

# prostate mapping

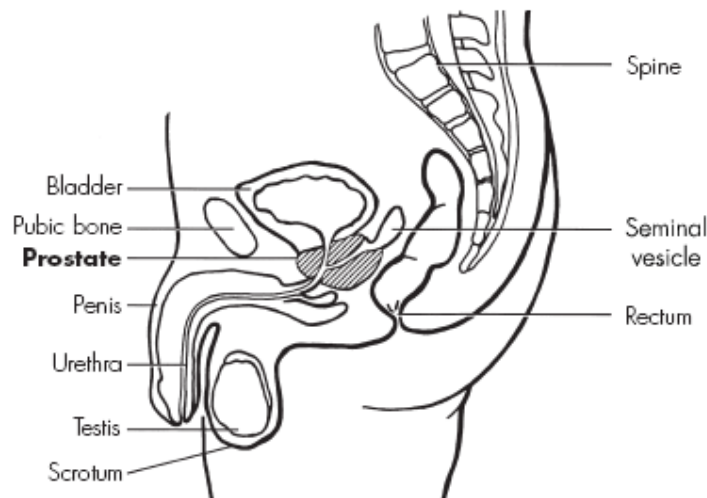
## Patient Information Sheet

This information sheet covers the following topics:

- What is the prostate?
- Prostate cancer and the PSA blood test
- The need for Prostate Mapping
- Magnetic resonance imaging of the prostate
- Template guided prostate biopsies
- Your route through Prostate Mapping
- Results and the next steps

### **WHAT IS THE PROSTATE?**

The prostate is a gland found only in men that sits just below the bladder. When you pass urine it flows through a tube (urethra) and out through the penis. The urethra has to pass through the prostate before reaching the penis. Fluid produced by the prostate forms part of the semen and may help to nourish sperm.



### **PROSTATE CANCER AND THE PROSTATE SPECIFIC ANTIGEN (PSA) BLOOD TEST**

Prostate cancer affects thousands of men every year. It is the most common cancer in men and the third highest cause of death from cancer in men overall. Because it is so common, it is important to identify men who have this disease at an early stage and accurately identify the risk it poses to them.

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You may have heard of the 'prostate specific antigen' (PSA) blood test. It is a blood test which is used to assess the risk of prostate cancer. If your PSA is higher than usual for your age, and if you have various other risk factors, then you may be at greater risk of prostate cancer.

PSA is not specific. It can be raised in inflammation, infection and in large prostates, and is therefore not a reliable indicator of the presence of prostate cancer. You have a 1 in 4 chance of having prostate cancer if you have a raised PSA score.

## **TRANSRECTAL ULTRASOUND AND BIOPSY**

Standard practice is to have a trans-rectal ultrasound (TRUS) and biopsy if you have either a raised PSA or the prostate gland feels abnormal on direct examination using a gloved finger. An ultrasound scanning probe is inserted into the rectum (back passage) and a local anaesthetic is given via a needle also through the back passage, around the prostate gland.

A biopsy needle is inserted through the lining of the back passage and between 6 and 14 samples of tissue are taken. As ultrasound is not very good at picking up the location of the cancer, the biopsies are taken throughout the gland in a fairly random pattern.

As well as being randomly placed, TRUS and TRUS biopsy can give no detailed information as to whether the cancer (if found) has spread beyond the confines of the prostate gland.

## **RISK STRATIFICATION**

Risk of death from prostate cancer is linked to numerous factors. As well as the PSA value at diagnosis, three of the most important are:

1. How aggressive the cancer cells are (the 'grade')
2. How much cancer there is within the prostate (the 'burden')
3. How far the cancer extends into and beyond the prostate (the 'stage')

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Based on these factors you are stratified as low, medium or high 'risk'. Your risk also influences the types of treatment you may be offered; if you are 'low risk' you may be followed up intensively without actual treatment of the cancer unless something changes (so called 'active surveillance'). If you are 'high risk' the decision to treat may be more pressing.

The type of treatment also varies according to 'burden'. Newer treatments such as cryotherapy and high intensity focused ultrasound (HIFU) have the ability to treat specific areas within the prostate gland if the burden is low, or the cancer is confined to only a specific region. It is hoped that by doing this the risks associated with treating the whole prostate, such as impotence and incontinence, will be reduced.

It is essential, therefore, that the information upon which you determine your own risk is as accurate as possible.

## **THE PROBLEM WITH 'STANDARD PRACTICE'**

### **CANCER STAGE INCORRECTLY REPORTED**

An MRI scan is the most accurate, non-invasive method of determining the local 'stage', or how far the cancer has spread within and beyond the prostate. This is not routinely offered as part of 'standard practice'. Where it is, there may not be provision for an experienced prostate Radiologist to review the images. This could result in a patient being told that the cancer has spread outside the prostate when it hasn't and, in some cases, lead to unnecessary treatment to the prostate.

### **FALSE NEGATIVES**

Unfortunately it is a fact that the current standard-practice TRUS and biopsy can be negative in up to 20% of men who actually have cancer. This is because it misses large areas of the prostate such as the ends of the prostate as well as areas high up in the prostate (known as 'under sampling').

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## **CANCER IS MISSED**

Over half of men have more areas of cancer than detected by prostate biopsy.

## **CANCER AGGRESSIVENESS UNDER ESTIMATED**

TRUS and biopsy can also give incorrect information about how aggressive the prostate cancer is, and 20% of men actually have a more aggressive disease than originally detected on standard prostate biopsy.

It is important to get an accurate diagnosis to ensure that each individual patient receives the most effective and appropriate treatment. It is very important for you to know how inaccurate the standard NHS diagnostic tests actually are.

It is for these reasons that we feel the 'standard practice' of TRUS and biopsy is not necessarily an adequate standard for you if you potentially have prostate cancer. We feel that if you have a raised PSA, you have a right to know with at least 95% accuracy whether or not you in fact have prostate cancer, and if you do how extensive and how aggressive it really is. Only Prostate Mapping will give you this level of accuracy and precision.

## **THE NEED FOR PROSTATE MAPPING™**

Prostate mapping involves a multi sequence MRI scan and template prostate mapping biopsies. Both of these in combination give state of the art information about the position, amount and aggressiveness of the cancer within the prostate to a higher degree of accuracy than other current diagnostics techniques. Prostate Mapping offers an accuracy of 95% in cancer detection, staging, grading and burden.

## **WHY SHOULD I HAVE THIS PROCEDURE?**

There are a number of reasons why MRI and prostate mapping biopsies may be suitable for you:

### **PRECISION DIAGNOSIS:**

- If you have a raised PSA, need to have a prostate biopsy, and wish to have the most accurate diagnosis of whether you have prostate cancer and if you do, the extent and aggressiveness of the disease. **OVER 20% OF PATIENTS REQUIRE A SECOND BIOPSY WITH STANDARD TRUS BIOPSY.** Prostate Mapping biopsies get accuracy and precision in one biopsy.

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- If you have a raised PSA and although one or more prostate biopsies have not detected any cancer so far, there is chance that you may still have prostate cancer that has been missed.
- If you have a raised PSA and need to have a prostate biopsy, but **DO NOT WISH TO HAVE A BIOPSY UNDER LOCAL ANAESTHETIC**
- If you have been told that you have a low grade and non-aggressive cancer and you want to be sure that this is an accurate diagnosis
- If you want to have a precise location for your cancer to help you decide if you would like one of the newer minimally invasive treatments

## **PRECISION RISK STRATIFICATION:**

Prostate Mapping is the most accurate way to risk stratify you without removing the prostate itself. This will put you in the best position to make informed choices about your treatment and may also make it possible to have one of the newer, less invasive methods of treatment which specifically target the cancer within your prostate.

## **MAGNETIC RESONANCE IMAGING OF THE PROSTATE**

### **WHY HAVE AN MRI SCAN OF THE PROSTATE?**

Biopsies identify cancer within the prostate, but it is also important to know whether any cancer has spread beyond the confines of the gland into the surrounding tissue. The latest guidelines from the European Association of Urology highlight magnetic resonance imaging (MRI) as 'the most accurate non-invasive method' of identifying so called 'locally advanced' prostate cancer. It is important to know whether any cancer has spread to the surrounding tissue as it has an impact on the type of treatment you may be recommended.

Although MRI scans may be performed at any time before definitive treatment, there are several reasons why it may be best performed before biopsy:

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- Biopsies create 'artefact' within and around the prostate gland due to bleeding which may persist for several weeks. These make interpretation of the MRI images more challenging.
- MRI may be helpful in localizing cancer within the prostate gland itself.
- By having a 'multi-sequence' MRI taken as a baseline before biopsies, it may be possible to then go into one of the clinical trials assessing new therapies for prostate cancer. The aim of these trials is to reduce the side-effects experienced by men from traditional therapies.

## **WHAT IS 'MULTI-SEQUENCE' MRI?**

Magnetic Resonance Imaging (MRI) is a method of scanning the body to produce very detailed pictures without using radiation (such as in X-rays or CT scanning). There are many possible types of 'sequence' in MR scanning – each sequence is designed to look at different aspects of the body, for instance some sequences detect fluid very clearly whilst others are designed to show blood supply. The Prostate Mapping team has been at the forefront of high resolution prostate imaging for several years and have developed specific sequences to look for prostate cancer both around and within the prostate. By using a 'multi-sequence' approach and the skills of dedicated prostate Radiologists, we are able to offer the most accurate diagnostic service possible.

## **WHAT IS THE PREPARATION FOR MRI OF THE PROSTATE?**

The MRI scanner uses a strong magnetic field to produce images of the body and although it is a very safe procedure, there are certain things which can interfere with MRI. No specific preparation is required before a prostate MRI scan but you will be asked questions about items which can interfere with MRI, such as:

- Do you have a pacemaker or have you ever had any operations to your heart?
- Have you ever had any operations to your head? (In particular do you have a hydrocephalus shunt?)
- Have you had any operations at any time to other parts of your body?
- Do you suffer from any kidney or liver problems?

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- Have you any joint/ limb replacements or any implants?
- Have you ever had any metallic fragments in your eyes? (Particularly from an engineering or DIY accident?)
- Have you ever had any injury involving bullets or shrapnel?
- Have you ever had cosmetic surgery or tattoos?
- Are you wearing a hearing aid or a removable metal dental plate?

If the answer is 'yes' to any of the above questions, it does not necessarily exclude you from having an MRI scan, but it is important that you tell us so that the options can be discussed. We will be happy to provide you with further information if you are unsure about anything.

## **WHAT HAPPENS ON THE DAY OF THE SCAN?**

The MRI scan takes place in a dedicated MR unit and may take up to one and a half hours in total. After being welcomed into the department, you will be asked to complete and sign the MRI checklist, if you have not already done so. The scan requires the injection of MRI contrast fluid into a vein, which is delivered through a small tube placed into the arm or hand. The scan is noisy, so you will be given headphones to wear. If you enjoy any specific music and have it available on a CD, then we will be able to play it to you during the procedure.

You will be asked to lie down on your back on the scanning bed, a special belt (called a 'coil') will be placed over your abdomen and the small tube in your arm or hand will be connected up to a pump containing the contrast fluid. The scanning bed will then slide into the MRI 'tunnel' and the scan will begin. At any point you will be able to talk to the Radiographers (the professionals who actually perform the scan) via the speaker system should you have any questions.

After the scan you will be free to resume normal activities immediately.

## **WHEN WILL THE RESULTS BE AVAILABLE?**

The results of the MRI scan will be made available at the same time as the template guided biopsy results. How these results will be made available to you will be discussed below.

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## Template Guided Prostate Biopsies

### WHAT IS THE DIFFERENCE BETWEEN A 'TRUS AND BIOPSY' AND A 'TEMPLATE GUIDED PROSTATE BIOPSY' FROM PROSTATE MAPPING

A 'TRUS and TRUS biopsy' refers to a trans-rectal ultrasound and trans-rectal biopsy of the prostate in which 6 to 14 biopsy samples (typically) are taken through the prostate in a non-specific pattern. This is performed under local anaesthetic.

A template guided biopsy is carried out under a light **general anaesthetic**. After the anaesthetic has been administered, an ultrasound probe is gently inserted into the back passage and the prostate is scanned. A soft, flexible tube is inserted through the penis into the bladder (to drain it) and is left in place for the duration of the procedure. Strong antibiotics are then given through a vein. Using a grid (template) with holes placed every 5mm placed against the perineum (the area between the scrotum and anus), a biopsy needle is inserted through each hole and the prostate is sampled every 5mm. Each biopsy we take is placed in a separate pot for a Consultant Histopathologist to examine separately under the microscope. A report is given telling us whether each biopsy has cancer in it or not. Other information is also given such as whether the tissue looked inflamed or whether there are other features such as precancerous areas in the prostate. Typically between 30-50 biopsy samples are taken and the whole procedure last between 20-40 minutes.

At the end of the procedure the template is removed and the perineum injected with a long-acting local anaesthetic. A thick padding will be placed over the area of skin that the needle has gone through to prevent a lot of bruising. This padding should be left for at least 6 hours.



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## **WHAT IS THE PREPARATION FOR TEMPLATE GUIDED PROSTATE BIOPSIES?**

You will need to be admitted to hospital a few hours before the procedure. You should not eat anything for 6 hours before your procedure time to ensure your safety under anaesthetic. You can drink water up until 2 hours before your procedure time. You will also be given a phosphate enema 1 or 2 hours before hand to clear the back passage of faeces, so that the prostate can be scanned by the ultrasound clearly.

You will be seen by the surgeon prior to the procedure. He will answer any questions you may have. You will be asked to sign a consent form to state that you agree to have the procedure if you have not already done so. The anaesthetist will see you prior to the procedure to discuss the anaesthetic with you.

## **WHAT ARE THE RISKS OF TEMPLATE GUIDED BIOPSY?**

Transperineal biopsies carry no extra risk than a normal prostate biopsy carried out through the rectum. Complications of both include:

- Bruising of perineum that occasionally spreads to the scrotum
- Temporary discomfort or pain in the back passage area (most men)
- Bloody urine for the first few hours to 2 days (most men )
- Bloody semen for a few days in most men (lasting for up to 3 months in a few men)
- Prostatitis (inflammation or infection of the prostate) in some men
- Retention of urine requiring a temporary catheter (2-10 in 100)
- Infection (requiring admission and intravenous antibiotics, 0-1 in 100)
- A few men have experienced temporary poorer erections

## **WHAT SHOULD I EXPECT WHEN I GO HOME?**

You will be given antibiotic tablets and pain killers to take for seven days after the procedure. You may experience some perineal pain or discomfort after the procedure but paracetamol or other simple pain killers should be adequate. You should avoid any medication containing aspirin for 24 hours as it causes blood thinning and will therefore increase the risk of bleeding.

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You can expect to see some blood in your urine for 1 - 2 days following the biopsies. You may notice some blood in your semen for up to 3 months. If the bleeding becomes excessive, prolonged or if you start to pass blood clots then you should seek medical attention.

Occasionally swelling may occur in the prostate gland as an inflammatory response to the biopsies being taken. This can cause difficulty in passing urine

and may very occasionally cause the ability to pass urine to stop completely. This is known as urinary retention and you would then need a catheter inserted to drain your bladder for a few days. You will not be allowed to go home until you have passed urine.

There is a <1% risk of developing sepsis (a very bad infection) following prostate biopsy. The antibiotics you will be given should help prevent this. If you develop flu-like symptoms within 24 hours of the biopsies being taken (fever, cold shivers, general aching) you should seek medical assistance immediately.

You should drink plenty of fluids.

One of the Prostate Mapping team will call you on the day following your discharge from hospital to see how you are doing and you will be given contact numbers which you can call at any time should you have a problem.

## **WHEN CAN I GO BACK TO WORK?**

You can usually return to work the day after you have been discharged from hospital, if you feel ready to do so.

## **WHEN CAN I DRIVE?**

You need to check with your insurance company about your cover following anaesthetic. You also need to feel comfortable doing an emergency stop. If you are taking any medication, check with the pharmacist whether it is safe to drive while taking them.

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## **WHEN WILL THE RESULTS BE AVAILABLE?**

The results will be available 3 to 4 working days after the biopsy. How these results will be given to you will be discussed below.

## **Your route through Prostate Mapping**

There are a number of ways in which you can access Prostate Mapping. The most common route will be through direct referral from your own doctor, be they a General Practitioner, Non-Urology Specialist Doctor or Urology Consultant. If this is the case, you should ask for a letter of referral to the Prostate Mapping Team which includes the relevant documentation necessary to ensure that you are a suitable candidate.

We also accept self referrals, however the same principles apply; the relevant documents will be required to ensure suitability before the procedures can be carried out. We would prefer to liaise with your own doctor(s), even if you refer yourself, so as to ensure continuity of care, however this is not a stipulation.

The information that we require your doctor or yourself to provide includes:

1. Your latest PSA result from the laboratory that measured it.
2. Your histopathology reports detailing any previous prostate biopsies you may have had (if relevant).
3. Any imaging of the prostate you may have had, ideally both the images themselves on a CD and the typed reports (if appropriate).
4. A completed MRI safety checklist.
5. A completed pre-operative check list.

Not all men are suitable for Prostate Mapping. For example, if you are not fit enough to have a general anaesthetic, Prostate Mapping would not be indicated.

Once your details have been sent to us, the Prostate Mapping Secretaries will let you (and with your permission - your doctor) know whether you should go on to discuss things further with a member of the Clinical Prostate Mapping Team. If you are eligible, a free telephone appointment will be made to speak with one of the Prostate Mapping team, or if you prefer, a face to face appointment with one of our clinicians.

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You will have an opportunity to discuss this information sheet in detail, and any questions you may have will be addressed. Appointments for the MRI and template biopsy can be made for mutually acceptable times.

We will discuss with you how you wish the results conveyed; you have a choice of either returning to your referring doctor (if you have one) to discuss the results or to be followed up with the Prostate Mapping team. At the time of your follow up appointment you will also be given a unique website code which will allow you to access your own results on-line. An example of how these results are presented is available on the website ([www.prostatemapping.com](http://www.prostatemapping.com)).

## Results and next steps

The results of the MRI and template biopsy will be made available simultaneously 2 – 4 days after the template biopsy. If any cancer is found within or around the prostate gland we have developed a unique package that combines both the MRI and biopsy results to demonstrate exactly where it is, how much cancer there is in relation to the size of the prostate, how aggressive it is and whether it has spread outside the gland.

As well as the results of your MRI and template biopsy, you shall also receive a broad indication of what types of therapy may be available to you given your diagnosis. If you wish to be followed up by the Prostate Mapping team these may be explored in greater detail.

The Prostate Mapping Team has a great deal of experience with all types of prostate cancer treatment and will be able to discuss these with you. If you are suitable for one of the newer, potentially less harmful prostate cancer treatments then we can advise you accordingly.

If you choose to be followed up by your referring doctor, we will send them a copy of your results prior to your follow-up meeting with them so that they can go through the results with you themselves.

If you live a long way away, you may wish to receive your results over the telephone in conjunction with accessing them on the secure website. This is not our preferred option, as we would always advocate face-to-face consultations, It is important to remember that there may be a diagnosis of prostate cancer, or worsening disease even if the diagnosis of cancer was known previously.

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## **WHAT TREATMENTS ARE AVAILABLE IF I DO HAVE PROSTATE CANCER?**

At the time of diagnosis, prostate cancer may be confined to the prostate itself, or may have spread to other sites within the body. If prostate cancer is confined to the prostate, so-called localized prostate cancer, there are a number of treatments available. Many men over the age of 50 years actually have prostate cancer that 'they will die with rather than die from'. In other words, the prostate cancer in many cases will not kill.

men with localised prostate cancer have to choose between two extremes of care - active surveillance versus radical therapy.

Active surveillance involves monitoring the disease with regular 3 monthly blood tests (a PSA test), examination of your prostate in clinic, and 2 or 3 yearly biopsies. If any of these show signs that the disease is progressing, then treatment will be recommended.

Radical therapy involves treatment that aims to destroy the whole prostate. These include surgery (radical prostatectomy), external beam radiotherapy, brachytherapy (small implanted radioactive seeds), cryosurgery (freezing) or high intensity focused ultrasound (HIFU). The best evidence we have shows that the difference between active surveillance and radical surgery is not large in terms of preventing an individual from dying of prostate cancer within a 10 year period - 14% of men died within ten years whilst on active surveillance, compared to a rate of 9% for men who had surgery.

On the other hand, we know that the side effects of radical treatments are high - they include, amongst others, deterioration in urinary, sexual and bowel function. It is these harms of therapy that many men are keen to avoid. These harms arise because when the whole gland is treated, there is damage to surrounding areas such as the muscle that controls urine flow and the nerve bundles that control erections.

In men who are diagnosed with a PSA screening test, the difference between active surveillance and radical treatment may be smaller. This is because we are detecting men with lower risk prostate cancer at a younger age.

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## **HOW DO I DECIDE WHICH TREATMENT IS SUITABLE FOR ME IF I HAVE LOCALISED PROSTATE CANCER?**

The information that is used to decide whether you are suitable for certain treatments depends on a number of things:

- Your age may be used to decide whether you even need treatment since in most cases the prostate cancer can be watched carefully.
- Gleason grade score higher than 7 is usually not suitable for active surveillance
- Your health condition may influence whether you are fit for surgery or radiotherapy
- PSA levels above 10ng/ml are considered a 'higher risk'
- The more cancer in the prostate, the less likely that you will be suitable for active surveillance.

## **CONTACT**

Before embarking on any kind of medical test or therapy, it is essential that you are sure of what is being proposed and that you have had ample opportunity to discuss any concerns you may have.

There are several different routes of contacting the Prostate Mapping Team:

- Through your own Doctor, to allow them to make enquiries on your behalf
- Through the website: [www.prostatemapping.com](http://www.prostatemapping.com)
- By telephone to the Prostate Mapping Team on 01761 418 234 By email: [info@prostatemapping.com](mailto:info@prostatemapping.com)

We hope that you have found this Patient Information Sheet useful, and are happy to answer any concerns or queries you may have.