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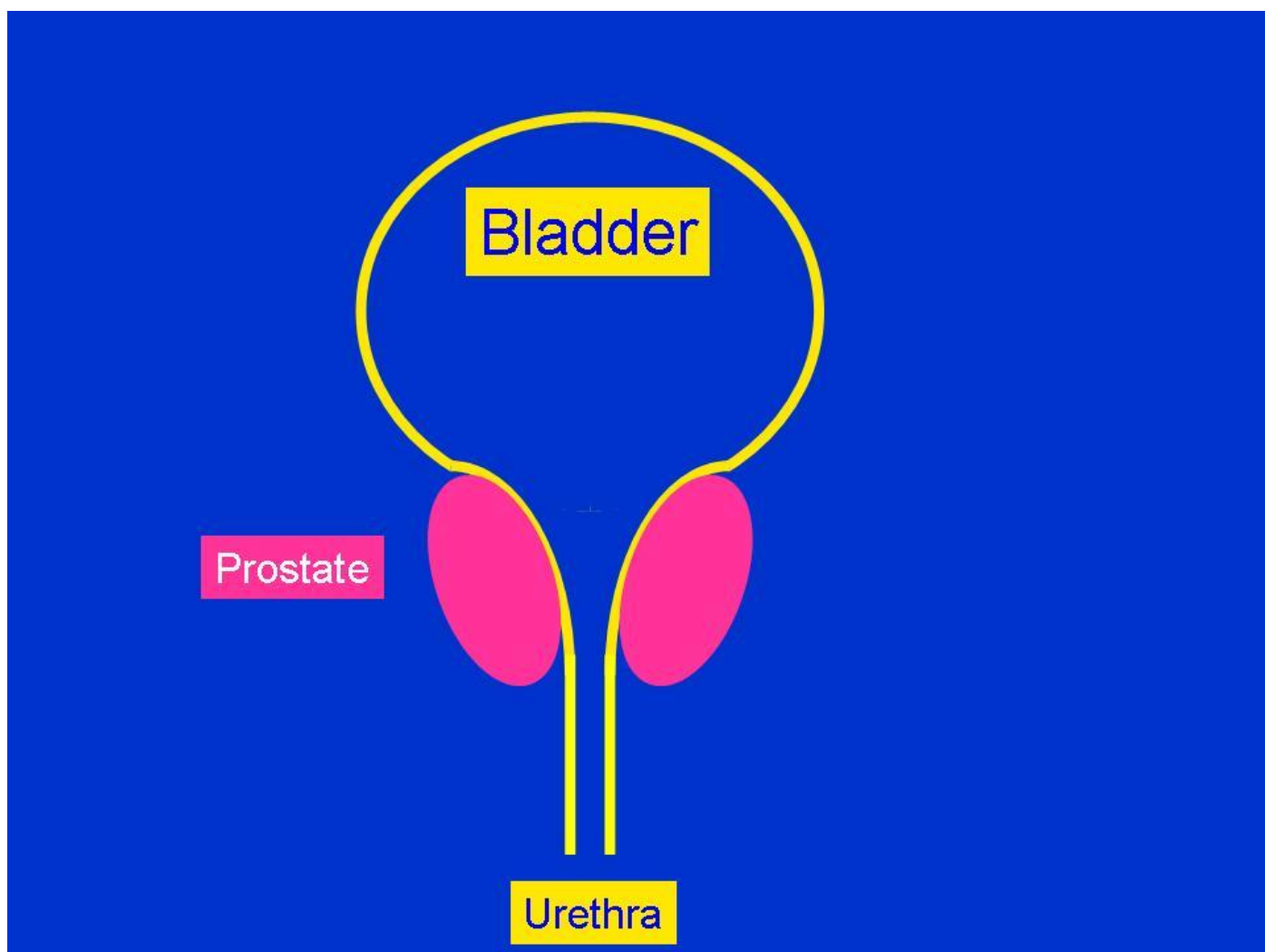
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# TEMPLATE BIOPSY PROSTATE MAPPING PATIENT INFORMATION LEAFLET

## WHAT IS THE PROSTATE?

The prostate is a gland found only in men that sits just below the bladder (**Figure 1**). 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. The main function of the prostate is to produce fluid in the semen, which helps nourish sperm.

**Figure 1: Anatomy of prostate, with respect to bladder and the urethra.**



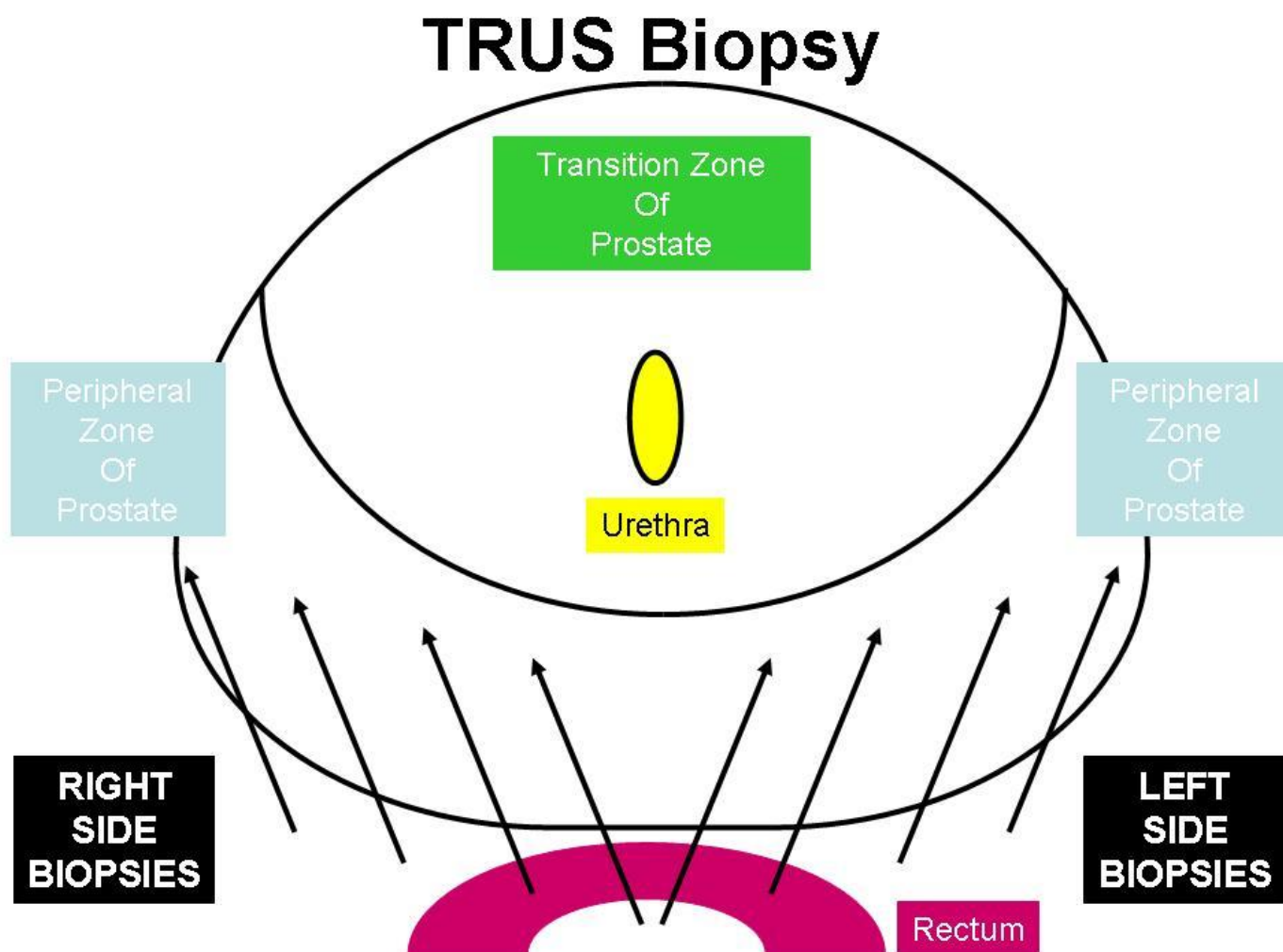
## PROSTATE CANCER

Prostate cancer is diagnosed every 10 minutes in the UK, affecting several thousand men. 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 accurately identify men who have this disease at an early stage and accurately identify the risk it poses to them.

## TRANSRECTAL ULTRASOUND AND BIOPSY

Currently, to establish a diagnosis, patients with suspected prostate cancer undergo Transrectal Ultrasound guided Prostate Biopsy (TRUS Biopsy). The patient undergoes this procedure under local anaesthetic, during which a probe is inserted into the rectum and subsequently, 5-6 samples of tissue are taken from the right side of the prostate and then the procedure is repeated on the left side (Figure 2).

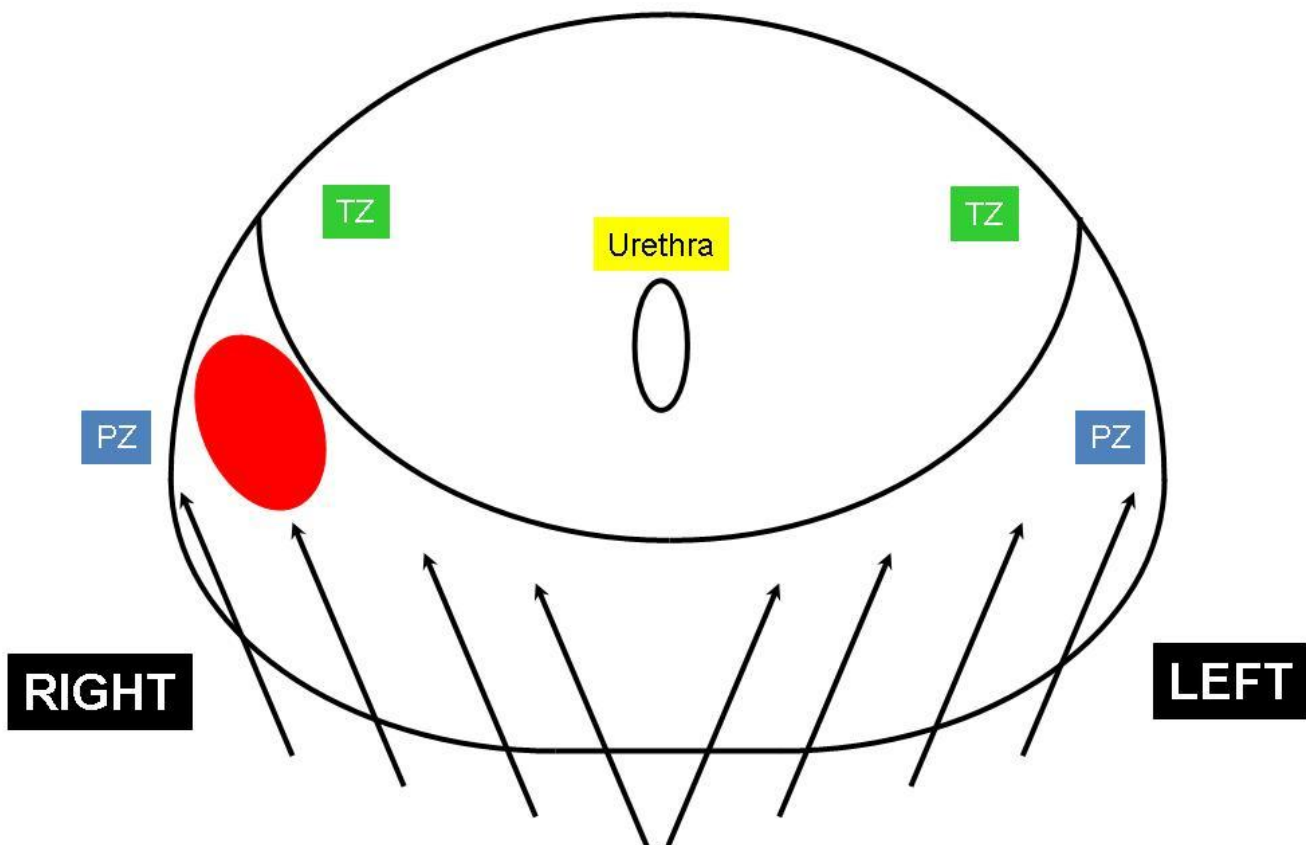
**Figure 2: Schema of how TRUS Biopsy is performed – mainly sampling the Peripheral Zone of the Prostate through the rectum, under Local Anaesthesia.**



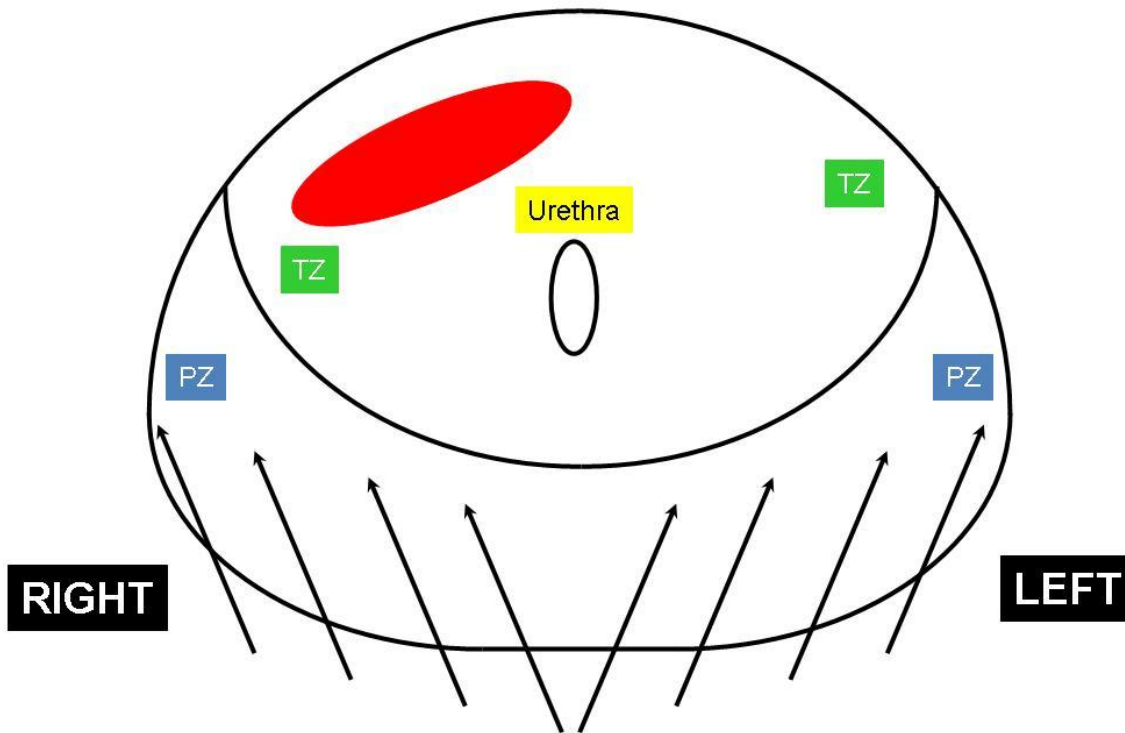
Whilst this technique has been used for many years, as it is easy to do and can be performed under local anaesthetic, crucially, it has become apparent recently, that the technique has significant disadvantages which may put patients at risk.

Firstly, TRUS biopsy is a random biopsy – similar to trying to find a needle in a haystack. It is the only organ in the human body which is sampled in this random manner. In addition, areas that are out of reach, such as the anterior prostate and some of the peripheral zone (Figure 3, 4 and 5), are either under-sampled or never sampled in this procedure. As such the positive cancer pick up rate is approximately 1 in 3 – hence 2 men needlessly undergo this procedure. In addition, as 30% of significant cancers are missed, subsequent, repeat biopsies are needed, duplicating workload and putting patients through multiple investigations.

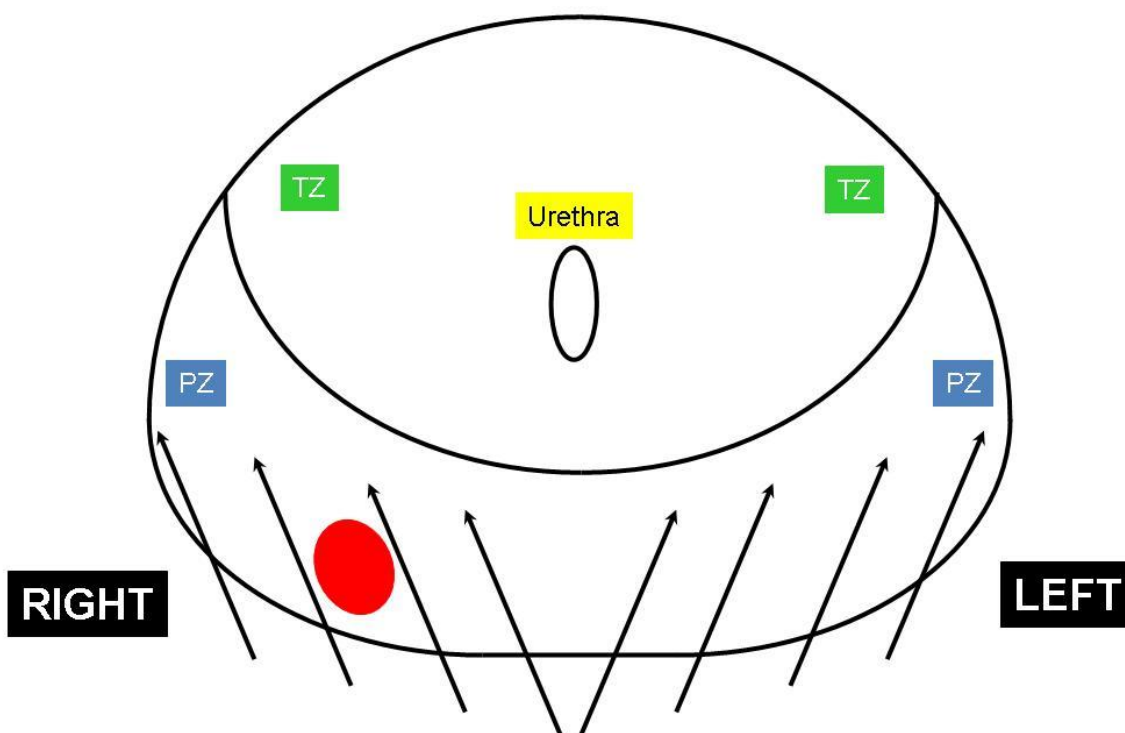
**Figure 3: Due to random nature of TRUS Biopsy, areas out of reach such as part of the Peripheral Zone are not sampled – hence, a significant prostate cancer can be missed.**



**Figure 4: Due to random nature of TRUS Biopsy, areas out of reach such as part of the Anterior Zone are not sampled – hence, a significant prostate cancer can be missed.**

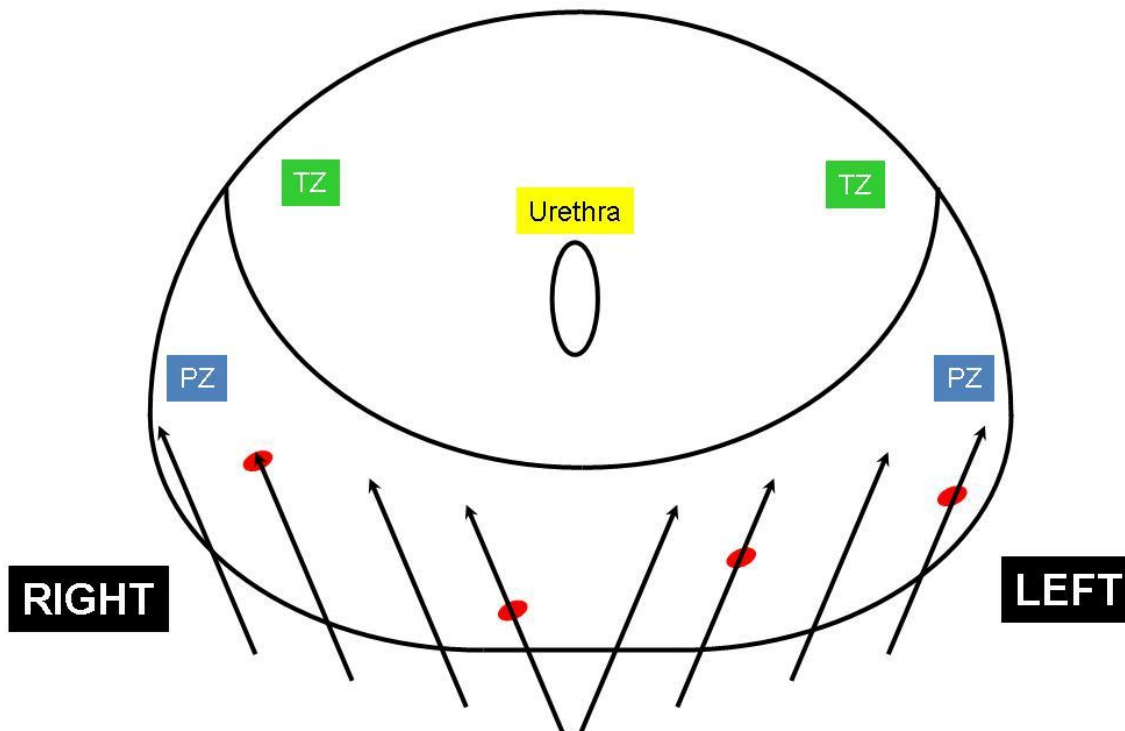


**Figure 5: Crucially, up to 30% of clinically significant prostate cancers are actually missed with this random sampling strategy, even in the Peripheral Zone.**



Secondly, areas of clinically insignificant cancer area are found, which may never have caused a man harm or prostate related death if left undetected and untreated (Figure 6).

**Figure 6: Insignificant cancer is commonly diagnosed on TRUS biopsy, potentially confusing patients and clinicians in their decision making.**



Thirdly, when a diagnosis of prostate cancer is made, information on the burden and exact location of disease, cannot be accurately determined using this technique.

Finally, infection is a serious and significant problem and may lead to intensive care admission. If you think about it, a needle is being placed through the rectum, passed through faeces, which contain the most bacteria in the body, and then passed into the prostate, which is one of the most vascular (large blood supply) organs in the body. Unsurprisingly, therefore the risk of bacterial infection getting into the bloodstream and causing septicaemia is extremely high. The risk of infection is approximately 2% with an incidence of 0.5% of patients needing hospitalisation following a TRUS biopsy. Worryingly, there has been an increasing trend of bacteria being resistant to antibiotics.

Hence, it is quite clear that there are significant disadvantages with TRUS Biopsy of the prostate.

To improve detection of cancer, and to reduce the risk of potentially life threatening complications such as sepsis, Template Biopsy Prostate Mapping was introduced.

1. Template Biopsy Prostate Mapping is associated with significantly fewer complications than standard prostate biopsies, such as lower risks of life-threatening infection, and hence is significantly safer for patients

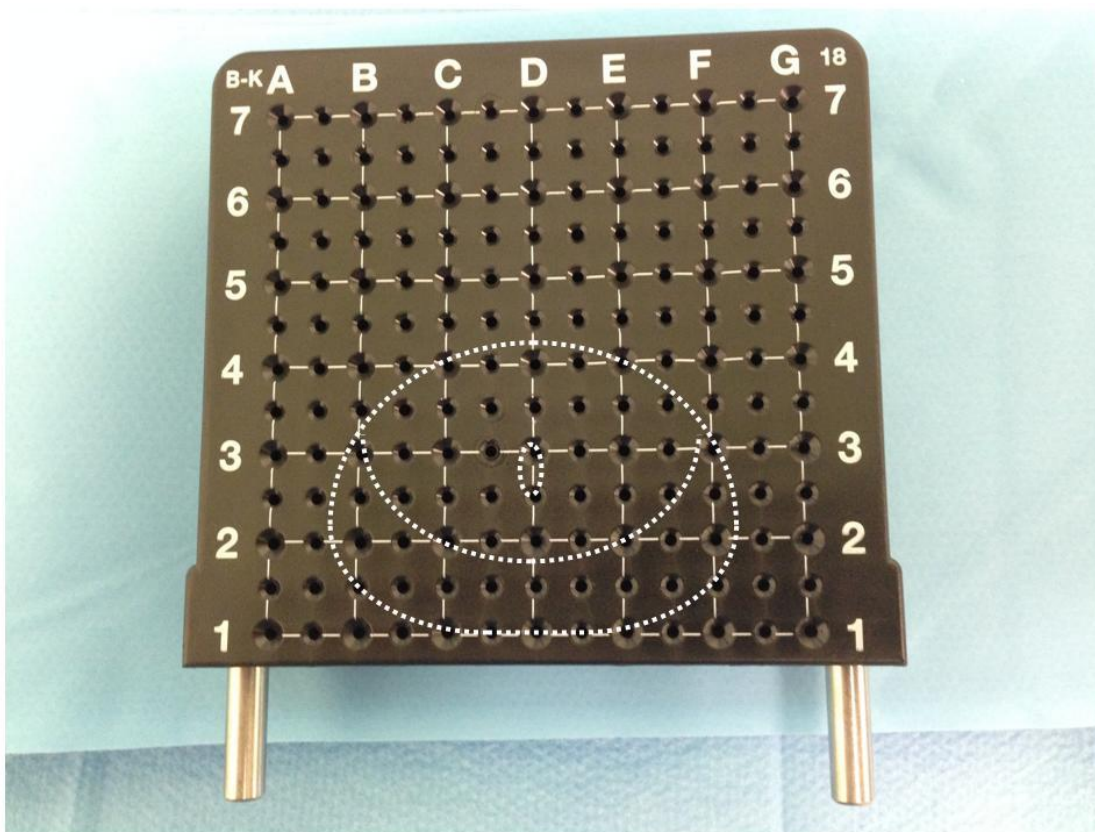


2. Template Biopsy Prostate Mapping allows more standardised and systematic sampling than standard prostate biopsies, which are performed in a random manner
3. Template Biopsy Prostate Mapping is associated with significantly more accurate identification and grading of prostate cancer, if detected, than standard prostate biopsies. This makes it easier for patients choose the most appropriate treatment because the Template Biopsy Prostate Mapping gives more information about the risk that a particular cancer poses to an individual man.
4. Template Biopsy Prostate Mapping is associated with fewer false negative results than standard prostate biopsies. This means that if the results come back normal, patients can be fully reassured they do not have prostate cancer (unlike after a standard prostate biopsy only). It is therefore less likely that they will need to have another prostate biopsy in the future.
5. Template Biopsy Prostate Mapping allows patients to undergo 21<sup>st</sup> century state-of-the-art diagnostic procedure.

### **How is Template Biopsy Prostate Mapping carried out?**

The Template Biopsy Prostate Mapping is performed as a minimally invasive surgical procedure under a short general or spinal (epidural) type anaesthetic lasting approximately 45 minutes. A soft flexible tube, called a catheter, is inserted through the penis into the bladder, and then, an ultrasound probe is gently inserted into the rectum. Both the catheter and the ultrasound probe are placed whilst the patient is under anaesthetic. A Template grid (like a battleship game grid) has holes every 5mm (**Figure 7**), and it is placed on the perineum (the area between the scrotum and the rectum).

**Figure 7: The Template grid used in Template Biopsy Prostate Mapping**



Patients gain significantly as the whole of the prostate is sampled in a very scientific and systematic manner, thus avoiding any risk of missing any cancer. Antibiotics are given before the start of the procedure through a vein and antibiotic tablets and pain killers will be given for 5-7 days after the procedure. The perineum skin is injected with local anaesthetic and at the end of the procedure, and a pressure dressing (thick padding) is placed over this area, to prevent a lot of bruising. This padding should be left for at least 6 hours.

### **What are the potential side effects of Template Biopsies Prostate Mapping?**

Template Biopsies Prostate mapping carry no extra risk than a normal prostate biopsy carried out through the rectum. The risk of sepsis is virtually negligible though. Other potential complications include:

- (1) Bruising of skin in all men and occasionally bruising that spreads to the scrotum
- (2) Temporary discomfort or pain in the back passage area (most men)
- (3) Bloody urine for the first few hours to a maximum of 2 days in most men
- (4) Bloody semen in most men lasting for up to 3 months in a few men
- (5) Retention of urine requiring a temporary catheter (2-10% - risk is higher with large volume prostates)
- (6) Urine infection (requiring admission and intravenous antibiotics, 0-1 in 100)
- (7) A few men have experienced temporary poorer erections

### **What happens on the day of the Template Biopsy Prostate Mapping procedure?**

The Template Biopsy Prostate Mapping is performed as a minimally invasive surgical procedure under a short general or spinal (epidural) type anaesthetic lasting approximately 45 minutes. You will be admitted to hospital on the morning of the procedure, but will be asked to not eat anything for at least 6 hours before the procedure and not drink anything for at least 4 hours before the procedure. You may 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 assessed by a Consultant Anaesthetist who will discuss the anaesthesia.

### **What happens after the Template Biopsy Prostate Mapping procedure?**

You will be discharged on the day, providing you have fully recovered from the procedure. You will be discharged with oral antibiotics for 5 days. If you have been discharged with a catheter, we will request you to re-attend the ward in 7-10 days time for removal of the catheter, under supervision. The Template Biopsy Prostate Mapping biopsies results will be discussed with you, 2 weeks after your procedure. Mr Shergill will arrange to see you in clinic for this purpose. The reports will indicate if there is any cancer or if all biopsies are benign. If prostate cancer is detected, Mr Shergill will show where the cancer is, how much cancer and how aggressive it is by denoting the Gleason score of each focus and also tell you how many biopsies were positive in each location.

### **Who may benefit from Template Biopsy Prostate Mapping?**

The current clinical indications for Template Biopsy Prostate Mapping include

#### **(1) Previous negative TRUS biopsy with raised PSA**

This will allow a definitive answer without the need for multiple repeat biopsies or prolonged outpatient follow up. This is particularly relevant in those with an evasive anterior lesion, in whom a diagnosis would not have been made with TRUS biopsy, regardless of the number

performed, due to the position of the lesion in the gland. The Template Biopsy Prostate Mapping technique allows sampling of these more difficult areas.

**(2) Patients with a high risk of sepsis.**

Clearly as sepsis is not seen with Template Biopsy Prostate Mapping, this should be first line investigation in this group.

**(3) Prior to Active Surveillance of prostate cancer**

This allows accurate reassurance to patients that they truly have low-risk disease. Template Biopsy Prostate Mapping, with sampling of the gland up to every 5mm, allows significantly more accurate confirmation, or otherwise, of low-risk status prior to initiation of active surveillance. Template Biopsy Prostate Mapping is likely to become the standard for inclusion into active surveillance. Currently it shows a 30% upgrading rate, moving some patients into the radical treatment group.

**(4) For planning focal therapy, such as Focal HIFU treatment.**

Template Biopsy Prostate Mapping can provide an accurate map of disease burden and location (see Figure 8). The results of the biopsy could guide targeted, or 'focal therapy', to the cancer lesion, with confidence that untreated tissue does not contain clinically significant disease. Template Biopsy Prostate Mapping has been recommended as the 'gold-standard' on which to plan focal therapy, and has been adopted within published prospective focal therapy trials.

**Figure 8: The biopsies results allow meaningful discussion about true extent of cancer.**

# Template Biopsies Results

