

*This vision does not represent government policy but provides useful insight into how prostate cancer services might develop over the next 5 years*

**Annex H**

## **Prostate Cancer 2015**

### Summary - Improving Outcomes for Prostate Cancer Patients

By 2015, there will be:

- Increased awareness about the prostate, the variability in risk with respect to the different forms of prostate cancer, and testing for prostate cancer
- Provision of high quality decision aids supported in the community by trained people
- Prompt PSA testing and biopsy for all men who wish to access them
- Increased research into the identification of important disease at an early stage
- A decrease in the number of unnecessary biopsies achieved by risk stratification
- Biopsies that are necessary will be done to a high standard with low morbidity, supported by high quality uro-pathology
- Open access to accurate information to drive choice and the free movement of patients
- Treatments delivered to a high standard, with published local clinical and patient related outcomes
- Strong support for patients by health professionals who understand prostate cancer
- High quality end of life care
- More emphasis on measuring patient outcomes and quality of life (through PROMs)
- Prostate cancer research will continue to be the best structured in Europe

### Introduction

1. Significant progress has been made on cancer services and outcomes since the publication of the Calman-Hine report in 1995, with the NHS Cancer Plan (2000) and the Cancer Reform Strategy (CRS - 2007) contributing to this progress. Cancer mortality has fallen, survival rates are improving for many cancers and patients' experience of their care has improved
2. Despite the considerable progress, survival rates in England for many cancers are currently lower than in many comparable countries. The Coalition Government wants to tackle this, and to focus on improvement in quality and outcomes for cancer patients.
3. The Coalition Government therefore asked Professor Sir Mike Richards to review the CRS to ensure that we have the right strategy, subject to the 2010 Spending Review, to deliver improved survival rates. The aims of the review of the CRS are to:
  - align cancer strategy with the White Paper, *Equity and excellence: Liberating the NHS*
  - set the direction for the next 5 years, taking account of progress since the CRS was published in December 2007
  - show how outcomes can be improved despite the difficult financial position
4. As part of the review process, the Prostate Cancer Advisory Group (PCAG) met on Thursday 7<sup>th</sup> October 2010 to update their original vision for prostate cancer services in 2012 which was produced for the CRS in 2007.

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#### Background

5. 30,893 men were diagnosed with prostate cancer in England in 2008, and 8,659 men died of prostate cancer in England in 2007. The incidence of prostate cancer is likely to rise, due to an ageing population, continuing earlier diagnosis, the changing ethnic composition of society and the influence of a westernised lifestyle.
6. Since the publication of the Cancer Reform Strategy in 2007, three important papers have reported on the outcome of screening studies. It is now clear that PSA testing and screening reduces death from prostate cancer. However, this comes at the price of diagnosing many low risk prostate cancers and a risk of some men with such low risk cancers undergoing unnecessary radical treatments, which carry morbidity.
7. As a consequence, delivering significant improvements in the management of prostate cancer will be challenging. Research-based progress is being made into distinguishing aggressive cancers from others that are slow growing and may not cause health problems. Developing ways of distinguishing these cancers in the clinic will be central to our ability to improve prostate cancer services over the next five years. Given the unique nature of prostate cancer, different approaches to those adopted for many other cancers may be necessary. The goal for prostate cancer must be to reduce mortality, while at the same time reducing unnecessary treatment for those with clinically insignificant disease and maintaining improving the patient experience reported by all men with prostate cancer. The Prostate Cancer Advisory Group's view on what a quality prostate cancer service should look like is at Annex A.

#### **Prostate cancer services in 2015 – a vision**

##### Prevention and public awareness

8. Major advances have been made in our knowledge about genetic pre-disposition to prostate cancer. Further research now is needed to translate this knowledge into determining whether targeted screening might identify populations at high risk. Although research efforts are underway, it may be that developments in our understanding of the prevention of prostate cancer will not have translated into clinical practice by 2012. However, current genetic epidemiology studies may have identified particular groups of men at increased risk of prostate cancer, resulting in trials of screening or chemoprevention strategies.
9. All men will be aware that they have a prostate, what it does, and what can go wrong with it. To ensure equality, all men will be aware of appropriate tests for prostate cancer (currently the PSA test) and the advantages and disadvantages of having the test so they can make an informed choice. This will be especially important for black men and men with a significant family history, who have an increased risk of prostate cancer. Pilots will have taken place to test the most appropriate way of achieving "universal informed choice". There will also be a greater understanding that prostate cancer can take many forms, from a life threatening disease to a long term medical condition or even a condition which can be of no clinical significance.
10. A publicly funded prostate awareness campaign will have been introduced, delivered in close partnership with the voluntary sector.

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Early detection

11. In the community and primary care there should be easy access for men to information about early diagnosis of prostate cancer and balanced information on the pros and cons of PSA testing and of biopsy. Support from appropriately trained health professionals and decision support aids should be available in primary care to help men make this decision.
12. Once a diagnosis is made, men will be given information as to the degree of risk of the prostate cancer, to allow men to make appropriate decisions as to treatment policies.
13. All men will have access to a PSA test and will be helped to make an informed choice on whether this is the best course of action for them. The calibration of PSA measurements will have been standardised to enable a common approach to their interpretation.
14. The PSA test will be one of a number of pointers for the risk of significant prostate cancer, used as part of a package of measures to help a man decide whether to undergo further investigation. These include PSA level; digital rectal examination; age; ethnicity; and family history. The incidence of prostate cancer found at different PSA levels should be made available to men. The nomograms available for providing advice to men on prostate cancer risk are not based on UK characteristics. In five years time, data from the ProtecT trial on characterising these models within an English population will be available.
15. Major efforts to identify new diagnostic tests will continue and promising new approaches will have been identified. The Department of Health will, through the NCRI and the Prostate Cancer Research Collaboratives, stimulate further research into biomarkers of prostate behaviour, accelerating the UK's contribution to the global search for an effective test for prostate cancer – capable of distinguishing aggressive from clinically insignificant cancers. However, it is likely that no consensus will have emerged on an obvious replacement for the PSA test as a diagnostic tool by 2015. The case for screening will continue to be re-examined in the light of emerging evidence. It is likely that risk based approaches will have been developed and tested to better target those men most at risk of developing prostate cancer.

*Models for advising men on prostate health issues*

16. A range of models for providing advice to men on prostate health issues will be available, including through general practice, pharmacies, men's health clinics, the workplace and community based prostate health clinics. A variety of approaches to the delivery of advice on prostate health will have been tested and evaluated. These models will aim to address the fact that men have historically been reluctant users of traditional primary care services, therefore helping the NHS meet its obligations under the Equality Act 2006. They will also address particular access issues experienced by men from BME communities.
17. All models will conform to a robust national service standard used by all commissioners, who will then choose the most appropriate models of provision for the local population they serve.

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18. Many men will receive advice and support on prostate health issues at dedicated community-based prostate health clinics. Information should be available at the following points in the pathway:
- Men without symptoms considering having a PSA test or equivalent
  - Men with urinary or other potential symptoms of prostate cancer
  - Men considering having a biopsy for prostate cancer
  - Men diagnosed with benign prostate disease
19. Improved support for men in making decisions about further investigation or treatment will not be a form of rationing, but rather a way of ensuring that men have the best possible information and support when making difficult decisions. Improved support for men will ensure that more appropriate referrals for biopsy or further care will be made, reducing unnecessary interventions and complications, saving significant levels of NHS resources.

#### Biopsy

20. As a result of risk stratification, the number of unnecessary biopsies will be reduced. Biopsies will be performed to high national quality standards across England. Measuring the experience reported by patients undergoing biopsy will be a standard requirement of the service, with appropriate incentivisation and accountability through commissioning. Standards will include both those relating to the technical conduct of biopsies, including Gleason scoring, and to the effective and consistent use of anaesthesia/analgesia. Improved data on the outcomes (both clinical and patient experience) of prostate cancer biopsies, including complication rates, will be available to support men in making a decision about undergoing a biopsy and choosing a diagnostic provider.

#### Access and capacity

21. Patients themselves will drive change, with good quality information at the heart of decision making about testing and treatment. Men considering a PSA test will be given an appointment with a decision adviser, which will include all the necessary tests and patient information (including decision support aids) to enable men to make an informed choice based on the algorithm. Men with very high PSAs should be referred directly to the urology multi-disciplinary team (MDT), and seen within 2 weeks.
22. All treatments for prostate cancer should take place within 31 days of a decision to treat being made (and a man being clinically fit for treatment, for example allowing post biopsy inflammation to settle down prior to radical prostatectomy). All patients will be able to elect to “stop the clock” if they wish to have further time to reflect on the most appropriate treatment for them, with an additional 31 days allowed on top of the 62 day pathway if the patient so wishes. Stopping the clock will not impact on a man’s right to receive prompt treatment once he is ready. Urology MDTs will be able to upgrade men referred under a non-urgent route to the 62-day pathway where they consider it to be clinically necessary.
23. New treatments for more advanced prostate cancer will have placed increased pressure on services. Demand for surgery, chemotherapy and, to a less predictable extent, radiotherapy facilities will have necessitated the development of additional capacity. More consultant oncologists will be needed to help meet this demand.

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#### Treatment

24. Men will continue to be managed by multi-disciplinary teams which are compliant with the range of standards contained in the manual for cancer services, ensuring that treatment decisions are informed by the full range of relevant expertise.
25. Men will be given accurate information about the degree of risk that their prostate cancer poses, so that they can take charge of their treatment plans in a way that suits them and their values. We should be able by 2015 to identify those men with prostate cancer who are at low risk of future morbidity from their disease (< 1 in 20) so that they can be counselled appropriately in order to avoid unnecessary treatment related morbidity. High quality MRI should be available to provide good staging data.
26. The ProtecT trial will have reported its early findings, informing a clinical consensus on the most appropriate treatment options for localised prostate cancer. These options will include:
  - Surgery – most patients will make decisions about what form of surgery to have based on clinicians’ surgical outcomes rather than the type of technology used, although evidence from Europe and the USA suggest an increasing role for robotic surgery
  - Radiotherapy – the use of brachytherapy will continue to increase and commissioners will have developed services based on the Department of Health’s brachytherapy framework
  - Active surveillance
  - Traditional watchful waiting
27. Evidence will continue to be gathered and evaluated for other treatments, such as HIFU and Cryotherapy.
28. Men will be offered an informed choice about what treatments to have, when, and where those treatments will be provided and about who will be responsible for their care – “no decision about me without me”. This choice will be informed by publicly available information about the outcomes (both clinical and patient experience) of different treatments and centres through data and decision support tools available on NHS Direct and results of Patients Reported Outcomes Measures (PROMs) surveys. Clinical nurse specialists will be available to advise:
  - Men with cancer considering the treatment options available
  - Men suffering from treatment complications, such as impotence and incontinence
  - Men with cancer requiring supportive care
  - Men living with prostate cancer
  - Men requiring community based palliative care in the late stages of life
29. Treatments of proven clinical and cost effectiveness will be uniformly accessible to men with prostate cancer wherever they live. A national clinical audit for prostate cancer will have been developed and will be carried out to monitor the take up of different treatment options across the country, including on patient demographics to ensure there are no inequalities in access to different treatments.
30. For more advanced disease, it is likely that by 2015 there will be:
  - More chemotherapy – trials of new drugs are showing promise
  - More radiotherapy

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- New hormonal treatments
- Novel approaches to treating prostate cancer (eg immunotherapy, monoclonal antibodies, radio isotopes)
- Better management of bone metastases

31. People with more advanced prostate cancer will live longer and have a better quality of life. Less of their care will be provided on an inpatient basis and more effective disease management will have resulted in fewer emergency or unplanned hospital admissions. Patients with all stages of prostate cancer will be offered the opportunity to participate in appropriate clinical trials.
32. The 2002 Improving Outcomes Guidance will have been fully implemented and its implications evaluated. A review of the need for further centralisation of some specialised services will have been undertaken. A more comprehensive clinical audit will be in place to monitor treatments being used, outcomes and frequency of side effects. Commissioners will have made it a condition of payment that full data be submitted to the appropriate sources, including the BAUS Registry and the new national prostate cancer clinical audit. This will include data on staging to better inform outcomes and future services.

#### Supportive care and patient experience

33. All men with prostate cancer will have received appropriate information (including information prescriptions) and decision making tools at all stages of the treatment pathway. This will include a survivorship end of treatment care plan, including linkages with services outside the NHS (eg benefits, patient groups, charities). The role of the CNS will be vital in providing this support. Information and support will be provided in a culturally appropriate way. UK Prostate Link will continue to provide an internet portal for quality-assessed information on prostate cancer.
34. All men will have access to a CNS in discussing treatment options and providing information on and support in managing side effects. Significant investment in CNSs will have been required to ensure that there are sufficient numbers of appropriately qualified and experienced personnel available to ensure that all men have access to them. All men will receive support that helps them manage the impact of prostate cancer and the side effects of treatment. Comprehensive support services that meet the needs of men with prostate cancer should be available in all areas of England.
35. Local cancer teams will conduct regular patient surveys (at least on an annual basis) to inform the improved quality of the service. There will be a nationally-agreed tool for surveying the experience of patients, ensuring patients, commissioners, policy makers and healthcare professionals are able compare data. Data will be used to target interventions to improve the experience reported by men with prostate cancer, particularly those from BME communities. Survey results will be made public to:
- Provide accountability on local and national progress
  - Help men to make an informed choice about what treatments to have and when, where and by who they will be provided
  - Ensure services which succeed in improving the patient experience are appropriately incentivised and rewarded
36. These surveys should be embedded in the service.

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### Research

37. Historically our knowledge of prostate cancer has been poor, but England has developed the best research structure in Europe and this will be maintained. Significant questions remain, including what causes it, whether it can be prevented, how to distinguish between aggressive and clinically insignificant forms of the disease, whether it is beneficial to screen for it and how best to treat it. Prioritising further research into prostate cancer will be crucial. The following areas have been identified for further research:
- The role of diet in preventing or managing prostate cancer
  - The development of a specific and sensitive diagnostic test to identify aggressive prostate cancer and distinguish it from indolent cancer
  - The reasons for variations in prevalence of prostate cancer according to ethnicity, and the impact that this can have on health outcomes
  - Biomarkers of prostate behaviour
  - The development of more effective treatments for men diagnosed with advanced prostate cancer to enable them to survive longer with the disease and manage it as chronic long term condition
  - The impact of hormone therapy on the lives of men (and their partners) and interventions to help them cope with and manage side effects
  - Better understanding of the mechanisms of castration independent disease which will lead to better biomarkers and better treatments for men at most risk of death from the disease
  - The impact of different service models for the provision of information and advice on prostate health
38. Advances in basic science will continue, particularly on:
- Genome wide scanning, which has already identified over 30 single nucleotide polymorphisms (SNPs) that provide an increased risk to prostate cancer
  - Biomarkers developed from these SNPs, such as the measurement of urinary microseminoprotein-B (MSMB)
  - How the androgen receptor binds to the human genome

**Prostate Cancer Advisory Group (PCAG)  
December 2010**

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## **Annex A**

### What does a high quality prostate cancer service look like?

#### Presentation and Diagnosis

- 1 In the community and primary care there should be easy access for men to information about early diagnosis of prostate cancer and balanced information on the pros and cons of PSA testing and of biopsy, including the likely risk of a positive biopsy in their particular circumstances. Those who wish to undergo PSA testing and a biopsy should be able to obtain this quickly. Appropriately trained counsellors and advisors should be available to help men make this decision.
- 2 Men referred for early diagnosis of prostate cancer from primary care who wish to avail themselves of biopsy should have biopsy carried out by appropriately trained and expert people. The biopsy should be carried out under local anaesthetic with appropriate antibiotic cover and the number and position of the biopsies needs to be defined according to local network guidelines. Local information should be available on the outcomes of biopsies including sepsis, in addition to diagnostic rates by grade for men with respect to clinical characteristics such as PSA, age, DRE, ethnicity and family history. In the near future early access to other biomarkers and high quality MRI may be required .
- 3 The pathology assessment of prostate biopsies should be carried out in a timely manner by appropriately trained expert histopathologists . The pathology should be subject to review in the local MDT.

#### Management of men with localised disease

- 4 For men with localised prostate cancer their disease should be categorised into an individualised risk assessment based on a number of freely available protocols but for example this might include the D'Amico classification of being classified into low, intermediate and high risk. There should be access to MRI and bone scanning for staging. However, increasingly men with low risk disease might require more accurate staging by means of high intensity “template” biopsies.
- 5 Men should be given appropriately balanced information about possibilities for management including access to watchful waiting (for the unfit or elderly), active monitoring/active surveillance programmes, expert surgery and expert radiotherapy (including brachytherapy). These are standard modes of management.
- 6 Men should be guided and supported in their decision making along with their families by appropriately trained people including access to balanced information. Web information such as the informed decision aid project may also be useful to them in working out what methods of management should be carried out.



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- 7 Prior to treatment, men should have access to a urologist, an oncologist and a specialist nurse

*Specialised and complex treatments*

- 8 Some men may wish to explore more innovative and as yet unproven methods of management which may include local ablative treatments including HIFU.

- 9 Commissioners must ensure that appropriately audited local information is available on outcomes from these various forms of treatment.

- 10 Radiotherapy should be carried out according to the NICE Prostate Cancer guideline, by expert oncologists who will know their local outcomes on the following:

- a. Acute urinary and bowel complications;
- b. Functional outcomes in terms of bowel symptoms, continence and potency should be available and these should be derived from appropriate patient reported outcome measures using validated independent questionnaires.

- 11 Surgery should be carried out by expert surgeons who will know their own local outcomes on the following:

- a. Peri-operative complications;
- b. Rate of transfusion;
- c. Rate of return to theatre;
- d. Positive margin rate for pathological T2 disease and positive margin rate for pathological T3 disease.
- e. Functional outcomes in terms of continence and potency should be available and these should be derived from appropriate patient reported outcome measures using validated independent questionnaires.
- f. There is strong evidence of volume outcome relationships in open, laparoscopic and robotic assisted radical prostatectomy; and good evidence that the best outcomes combined outcomes for cancer outcomes, continence and potency (where indications for nerve sparing exist in men with good pre-operative function). The literature suggests that over two to three hundred cases are required for this with continued practice to maintain.
- g. The individual man should be aware of who is operating on them and what their personal outcomes are and where they are on the learning curve.

- 12 Pathology for radical prostatectomy specimens should be assessed by expert pathologists and ideally independently verified by a second pathologist and the results should be presented to the SMDT.

- 13 Practice should be evidence based and there is evidence that a proportion of men with high risk disease (extracapsular extension or seminal vesicle involvement or positive margins) following surgery may benefit from post-operative radiotherapy. The timing of this radiotherapy is open to question and this should be discussed with the patient or the patient should be offered access to appropriate randomised trials such. Evidence based treatment requires research and there is good evidence that patients entered into trials have better outcomes. Commissioning should support high quality research.

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- 14 Men suitable for radical treatment who have high risk disease - either because this is locally advanced (T3) or if it is high grade should be offered the option of appropriate radical treatments and commissioners should assure themselves that such men who are fit are offered access to such treatments, rather than simply being offered hormonal treatment. External beam radiotherapy with adjuvant hormonal deprivation is the current standard, but radical surgery is also being used offered with appropriate counselling regarding the need for possible adjuvant radiotherapy.
- 15 Imaging prior to surgery should include high quality MRI in men with high risk disease. There is a trend to carry out MRI prior to biopsy to try and assess the true extent of the tumour and this is being tested currently in research based protocols. If MRI is carried out after biopsy appropriate time (at least 4 weeks) should be left between the biopsy and the MRI.

#### Follow up

- 16 Many men with prostate cancer can be followed up in part or totally in primary care. For such men there needs to be individualised patient care follow up including triggered re-referral to hospital based on PSA or other end points. Each man should know what triggers would require them to be re-referred back to the hospital. Within primary care for follow up men should be able to obtain appropriate advice about the possible side effects of treatment including psychological effects and effects on sexual and bladder function in addition to general support with respect to prostate cancer. Appropriately expert advice should be available in primary care from Cancer Nurse Specialists, specially trained General Practitioners or community based Urologists.

#### End of life care

- 17 Appropriate support will be available for men requiring end of life care who have more advanced disease. *(needs more detail)*

#### More Advanced Disease

- 18 For men with more advanced disease a discussion should take place about the timing and nature of hormonal therapy, including risks of complications. If androgen deprivation therapy is being carried out the adequacy of this should be tested by measurement of testosterone levels.
- 19 Bone health is also important and men who are on androgen ablation are at risk of developing osteoporosis and bone problems associated with this in addition to possible metastatic problems related to bone disease. DEXA scanning should be carried out in men at high risk of developing osteoporosis prior to androgen ablation (the individual risk of osteoporosis may be estimated using the FRAX score: <http://www.sheffield.ac.uk/FRAX/>). Additional therapy may be necessary for those men at high risk of bone disease caused by androgen depletion.
- 20 Throughout their care men should be supported by appropriately trained personnel and health care staff who are trained in counselling and support in addition to being able to offer access to treatment for sexual and urinary

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dysfunction caused by treatments, and to appropriate support to deal with the psychological impact of treatment side effects.

- 21 Men with castration independent disease should be discussed at an MDT and appropriate men (defined in NICE docetaxel guidance) should access treatment with docetaxel; and novel therapies such as abiraterone will be no doubt assessed in due course by NICE for inclusion in treatment protocols.
- 22 Men who are developing local symptoms such as bowel problems or urinary problems related to local progression of disease should be offered early access to management by urologists and colorectal specialists.