

# UNDERTAKING A TRANSRECTAL ULTRASOUND GUIDED BIOPSY OF THE PROSTATE

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# I. INTRODUCTION

The Prostate Cancer Risk Management Programme (PCRMP) is managed by the NHS Cancer Screening Programmes and is advised by an expert multidisciplinary Scientific Reference Group. A main role of the PCRMP is to ensure that men requesting a prostate-specific antigen (PSA) test are provided with information about the benefits, limitations and risks associated with the test to enable them to make an informed choice. The PCRMP is also responsible for improving the quality of PSA testing, for the quality of processes in the diagnosis of prostate cancer and for providing a systematic and standardised follow up pathway as far as the point of diagnosis.

Work began on the development of NHS guidelines for transrectal ultrasound guided biopsy of the prostate in 2003. A PCRMP sponsored conference organised by the Department of Pathology, University of Liverpool, brought together key professionals to identify and discuss the important factors relating to all stages of the prostate biopsy technique.<sup>1</sup> In addition to this, a systematic review was commissioned by the Centre for Reviews and Dissemination, University of York, to evaluate systematic prostate biopsy methods in the investigation for prostate cancer.<sup>2</sup>

Definitive evidence of the most appropriate way to perform many aspects of the prostate biopsy technique is still lacking, which has inhibited the production of evidence based guidance. Where there is good evidence to support a particular practice, the appropriateness of introducing this within the confines and constraints of NHS resources has to be considered. The development of this publication has therefore brought together key NHS professionals working in the field to produce guidance that will ensure patients receive a good standard of care, wherever they attend for a prostate biopsy in England.

Initially, the guidance development group met to define the aspects of the procedure that the guidance would address. Because of the vast amount of potential material, the contents were limited to areas where there was current concern and where the greatest impact could be made in terms of benefit to the patient. Aspects of the procedure were then formulated into a series of statements or criteria of good practice and presented in a questionnaire. Each individual member of the group was asked to rate (in private) their level of agreement with each statement against a nine point scale, ranging from 1 (strongly disagree/never appropriate) to 9 (strongly agree/always appropriate). They were provided with available research evidence and asked to take this into account in forming their judgement. The responses were aggregated and presented to the group members at a second meeting, together with a reminder of their personal initial rating. All statements for which there was a lack of consensus were discussed to determine the reasons. Particular attention was given to areas where there was least agreement. A record of the reasons for disagreement was made by an observer taking notes and by audiotaping the discussion.

Draft guidance was drawn up based on the group's views and circulated to group members for comment. The guidance was subsequently modified, and this version was tested in the wider community of relevant practitioners. Following this, the guidance was revised where necessary and sent back to group members for their final endorsement before publication in its present form.

## 2. PHYSICAL ENVIRONMENT

Prostate biopsies should be undertaken as part of the local multidisciplinary service for urological cancers.

Prostate biopsies should be performed in a setting that is designated for the procedure and where resuscitation equipment is readily available.

Resuscitation equipment should comprise oxygen, arrest trolley, defibrillator, emergency drug pack and monitoring equipment and there should be evidence that staff are trained in its use.

An appropriate area is also necessary for patients to sit and recover following the procedure, prior to going home.

## 3. MANPOWER REQUIREMENTS

### 3.1 Operator

Urologists and radiologists commonly perform prostate biopsies; however, this role should not be limited to these individuals. It is acceptable for other health professionals with extended roles to perform prostate biopsies provided that they have the appropriate knowledge, skills, training and back up support. The attributes which should apply to all individuals undertaking this task have been detailed in the workforce competence *Undertake Transrectal Ultrasound Guided Biopsy of the Prostate*, produced by Skills for Health.<sup>3</sup>

Trainee staff will also need to perform prostate biopsies while completing their training, but this should always be under the **direct** supervision of a competent operator.

### 3.2 Support staff

There should be one other member of staff present while the biopsy is being performed. This could be either a healthcare assistant or a nurse.

Additional support staff may be required depending on the workload undertaken in any one clinic. For the purposes of organising clinic time, it would be expected that at least six patients undergoing a prostate biopsy could be accommodated in a four hour session.

## 4. PATIENT INFORMATION

The patient should be provided with comprehensive information about the procedure. This should include estimates of the risks of potential complications and post-procedure events, such as:

- infection
- haematuria
- haemospermia
- rectal bleeding
- retention of urine
- mortality.

In addition to the information given orally by the individual performing the biopsy or by a member of the nursing team, patients should be provided with written information that they can keep.

Patients require information at several points in their care pathway. Initially, patients should be provided with information about the biopsy before they attend for the procedure, eg by mailing this to patients along with their appointment details. If biopsies are performed immediately after a clinic appointment, it is essential that patients are first provided with this information. Patients require information when they attend for biopsy as well as allowing time for discussion and for questions to be answered. Finally, information should be provided to patients on discharge following the biopsy, detailing the signs that patients need to look out for, what action to take, relevant contact details and how they will receive their results.

## 5. CONSENT

Written informed consent should be obtained from patients before initiating the procedure.

## 6. ENEMA

There is no requirement for patients to be given an enema before undergoing the procedure.

## 7. ANTICOAGULATION

Anticoagulant therapy in the form of warfarin should be stopped before undertaking the biopsy. If it is not possible to stop such therapy for longer than a few hours, conversion to intravenous heparin should be considered.

The anti-platelet agent clopidogrel should be ceased before performing a prostate biopsy.

It is not necessary to cease aspirin and non-steroidal anti-inflammatory drugs before the procedure. However, if a combination of aspirin and clopidogrel is being administered, this should be ceased prior to the procedure.

## 8. ANTIBIOTIC PROPHYLAXIS

Antibiotic prophylaxis must be provided to all patients undergoing a prostate biopsy. A minimum of one antibiotic should be used, such as an oral quinolone. The use of a second antibiotic against anaerobic bacteria should be considered.

Patients should receive antibiotic prophylaxis at least 30 minutes before the procedure, and such prophylaxis should continue for two to three days following the procedure.

Additional prophylaxis may be necessary for patients with artificial heart valves according to the recommendations in the British National Formulary.

## 9. PAIN CONTROL

### 9.1 Local anaesthesia

Prostate biopsies should normally be performed under local anaesthesia.

Appropriate regimes for inducing adequate local anaesthesia are:

- injection into the plane between the rectum and the prostate at the apex
- infiltration into the fat plane between the seminal vesicle and the rectal wall.

Local anaesthetic should **not** be injected into the neurovascular bundle as this procedure itself may inflict pain to the patient. Rectal anaesthetic gel should not be used instead of local anaesthetic infiltration.

### 9.2 Analgesia

General analgesia is rarely necessary. If a patient is extremely apprehensive, Entonox may be used. However, patients should be advised that they must not drive home following the procedure, as transient drowsiness may occur.

Routine sedo-analgesia is not appropriate.

## 10. MACHINE AND INSTRUMENTATION REQUIREMENTS

Transrectal ultrasound technology can be adequately performed with dedicated end-fire probes with curved array or biplanar dual side firing transducers.

The imaging equipment should be capable of providing the operator with a measurement of the prostatic volume, as this is likely to assist with later management. In addition, the equipment should provide satisfactory resolution of the zonal anatomy of the prostate and be capable of viewing the prostate in both longitudinal and transverse planes to aid placement of the needle and to target biopsy.

Only sterile disposable needle guides should be used; therefore, machines should have the capability of using such devices.

All needles used to inject local anaesthetic agents and to obtain biopsy cores should be sterile and disposable.

## 11. BIOPSY SCHEME

### 11.1 Approach

The prostate should be sampled through the rectum (transrectal) unless there is a specific condition that prevents this, such as an abdomino-perineal resection.

### 11.2 Number and origin of cores

The scheme used at first biopsy should be a 10 to 12 core pattern that samples the midlobe peripheral zone and the lateral peripheral zone of the prostate only. The addition of samples from the transition zone and possibly of the midline peripheral zone, ie a five region pattern, has not been shown to significantly increase the sensitivity of the procedure at initial biopsy.<sup>2</sup>

Directed cores should also be sampled from any hypoechoic areas identified during the procedure.

In cases where a locally advanced prostate cancer has been identified, the operator may wish to perform a limited number of cores from a prognostic viewpoint, rather than the full 10 to 12 core pattern.

Anterior/transition zone samples may be appropriate at a repeat biopsy.

### 11.3 Adequacy of needle core biopsies

The operator performing the prostate biopsy should ensure that the sample cores taken are adequate for histopathology by comparing the length of the core with the length of the needle notch. Any deemed unsatisfactory should be repeated if the patient can tolerate further biopsies.

## 12. SAMPLE PROCESSING IN THE BIOPSY CLINIC

### **12.1 Patient identification**

To ensure correct patient identification, there should be only one set of patient notes/details and self-adhesive patient labels in the procedure room at any one time.

Local policies and procedures should be followed for labelling and checking sample containers to ensure correct patient identification.

### **12.2 Sample transfer**

The transfer of biopsy cores should be directly onto either a cassette or a piece of filter/blotting paper before placing into fixative solution. This will minimise damage/fragmentation of the samples.

### **12.3 Identification of cores**

It is desirable for each core to be processed so as to maintain the identity of its source in the prostate gland. Many units are now moving towards this practice.

As a minimum requirement, cores should be identifiable according to the side (right/left) of the gland that they originated from. This information is of paramount importance as it may enable a unilateral nerve sparing prostatectomy to be performed when a cancer involves only one side of the gland.

## 13. DISCHARGE CRITERIA

The patient should be observed for at least 30 minutes following the procedure before going home.

## 14. LABORATORY PROCESSING

### **14.1 Non-medical laboratory personnel**

The preparation of specimens once they have arrived in the laboratory, including embedding, staining and sectioning, should be performed by laboratory personnel competent to perform such tasks. It is the responsibility of the laboratory manager/head of department to ensure that staff performing such roles are competent. An iterative process through audit should assess this.

### **14.2 Flat embedding**

Flat embedding should be employed in order to allow sectioning at multiple levels through the entire length of the core. This will maximise the amount of tissue for evaluation by the pathologist because cores can often become curved after fixation.

### **14.3 Identification of cores in the cassette**

The identity of the cores according to the side (right/left) of the gland that they originated from should be maintained.

Separation of individual cores is desirable as it allows for more accurate localisation and quantification of tumour burden. Also, individual cores can more easily be laid straight and flat after processing for blocking out, facilitating sectioning. This can be achieved by using individual cassettes, by cassettes with internal divisions or by 'sandwiching' cores between two foam inserts (or other appropriate material depending on local practice) in a specific order.

### **14.4 Sectioning**

When sectioning the cores, the laboratory should ensure that the cores have been optimally sectioned in order to identify even small foci of cancer. As a minimum, the laboratory should take sections at three separate levels of the core. Level 1 should lie in the top half of the core, level 2 in the middle and level 3 in the bottom half of the core.

Spare sections at each level should be prepared at the initial time of sectioning because this will reduce the chance that the patient may need to be re-biopsied. As a minimum, four sections should be prepared at each level, one for haematoxylin and eosin (H&E) stain, two for immunohistochemistry and one as a spare.

Only one section need be stained and examined at each level.

Further sections at shallow levels should be performed if the pathologist finds something suspicious at a particular level.

## 15. REPORTING

### 15.1 Personnel

Specimens should be examined and reported by a trained pathologist.

If trainee pathologists examine specimens, these should be reported by a trained pathologist.

### 15.2 Terminology

When reporting prostate biopsies, ambiguous terms should be avoided. The following standard nomenclature should be used:

- benign
- acute inflammation
- chronic granulomatous inflammation
- atrophy
- high grade prostatic intraepithelial neoplasm (PIN)
- suspicious (lesion too small or insufficient criteria present)
- adenocarcinoma.

### 15.3 Immunohistochemistry

In cases for which the diagnosis of cancer is equivocal, immunohistochemistry for basal cell markers (high molecular weight cytokeratins, p63, etc.) should be used. The absence of a demonstrable basal cell layer is supportive, but not diagnostic, of malignancy.

### 15.4 Equivocal cases

An early referral to a pathologist with expertise in the area of prostate biopsies should be made for all cases in which the diagnosis of cancer is equivocal. This will avoid delaying the diagnosis and reduce the possibility of a repeat biopsy. Equivocal cases may arise when the pathologist is uncertain and also when the operator who took the biopsy has a high clinical suspicion despite the absence of histological confirmation. Appropriate expertise can be sought from multidisciplinary team meetings and pathology networks.

### 15.5 Differentiation grade

The Gleason scoring system should be used to provide information concerning the differentiation of the identified tumour.

## 16. QUALITY STANDARDS AND AUDIT

The following information should be recorded and audited:

- the time from when the biopsy is taken to the time when the histology result is available to the clinical team
- the time from when the biopsy is taken to the time when the histology result is communicated to the patient
- the time from when the biopsy is requested to the time when the histology result is communicated to the patient
- the prevalence of prostate cancer among patients undergoing prostate biopsies
- the median number of biopsies performed per patient
- cancer rates within specified PSA ranges
- the sensitivity and specificity of initial biopsies for prostate cancer
- patient satisfaction with the procedure
- the incidence of urinary retention after biopsy
- the incidence of serious rectal bleeding
- the number of patients and reasons for admission for all patients requiring hospital admission within seven days of the biopsy
- the percentage of cores that contain prostatic tissue; the minimum percentage of cores found to contain prostatic tissue should be 95%
- the percentage of biopsies reported as 'suspicious'; this may reflect a number of factors, including the quality of the specimen, the population served and the certainty of the pathologists' reporting, but would not be expected to be more than 10%.

## 17. RESEARCH ISSUES

There is a requirement for a large scale study of adverse events after prostate biopsy to obtain more accurate incidence data.

Continual monitoring of infection is important as resistance to quinolones may emerge.

Should prostate biopsy cores be stretched or flattened during fixation to prevent curling? If so, how is this best achieved?

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