half of patients with the disease have access to a specialist nurse.[10] Furthermore, there is wide variation across the country in the provision of CNSs who specialise in urological cancers,[13,14] suggesting that patients with prostate cancer in some areas will have poorer access than others to this much-valued resource. Also, some of the CNSs who take part in prostate cancer care have a broad-based specialty, such as all male urological cancers, and hence a large, varied caseload. Ideally, the CNS keyworker will have a job description that specifies solely prostate cancer, allowing time to provide a holistic, proactive service.

THE IDEAL PATIENT PATHWAY FOR PROSTATE CANCER CENTRES ON A NAMED PROSTATE-CANCER-SPECIFIC CLINICAL NURSE SPECIALIST, WHO ACTS AS THE PATIENT'S KEYWORKER AT EVERY STAGE OF THE DISEASE.

IDEALLY, THE CLINICAL NURSE SPECIALIST KEYWORKER WILL HAVE A JOB DESCRIPTION THAT SPECIFIES SOLELY PROSTATE CANCER.

ADVANCED PROSTATE CANCER:
KEY ISSUES

Prostate cancer is a Cinderella disease, i.e. compared with many other diseases; it does not attract a high level of interest from policymakers or the media. The unresolved debate over population screening and the complexity of the treatment pathway may contribute to its low priority, despite the government's stated commitment to cancer care. The patients themselves—male and generally in middle or later life—comprise a population that may not engage proactively with healthcare services or seek out health information in newspapers/magazines or online resources.

Against this background, there are also several specific issues relating to national policy (Box 1), local commissioning policy (Box 2) and NHS care delivery (Box 3) with regard to prostate cancer in general, and to advanced prostate cancer in particular.

THERE IS NO CLEAR POLICY FOR EARLY IDENTIFICATION OF ADVANCED PROSTATE CANCER, AND A LACK OF A ROBUST, INTEGRATED CARE PATHWAY ACROSS BOTH PRIMARY AND SECONDARY CARE

BOX 1. National policy

- There is no clear policy for early identification of advanced prostate cancer, and a lack of a robust, integrated care pathway across primary and secondary care, so that optimal interventions can be offered in a timely fashion
- Prostate cancer is not among the cancers listed in the National Outcomes Framework
- The UK lacks a centralised prostate cancer database and tissue archive, which would help to direct care, and would also be a valuable resource for future research

BOX 2. Local commissioning policy

- There is variation in the treatment received by patients in different parts of the country, including (in England only) access to newer treatments via the Interim Cancer Drugs Fund (initially) and the Cancer Drugs Fund (currently) to pay for the treatment of prostate cancer[15]
- Many people may regard the survival statistics reported for new prostate cancer treatments as small (i.e. weeks or months), but:
  - For some individual patients, the survival gain may be relatively long
- It is anticipated that the benefits of the expanding range of new treatments will prove to be additive, such that patients have the possibility of surviving for months or years
- Research activity in the treatment of prostate cancer is currently at an unprecedented level and it is likely that new effective treatments will be available within the next 2–3 years

Box 3. NHS care delivery

- There is variation across the UK in doctors' understanding of the management of advanced prostate cancer and in the interventions provided
- The efficacy of communication between primary and secondary care varies, which may sometimes lead to lack of timely referral of patients back into the specialist sector after a period of symptom monitoring by their GP practice
- Referral from urology to oncology may be suboptimal in some areas, limiting patients' access to effective treatment and to participation in clinical trials
    - The reasons are historical, from the time when oncologists had no survival-enhancing treatments to offer for advanced prostate cancer
    - Various new, effective treatments are available or on the horizon, hence the current need for robust referral pathways
- Care for prostate cancer is often disjointed. As patients move between different services there are often perceived gaps in information, and concern that the various specialties do not communicate effectively with each other. This fragmentation serves to increase anxiety at a time when patients are coping with their cancer diagnosis (see page 9)
- Although MDTs play a key role in the management of newly diagnosed patients, MDT input is not routine practice in the UK for patients who develop advanced disease. Input from the consultant oncologist is essential at this stage, to ensure timely consideration of chemotherapy and other medical treatments
- Access to support and counselling on issues such as mental health and sexual function is varied, fragmented and underfunded—and such services are currently being cut back in many areas
- Access to palliative care across the UK is variable
- Despite the demonstrated efficacy of the CNS in the management of patients with cancer, e.g. as a named keyworker across the whole of the patient's cancer journey, most men with prostate cancer lack access to a CNS,[10] and hence tend to receive a disjointed service (see page 9)
- Patients in some parts of the UK face lengthy travel to their nearest treatment centre
- There is often inadequate focus on the management of the side effects of hormonal treatments, and the prevention of serious complications such as cardiovascular disease and metabolic syndrome
- The symptoms of advanced disease, e.g. bone pain, are not always adequately managed
- End-of-life care for men with prostate cancer tends to be poor, with lack of consistency in the implementation of quality-based tools, such as the Gold Standard Framework in primary care[16]
- Patients' access to charitable support services is limited by poor awareness among healthcare practitioners of local, regional and national organisations

CONCLUSION

This is an exciting time in the field of prostate cancer, with a lively research agenda in the UK and around the world, and new and emerging treatments. However, inequalities remain in the care received by individual patients, e.g. geographical variation in access to certain treatments.[15] Furthermore, prostate cancer has a low profile in the media—despite being the most common cancer in UK men.[2]

Our Calls to Action focus on the need for high-quality care for all men with prostate cancer and an end to inequalities. They emphasise the crucial role of the MDT—not only at diagnosis but also for men whose disease becomes advanced—and the need for a robust policy and integrated pathway for advanced prostate cancer. At every stage of the disease, access to a keyworker, ideally a dedicated CNS, is essential.

If our Calls to Action are heard, we believe the UK may "get it right" for men with prostate cancer.

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Glossary

Advanced prostate cancer

Where the cancer has extended beyond the local area of the prostate, and cannot be cured, although there are treatments available that may extend or improve the quality of a patient’s life.

All Wales Medicines Strategy Group

An organisation that brings together healthcare professionals, academics, health economists, industry representatives and patient advocates to advise the Welsh Assembly on new and future developments in medicine.

Advisory Group for National Specialised Services

An NHS framework for making national decisions on funding of treatments.

Biopsy

Removal of a sample of tissue from a patient for laboratory investigation.

Cancer Drugs Fund (CDF)

A fund available in England since April 2011 to pay for cancer treatments not yet recommended by NICE. Usage is through application by local healthcare providers. An Interim CDF was implemented during the 6 months preceding the launch of the CDF.

Clinical nurse specialist (CNS)

A senior nurse who is highly trained and experienced in a particular specialty, and provides patient-focused one-to-one care.

Clinical trial

The means by which potential new medications are tested in patients, in a scientific and ethically regulated manner.

Chemotherapy

A treatment administered into the bloodstream (e.g. intravenously or orally) with the purpose of destroying tumour cells. Because chemotherapy also destroys some normal cells, it is generally associated with a range of side effects.

Commissioning

The process of deciding, at local level, which treatments and services will be available to patients via the NHS.

Course

In chemotherapy, the total number of doses (cycles) of treatment delivered, often over several weeks or months.

Cure/curable (cancer)

Eradication of cancer such that it does not recur. There are also treatments for cancer that extend survival, possibly for several years, but do not bring about a cure.

Cycle

In chemotherapy, one dose out of a planned series of doses, generally delivered regularly over several weeks or months (see also Course).

Gold Standard Framework

A national system for ensuring systematic, evidence-based optimal care for patients nearing the end of life who are being managed outside of the specialist setting.

Interim Cancer Drugs Fund

Please see Cancer Drugs Fund.

Multidisciplinary team (MDT)
A group of professionals (including doctor and nurses) who each bring their own expertise to the management of the individual patient.

National Institute for Health and Clinical Excellence (NICE)
An organisation that provides guidance and sets quality standards for the NHS in England and Wales. The details of its role are expected to change with the ongoing reforms to the NHS.

National Outcomes Framework
A government proposal for assessing the effectiveness, safety and patient experience of NHS interventions.

Oncology
A branch of medicine devoted to cancer.

Oncologist
A doctor specialising in oncology.

Orthopaedics
A medical and surgical specialty that focuses on bones and joints.

Palliative care
Treatment given to alleviate symptoms without curing the underlying disease.

Primary care
Non-hospital, community-based healthcare, e.g. general practice.

Prostate
A walnut-sized gland in the male reproductive system that produces and releases part of the fluid component of semen. It partially surrounds the urethra (the tube that carries urine from the bladder), and enlargement of the prostate can affect urinary continence. Prostate cancer is the most common male cancer in the UK.

Radiotherapy
The use of high energy x-rays and similar x-rays (such as electrons) to treat disease.

Secondary care
Hospital-based healthcare services.

Scottish Medicines Consortium
Advises the NHS in Scotland about the clinical and cost-effectiveness of new medicines and new uses of existing medicines.

Urology
A medical and surgical specialty that focuses on diseases of the male genitourinary tract.