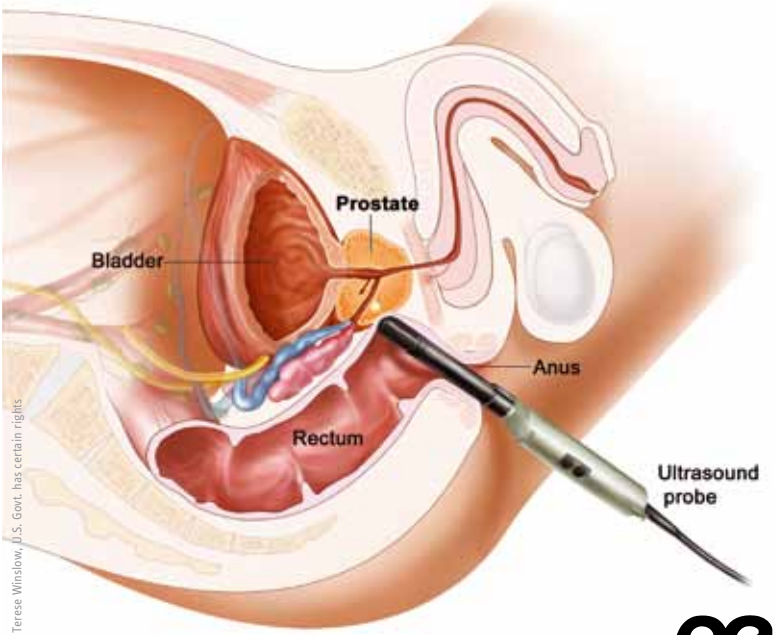
Evidence-based Guidelines for Best Practice in Health Care

# Transrectal Ultrasound Guided Biopsy of the Prostate

2011






European Association of Urology Nurses

Evidence-based Guidelines

for Best Practice in Health Care

# Transrectal Ultrasound Guided Biopsy of the Prostate

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# Introduction

**The European Association of Urology Nurses**
The European Association of Urology Nurses (EAUN) was established in April 2000 to represent the interests of European urological nurses. The EAUN's underlying goal is to foster the highest standards of urological nursing care throughout Europe. With administrative, financial and advisory support from the European Association of Urology (EAU), the EAUN also encourages research and aspires to develop European standards for education and accreditation of urology nurses.

Improving current standards of urological nursing care has been top of the agenda, with the aim of directly helping our members develop or update their expertise. To fulfil this essential goal, we are publishing the latest addition to our Evidence-based Guidelines for Best Practice in Health Care series, a comprehensive compilation of theoretical knowledge and practical guidelines on Transrectal Ultrasound Guided Prostate Biopsy (TRUS Biopsy). Many thousands of prostate biopsies are undertaken in each country throughout Europe and the rest of the world each year. It remains the gold standard investigation for diagnosing and excluding prostate cancer. First described in 1937 it allows for tissue samples of the prostate to be obtained for histological analysis. Although there is considerable literature on TRUS Biopsy, to our knowledge prior to this publication there was only limited evidence-based guidance available on this topic. The EAUN Guidelines Group believes there is a need to provide guidelines with recommendations clearly stating the level of evidence of each procedure with the aim of improving current practices and delivering a standard and reliable protocol.

The role of the nurse has changed dramatically evolving from basic practice to an independent practitioner with advanced practice qualifications. [1] Increasing numbers of nurses now undertake this procedure independently. The role of nursing continues to progress and to cross professional boundaries. Nurses working at an advanced level should be autonomous in their practice. Sharing this knowledge equips nurses with the context and skill required to continue to develop the foundations for quality nursing practice and for the growth of the discipline. [2] In acknowledging the ever changing demands of patient care and the resultant diversity and extension of roles undertaken in urological nursing practice across Europe, the EAUN has developed guidelines on TRUS Biopsy. These guidelines could also be used as a guide for residents in urology, urologists and others working in the field of urology.

**Aim**
Health care is not bound by geographical boundaries and the role of the nurse should reflect a sound knowledge and skills base across all European countries. The application of these competency standards and professional practice guidelines by the EAUN are to enhance urological nursing practice and assist the professional development of the individual in the development and provision of TRUS Biopsy, ensuring patient safety, dignity and comfort, and the delivery of the highest quality patient care. In addition its aim is that the quality of the provision of this clinical procedure is not compromised and that they provide a benchmark against which the individual can be measured and their competence be assessed.
These guidelines are intended to complement, or provide support to, established clinical

practice. With our emphasis on delivering these guidelines based on a consensus process, we intend to support practitioners who are already assessed as competent in this procedure. The intended readership is the specialist urology nurse and healthcare professionals working in a related field.

**Inclusions**
This guideline includes anatomy and physiology of the prostate, aetiology of prostate cancer, how to undertake the procedure, its complications and the knowledge and understanding required by the healthcare professional as well as extensive references and annotated procedures.

**Limitations**
This guideline is limited to TRUS Biopsy and does not include TRUS guided transperineal biopsy although the working group recognises that this approach is becoming more widely used and it may be addressed in a future document.

These guidelines should be used within the context of local policies and existing protocols. It is acknowledged that throughout Europe nurses in different countries have different levels of involvement; some undertake the procedure independently whilst others assist medical colleagues. Additionally, it is acknowledged that there is wide variation in nursing titles: for the purpose of this document the term 'specialist nurse' will be used.

**Distribution**
This text is made available to all individual EAUN members, both electronically and in print. The full text can be accessed on the EAU website (http://www.uroweb.org/nurses/nursing-guidelines/) and the EAUN website (www.eaun.uroweb.org).
Hard copies can be ordered through the EAU website via the web shop (https://www.uroweb.org/publications/eaun-good-practice/) or by e-mail (eaun@uroweb.org).

# Table of contents

# 1. Methodology, disclosures

## 1.1 Guidelines working group

The guidelines working group consisted of a multi-professional group of specialist nurses and a medical colleague. Information about the authors can be found on page 49.

## 1.2 Literature search

The information offered in this guideline was obtained through a systematic literature search and through review of current procedures undertaken in various member countries of the EAUN. All group members participated in the critical assessment of the scientific papers identified. Bibliographical databases consulted included Embase, Medline and the Cochrane library database CENTRAL. The search was based on the keywords (listed below). Both Embase and Medline were searched using both 'Free text' and the respective thesauri MesH and EMTREE. The time frame covered in the searches was January 2000 – September 2010.

## 1.3 Limitations of the search

In Medline and Embase the search results were limited to randomised controlled trials (RCTs), in Central to Controlled Clinical Trials. In all databases, output was limited to human studies and English language publications.

## 1.4 Search keywords

The reference search included the following key words (in alphabetical order):

- Antibiotic
- Biopsy
- Cancer
- Ciprofloxacin
- Doppler
- Infectious
- Competency
- Complication
- Consent
- Digital rectal examination
- Examination
- Guideline
- Histology
- Leucocytes
- Lidocaine
- MRI
- Nitrates

- Patient education
- Prophylaxis
- Prostate
- Prostate biopsy
- Prostate cancer
- Prostatic neoplasms
- PSA
- Safety
- Training requirements
- Transrectal
- Transrectal ultrasound and prostate biopsy
- TRUS
- Ultrasound
- Vascularity
- Volume

## 1.5 Search results

EAUN commissioned a company to do an initial search on TRUS, ultrasound, prostate and biopsy which resulted in a total of 477 scientific publications (312 papers in CENTRAL and 165 in Embase/Medline).
An additional search focusing on infectious complications and increased volume of the prostate gave 40 level 1 publications but none of them proved relevant to this guideline.
Two group members made a selection of the most relevant abstracts for this document.
It was a policy decision to restrict the search in this way, though the group were aware that more complex strategies were possible, and would be encouraged in the context of a formal systematic review.

## 1.6 Disclosures

All members of the EAUN guidelines working group have provided disclosure statements of all relationships that might be a potential source of conflict of interest. The information has been stored in the EAU(N) database.
The EAUN is a not for profit organisation and with the exception of administrative assistance, travel and meeting expenses, no honoraria or other reimbursements have been provided.
Printing and distribution of this guideline was made possible through educational grants supplied by Novartis, Amgen and AstraZeneca. Industry representatives have had no influence on working group composition, content selection nor have they been included in the (blinded) review process prior to publication.

## 1.7 Limitations of document

The EAUN acknowledge and accept the limitations of this document. Guidelines provide a standardised approach to patient care and management and the practitioner must tailor

care towards the individual patient. Their aim is to help healthcare professionals to make informed decisions about their patients. Adherence to a guideline does not guarantee a successful outcome. Ultimately, healthcare professionals must make their own decisions about care on a case-by-case basis, using their clinical judgement, knowledge and expertise, and after consultation with their patients. Therefore these guidelines provide recommendations without legal implications.

Cost-effectiveness considerations and non-clinical questions are best addressed locally and therefore fall outside the remit of these guidelines. Other stakeholders, including patient representatives, have not been involved in producing this document.

This guideline discusses transrectal ultrasound and prostate biopsy. Transperineal biopsy is not addressed. When high quality publications were lacking, the recommendations were based on expert reports or expert consensus. This is clearly indicated in the document.

## 1.8 Review process

Prior to publication, blinded review was carried out by 8 reviewers. Involved were nurse specialists, urologists, an oncological pathologist and an oncologist. After discussion of all comments received, appropriate revisions were made by the working group and the document was approved by the EAUN Board and the EAU Executive Board member responsible for EAUN activities.

## 1.9 Rating system

The recommendations provided in these documents are based on a rating system modified from that produced by the Centre for Evidence-based Medicine. [3]
Some of the literature was not easy to grade. If, however, the EAUN working group thought the information would be useful in practice, it is ranked as level of evidence 4 and grade of recommendation C.

**Table 1. Level of evidence (LE)**

| Level | Type of evidence |
|---|---|
| 1a | Evidence obtained from meta-analysis of randomised trials |
| 1b | Evidence obtained from at least one randomised trial |
| 2a | Evidence obtained from one well-designed controlled study without randomisation |
| 2b | Evidence obtained from at least one other type of well-designed quasi-experimental study |
| 3 | Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports |
| 4 | Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities |

**Table 2. Grade of recommendation (GR)**

| Grade | Nature of recommendations |
|---|---|
| A | Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial |
| B | Based on well-conducted clinical studies, but without randomised clinical trials |
| C | Made despite the absence of directly applicable clinical studies of good quality |

*Adapted from The Oxford 2011 Table of Evidence [3]*

# 2. Definitions and descriptions

- **Digital rectal examination** — Examination of the anus, lower rectum and prostate with the index finger.
- **Prostate** — Accessory male reproductive gland; produces a third of seminal volume including fluids that activate sperm.
- **Seminal vesicles** — Coiled glands which secrete a significant proportion of fluid which ultimately becomes semen.
- **Transrectal ultrasound** — An ultrasound technique whereby an ultrasound probe is inserted into the rectum.
- **Prostate biopsy** — A procedure whereby prostatic tissue is obtained for histological evaluation. Usually guided by transrectal ultrasound.
- **Specialist nurse** — A nurse working in a specialist area, often working at an advanced level with advanced practice qualifications. May be synonymous with the term nurse practitioner.

# 3. Prostate anatomy and physiology

There is a requirement to be intimately familiar with the gross or glandular anatomy of the prostate as well as ultrasound appearances. (Fig. 4)

## 3.1 Gross anatomy

In the post pubescent male the prostate gland has a volume of up to 25 ml, being approximately 3.5 cm long, 4.0 cm wide and 2.5 cm deep from posterior to anterior – which is about the same size as a walnut.

The prostate is an extraperitoneal structure, lying anterior to the rectum and at the bladder neck. The prostate encircles the urethra and it empties its secretions into the urethra. It comprises a number of smaller glands that are surrounded by smooth muscle and connective tissue. During ejaculation the smooth muscle contracts and compresses the glands, forcing secretions into the urethra. Prostatic secretions contain several enzymes such as PSA which help to liquefy the semen by breaking down coagulation factors and citrate, which the sperm uses for energy.
Between the gland and the rectum lies the Denonvilliers' fascia - an obliterated peritoneal plane or a potential space. The prostate shape conforms to the anatomical limitations of the deep pelvic boundaries, and it looks like an inverted cone or pyramid. On either side are the levator ani and obturator internus muscles. The base of the inverted cone lies against the bladder and the apex on the urogenital diaphragm, a fibrous supporting ring that also contains the urethra. The gland is surrounded by the prostate (pseudo)capsule. (Fig. 2 and 3)

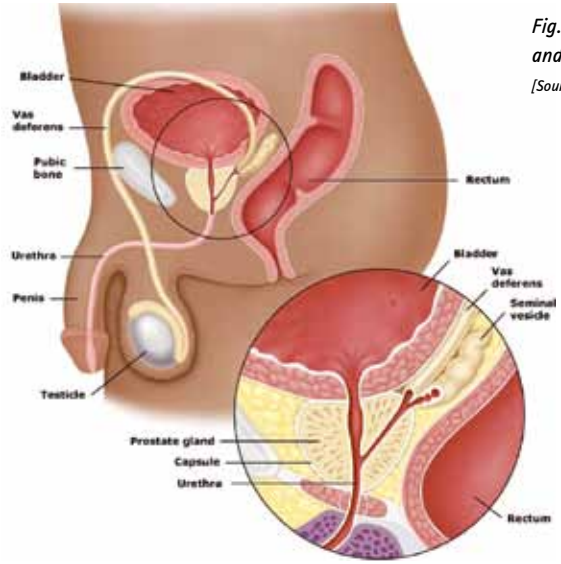



*Fig. 2 Gross anatomy – male reproductive and urinary system*
*[Source: unknown]*

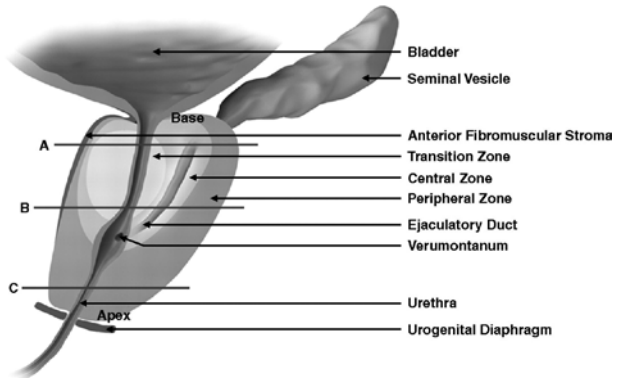



*Fig. 3 Gross anatomy – prostate (saggital) - A base, B mid, C apex of gland*



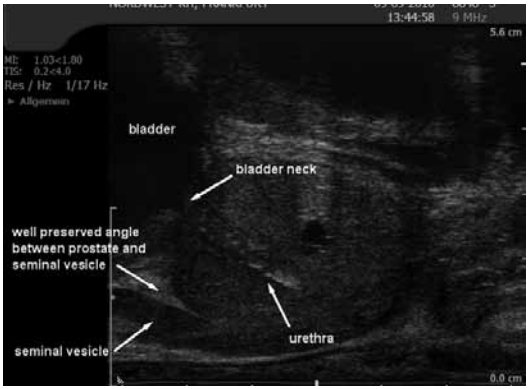



*Fig. 4 Ultrasound of the gross anatomy of the prostate demonstrated on TRUS*

*[Source: S. Hieronymi]*

## 3.2 Zonal anatomy

In the prostate three glandular regions can be identified: the central, peripheral and the transition zones. There is a further non-glandular area called the anterior fibromuscular stroma. (Fig. 5 and Fig. 6)

The peripheral zone accounts for 75% of the prostate tissue in young men but as the man ages the transition zone increases in size due to benign prostate enlargement (BPE) whilst the central zone atrophies and the peripheral zone stays static. Thus, for clinical purposes the important regions are the peripheral and transition zones.

It is the peripheral zone in which the majority of prostate cancers occur whereas BPE arises in the transition zone.

Under former classification the prostate has been divided into 5 lobes: anterior lobe, posterior lobe, median lobe and two lateral lobes. (Fig. 7)

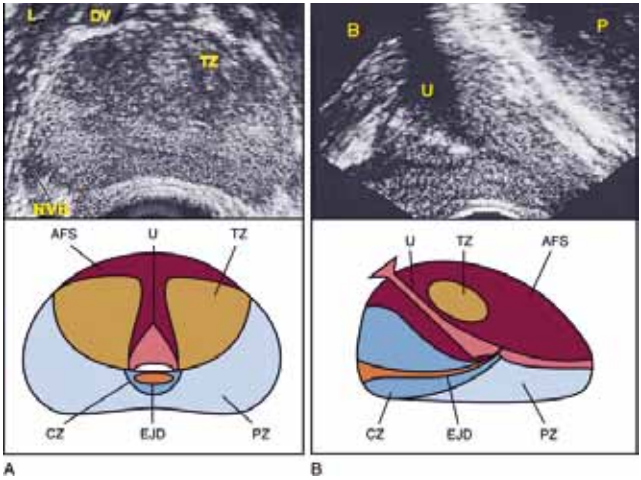



*Fig. 5 Normal prostate ultrasound images with zonal anatomy*
*Normal prostate ultrasound images (top) with diagrams (bottom) at approximately the level of the verumontanum demonstrating zonal anatomy. A, Transverse view. B, Sagittal view. AFS, anterior fibromuscular stroma; CZ, central zone; DV, dorsal vascular complex; EJD, ejaculatory ducts; NVB, neurovascular bundle; L, levator muscles; PZ, peripheral zone; TZ, transition zone; U, urethra.*
*[Source: Campbell Walsh Urology, permission see page 40.]*

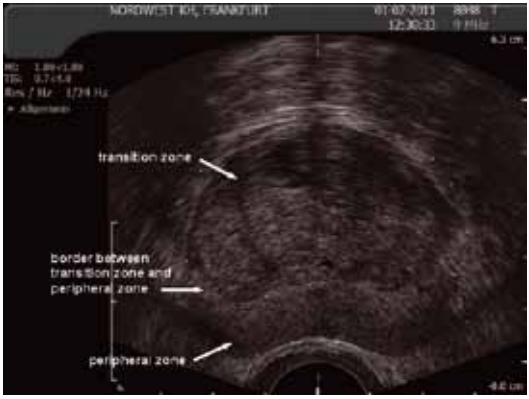



*Fig. 6 Ultrasound image of transition and peripheral zone*
*[Source: S. Hieronymi]*

## 3.3 Vascular anatomy

The prostate has a rich arterial blood supply. The prostate artery is a branch from the inferior vesical artery (Fig. 7), a branch of the internal iliac artery, which divides into capsular and urethral arteries. Branches of the inferior vesical artery supply the seminal vesicles and occasionally the base of the gland.
Santorini's venous plexus lies anteriorly and has small perforating vessels to the prostate. The neurovascular bundles lie postero-laterally at 5 and 7 o'clock and contain the branch arteries, veins and nerves that mainly go to the penis.

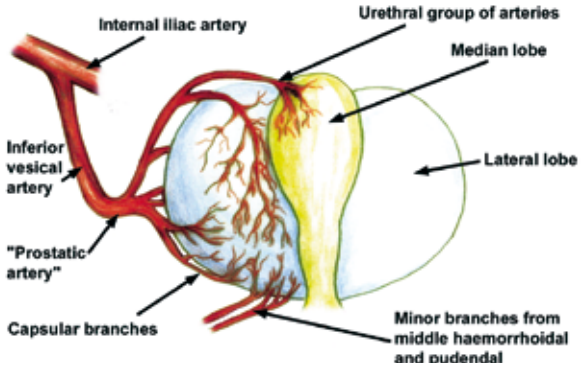



*Fig. 7 Prostate arterial supply*
*[Source: eMedicine.com, permission see page 40.]*

## 3.4 The prostatic urethra

The prostatic urethra runs through the prostate from the base of the bladder to the apex of the prostate. It is a midline structure unless there is asymmetric glandular enlargement. There is a triangulated portion at the verumontanum and the ejaculatory ducts drain into the urethra.
There is a variable amount of smooth muscle around the urethra and this, with the urogenital margin, accounts for its sono-visibility on ultrasound in the collapsed state.
See Fig. 4 Ultrasound gross anatomy (3.1)

## 3.5 Seminal vesicles and ejaculatory ducts

The seminal vesicles are paired sac-like structures of variable size and shape and lie just posterior and superior to the base of the prostate. A minor degree of asymmetry is common. The paired ejaculatory ducts formed by the union of the vas deferens and the seminal vesicles run through the prostate in the central zone. They communicate with the prostatic urethra at the verumontanum. [4, 5, 6] See Fig. 4 Ultrasound gross anatomy (3.1)

# 4. Prostate cancer

The incidence of prostate cancer varies considerably internationally with the lowest incidence in Southeast Asia and highest in North America and Western Europe. [7, 8] The age-standardized incidence rates range from around 1 per 100 000 in Asia to 160 per 100 000 in the U.S. with highest rates among African Americans. [8, 9] The mortality rate varies from about 1 to 30 per 100 000. [8] Worldwide, prostate cancer is among the most common cancers with an estimated 650 000 new cases and over 220 000 deaths in 2002. [8] The incidence of prostate cancer has increased significantly over the past two decades - in some areas almost exponential. [10, 11, 12] This increased incidence is explained by the introduction of the PSA blood test [13, 14] and an ever ageing population.

Mortality of prostate cancer has been largely stable. Autopsy studies shows that the prevalence of prostate cancer increases sharply with age, and foci of prostate cancer can be detected in up to 70-80% of 80-year-old male who died of other causes. [15, 16, 17] In contrast to the rate of clinical or biopsy detectable prostate cancer, there is no significant international differences in the incidence of prostate cancer in autopsy studies. [15, 16, 18] International variation in the incidence of prostate cancer and the fact that prostate cancer incidence rises in the first and second generations of migrants from low to high risk areas indicates that the manifestation of clinically significant prostate cancer depends on exogenous factors. [19, 20, 21]

## 4.1 Aetiology

There is limited knowledge on the aetiology of prostate cancer. Racial differences in the incidence of clinical prostate cancer and a tendency to familial accumulation suggest a genetic component, but also infectious / inflammatory, hormonal (androgen), dietary and lifestyle factors appear to play a role in the development of prostate cancer. [22] There are three well established risk factors for prostate cancer: genetics, ethnicity and increasing age.

## 4.2 Pathogenesis

Prostate cancer often develops very slowly compared with most other cancers and the natural history often spans several decades. However, some cancers grow fast and will give rise to early metastases and death. At diagnosis, it is still difficult to differentiate those prostate cancers that remain indolent and those that will proliferate more quickly. There is no fixed pattern of proliferation; it is often multifocal and usually grows locally. Prostate cancer can infiltrate and penetrate the prostatic (pseudo)capsule; often penetration is basal and lateral and continues towards the seminal vesicles or follows the neurovascular bundles. [23, 24]

It may spread into regional lymph nodes to finally give rise to distant metastases. [25, 26, 27, 28] The risk of lymph node metastasis increases with increased tumour volume and poor histological differentiation. [29]

## 4.3 Diagnosis

The principal diagnostic tools for evaluating the risk for prostate cancer include a combination of Digital Rectal Examination (DRE) and Prostate Specific Antigen (PSA) prompting a decision to perform a Transrectal Ultrasound (TRUS) guided prostate biopsy.

### 4.3.1 Digital Rectal Examination (DRE)

Approximately 70% of prostate cancers are located in the peripheral zone of the prostate and may be detected by DRE when the tumour volume is about 0.2 ml or larger. [30]. A suspicious DRE is an absolute indication for prostate biopsy. [30] It was previously reported that in about 18% of all patients, prostate cancer is detected by a suspicious DRE alone, irrespective of the PSA level. [31] (Level of evidence: 2a)

### 4.3.2 Prostate Specific Antigen (PSA)

PSA is currently the only serological marker routinely used in the diagnosis, staging and monitoring of treatment response or failure in prostate cancer. [32] PSA remains a better predictor of prostate cancer than DRE or transrectal ultrasound. A number of new markers that can be applied in the diagnosis and monitoring of the disease are under development.

PSA is an organ-specific glycopeptide which is produced exclusively in the prostate gland cells originally isolated in the ejaculate where its concentration is 106 times greater than serum concentrations. [33, 34, 35] PSA is a proteolytic enzyme, whose physiological function is to dissolve the coagulated semen. Half-life in serum is about 3 days. [36, 37]

PSA is a tissue and not tumour-specific marker, which is important because elevated levels of PSA may occur in: instrumentation of the urinary tract, BPE, urinary tract infection, prostatitis, acute urinary retention or large urinary residual, TRUS with or without biopsy and to a lesser extent DRE. [30]

Treatment with 5-alpha reductase inhibitors reduce the PSA concentrations by around 50% (after 3 to 6 months of treatment) and the PSA reading should be doubled in these instances. [30]
There are no universally accepted cut-off limits for PSA [30] and as such it is important to follow agreed local guidelines. The finding that many men may harbour prostate cancer, despite low levels of serum PSA, has been underscored by recent results from a US prevalence study. [38] (Level of evidence: 2a)

**Free PSA**

The free/total PSA ratio is the concept often used to discriminate BPE from prostate cancer. The ratio can be used to stratify the risk of prostate cancer for men who have total PSA levels between 4 and 10 ng/ml and a negative DRE. In a prospective multicentre trial, prostate cancer was found on biopsy in 56% of men with a free/total < 10, but in only 8% of men with free/total > 0.25. [39] (Level of evidence: 2a). This concept however should be used with caution as assay characteristics may vary with concomitant BPE which may result in a ‘dilution effect’ according to Stephan (1997). [40]

**Screening for prostate cancer**

Population or mass screening is defined as the examination of asymptomatic men (at risk). Two very important studies were conducted and published in March 2009, Screening and Prostate – Cancer mortality in a randomized European Study (ERSPC), [41] and Mortality results from a randomized Prostate – Cancer Screening Trial (PLCO). [42]

The difference between both trials was as follows:

| | Prostate, Lung, Colorectal, and Ovarian (PLCO) | European Randomised Study on Prostate Cancer (ERSPC) |
|---|---|---|
| **Age** | 55-74 | 55-74 |
| **Method** | PSA & DRE | PSA only |
| **PSA cut-off** | 4 ng/mL | 3 ng/mL |
| **Ethnicity** | 85% Caucasian/ 15% minority groups | Mostly Caucasian |
| **Screening interval** | Yearly | 4 yearly |
| **Contamination** | > 40% | 20% (estimated) |
| **Sample size** | 76,000 | 162,000 |

The conclusion from the PLCO study after 7-10 years of follow up, was that the rate of death from prostate cancer was very low and did not differ significantly between the two study groups. (Level of evidence: 1b)

The conclusion from the ERSPC study was that PSA-based population screening reduced the rate of death from prostate cancer by 20%, but was associated with a high risk of overdiagnosis and overtreatment. It was estimated that 48 men needed treatment in order to save one man's life. (Level of evidence: 1b)

Both trials provide important information on the utility of prostate cancer screening but it is difficult to compare them directly.

Based on these two large, randomised trials, most of the major urological societies conclude that presently widespread mass screening is not appropriate but early detection (opportunistic screening) should be offered to the well-informed man. Two key items remain open and empirical:

- At what age should early detection start
- What is the interval for PSA and DRE

A baseline PSA determination at age 40 years has been suggested upon which the subsequent screening interval may then be based according to Borgermann. [43] (Grade of recommendation: B). A screening interval of 8 years might be adequate in men with a presenting PSA of < or equal to 1 ng/ml. [44] Further PSA testing is not necessary in men over 75 years and a baseline PSA of less than or equal to 3 because of their very low risk of dying from prostate cancer. [45] [39], [40], [46]

## 4.4 Transrectal ultrasound and prostate biopsy

Many thousands of prostate biopsies are undertaken every year throughout Europe. It remains the gold standard investigation for diagnosing prostate cancer. First described by Astraldi in 1937 [47] it allows for tissue samples of the prostate to be obtained for histological analysis. The need for prostate biopsies should be determined on the basis of the PSA level and/or a suspicious DRE. Biopsy should only be undertaken if it influences the management of the patient and factors such as patient age and co-morbidities must be considered. [30] There are many indications for prostate biopsy which include:

a) Raised PSA level in the absence of urinary tract infection, acute urinary retention or acute prostatitis
b) Abnormalities identified through digital rectal examination of the prostate
c) Patients being assessed for radiation failure i.e. PSA increase post radiotherapy
d) Patients on an active surveillance protocol requiring repeat biopsies
e) Patients with previous histology requiring repeat biopsy e.g. high grade prostatic intra-epithelial neoplasia or suspicious but not diagnostic for carcinoma
f) Patients on an ethically approved clinical trial

The first elevated PSA level should not prompt an immediate biopsy; the PSA should be repeated a few weeks later under the same conditions in the same laboratory using the same assay. [48, 49] (Level of evidence: 2a)

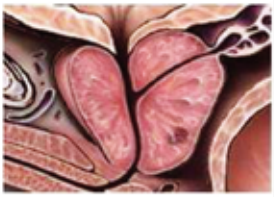
## 4.5 Staging and grading

Following diagnosis, prostate cancer is graded using the modified Gleason system [50, 51, 18] and staged using the common Tumour, Node and Metastases (TNM) classification. [52]

See Table 3., page 20.

**Table 3. Tumour Node Metastasis (TNM) classification of PCa [52]**

**T 1**



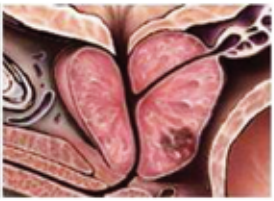
**T1** Clinically inapparent tumour not palpable or visible by imaging

**T1a** Tumour incidental histological finding in 5% or less of tissue resected

**T1b** Tumour incidental histological finding in more than 5% of tissue resected

**T1c** Tumour identified by needle biopsy (e.g. because of elevated prostate-specific antigen (PSA)

**T2**



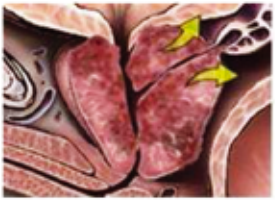
**T2** Tumour confined within the prostate[1]

**T2a** Tumour involves one half of one lobe or less

**T2b** Tumour involves more than half of one lobe, but not both lobes

**T2c** Tumour involves both lobes

**T3**

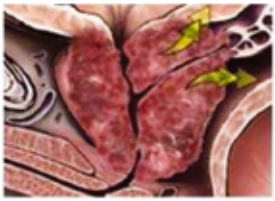


**T3** Tumour extends through the prostatic capsule[2]

**T3a** Extracapsular extension (unilateral or bilateral) including microscopic bladder neck involvement.

**T3b** Tumour invades seminal vesicle(s)

**T4**



**T4** Tumour is fixed or invades adjacent structures other than seminal vesicles: external sphincter, rectum, levator muscles, and/or pelvic wall

**T Primary tumour**
**TX** Primary tumour cannot be assessed
**T0** No evidence of primary tumour

**N Regional lymph nodes**[3]
**NX** Regional lymph nodes cannot be assessed
**N0** No regional lymph node metastasis
**N1** Regional lymph node metastasis

**M Distant metastasis**[4]
**M0** No distant metastasis
**M1** Distant metastasis
**M1a** Non-regional lymph node(s)
**M1b** Bone(s)
**M1c** Other site(s)

[1] *Tumour found in one or both lobes by needle biopsy, but not palpable or visible by imaging, is classified as T1c.*
[2] *Invasion into the prostatic apex, or into (but not beyond) the prostate capsule, is not classified as T3, but as T2.*
[3] *Metastasis no larger than 0.2 cm can be designated N1 mi.*
[4] *When more than one site of metastasis is present, the most advanced category should be used.*

*Adapted from Sobin (2009). [52]*

# 5. TRUS and biopsy procedure

It is important that the environment is suitably prepared and all the required equipment is available and checked to be in working order before commencing the procedure. All staff should be familiar with their expected roles and emergency procedures, the location of any emergency equipment and the ability to contact a senior clinician should the need arise.

When the room and equipment are suitably prepared the patient preparation can then begin. It is the responsibility of the person performing the biopsy that the patient is suitably prepared; this must be checked before commencing the procedure. Any doubts regarding the suitability should be made known to a senior clinician for further advice.

## 5.1 Room preparation

A **clinical room** which is spacious enough for at least 3 people is required and should be suitably furnished with flooring and equipment which can be decontaminated if there are spillages of body fluids. The standard equipment required includes:

- Examination couch
- Curtains or a screen to maintain privacy
- Ultrasound machine
- Ultrasound probe
- Linen skip
- Clinical waste bin
- Sharps bin

A **clinical trolley** should be prepared in advance with the following items:

- Biopsy gun and needles or single use device
- Long spinal needles (to administer anaesthetic)
- Condoms/sheaths (for ultrasound probe)
- Antibiotics (if not previously administered)
- Local anaesthetic
- Specimen pots
- Lubricating jelly
- Wipes/gauze
- Gloves
- Needle guide

See Fig. 8.

Also required are:

- Pathology requisition form
- Procedure pro-forma (to record details of procedure)

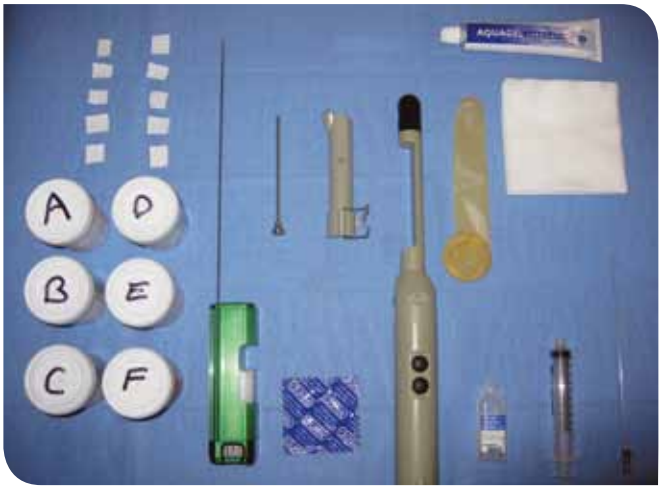



*Fig. 8 Example of equipment needed for TRUS prostate biopsies*

*[Source: Urology News, permission see page 40.]*

**Emergency equipment** should be easily accessible in the rare event of a major complication. This should include:

- Oxygen
- Suction
- Cardiac arrest trolley
- Defibrillator
- Emergency drugs
- Anaphylaxis kit
- Monitoring equipment
- Intravenous fluids

## 5.2 Patient preparation

All patients need to have a history and assessment prior to the procedure. The patient's biological age, co-morbidities (ASA Index and Charlson Comorbidity Index) and the therapeutic consequences should also be considered. [30] Antibiotics should be administered according to local policy.

There is a lack of agreement in the literature specifying those with an increased risk of complications. It is therefore at the discretion of the person performing the procedure to act in accordance with local policy and professional judgement but reference should be made to the chapter on complications. (Chapter 6.0)

Patients with the following risk factors may require special preparation:

a) Patients on anticoagulation therapy or with coagulation disorders which may interfere with haemostasis and increase the risk of haemorrhage

b) Risk of endocarditis from previous rheumatic fever, heart valve replacement or endocarditis as these patients may require prophylactic antibiotic cover
c) Patients with impaired renal function (may require prophylactic antibiotic modification)
d) Patients with an identified urinary tract infection as the risk of septicaemia may be increased
e) Patients with an allergy to latex, antibiotics or local anaesthetic
f) Patients with diabetes mellitus who may be at increased risk of infection and may require a longer course of antibiotics
g) Patients on steroid medication which may increase the risk of infection and may require a longer course of antibiotics
h) Patients who are immunocompromised

It may be necessary to seek advice from other health care professionals on complex medical conditions. For further advice regarding the incidence of complications refer to chapter 6.0.

It is also important that the patient is made aware of the potential outcome of the prostate biopsy which may include:

a) false negative
b) need for repeat biopsy
c) cancer diagnosis

| Recommendations | LE | GR |
|---|---|---|
| • Caution has to be observed in patients on steroid medication as it has been shown to be a risk factor for sepsis [53] | 3 | C |
| • Cleansing enema before biopsy provides no clinically significant outcome advantage, and potentially increases patient cost and discomfort and is therefore not recommended [54] | 1b | C |
| • Low dose aspirin is not considered a contraindication to biopsy [55] | 1b | |
| • Broad spectrum antibiotic use is common practice but guidelines should be made locally in consultation with microbiology advice [30, 56, 57] | 3 | B |
| • Patients at risk of endocarditis should be considered for prophylaxis [58] | 3 | C |
| • Where possible single use equipment should be used, particularly single use needle guides to reduce the risk of infection [59] | 1b | B-C |

## 5.3 Patient information

A patient information leaflet should be given to each man undergoing a transrectal ultrasound guided prostate biopsy. The leaflet should provide detailed information on the procedure, possible side-effects, potential complications and instructions on who to contact in case of an emergency.

## 5.4 Consent

Patients should be aware of the main potential complications. Before undertaking the procedure the health professional must seek permission from the patient. This can be either implied or written consent as per local policy. However for the consent to be valid the patient must be competent to make the decision for the investigation to be undertaken. They must have sufficient information to make that decision and not acting under duress.

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Seeking consent is a matter of common courtesy between health professional and patient. [60]
It is not a legal requirement to seek written consent in all countries but it is recognised as good practice particularly if the procedure comes with significant risks or side effects or the procedure involves regional anaesthesia or sedation.

Consent should include

a) What the examination involves
b) What is its purpose
c) What are the risks
d) Whether the risk is major or minor
e) What happens if they do not undertake the examination

Taken from http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/index.htm

Patients should be made aware of the risk of a false negative test result and the potential need for repeat biopsy.

The health care professional responsible for carrying out the procedure is ultimately responsible for the patient consent for the examination. [60], [61], [62]

| Recommendations | LE | GR |
|---|---|---|
| • It is recognised as good practice to get written consent | 4 | C |
| • The patient should be informed of any risk factors specific to them | 4 | C |

## 5.5 Transrectal ultrasound

The prostate gland can be visualised with a transrectal probe allowing close-contact scanning. [4] Ultrasound is essential for examining the echotexture and size of the gland and to aid precision biopsies. It is more accurate than DRE examination in measuring prostate size. [63]

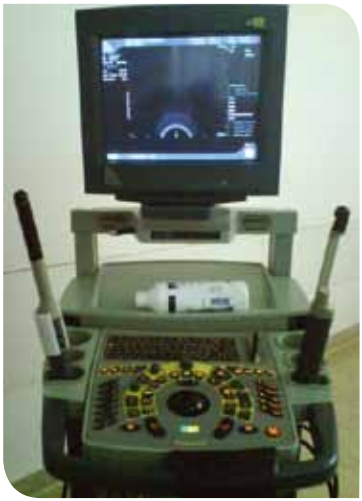


*Fig. 9 Ultrasound machine*
*[Source: S. Hieronymi]*

### 5.5.1 Probe choice and preparation

The ultrasound probe is a dedicated use which can vary in frequency between 6-9 MHz the most frequently used being 7.5 MHz. The probe allows visualisation of the prostate in both the transverse and saggital planes.

Probes are either end-firing, bi-plane or both and there are several designs marketed by different manufacturers. In practice the design of the probe is not important as full glandular scrutiny is achieved with either design; however, if true anatomical views are required then a biplane probe is essential. [4]

The probe is covered with a condom or probe cover and is decontaminated as per the manufacturer's recommendation before and after each patient.

### 5.5.2 Patient positioning

The patient is positioned in the left lateral position ensuring that the knees are bent up towards the chest or in the lithotomy position. The left lateral position is preferred; particularly with the end firing probe as imaging of the apex is easier and more comfortable. [4]

### 5.5.3 Performing a DRE

Immediately before the rectal probe is inserted a DRE is undertaken. Particular attention should be paid to the anal tone as a very tight sphincter may render the procedure particularly painful. Careful attention should also be taken to exclude the presence of anal pathology such as fissures and rectal tumours. A circumferential examination of the rectum should be undertaken and examination of the prostate ensues. The prostate should be examined for symmetry, size, the presence of nodules or tenderness and pain.

## 5.6 Ultrasonic appearance

The sonographic appearances are a combination of the gross and zonal anatomy.
The peripheral zone is a homogenous texture (same level of echoes) throughout and is more echogenic (brighter) than the rest of the gland. The rest of the gland is heterogenous texture (different levels of echoes) and echo poor. [4] It is not possible to differentiate between the central and transition zones on transrectal ultrasound. [4] When scanning the gland the seminal vesicles can be seen from the base on the transverse view and near the lateral in the saggital view.

See Fig. 4 (Gross anatomy) (3.1)

The sonographic appearance of the prostate is non specific but there are three ultrasonic findings which may be described as isoechoic (the same echogenicity as surrounding tissue), hyperechoic (brighter) or hypoechoic (darker). (Fig. 10 and 11)

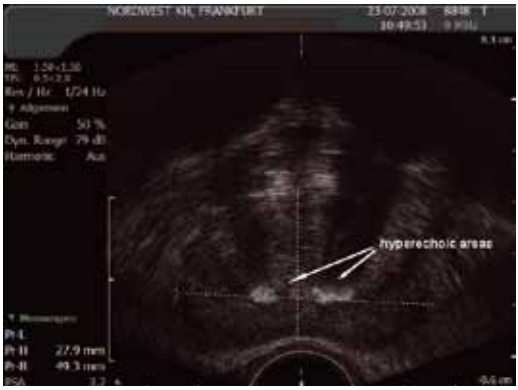



*Fig. 10 Hyperechoic areas*
*[Source: S. Hieronymi]*

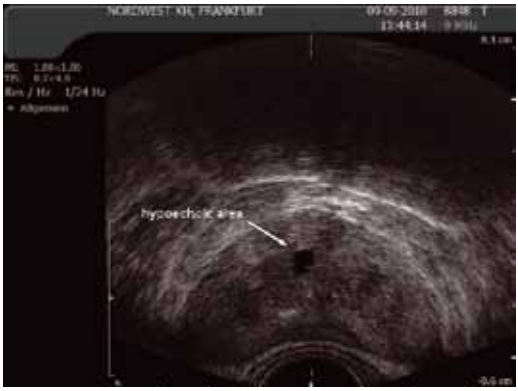



*Fig. 11 Hypoechoic areas*
*[Source: S. Hieronymi]*

**Ultrasonic findings:**

- Isoechoic area could be: normal tissue, tumour
- Hypoechoic area could be: cyst, abscess, tumour
- Hyperechoic area could be: calcification, tumour

## 5.7 Prostate measurement

It is routine to measure the prostate volume which may be important in offering treatment options. The prostate is measured in 3 planes.

In the transverse view 1) anterior to posterior (width) 2) height and in the longitudinal plane 3) from the bladder neck to the apex (length) this can be calculated using the formula:

Ω/6 x H x W x L (Ω/6 may be substituted by 0.51)

Most ultrasound machines will automatically calculate the volume. The normal prostate measures 2.5 - 3.0 x 2.5 - 3.0 x 2.0 - 2.5 with an estimated volume of 20 ml but this increases with age. The gland shape and volume can vary dependent on the probe used.

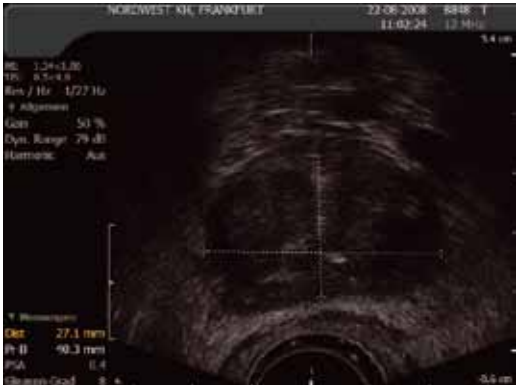


*Fig. 12 Prostate measurement – transversal view*
*[Source: S. Hieronymi]*

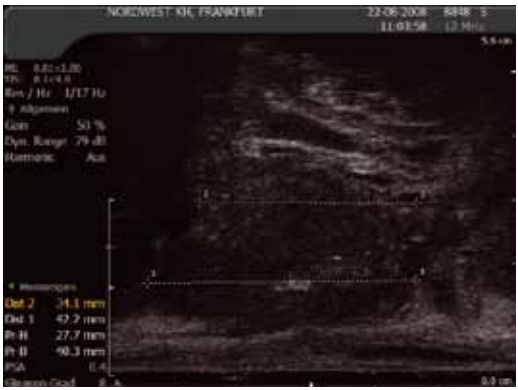


*Fig. 13 Prostate measurement – saggital view*
*[Source: S. Hieronymi]*

## 5.8 Prostate biopsy

### 5.8.1 Local anaesthesia

Ultrasound-guided peri-prostatic block is state-of-the-art. [64] (Level of evidence: 1b) It does not make any difference whether the depot is apical or basal. Intrarectal instillation of a local anaesthetic is clearly inferior to peri-prostatic infiltration. [65] (Level of evidence: 1b) (Fig. 14)

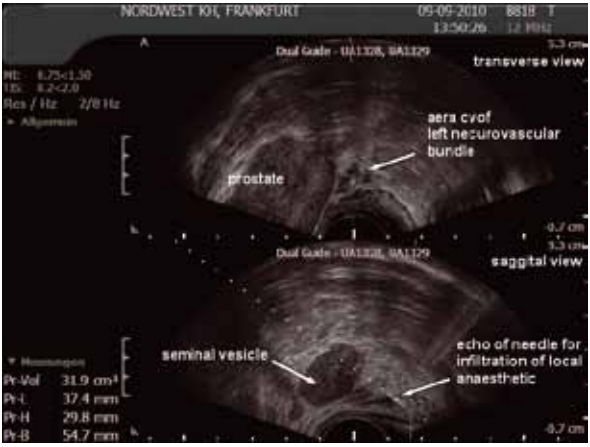



*Fig. 14 Ultrasound image of injection of local anaesthesia*

*[Source: S. Hieronymi]*

### 5.8.2 Number and location of prostate cores

Ultrasound does not detect areas of prostate cancer with adequate reliability and therefore targeted prostate biopsies are unproductive, although additional biopsies of abnormal areas may be useful. [30]

On the first biopsy (baseline biopsy) the sample sites should be as far posterior and lateral in the peripheral zone as possible. Traditional sextant biopsies are no longer considered adequate. At volume 30-40 ml at least 8 cores should be taken. [30] More than twelve cores have not been shown to be significantly more conclusive. [66] (Level of evidence: 1a). The British Prostate Testing for Cancer and Treatment Study recommends a 10 core biopsy. [67] (Level of evidence: 2a) In prostate > 50 ml up to 18 cores can be considered. [68] (Fig. 15)

Additional biopsy cores can be taken towards suspicious findings on DRE or TRUS. Indications for seminal vesicle biopsy are not well defined and their use remain controversial. Biopsies of the transition zone provide a low detection rate and sampling is not recommended on initial biopsy. [69] (Level of evidence: 2a)

Prostate biopsy cores taken from different sites are sent to the laboratory usually in separate pots. [30]

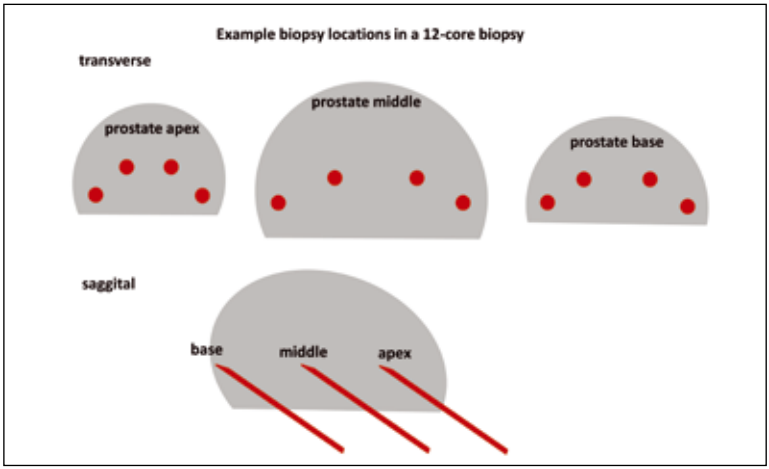



*Fig. 15 Example biopsy locations in a 12-core biopsy*

*[Source: S. Hieronymi]*

| Recommendations | GR |
|---|---|
| • The diagnosis of prostate cancer should be based on histopathological confirmation | B |
| • Biopsy and further staging investigations are only indicated if they affect patient management | C |
| • TRUS guided systematic biopsy is the recommended method in suspected prostate cancer (An abnormal DRE or a raised PSA are indications for prostate biopsy) | B |
| • Peri-prostatic local anaesthetic injection should be offered as analgesia when undergoing biopsy | A |
| • A minimum of 8 laterally directed biopsy cores are recommended | B |
| • One set of repeat biopsies are recommended in cases with persistent indication | B |
| • More than 2 transrectal biopsies for persistent indication cannot be recommended | C |

## 5.9 Transrectal ultrasound and prostate biopsy procedure

**Procedure taken from Skills for Health PB2 2005 [70]**
**Performance criteria**

This procedure and its component actions should be performed in accordance with national and local policies and guidelines:

| Environmental preparation | Rationale |
|---|---|
| 1. Check the environment, equipment and medication that everything is present for the procedure, including access to relevant personnel and emergency equipment.<br>2. Prepare the ultrasound machine by ensuring it is clean and prepare the probe by inserting some ultrasound gel into the end of the condom then roll the condom over the probe and carefully attached the needle guide without splitting the condom.<br>3. Prepare a trolley / work surface with the rest of the equipment required.<br>4. Ensure that competent staff are present to enable the procedure to be undertaken safely. | Items 1-4<br>To ensure the procedure will take place without delay for the patient and to ensure that the safety of the patient is addressed. |
| 5. Read the patient's record, referral letter and the results of any relevant investigations and identify any special instructions, investigations or items for which you need to seek advice or clarification. | To ensure correct identification of the patient and identify details that might necessitate an adaptation of the procedure. |
| **Patient preparation** | **Rationale** |
| 6. Greet and accurately identify the patient and introduce yourself and any colleagues present. | To reduce patient anxiety and to ensure correct identification of the patient. |
| 7. If not already done, take a comprehensive health history including presenting complaint, health history, medication, family and social history.<br>8. Determine the need for the biopsy and decide whether or not to proceed.<br>9. Assess the patient's fitness for the procedure and use of local anaesthesia including previous allergies to local anaesthetics. Identify any risk factors (see above) for which special precautions may be required. | Items 7-9<br>To identify any patient related risk factors that might need adaptation of the procedure to ensure its safety. |
| 10. Explain the procedure, potential complications, potential outcomes and discomfort to the patient and answer any questions at a level and pace that is appropriate to the patients under-standing, culture and background, preferred way of communicating and needs.<br>11. Ensure that informed consent has been obtained or obtain it.<br>12. Ensure that pre-procedure criteria have been met such as stopping relevant medications and administration of prophylactic antibiotics. | Items 10-12<br>To ensure safety of the patient and staff, to promote patient's comfort and reduce anxiety. |
| 13. Apply local procedure-specific infection control guidelines.<br>14. Position the patient correctly for the procedure (left lateral with legs abducted, or lithotomic position) and ensure their comfort within the constraints of the procedure.<br>15. Take appropriate action to protect the patient's privacy and dignity throughout.<br>16. Maintain communications with the patient and respond to any questions or needs throughout. | Items 13-16<br>To ensure safety of the patient and staff, to promote patient's comfort and reduce anxiety. |

| Ultrasound procedure | Rationale |
|---|---|
| 17. Undertake a digital examination of the prostate to identify the size and shape of the prostate and any abnormalities which may influence the procedure; ensure that the rectum is not full of faeces and decide whether or not to proceed. | To provide initial digital findings. This may necessitate additional biopsies to the standard biopsy protocol that is used. |
| 18. Check the local anaesthetic agent to be used then draw up into a syringe and attach an appropriate needle for administration. | To ensure patient safety. |
| 19. Apply lubricating gel to the trans-rectal ultrasound probe and insert the probe gently into the patient's rectum, whilst monitoring progress on the ultrasound image. | To promote patient comfort and enhance the quality of the scan. |
| 20. Scan and identify the prostate gland, seminal vesicles and surrounding structures, locating the apex and base of the prostate on the ultrasound image. | To orientate the operator and to identify areas to biopsy. |
| 21. Take volume measurements and either print images or store them on the ultrasound machine for future reference. Make note of any abnormalities detected on ultrasound and print or store images as required. | To provide information that may be useful when discussing treatment options with the patient in the future. |
| **Biopsy procedure** | **Rationale** |
| 22. Inform the patient that the local anaesthetic is about to be administered. | To reduce patient anxiety. |
| 23. Introduce the local anaesthetic needle through the biopsy channel of the ultrasound probe until the needle tip can be visualised on the screen in the peri-prostatic tissue.<br>24. Commence the infiltration of the local anaesthetic observing the passage of the fluid throughout the peri-prostatic area.<br>25. Withdraw the needle and continue with the trans-rectal ultrasound guided biopsy of the prostate. | Items 23-25<br>To promote patient comfort. |
| 26. Identify the appropriate locations for the biopsy samples<br>27. Introduce the biopsy needle until the needle tip can be visualised on the screen in the peri-prostatic tissue, adjacent to the target area. | Items 26-27<br>To ensure the correct areas are biopsied. |
| 28. Inform the patient that the biopsy is about to be taken, warn them of the sound of the biopsy gun and commence taking tissue samples.<br>29. Assess the patient's tolerance throughout the procedure and ensure they are happy to proceed. | Items 28-29<br>To ensure patient comfort and to reduce anxiety. |
| 30. Ensure that each biopsy sample is placed in the correct and accurately labelled sample container containing formal saline. | To ensure the correct results go to the correct patient. |
| 31. Ensure that the samples taken are adequate for histopathology by comparing the length of the core with the length of the needle notch.<br>32. Take additional samples. | Items 31-32<br>To assist the histopathologist to make an accurate diagnosis. |

| | |
|---|---|
| 33. Remove the trans-rectal ultrasound probe from the patient's rectum. | To promote patient comfort. |
| **Patient recovery** | **Rationale** |
| 34. Assess the patient for any complications and take appropriate action as appropriate.<br>35. Recognise the need for immediate management of acute emergencies associated with the procedure and respond appropriately.<br>36. Assess the patient's needs following the procedure and offer support, if appropriate. | Items 34-36<br>To ensure patient safety and comfort. |
| 37. Ensure the patient has all required information and medication. Re-iterate the possible complications and how they should be managed. | To ensure patient safety and reduce the risk of serious side effects following the procedure. |
| 38. Assess the patient's fitness for discharge, advise them of when they should leave the unit and make appropriate arrangements for follow up to discuss the histology results. | To ensure patient safety and that the patient will be followed up with the results. |
| **Completion of procedure** | **Rationale** |
| 39. Ensure that single use items and sharps are disposed of and that non-disposable equipment is cleaned and/or sterilised. | To ensure the safety of staff and patients. |
| 40. Complete the histopathology request form ensuring it matches patient identity and includes all relevant clinical details, particularly relevant previous treatment, procedures and biopsies. | To ensure the correct results go to the correct patient. |
| 41. Record the details of the procedure in the patient's record, including details of the local anaesthetic and any medication given.<br>42. Ensure that steps are made to inform any other relevant practitioners of the procedure and plan. | Items 41-42<br>To ensure patient safety and accurate records for other practitioners who may see the patient. |
| 43. Recognise when you need help and/or advice and seek this from appropriate sources. | To ensure patient safety. |
| 44. Collect and maintain a record of procedures for audit to include reviews of histology reports. | To provide evidence of good practice and/or areas for improvement and development. |
| 45. Ensure that you keep up to date with relevant clinical developments and changes to guidelines. | To ensure patients have access to the best treatments and techniques. |

# 6. Complications and their management

The rate of side-effects, procedural discomfort and major complications is independent of the number and location of prostate biopsy cores performed [71], and is independent of initial and re-biopsy 6 weeks later. [72] Younger men (less than 60 years of age) have significantly more discomfort compared with men in the older age groups. [72].

Aerobic or anaerobic organisms may be introduced when performing the transrectal biopsy, the more common being Escherichia coli, Streptococcus faecalis and bacteroides. [4] Thus the use of broad spectrum antibiotics is common practice but guidelines should be made locally in consultation with microbiology advice taking into consideration regional antibiotic resistance. [73]

Currently fluorquinolones (e.g. ciprofloxacin) are the antibiotics of choice in TRUS guided prostate biopsy. Fluorquinolones are well absorbed orally and have good prostate tissue levels [74, 75]. Evidence suggests that one dose is as effective as multiple dose prophylaxis [56, 76]. Optional is the addition of gentamycin or metronidazole. [77]

Cleansing enemas before biopsy do not reduce the risk of infection but increase cost and patient discomfort. [54] Most antibiotic regimens include the use of fluorquinolones which have been found to give superior prophylactic cover. [56] (Level of evidence: 1b)

## 6.1 Minor complications

Most patients will tolerate the procedure with minimal discomfort and experience minimal side-effects which include haematuria, haematospermia, blood in the stools, and dysuria. Haematospermia is the most frequent complaint (6.5% to 74.4% of cases), followed by haematuria (up to 14.5% of cases), rectal bleeding (2.2% of cases), prostatitis (1.0%) and epididymitis (0.7% of cases). [72] [78] [30]

These complications may persist for around two weeks and are mostly self-limiting. Patients with urethral catheter, diabetes mellitus or those to undergo biopsy from more sites than ten cores should be closely monitored for signs of infection as these have been found in some studies to increase the risk. [79]

## 6.2 Severe complications

The rate of severe complications following prostate biopsy is low. [72, 30, 78] Procedural related infections or fever episodes have been reported in up to 6.6% of cases [72, 78], with urosepsis with aerobic bacteriae (such as E. coli) in 0.3% of cases only [72, 30]. Septicaemia due to anaerobic bacteriae has been reported infrequently in case studies [80, 81]. Urinary (or clot) retention is described in 0% to 4.6% of cases. [30, 78] Severe rectal bleeding is a rare complication and is treated by endoscopic haemostasis. [82] Hospitalisation following prostate biopsy is needed in up to 1.6% of men. [78]

**Table 4. Percentage given per biopsy session, irrespective of the number of cores***

| Biopsy complications | % of biopsies |
|---|---|
| Haematospermia | 37.4 |
| Haematuria > 1 day | 14.5 |
| Rectal bleeding < 2 days | 2.2 |
| Prostatitis | 1.0 |
| Fever > 38.5°C (101.3°F) | 0.8 |
| Epididymitis | 0.7 |
| Rectal bleeding > 2 days ± requiring surgical intervention | 0.7 |
| Urinary retention | 0.2 |
| Other complications requiring hospitalisation | 0.3 |

**) Adapted from Adapted from NCCN Guidelines Prostate Cancer Early Detection. V.s.2010. [83].*

## 6.3 Management of complications

Depending on the indication, patients with a severe complication after TRUS guided prostate biopsy should have a prolonged course of antibiotic treatment (fever, urinary tract infection, acute bacterial prostatitis). Some patients may require admission to hospital such as those requiring intravenous antibiotics (urosepsis), or require catheter insertion (clot retention).

Severe rectal bleeding may require pressure by either finger or probe. Insertion of a Foley catheter into the rectum and the balloon filled with 50 ml has been shown to reduce haemorrhage. [84]

Any patient with a major complication must be discussed and assessed by a senior urologist.

## 6.4 Patient information on discharge

| Recommendations | LE | GR |
|---|---|---|
| • Ensure that the patient understands the potential complications of the procedure and what he must do in case of fever, infection, clot retention, urinary retention or persistent bleeding and who to contact | 4 | C |
| • Patients should be advised on rest, fluid intake, prophylactic antibiotics and follow-up | 4 | C |
| • Patients with urethral catheter should be closely monitored for signs of sepsis | 2a | B-C |
| • Patients with diabetes mellitus should be closely monitored for signs of sepsis | 2a | B-C |

# 7. Knowledge and understanding

It is of paramount importance that the health care professional is able to demonstrate knowledge and understanding in several areas: legislation, clinical expertise, technical knowledge and the ability to communicate effectively to the patient. In addition it is paramount that the health care professional is aware of any limitations in knowledge or ability to manage a situation and that the health care professional knows how and when help from a senior colleague is required.

You need to apply:

| Legislation and guidelines | Rationale |
|---|---|
| In-depth understanding of: | To ensure: |
| • national guidelines and local policies and guidelines for undertaking trans-rectal ultrasound guided biopsy of the prostate. | • that national guidelines and local policies are integrated into practice and personal practice is reflective of such guidelines and policies. |
| • national and local infection control and policies and guidelines and their application to trans-rectal biopsy of the prostate. | • patient safety and to minimise the risk of cross infection. |
| • national and local policies and guidelines for patient identification. | • the correct procedure is undertaken on the correct patient and that histological samples are labelled appropriately to avoid incorrect diagnosis. |
| • national and local policies and guidelines for informed consent. | • that informed consent is obtained from the patient and that the method of consent is appropriate. |
| • national and local policies and guidelines for patient records, their storage and confidentiality of information. | • accurate records are maintained and to protect all confidential information. |
| • the range of information which should be made available to the patient. | • the patient received adequate information to make an informed choice regarding treatment options. |
| • the national and local policies and guidelines for risk management and adverse incidents. | • that unexpected incidents are reported appropriately to minimise risk to patients. |

| Clinical knowledge | Rationale |
|---|---|
| In-dept understanding of: | |
| • the normal and abnormal anatomy of the prostate and surrounding structures. | • To aid adequate transrectal ultrasound and the identification of the prostate and related structures. |
| • abnormal anatomy of the prostate visible using ultrasound and the significance of such abnormalities. | • To aid in diagnosis of conditions of the prostate and related structures. |
| • the common pathologies of the prostate. | • To ensure that the correct diagnosis is achieved. |
| • the clinical indications for the procedure. | • To ensure appropriate patients are biopsied. |
| • the clinical conditions which require special precautions to be applied. | • To reduce the risk of infection or haemorrhage to those at increased risk. |
| • the complications of the procedure and remedial strategies. | • To ensure the patient is aware of the risks and to act promptly if complications arise to protect the patient. |
| • the local anaesthetics for use in the proce-dure, their complications, indications of acute allergic reactions and the responses required. | • To ensure the patient receives adequate pain control and any complications are dealt with promptly to protect the patient. |
| • the relevant pharmacological agents and their interactions and complications. | • To ensure patient safety in terms of medicines. |
| • the clinical indications of the acute emergencies associated with the procedure and of the initial response required. | • To ensure rapid action is taken if an emergency arises to minimise the risk of patient deterioration. |
| • the importance of keeping up-to-date with relevant clinical developments and guidelines. | • To ensure practice is based on evidence based, and up-to-date. |

| Technical knowledge | Rationale |
|---|---|
| In-depth understanding of: | |
| • the functions of the equipment used in trans-rectal ultrasound guided biopsy of the prostate. | • To be able to carry out the procedure in a competent, timely fashion. |
| • the functions of the equipment used for infiltration of local anaesthetic for ultrasound guided biopsy of the prostate. | • To ensure local anaesthetic is administered in a way to optimise its effect. |
| • the impact of equipment controls and manipulation of the trans-rectal probe on the visual image and identification of possible equipment faults. | • To ensure familiarity with the techniques available to improve the ultrasound image of the prostate and related structures. |
| • the processes involved in the production of an ultrasound image. | • To improve the ultrasound image of the prostate and related structures. |
| • the preparation of the environment, equipment and medications for the procedure. | • To ensure overall familiarity with the procedure and the equipment required; to guide both the practitioner undertaking the procedure and the assistant. |

| Communications and roles | Rationale |
|---|---|
| • Factual knowledge of the roles and responsibilities of other team members. | • To ensure patient safety. |
| • An understanding of the limits of one's own knowledge and experience and the importance of not operating beyond these. | • To ensure patient safety and maintain professional conduct. |
| • An understanding of the importance of clear and direct communications. | • To minimise the risk of miscommunication. |
| • An understanding of the audit process and the application of this to one's own practice. | • To be able to audit one's own practice and outcomes. |

## 7.1 Skills acquisition and development

The ability to undertake prostate biopsy competently and safely is a developmental process and is a skill only expected to be undertaken by a specialist healthcare professional (HCP). The HCP is not simply expected to act as a technician but as a rational decision maker. The HCP must have an expert understanding of the prostate cancer patient journey, the risks, benefits, complications and disadvantages of prostate biopsy.

The HCP is required to have an intimate understanding of the anatomy and physiology of the male urinary system, factors which affect PSA measurement and other conditions

of the urinary system and their management. An understanding of the role of transrectal ultrasound and possible ultrasound findings are important.
The HCP must also be familiar with the possible complications of TRUS and their management and must always ensure that the senior staff are available should an emergency situation arise.

The HCP should be trained by a competent HCP but ultimately competence should be assessed by the senior urologist.

The individual HCP is responsible for their continuing professional development in relation to prostate cancer and prostate biopsy and should work within their own professional code of conduct.

| Recommendations | LE | GR |
|---|---|---|
| • Health care professionals undertaking prostate biopsies should be trained by a competent practitioner | 4 | C |
| • Health care professionals undertaking prostate biopsies should be trained in physical assessment including digital rectal examinations | 4 | C |
| • Health care professionals undertaking prostate biopsies should have at least 3 years experience in working with prostate cancer patients | 4 | C |
| • Health care professionals undertaking prostate biopsies should be a registered practitioner and carry liability insurance | 4 | C |
| • Health care professionals are deemed competent after performing a minimum of 20 biopsies satisfactorily without supervision at an acceptable speed | 4 | C |
| • Direct supervision should be undertaken until the health care professional is deemed competent to undertake the procedure independently | 4 | C |
| • Final competence should be assessed and signed by a senior urologist | 4 | C |
| • Health care professionals are required to keep current of the latest advances in the field for which they should be a member of a professional organisation and follow continuing education | 4 | C |

# 8. Glossary and abbreviations

## Glossary

- Saggital — Longitudinal (vertical) plane that divides the body or its parts into right and left portions.
- Transverse — A horizontal plane running from left to right separating the body or its parts into inferior or superior parts.
- Transperineal — Through, across or beyond the perineum

## Abbreviations

- AFS — Anterior fibromuscular stroma
- BPE — Benign prostate enlargement
- CEBM — Centre for Evidence Based Medicine
- CZ — Central zone
- DRE — Digital rectal examination
- DV — Dorsal vein complex
- EJD — Ejaculatory ducts
- ERSPC — European Randomized Study of Screening for Prostate Cancer
- HCP — Health care professional
- L — Levator muscles
- NCCN — National Comprehensive Cancer Network
- NVB — Neurovascular bundle
- PCa — Prostate cancer
- PLCO — Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial
- PSA — Prostate-specific antigen
- PZ — Peripheral zone
- RCT — Randomised controlled trial
- SV — Seminal vesicles
- TNM — Tumour, node, metastases
- TRUS — Transrectal ultrasound
- TZ — Transition zone
- U — Urethra

# 9. Other resources

If you would like to read more on transrectal ultrasound and biopsy of the prostate we refer to the following publication:
Patel U, Rickards D. Handbook of Transrectal Ultrasound and Biopsy of the Prostate. Martin Dunitz Ltd, London, 2002.

Following the publication of this guideline on the EAUN website a Transrectal Ultrasound and Biopsy of the Prostate Competency Assessment Document will be posted to enable health care professionals in training for this procedure to assess their competency.

# 10. Figure reference list

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# 12. About the authors

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Graduated from the University of Wales, Swansea in 2001. Initially worked in critical care (Burns, ICU, A+E) and general surgery. Established role of trainee uro-oncology nurse practitioner in London, 2004 and has now developed and leads a comprehensive nurse led service in uro-oncology including haematuria, prostate cancer management, metastatic bone disease, intravesical therapies and prostate biopsy.

Graduated from City University with MSc Advanced Nursing Practice and is an Independent Nurse Prescriber. Works as uro-oncology nurse practitioner at Homerton University Hospital and Whipps Cross University Hospital.

Special interests include urinary markers for urological cancers and metastatic prostate cancer.

### Philippa Aslet, BA (Hons), RGN (UK)

Trained as an RGN in 1986 in Chelmsford, Essex. Once qualified worked in the field of Nephrology then moved to Dialysis and transplantation, initially at St Georges and then Addenbrooke's Hospital Cambridge. Here she completed a BA (Hons) in Nursing and a diploma in Critical Care / Renal Nursing.

While in Cambridge she moved to a new post as the first Nurse Practitioner in Urology, she worked with the team to set up and run a number of nurse led clinics and services including LUT's assessment, Intravesical chemotherapy, Erectile dysfunction and Intermittent self catheterisation. In addition she worked as the Urology research nurse coordinating Urology trials. In 2000 she became a lecturer Practitioner and set up and ran the Urology Course through Homerton College Cambridge.

From Cambridge Philippa moved to Basingstoke in 2004 to take up the post of Senior Urology Nurse Specialist. In this post she continues to run nurse led clinics predominantly for patients with Prostate cancer. Seeing new and follow up patients. Performing diagnostic transrectal ultrasound and biopsy. Is an independent nurse prescriber and lead for non medical prescribing for the hospital.

Philippa is in her second term on the council of the British Association of Urology Nurses (BAUN) and chairs the Education sub Group.

### Lawrence Drudge-Coates, MSc, Dip/He, RGN (UK)

Graduated from the University of Essex in 1994 - working in urological fields ever since. Awarded MSc Advanced Nursing Practice (Urology) in 1999.

Responsible for commissioning of community based prostate assessment clinics in North East Essex. Both project and programme manager for cancer services development and delivery in the UK. Honorary Lecturer –Department of Specialist Care, Florence Nightingale School of Nursing and Midwifery, King's College London.

Special interests: Bone health, Prostate cancer, Bone metastases

## Helen Forristal, RGN, BSc (Hons) Professional Nursing (IE)

Born in Ireland, trained Registered General Nurse in the United Kingdom, enhanced Urology career by completing a post registration diploma in Renal and Urology at the Institute of Urology, in London, 1990. Established role of Urology Nurse Practitioner in Urology in Essex and eventually sub-specialised in Uro-oncology as the 4th Macmillan Clinical Nurse Specialist in the United Kingdom in 1997, with a special interest in supporting men end their families with Prostate cancer.

Founder of two Prostate cancer support groups both still very successful in Essex and Kent. Worked as a Lead Cancer Nurse in Essex and finally worked as a Nurse Director in South Essex Cancer Network before moving back to Ireland in 2005 to work in the clinical field of Urology as a Cancer Nurse Co-ordinator at St. Vincent's University Hospital, Dublin.

Currently undertaking MSc in Advanced Nursing Practice at University College Dublin. A member of the Irish Association of Urology Nursing, Ireland and an expert member of the National Cancer Control Programme (NCCP) for Prostate cancer in Ireland.

Special interests include renal cancer as well as prostate cancer, the management of patients with superficial bladder cancer, the psychological support of men and their families with prostate cancer and health promotion and quality of life for all our patients.

## Lisa Gruschy, CRN (DK)

Graduated in 1999, with a short detour to the vascular surgical specialty, Lisa has always worked in urology. She has since 2000 been employed at Rigshospitalet, Copenhagen University Hospital, where for 3 years she was responsible for management of the prostate cancer team, which included outpatient activities and day section.

Since 2003 she has been employed as a research nurse under Professor Peter Iversen. In this position she is responsible for coordinating the Department clinical research on prostate cancer. Besides clinical studies, Lisa is responsible for a prostate cancer database which feeds data to a PhD thesis and a number of publications to which she is co-author. Lisa also undertakes teaching assignments and keeps several lectures.

Special interests: localised prostate cancer, radiation therapy and endocrine treatment of metastatic prostate cancer.

## Susanne Hieronymi, RN (DE)

Registered Nurse. After qualification as a nurse was first employed in the Urology ward and later in the Outpatient Clinic of Urology of the Dr. Horst-Schmidt-Kliniken in Wiesbaden.

Since 2001 she worked in the OR of Krankenhaus Nordwest (Frankfurt) and later in addition became manager of the Outpatient Clinic of Urology. Responsible for the in-house education and training of all nurses working with urology patients and hands-on trainer in workshops for cryotherapy.

Authorised person for quality management in the OR as well as in Urology, including creation and implementation of standard operating procedures (SOP) for both departments.

Special interests: Prostate cancer, minimally invasive procedures for prostate cancer.

## Katie Mowle, RGN, Dip NP, BSc (Hons) Specialist Practice (UK)

Qualified in 1989 at Ipswich Hospital NHS Trust in Suffolk UK and continues to work there. Until 1996 she worked as an RGN on a urology / general surgery ward when she undertook the role of Urology Nurse Specialist for the trust.

She jointly runs the Urology Investigation Suite which undertakes all urology investigations including TRUS and biopsy, flexible cystoscopy and urodynamics.
Katie initiated the lower urinary tract symptom clinic when she first took up her post. In 2003 she commenced undertaking a nurse led biopsy service and at present has undertaken well over 1,000 independent biopsies for the trust.

Special areas of interest: Both benign and malignant disease of the prostate and patients who have renal calculi.

## Michele Pietrasik, BSc, RGN, Cert. ED (UK)

Michele graduated from Liverpool University in 1988 with a BSc (Microbiology) and as a Registered Nurse. Her initial nursing experience was in high dependency before moving into urology in 1990.

She spent 7 years as a lecturer in nursing and health studies teaching diploma and degree nurses. Michele took up her current post as Urology Cancer Nurse Specialist at The Royal Surrey County Hospital in 2000.

In 2002, she was one of the first nurses in the UK to be trained to undertake Transrectal Ultrasound Scans and biopsies and since then has run her own nurse led clinics.

## André Vis, MD, PhD, FEBU (NL)

Registered urologist, staff member at the department of Urology of the Free University Medical Center (VUmc) in Amsterdam, the Netherlands.

André was trained at the department of Urology of the Erasmus MC in Rotterdam, the Netherlands, and actively participated in the European Randomized Study of Screening of Prostate Cancer (ERSPC) under the supervision of Prof. Dr F.H. Schröder. He wrote a PhD thesis on the subject of early detection of prostate cancer.

His current activities in the VUmc focus on the subspecialties of minimal invasive urology and robotic urology. He is also involved in the training of urology residents and in scientific research; mainly concerning topics related to (advanced) prostate cancer.

Special interests: Prostate cancer, minimal invasive urology and robotic urology.

If you have questions or comments regarding this publication, please contact:
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