

Chapter 1

Diagnostic investigations

Procedure guidelines

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2 Overview

In clinical practice, cancer nurses or other nurses are required to instigate, participate or assist in diagnostic tests and the collection of body fluids and/or specimens for varying diagnostic purposes. This chapter will discuss various diagnostic tests encountered in clinical practice that are used during the diagnostic process, to support ongoing treatment decisions and surveillance of cancer. These include:

- tumour markers
- cervical smears
- diagnostic radioisotope procedures (nuclear medicine)
- transrectal prostate biopsy
- flexible cystoscopy
- breast diagnostics
- genetic testing.

Diagnostic tests and investigations

Definition

A diagnostic test is a procedure that is used to aid in the detection and/or diagnosis of disease (Chernecky and Berger 2013, Higgins 2013).

Related theory

Diagnostic tests and investigations are undertaken to aid in diagnosis and treatment of various conditions. The investigations are used to identify diseases from their characteristics, signs and symptoms and to identify changes or abnormalities. Diagnostic tests include the collection of blood, tissue or body fluids.

Evidence-based approaches

Rationale

Diagnostic tests and investigations are essential in cancer care, however their selection and use must be considered carefully. The overuse of diagnostic tests is a contributor to needless healthcare costs. This leads to poor quality services and continuing financial pressure on departments and organizations (Korenstein et al. 2012), hence it is essential that healthcare providers and professionals ensure that the tests used are of adequate benefit to the patient's health (Qaseem et al. 2012).

Indications

Conducting a diagnostic test or collecting a specimen is often the first crucial step in determining diagnosis and subsequent mode of treatment for patients with suspected infections or to aid in the diagnosis of specific conditions. In other aspects the collection or test may help determine variation from normal values such as blood sampling or endoscopic findings (Box 1.1).

Box 1.1 Good practice in specimen collection

- Appropriate to the patient's clinical presentation.
- Collected at the right time.
- Collected in a way that minimizes the risk of contamination.
- Collected in a manner that minimizes the health and safety risk to all staff handling the sample.
- Collected using the correct technique, with the correct equipment and in the correct container.
- Documented clearly, informatively and accurately on the request forms.
- Stored/transported appropriately.

Source: Adapted from NHS Pathology (2014), WHO (2015).

Principles of care

Cancer nurses and nursing staff play a key role within the diagnostic testing process because they often identify the need for diagnostic investigations, initiate the collection of specimens and assume responsibility for timely and safe transportation to the laboratory (Higgins 2013). Nurses are vital in the screening and surveillance of disease progression and may undertake ongoing surveillance procedures.

Methods of investigation

Initial examination

The initial assessment of the patient will determine the potential diagnostic tests or samples that are required. The patient's clinical history and/or symptom progression will determine the need for further diagnostic or surveillance tests.

Cytology

Cytology is the study of the cell, its structure, structural transformations, molecular biology and cell physiology. The specimen can be a fine-needle aspiration, a sample of body fluid or a scrape/brush. The specimen is placed onto a glass slide and examined for the presence of abnormal cells. This includes benign, pre-cancerous or cancer cells. The test can also be used to diagnose infective processes (Chernecky and Berger 2013).

Histology

Histology is the study of cells and tissues within the body. It also studies how the tissues are arranged to form organs. The histological focus is on the structure of individual cells and how they are arranged to form the individual organs. The types of tissues that are recognized are epithelial, connective, muscular and nervous (Kierszenbaum and Tres 2016, Mescher 2016).

The tissues are examined under a light microscope where light passes through the tissue components after they have been stained. As most tissues are colourless, they are stained with dyes to enable visualization. An alternative is the electron microscope in which the cells and tissue can be viewed at magnifications of about 120,000 times (Kierszenbaum and Tres 2016, Mescher 2016).

Legal and professional issues

An organization providing diagnostic services must have clear identifiable policies and procedures in regards to diagnostic tests. Bidirectional communication must be open between the department, organizational board and national bodies such as the Medicines and Healthcare products Regulatory Agency (MHRA) to ensure appropriate care is delivered. Internal monitoring processes must be in place to identify potential clinical or organizational risks.

Competencies

In accordance with the Nursing and Midwifery Council (NMC)'s *The Code: Professional Standards of Practice and Behaviour for Nurses and Midwives* (NMC 2015), the collection of specimens should be undertaken by professionals who are competent and feel confident that they have the knowledge, skill and understanding to do so, following a period of appropriate training and assessment.

Consent

It is essential that healthcare practitioners gain consent before beginning any treatment or care; this includes the collection of samples or conducting a diagnostic test. Consent is continuous throughout any patient episode and the practitioner must ensure that the patient is kept informed at every stage (RCN 2016a, 2017b). For specimen collection this includes:

- informing the patient of the reason for specimen collection
- what the procedure will involve
- ascertaining their level of understanding
- how long the results may take to be processed

- how the results will be made available
- information about the implications this may have for their care or treatment plan.

Risk management

New research and evidence continue to be produced. It is essential that any risk or change in practice is communicated to clinicians. Alerts from the MHRA and changes in practice should be acted upon. Several agencies such as the Health Protection Agency (HPA) also contribute new guidance and best practice using the the latest available evidence.

Accurate record keeping and documentation

Good record keeping is an integral part of nursing practice, and it is essential to the provision of safe and effective care (NMC 2010a). Accurate, specific and timely documentation of specimen collection or diagnostic tests should be recorded in the patient electronic or paper notes, care plan or designated record charts/forms. This assists in the communication and dissemination of information between members of the inter-professional healthcare team.

Pre-procedural considerations

Equipment

There is a variety of equipment/tools designed for the collection of specimens such as blood bottles, specimen pots and other receptacles (Figure 1.1 and Figure 1.2). It is essential that the specimen and its transport container are appropriate for the type of specimen or sample. Failure to utilize the correct collection method leads to inaccurate results so it is vital that an adequate quantity of material is obtained to allow complete examination.

Equipment used for transportation

Within healthcare institutions, specimens should be transported in deep-sided trays that are not used for any other purpose and are disinfected weekly and whenever contaminated (HSE 2003), or robust, leak-proof containers that conform to 'Biological Substances, Category B – UN3373' regulations (HSE 2005). Specimens that need to be moved outside the hospital must be transported using a triple-packaging system dependent on the infectious status of the sample (HSE 2005, WHO 2015). This consists of a watertight, leak-proof, absorbent primary container, a durable, watertight, leak-proof secondary container and an outer container that complies with 'Biological Substances, Category B – UN 3373' standards (HSE 2005). A box for transportation is essential and should carry a warning label for hazardous material. It must be made of smooth impervious material, such as plastic or metal, which will retain liquid and can be easily disinfected and cleaned in the event of a spillage (HSE 2003, WHO 2015).



Figure 1.1 Blood bottles.



Figure 1.2 Specimen pots.

Handling specimens

Specimens should be obtained using safe techniques and practices and practitioners should be aware of the potential physical and infection hazards associated with the collection of diagnostic specimens within the healthcare environment. Standard (universal) infection control precautions should be adopted by healthcare workers who have direct contact or exposure to the blood, bodily fluids, secretions and excretions of patients (Gould and Brooker 2008). In addition to personal protection, the person collecting the specimen should also be mindful of the collective health and safety of other people involved in the handling of samples. Every health authority must ensure that medical, nursing, phlebotomy, portering and any other staff involved in handling specimens are trained to do so (RCN 2017a, WHO 2015).

In relation to specimen collection, standard (universal) infection control precautions should include the following (RCN 2017a):

- hand hygiene
- the use of personal protection equipment (PPE)
- safe sharps management
- safe handling, storage and transportation of specimens
- waste management
- clean environment management
- personal and collective management of exposure to body fluids and blood.

Selection of PPE should be based upon an assessment of risk of exposure to body fluids. As minimum precautions, gloves and aprons should be worn when handling all body fluids. Protective face wear (e.g. goggles, masks and visors) should be worn during any procedure where there is risk of blood, body fluid, secretions or excretions splashing into the eyes or face (RCN 2017a).

Specimens should be placed in a double, self-sealing bag with one compartment containing the specimen and the other containing the request form. The specimen container used should be appropriate for the purpose and the lid should be securely closed immediately to avoid spillage and contamination. The specimen should not be overfilled and not be externally contaminated by the contents. Any accidental spillages must be cleaned up immediately by staff wearing appropriate protective equipment (HSE 2003, RCN 2017a, WHO 2015).

If a specimen is suspected or known to present an infectious hazard, particularly Hazard Group 3 pathogens (such as hepatitis B or C virus, human immunodeficiency virus [HIV],

Mycobacterium tuberculosis), this must be clearly indicated with a 'danger of infection' label on the specimen and the request form to enable those handling the specimen to take appropriate precautions (HSE 2003, WHO 2015).

Specimens from patients who have recently been treated with toxic therapy such as gene therapy, cytotoxic drugs, radioactivity or active metabolites need to be handled with caution. Local guidelines on the labelling, bagging and transportation of such samples to the laboratory should be followed. For example, in the case of gene therapy, the specimen must be labelled with a 'biohazard' label, double bagged and transported to the laboratory in a secure box with a fastenable lid (HSE 2003, WHO 2015).

Selecting specimens

Selecting a specimen that is representative of the disease process is critical to the ability of the laboratory to provide information that is accurate, significant and clinically relevant. Incorrect specimen selection or technique can be life threatening to patients (Wegerhoff 2006). Specimens should only be taken when indicated.

Assessment and recording tools

Request forms

The form should include as much information as possible as this allows the laboratory or department conducting the investigation to select the most appropriate equipment and/or media examination (NHS Pathology 2014).

Request forms should include the following information:

- patient's name, date of birth, ward and/or department
- hospital number
- investigation required so as to avoid indiscriminate specimen analysis which wastes time and money
- date and time of specimen collection
- type and site of specimen; this should specify the actual anatomical site
- diagnosis and relevant clinical information which can help in the interpretation of a sample (Higgins 2013)
- relevant signs and symptoms
- relevant history, for example recent foreign travel
- present or recent antimicrobial therapy
- whether the patient is immunocompromised as these patients are highly susceptible to opportunistic infections and non-pathogenic organisms (Weston 2008)
- consultant's name
- name and contact details of the doctor requesting the investigation, as it may be necessary to telephone the result before the report is dispatched.
- labelled with 'danger of infection' if the specimen is high risk (HSE 2003, WHO 2015).

Communication

For certain specimens that have specific collection techniques or require prompt processing, communication with the laboratory before the sample collection is essential. Providing specimen arrival time to the laboratory can improve efficiency of processing and accuracy of results. Where a diagnostic test is to be undertaken, it is essential that the patient is prepared appropriately with consideration of fasting times, the cessation of certain medications and post-procedural care. A patient information leaflet explaining the test can be given to prepare the patient for pre- and post-procedural care. Communication with the department where the test will be conducted is essential.

Collecting specimens

The production of high-quality, accurate results which are clinically useful is very much dependent upon the quality of the specimen collection (Higgins 2013, Wegerhoff 2006). The greater the quantity of material sent for laboratory examination, the greater the chance of isolating a causative organism. Specimens should

be taken as soon as possible after the manifestation of clinical signs and symptoms.

Specimens are readily contaminated by poor technique, and analysis of such specimens could lead to adverse outcomes such as misdiagnosis, misleading results, extended length of stay, inappropriate therapy or potentially disastrous consequences for the patient (Wegerhoff 2006). Therefore, care must be taken to avoid inadvertent contamination of the site of the sample or the specimen itself.

Post-procedural considerations

Immediate care

Clinical waste

It is essential that all clinical waste is disposed of appropriately. This ensures that healthcare activities do not go on to pose further infection risks and that waste is securely managed. There are various regulatory regimes that pertain to the destruction of healthcare waste, which include environment and waste, controlled drugs, infection control, health and safety and transport. Specialist disposal of cytotoxic and radioactive waste must also be considered. Due to variation in product availability and local waste arrangements it is important to follow local policy and guidelines (DH 2013).

Transporting specimens

An awareness of the type of organism being investigated and its growth requirements gives the healthcare professional an insight into the correct collection, storage and transportation methods. Delays in transporting a specimen to the laboratory can compromise the specimen's integrity, leading to false-negative or -positive results, because the sample is no longer representative of the disease process (Higgins 2013). If delays are anticipated, samples need to be stored appropriately, depending on the nature of the specimen, until they can be processed. This could be in a specimen fridge, freezer or another storage unit (HSE 2003, WHO 2015).

The transport of clinical specimens must conform to health and safety legislation and regulations, and there are more specific guidelines on the labelling, transport and reception of specimens within clinical laboratories and similar facilities (HSE 2003, WHO 2015).

Documentation

Labelling specimens

Prompt specimen analysis is only possible if specimens and their accompanying request forms are sent with specific, accurate and complete patient information. Incorrectly labelled or unlabelled specimens will be discarded (HSE 2003, NHS Pathology 2014).

Samples should include the following information:

- patient's name, date of birth, ward and/or department
- hospital number
- date and time of specimen collection
- type and site of specimen. This should specify the actual anatomical site
- labelled with 'danger of infection' if a specimen is high-risk (HSE 2003, WHO 2015).

Tumour markers

Definition

Tumour markers are molecules of widely divergent characteristics that may indicate the presence of cancer or a malignancy. They are laboratory based tests that are also able to indicate the likely future behaviour of a cancer. Although generally not diagnostic they can provide information that may contribute to the diagnostic process. A tumour marker can be obtained from serum and tissue with other tests undertaken on body fluids (Duffy 2013, European Group on Tumour Markers (EGTM) 2018).

Related theory

The diagnostic value of the tumour marker is dependent on its specificity and sensitivity and the prevalence of cancer in the population. The specificity is the percentage of persons with benign conditions where a negative result is obtained; the greater the specificity, the fewer the false positives. The sensitivity is the number of test results that are positive in the presence of a tumour; the greater the sensitivity, the fewer the false negatives. The limitations of tumour markers for cancer screening particularly are associated with the lack of sensitivity for early invasive disease or pre-malignant lesions and the lack of specificity for malignancy (Association for Clinical Biochemistry and Laboratory Medicine (ACB) 2013, Duffy 2013, EGTm 2018). The low

prevalence of cancer in the general population prohibits most bio-markers being used in cancer screening. Some markers or tests have been evaluated or are undergoing evaluation for asymptomatic cancer screening such as prostate-specific antigen (PSA) and carbohydrate antigen 125 (CA 125) (Duffy 2013) (Table 1.1).

There are no tumour markers that are specific for malignancy. An elevated tumour marker may be due to another malignancy or benign disease. A normal tumour marker result does not exclude the presence of a malignancy or recurrence, and in general serum tumour markers are rarely elevated in patients with early malignancy (EGTM 2018). The tumour marker results should always be interpreted in context of laboratory and clinical information, particularly serial results. The results obtained

Table 1.1 Common tumour markers and clinical application

Tumour marker or test	Sample source	Normal ranges	Purpose/findings
AFP (alpha-fetoprotein)	Serum	<14 µg/L	Indication: screening (high-risk groups) and monitoring hepatic carcinoma, diagnosis hepatoblastoma, diagnosis and monitoring germ cell tumours Elevated levels: hepatocellular carcinoma, germ cell, hepatoblastoma, lung and pancreatic with metastasis, gastric with liver metastasis Potential false positives: autoimmune disease, hepatobiliary disease, pregnancy
B₂M (beta ₂ -microglobulin)	Serum	1.2–2.4 mg/L	Indication: monitoring haematological malignancy, multiple myeloma, lymphoma Potential false positives: chronic liver disease, infection, autoimmune diseases, renal failure
CA 15-3 (carbohydrate antigen 15-3/cancer antigen 15-3)	Serum	<32 KU/L	Indication: monitoring treatment for advanced breast cancer, detecting recurrence in breast cancer Elevated levels: advanced breast cancer (80% of patients), may also be elevated in adenocarcinoma with distant metastasis, lung, liver, pancreas, colon, ovarian, cervix and endometrium, prostate Potential false positives: treatment with colony-stimulating factor of granulocytes, lung infection diseases, autoimmune diseases, ovarian cysts, renal failure, pregnancy
CA 19-9 (carbohydrate antigen 19-9/cancer antigen 19-9)	Serum	<37 KU/L	Indication: diagnosis, pre-operative marker for resectability, surveillance and monitoring in pancreatic carcinoma. Diagnostic aid in cholangiocarcinoma Elevated levels: pancreatic, colorectal, gastrointestinal, hepatobiliary, lung, testicular carcinoma and cholangiocarcinoma Potential false positives: benign lung diseases, gastrointestinal pathology, renal failure, ovarian cysts, liver diseases, pancreatitis, cholestasis, bronchiectasis
CA 125 (carbohydrate antigen 125/cancer antigen 125)	Serum	0–35 KU/L	Indication: monitoring ovarian and breast carcinoma, monitoring response to chemotherapy, pre-operatively, post-operatively and during first three treatments of chemotherapy, annually in women with hereditary ovarian cancer syndrome Elevated levels: stage I epithelial ovarian (50% of women), stage II epithelial ovarian (90% of women), stage III and IV epithelial ovarian (90% of women), breast, cervix, colon, endometrial, gastrointestinal, liver, lung, lymphoma, non-Hodgkin's lymphoma, ovarian, pancreatic Potential false positives: ovulation, menstruation, COPD, lung infections, nephritic syndrome, endometriosis, liver failure, kidney failure, pregnancy, fluid retention
Calcitonin	Serum	Male: <11.8 ng/L Female: <4.8 ng/L	Indication: diagnosis and monitoring medullary thyroid cancer, multiple endocrine carcinoma screening, lung cancer, neuroendocrine tumours
CEA (carcinoembryonic antigen)	Serum	<5 µg/L	Indication: determining prognosis pre-operatively, surveillance post curative resection, monitoring advanced colorectal carcinoma Elevated levels: colorectal carcinoma (60% of patients and 80–100% with hepatic metastasis), may also be elevated in advanced adenocarcinomas of the lung, breast, pancreas, liver, stomach, ovary, prostate, rectum Potential false positives: smokers, benign diseases, liver failure, kidney failure, Crohn's disease, ulcerative colitis
Chromogranin A	Serum (EDTA)	0–60 pmol/L	Indication: monitoring and detecting recurrence of neuroendocrine tumours, neuroblastomas Potential false positives: hypertension, sepsis, cardiac failure, cardiomyopathy

(continued)

6 **Table 1.1** Common tumour markers and clinical application (*continued*)

Tumour marker or test	Sample source	Normal ranges	Purpose/findings
CYFRA 21-1 (cytokeratin fragment)	Serum	<3.3 ng/mL	Indication: differential diagnosis lung cancer, prognosis non-small cell lung cancer (NSCLC), treatment monitoring NSCLC, detection or recurrence in squamous cell lung cancer Potential false positives: effusions, psoriasis, liver diseases, cirrhosis of the liver, renal failure
hCG (human chorionic gonadotrophin)	Serum Urine CSF	<5 IU/L <25 IU/L <2 IU/L	Indication: diagnosis, prognosis and monitoring of germ cell tumour and gestational trophoblastic disease, metastatic spread to brain (CSF) Elevated levels: testicular seminoma, gestational trophoblastic disease, non-seminomatous germ cell of testis and ovary Potential false positives: autoimmune diseases, marijuana use, renal failure, pregnancy
HER-2/neu (human epidermal growth factor receptor)	Tissue	IHC test: 0–1+ FISH test: negative	Indication: breast cancer Elevated levels: prostate, lung cancer Potential false positives: renal failure, liver diseases
HE4 (human epididymis protein 4)	Serum	<150 pmol/L	Indication: ovarian, endometrial, lung, adenocarcinoma Potential false positives: liver disease, effusions, renal failure
NSE (neuron-specific enolase)	Serum	<13 ng/mL	Indication: diagnosis in lung cancer, support diagnosis in small cell lung cancer (SCLC), differential diagnosis in lung cancer of unknown origin, pre-treatment and follow-up in SCLC, prognosis in SCLC and NSCLC, treatment and follow-up of neuroblastoma, differential diagnosis between Wilms' tumour and neuroblastoma in paediatrics Elevated levels: adrenocortical carcinoma, medullary carcinoma of the thyroid, neuroblastoma, pancreatic islet cell tumour Potential false positives: liver disease, lung disease, renal failure, cerebral haemorrhage and ischaemia, haemolysis
PLAP (placental alkaline phosphatase)	Serum	<100 mIU/L	Indication: aid in germ cell tumour diagnosis, monitoring progression, testicular seminoma, ovarian carcinomas Potential false positives: smokers
PSA (total) (prostate-specific antigen)	Serum	<4 µg/L	Indication: aid diagnosis, determine prognosis, monitoring and early detection of recurrence in patients with prostate cancer Elevated levels: prostate cancer
SCCA (squamous cell carcinoma antigen)	Serum	0–150 ng/dL	Indication: squamous cancers, cervical cancer, lung cancer Potential false positives: liver or lung diseases, renal failure
S-100	Serum	<0.2 ng/mL	Indication: malignant melanoma Potential false positives: liver disease, autoimmune disease, renal failure

Source: Adapted from Chercecky and Berger (2013), Duffy (2013), EGTm (2018).
COPD, chronic obstructive pulmonary disease; CSF, cerebrospinal fluid; EDTA, ethylenediaminetetraacetic acid; FISH, fluorescence *in situ* hybridization; IHC, immunohistochemistry.

using different methods are not necessarily comparable (ACB 2013).

A tumour marker should have the following characteristics (Duffy 2013):

- a high positive and negative predictive value
- an inexpensive, standardized and automated assay
- clearly defined reference limits
- acceptable to patients undergoing the test
- a large prospective trial to validate its clinical value.

Evidence-based approaches

As there are over 200 cancer types with each having different but sometimes overlapping features, there is a variation in referral and testing for possible cancers. The National Institute for Health and Care Excellence (NICE 2015b) has produced evidence-based guidance (NG12) for suspected cancers and their recognition and referral in children, young people and adults. Recommendations are presented by the site

of the cancer. Further NICE (2010) guidance (CG104) has been produced for malignancy of undefined primary origin (MUO) and metastatic malignant disease of unknown primary origin in adults.

In 2013, the ACB made the following recommendations as a result of the ACB national audit on tumour marker service provision. Laboratories should:

- adopt local guidelines for non-specialist laboratories informing them of the most appropriate use of tumour markers that are based on nationally or internationally developed evidence-based guidelines
- provide guidance on frequency of tumour marker measurement
- regularly audit their tumour marker service to review the requesting patterns and use
- review their tumour marker requests, in particular those sent to another laboratory assay
- state on reports for tumour markers measured on fluids that these results have not been validated

- state the relevant reference range on the report and that the results are not well defined and are to be only used for guidance
- state that a result out of the reference range does not imply tumour presence or exclude tumour presence
- state that benign conditions may cause elevated serum results that can lead to misinterpretation
- state that medication, medical intervention and lifestyle can influence results
- advise users that factors such as urinary tract infection (UTI), catheterization prior to serum PSA and correct time of serum PSA after digital rectal examination may affect the result (ACB 2013).

Rationale

Tumour markers are used in cancer detection and management. The tests are potentially useful in cancer screening, aiding diagnosis, determining prognosis, surveillance post curative surgery, predicting drug response or resistance and monitoring therapy in advanced disease (ACB 2013, Duffy 2013). Tumour markers should only be requested where the results can influence clinical practice and have a favourable outcome for patients (ACB 2013).

Indications

The main indication for serum tumour marker testing is the monitoring of patients diagnosed with cancer.

- *Primary care* – the only tests that should be performed are PSA in males, CA 125 in females, and where the GP is following up a patient being cared for by a secondary physician.
- *Asymptomatic patients* – potentially used for screening in early malignancy.
- *Symptomatic patients* – to assist in differential diagnosis of benign and malignant disease, following diagnosis and surgical

removal of a cancer to assess prognosis, post-operative surveillance, therapy prediction, and monitoring the systemic therapy response (ACB 2013, Duffy 2013; EGTM 2018).

- *Metastatic malignant disease of unknown primary origin in adults: second diagnostic phase* – only in the following:
 - alpha-fetoprotein (AFP) and human chorionic gonadotrophin (hCG) in patients with germ cell tumours, particularly in young men with mediastinal and/or retroperitoneal masses
 - AFP in patients with hepatocellular cancer
 - PSA in men with prostate cancer
 - CA 125 in women with ovarian cancer including inguinal node, chest, pleural, peritoneal or retroperitoneal presentations (NICE 2010).

Contraindications

There are certain circumstances where tumour markers should not be used. These include:

- metastatic malignant disease of unknown primary origin in adults: second diagnostic phase (NICE 2010)
- patients with vague symptoms when likelihood of cancer is low (ACB 2013)
- multiple tumour marker requests in the attempt to identify a primary cancer or the presence of secondary cancers; this is rarely valuable (ACB 2013).

Pre-procedural considerations

There are various pre-procedural considerations such as timing of specimen collection, other current treatment or medications, the patient's renal function, possible contamination of samples, type of specimen and the stability of the specimen during storage (Table 1.2).

Table 1.2 Pre-analytical/pre-procedural considerations

Consideration	Potential tumour markers affected
Timing of specimen collection	• Pre-treatment: specimen desirable for all markers • Time of day variation: specimens can be taken any time for most markers • Post-operatively: CA 125 may be increased in peritoneal trauma • Menses: avoid sampling during menses, especially CA 125 for high-risk patients • Urology: prostate biopsy/transurethral resection of the prostate (TURP), catheterization and acute painful urinary retention may increase serum PSA • Prostatitis/UTI: may increase serum PSA. Sampling should occur several weeks after resolution of symptoms/infection • Digital rectal examination (DRE): transient elevation of serum PSA • Ejaculation: potential increase post ejaculation, note time post ejaculation • Chemotherapy: hCG specimen: post chemotherapy timings need to be checked to avoid misleading elevated results
Effects of other treatment/medication	• Immunometric methods: vulnerable to human anti-mouse antibodies (HAMA) • Monoclonal antibodies: previous treatment to be noted on request form • Radioisotopes: invalid CA 19-9 results if patient received radioisotopes within past 30 days • Radioactive dyes: invalidates B₂M results if taken within one week of the test
Effect of renal failure/impairment	• Potential elevation: in PSA, tissue polypeptide specific antigen (TPS) and other cytokeratins
Effect of cholestasis	• Potential marked increase: carbohydrate antigen 19-9 (CA 19-9)
Contamination with saliva	• Potential marked increase: CA 19-9, squamous cell carcinoma antigen (SCCA), carcinoembryonic antigen (CEA) and TPS
Type of specimen	• Serum or plasma: generally most appropriate and suited to most commercial assays • Serum and EDTA plasma: difference in results may be due to complement effects, however little evidence available on effect of gel tubes
Stability of specimen on storage	• Serum: stable. Separation of serum from clot and storage +4°C (short term) or –30°C (long term) preferably within 3 hours or as soon as possible • Heating: usually undesirable, e.g. PSA, human chorionic gonadotrophin (hCG) • PSA: separation of serum from clot and storage +4°C (short term) or –30°C (long term) preferably within 3 hours or as soon as possible. Refrigerate specimens up to 24 hours; beyond 24 hours specimens should be frozen at at least –20°C. Longer term storage –70°C

Source: Adapted from Chernecky and Berger (2013), EGTM (2018).

B₂M, beta-2 microglobulin; PSA, prostate-specific antigen; UTI, urinary tract infection.

8 Equipment

The equipment required will vary depending on the type of specimen to be collected such as serum, urine or cerebrospinal fluid (CSF). Please refer to Dougherty and Lister (2015) *The Royal Marsden Manual of Clinical Nursing Procedures, Ninth Edition*: Chapter 10 Interpreting Diagnostic Tests for the various types of equipment and method required, for example blood test, urine collection, CSF collection. The collection vessels or containers may vary according to each organization or laboratory. It is therefore essential to identify the required collection vessels or containers.

Post-procedural considerations

Ongoing care

It is important to ensure that the patient is informed in regards to the significance of the tumour marker results in the context of other clinical examinations and investigations. Refer to Chapter 4, Communication, in *The Royal Marsden Manual of Clinical Nursing Procedures, Ninth Edition*.

Cervical uterine smear

Definition

The cervical smear is a test in which a specimen of cellular material is scraped from the cervix. The specimen is then examined under a microscope by a cytologist to identify early cellular changes (Kumar and Clark 2016).

Anatomy and physiology

The cervix is the narrow neck of the uterus and is located between the vagina and the uterus. It projects into the vagina and the cavity of the cervix is known as the cervical canal. The cervical canal's glands secrete a mucus that blocks the entry of sperm except in the midcycle when a reduction in viscosity allows sperm to pass (Marieb and Hoehn 2015) (Figure 1.3).

Related theory

The intention of a smear test is to collect squamous epithelial cells and some endocervical cells from the transformation zone (see Figure 1.3) and squamocolumnar junction of the cervix where most cervical cancers arise. The sampling technique must take into consideration that the position of the squamocolumnar junction changes with age, contraception and parity (Higgins 2013, WHO 2014).

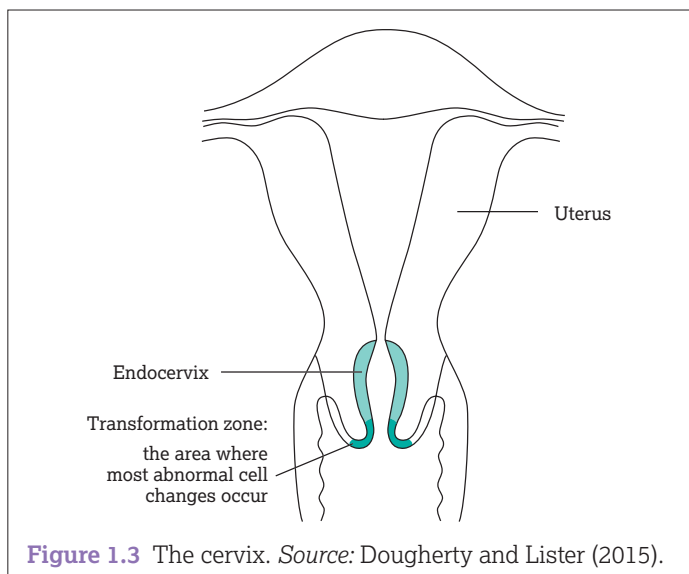


Figure 1.3 The cervix. Source: Dougherty and Lister (2015).

Evidence-based approaches

Rationale

The ideal time for obtaining a cervical smear is midcycle if the woman is premenopausal; this prevents contamination from menstrual flow and allows for accuracy of results (Higgins 2013, WHO 2014). It is not ideal to take a cervical smear if a woman is pregnant or immediately post partum as results obtained can be misleading. The WHO suggests that if a woman is in the target age group and there are concerns about access to screening post-partum, then a cervical smear should be taken following childbirth after consent is obtained (WHO 2014).

In the UK, 80% of cervical smears are taken in the primary care setting and most are taken by practice nurses. Screening is recommended in the UK for all women between the ages of 25 and 64 years and is an investigation to confirm that the cervix is healthy and there are no abnormal changes to the cells; it is not a test for diagnosing cervical cancer (Higgins 2013, NHSCSP 2004). Human papillomavirus (HPV) testing was included in the current NHS cervical screening programme in April 2011. HPV testing does not require any other additional procedures in addition to the regular smear test. In practice, the residual smear sample is used to test for HPV and this is conducted in a laboratory (NHSCSP 2013).

Indications

- Women between the age of 25 and 64.

Contraindications

- During pregnancy.
- Immediately post-partum.

Method for cervical smears: liquid-based cytology

Liquid-based cytology (LBC) is the established method for cervical smears in Europe and the USA. Other countries may still use the conventional cytology methods depending on human, infrastructure and financial resources. The sample used to test for human papillomavirus deoxyribonucleic acid (HPV DNA) can also be used to test for sexually transmitted diseases such as chlamydia and gonorrhoea (Schuiling and Likis 2013).

Legal and professional issues

It is advised that the practitioner offers the patient the option of having a chaperone. The chaperone may be a person of the patient's choice who will accompany them throughout the procedure. The decision of the patient in regard to a chaperone should be documented (RCN 2106b). Healthcare professionals conducting cervical smears should also be familiar with national guidance (NHSCSP 2015).

Governance

Smear tests are often performed by doctors and nurses. Training for cervical sample takers is designed to support the education and training of competent practitioners (NHSCSP 2017). Training should reflect current trends, developments and understanding of the cervical screening process in light of new recommendations (RCN 2013).

Risk management

It is essential that women are informed that the likelihood of an inadequate test is about 1–2% for LBC and 9% for conventional cytology (NHSCSP 2017).

Pre-procedural considerations

Equipment

There are several devices that are used in sampling the uterine cervix (Figure 1.4).

- *Vaginal speculum*: this is an instrument used during gynaecological examination to facilitate the visualization of the vagina



Figure 1.4 Vaginal specula and cervical broom.

and cervix. The speculum is introduced via the vagina, and its cylinder with a rounded end shape allows easy passage. Once *in situ*, the speculum is opened, holding the vagina open and allowing the healthcare professional to have access to the cervix and perform the cervical smear. Most speculums are now made of plastic and are single use, replacing those formerly made of metal and requiring sterilization after use. There are two categories of speculum: virgin and non-virgin. The latter is available in four sizes: small, medium, large and long. Special attention should be paid when selecting a speculum for use in women previously treated with pelvic radiotherapy or who are postmenopausal (Singh et al. 2013).

- **Cervical broom:** these are plastic broom-shaped tools with a pyramidal arrangement of flexible flat 'teeth'. The longer 'central' tuft fits into the cervical os and must be rotated clockwise through a full circle five times. When used to take a conventional smear, this brush is an adequate and effective sampling device (NHSCSP 2017). The brush should be inserted into the cervical

os with the lower bristles remaining visible, and rotated between a half and a whole turn to reduce trauma (Insinga et al. 2004).

LBC is the current standard method of screening in the NHS cervical screening programme (NHSCSP 2015). The National Institute for Health and Clinical Excellence (2003) recommended that LBC be used as the primary means of processing samples in the cervical screening programme in England and Wales. It achieves 'cleaner' preparations, which are generally easier to read. Its advantage is a reduction in inadequate samples and there may be gains in reducing borderline results and increasing sensitivity (NHSCSP 2004).

Whichever device is used, once the sample is taken it is vital that the cells collected are transferred onto a glass slide and preserved immediately or placed into the correct vial containing liquid preservative and fixative. Slides must not be placed in a refrigerator (Higgins 2013, NHSCSP 2017).

The environment is also important, with the following equipment required:

- height-adjustable couch
- angle-positioned light source which is ideally free standing for manoeuvrability (RCN 2013).

Specific patient preparation

The examination must be undertaken in a private room which cannot be entered during the examination. Adequate private changing facilities that are warm and comfortable should also be available. Where possible, face the examination couch away from the door to enhance privacy and dignity for the patient (RCN 2013).

The patient should be given the opportunity to empty her bladder prior to the examination. Ask the patient to undress and explain the position required on the couch. The most common position is prone or alternatively left lateral as it is comfortable and aids in the visualization of the cervix. Once the patient is ready, she should inform the practitioner. A modesty towel or covering should be supplied to enable the patient to partially cover herself (RCN 2013).

Education

Explain the procedure to the patient prior to commencing. It is good practice to offer the patient a demonstration of the speculum and to explain what part will be inserted into the vagina. Any possible side-effects such as spotting post examination should also be discussed prior to commencing the examination (RCN 2013).

Procedure guideline 1.1 Cervical uterine smear using liquid-based cytology

Essential equipment

- Alcoholic handrub
- Light source
- An examination couch
- Disposable clean paper couch covers
- Various sized specula (disposable or reusable)
- Disposable clean gloves
- Cervix brush
- LBC container
- Black ballpoint pen for labelling LBC container
- Specimen form and plastic specimen bag
- A container of warm water
- Box of tissue paper
- Clinical waste container
- Trolley
- Disposable apron
- Lubricant

Optional equipment

- A collecting container for Clinical Sterile Services (CSS) if reusable instruments are used

(continued)

10 Procedure guideline 1.1 Cervical uterine smear using liquid-based cytology (*continued*)**Pre-procedure****Action****Rationale**

- 1 Discuss benefits and limitations of screening and significance of smear results. Explain the purpose of the procedure and explain what will occur at each step.

To ensure that the patient/client understands that the procedure involves removing underwear and that the speculum will be inserted into her vagina, and consents to the procedure (NHSCSP 2017, **C**; RCN 2017b, **C**). Allows the woman time to ask any questions. **E**

- 2 Document the woman's clinical and screening history, specifically:
 - date of last menstruation
 - any abnormal bleeding
 - any unusual vaginal discharge
 - contraception
 - date of last cervical smear
 - any abnormal smear results
 - any treatment to the cervix.

To ensure relevant history is recorded (NHSCSP 2017, **C**).

- 3 Place all the equipment required for the procedure on the trolley.

To facilitate the efficient taking of the smear. **E**

- 4 Close room door or curtains and ask the patient/client to remove her underwear.

To provide privacy and comfort for the patient/client. **E**

Procedure

- 5 Turn the light source on and position at end of examination table.

To provide illumination of the cervix and increase the accuracy of the smear taking (NHSCSP 2004, **C**; NHSCSP 2017, **C**; RCN 2013, **C**).

- 6 Assist the patient/client into a supine position on the couch, with knees drawn up and legs parted. Keep her as covered as possible.

To facilitate easy access of the vaginal speculum and the taking of the cervical smear (NHSCSP 2004, **C**; NHSCSP 2017, **C**; WHO 2014, **C**).

- 7 Wash hands with antibacterial detergent and running hand-hot water. Ensure hands are dried with disposable paper hand towels.

To reduce the risk of contamination and cross-infection (Fraise and Bradley 2009, **E**; RCN 2017a, **C**).

- 8 Apply gloves and apron.

To reduce the risk of contamination and cross-infection (Fraise and Bradley 2009, **E**; RCN 2017a, **C**).

- 9 Select the appropriate size speculum, from very small, small, medium, large including a long-bladed narrow speculum if the vagina is long or the cervix is lying posterior. If a reusable sterilized speculum is used it can be warmed or cooled using clean tap water.

To promote patient comfort and reduce anxiety (NHSCSP 2017, **C**). If removed from a sterilizer, speculum may need to be cooled down, if cold then warmed up to reduce patient discomfort. It must be explained to the patient that the speculum has been sterilized but the water will not contaminate it. **E**

- 10 Apply lubricant to the speculum. Part the labia and, holding the speculum blades together sideways, slip the speculum into the vagina.

To insert the speculum and reduce patient discomfort (Fraise and Bradley 2009, **E**; WHO 2014, **C**; RCN 2013, **C**).

- 11 When the speculum is halfway into the vagina, turn it so that the handle is facing down.

To promote patient comfort and reduce contamination of the cervix with lubricants (NHSCSP 2017, **C**).

- 12 Gently open the blades of the speculum and look for the cervix. It may be necessary to move the speculum up or down until the entire cervix is visible.

To reduce patient discomfort and visualize the cervix (WHO 2014, **C**).

- 13 Using the cervix brush, insert the central bristles into the endocervical canal so that the shorter, outer bristles fully contact the ectocervix.

To ensure accuracy of site sampled (NHSCSP 2004, **C**; NHSCSP 2017, **C**; Singh et al. 2013, **R5**).

- 14 Using pencil pressure, rotate the brush in a clockwise direction five times and then remove the brush. *Note:* the plastic fronds of the brush are bevelled for rotation in a clockwise direction only.

To ensure good contact with the ectocervix and gather a high cellular yield (NHSCSP 2004, **C**; NHSCSP 2017, **C**). Firm pressure is required to ensure the cells cling to the brush (NHSCSP 2004, **C**; NHSCSP 2017, **C**).

Either:

Using Thinprep, using a swirling motion, rinse the brush into the fixative vial; then push the brush into the base of the vial at least 10 times, forcing the bristles apart.

To ensure a usable amount of cellular material is collected (NHSCSP 2004, **C**; NHSCSP 2017, **C**).

Inspect the brush for any residual material and remove any remaining material by passing the brush over the edge of the fixative vial.	To ensure the cellular material reaches the preservative solution (NHSCSP 2004, C ; NHSCSP 2017, C).
Ensure that the material reaches the liquid. Then tighten the cap so that the material passes the torque line on the vial and give the vial a shake.	To ensure that the cells do not cling to the device (NHSCSP 2004, C ; NHSCSP 2017, C).
Or:	
Using SurePath, remove head of the brush from the stem and place into the vial of fixative. Then screw lid on tightly and shake the vial. <i>Note:</i> it is essential that the sample is placed into the vial immediately in order to achieve fixation.	To ensure accurate preservation of cervical material (NHSCSP 2004, C ; NHSCSP 2017, C).
15 Gently pull the speculum out until the blades are clear of the cervix, then close blades and remove speculum, placing in clinical waste bin if disposable or into CSS container if reusable.	To prevent pinching cervix or vaginal walls and ensure safe disposal of contaminated equipment (NHSCSP 2017, C ; WHO 2014, C).
16 Cover the patient/client and offer tissue paper to wipe away any excess vaginal discharge.	To ensure dignity and privacy while promoting hygiene and comfort. E
Post-procedure	
17 Remove gloves and dispose of waste in clinical waste receiver.	Safe disposal of clinical waste (DH 2013, C).
18 Assist the patient/client off the examination table and allow her to dress.	To ensure safety and promote dignity and privacy. E
19 Using a black ballpoint pen, label the vial with patient/client name, clinic number and date of birth.	To ensure patient details are documented correctly. E
20 Place the vial into plastic specimen bag with the correctly labelled specimen form and send to laboratory.	To ensure safe handling and transportation of a biohazard (HSE 2003, C ; DH 2013, C ; WHO 2015, C).
21 Document the procedure in the patient's records.	To ensure timely and accurate record keeping (NMC 2010a, C).

Problem-solving table 1.1 Prevention and resolution (Procedure guideline 1.1)

Problem	Cause	Prevention	Action
Inadequate sample.	Cervix has not been scraped firmly enough to obtain adequate epithelial cells (WHO 2014).	Ensure adequate pressure to obtain sample.	Repeat cervical smear.
	Brush not rinsed immediately, allowing the sample to dry and causing the cells to become misshapen (NHSCSP 2015).	Ensure brush is rinsed immediately after scraping the cervix.	Repeat cervical smear.
	Sample contaminated with lubricants, spermicide or blood (Higgins 2013).	Ensure sample is not contaminated by educating the patient not to use lubricants or spermicide 24 hours prior to test.	Repeat cervical smear.
Unable to visualize the cervix.	Position of the patient or anatomical position of the cervix.	Adequate positioning of the patient.	Reposition the patient from the prone to the lateral position. Place a pillow under the buttocks or turn the speculum. Consider assistance from another sample taker or refer to colposcopy clinic if unable to visualize.

Post-procedural considerations

Immediate care

Ensure patient modesty is maintained throughout and directly after the examination. To maintain privacy and dignity, the nurse should leave the room while the patient gets undressed and dressed, and advise them to call when ready (RCN 2013).

Ongoing care

The results should be communicated to the patient and appropriate follow-up and/or referral to secondary services arranged

where necessary. It is important that the healthcare professional considers how the patient may react if abnormal results are to be delivered and ensures necessary support (RCN 2013).

Documentation

The nurse should ensure that the request form has been adequately completed and that the samples are also labelled correctly and accurately. If other microbiological tests are conducted, ensure the correct forms are completed and the samples are labelled and document any findings and resulting actions (RCN 2013).

Education of patient and relevant others

It is not unusual for the patient to experience some spotting after the cervical smear. This must be explained to the patient to ensure she is aware and will not be worried. The healthcare professional should promote health education providing advice in the prevention of cervical cancer and encouraging screening to those who are eligible such as accurate information and advice in the prevention of cervical cancer. Patient information leaflets are offered to patients to ensure they have the appropriate information (RCN 2013).

Diagnostic radioisotope procedures (nuclear medicine)

Definition

Nuclear medicine involves the administration of radioactive material in the form of a radiopharmaceutical to patients for diagnosis or therapy (DH 2016, HPA 2016). In both cases, the radioactive material is attached to a pharmaceutical chosen according to the organ or system to be investigated or treated. For example, radioactively labelled phosphates will be concentrated in the bone and are therefore used for bone scans, whereas radioactive iodine (given in the form of sodium iodide) concentrates in the thyroid and is used for both imaging and treating various thyroid conditions, forming a radiopharmaceutical (DH 2016, HPA 2016).

A radionuclide investigation involves administration of the appropriate radiopharmaceutical and using dynamic imaging or

waiting a predetermined time to allow the radiopharmaceutical to be taken up in the organ to be investigated (Table 1.3). The patient is then positioned on the camera table, usually lying flat, and is required to keep still during the scan. Movement causes artefacts which reduce diagnostic accuracy. The scan may last 15–60 minutes (DH 2016).

Evidence-based approaches

Rationale

The important properties that make the radiopharmaceutical useful for diagnostic purposes include:

- the physical half-life
- decay characteristics
- ease of incorporation into radiopharmaceuticals
- availability of radionuclide.

A desirable radionuclide should have a half-life just long enough to allow for preparation, administration and concentration in the region of interest, but short enough for radiation to effectively disappear after the test (Cherry et al. 2003). Imaging studies commonly performed in a nuclear medicine department include:

- assessment of structures and/or function of organs
- sites of infection
- presence of tumours.

Table 1.3 Radionuclide investigations

Investigation/target organ	Radiopharmaceutical	Procedures and clinical interventions
Imaging studies		
Bone scan		
Used to assess bone function in which malignancy, fractures and diseases such as osteomalacia and Paget's disease can be diagnosed	Technetium (^{99m}Tc) phosphate and phosphonate compounds, including methylene diphosphonate (MDP) and hydroxymethylene diphosphonate (HDP)	Patient to drink 5–6 cups of fluid and to empty bladder regularly while waiting for scan. This is to enhance soft tissue clearance and minimize absorbed radiation dose to the bladder
Renogram (dynamic renal study)		
Used to assess renal function by monitoring clearance of radiopharmaceutical via kidneys	^{99m}Tc MAG_3 Benzoylmercaptoacetyl triglycine ^{99m}Tc DTPA (diethylenetriamine penta-acetic acid)	Patients to drink approximately 600 mL of fluid and to empty bladder prior to scan, which takes approximately 1 hour Intravenous diuretic is to be administered to patient during the scan to diagnose obstructive uropathy (Russell 1998)
Static renal study		
Used to assess size, shape, position and function of kidneys. Used to diagnose renal scarring in children	^{99m}Tc DMSA (dimercaptosuccinic acid)	No preparation
Perfusion lung scan		
Used to assess blood supply to alveolar tree. Provides complementary information to a ventilation lung scan Used to diagnose pulmonary embolism	^{99m}Tc MAA (macroaggregated albumin)	Radiopharmaceutical is administered as a slow bolus intravenous injection. Patient to lie supine and breathe deeply while injection is being given. This is to enhance even distribution of MAA through the lung capillary bed. If the patient is pregnant, administered activity or dose needs to be reduced
Ventilation lung scan		
Provides complementary information to a perfusion lung scan in diagnosis of pulmonary embolism. Used to assess patency of airways	^{99m}Tc Technegas, ^{99m}Tc aerosol, ^{81m}Kr gas, ^{133}Xe gas	A chest X-ray performed within the preceding 24 hours is required prior to scan, to assist with interpretation of lung scan. Patient breathes the radiopharmaceutical through a special mouthpiece while scan is being performed

Investigation/target organ	Radiopharmaceutical	Procedures and clinical interventions
Cardiac studies: perfusion imaging Used to assess areas of viable perfused myocardium. This is a two-part test with myocardial perfusion monitored under stress and subsequently at rest. Stress may be exercise or pharmacologically induced. Often performed on patients with suspected coronary artery disease, recent myocardial infarction or those who have undergone coronary artery bypass surgery	^{99m}Tc MIBI (methoxyisobutyl isonitrile), ^{99m}Tc tetrafosmin, ^{201}Tl thallous chloride	Patient vital signs need to be closely monitored during post-exercise period because there is the potential risk of triggering a myocardial infarction after stress This test is usually performed within a cardiology unit with appropriately trained personnel and equipment. Patient is usually kept in the department until they have been assessed by a clinician
Cardiac studies: left ventricular ejection fraction/multiple gated acquisition scan Used to evaluate cardiac function in patients prior to and during courses of chemotherapy containing cardiotoxic agents such as epirubicin	^{99m}Tc -labelled red blood cells	Current weight of patient is required for calculation of dose of a red blood cell labelling agent, which ensures red blood cells are labelled with required radioactivity. The volume calculated is then administered intravenously 20–30 minutes prior to scan. Patient lies supine for 30–40 minutes
Thyroid scan May be used to confirm presence of one or more nodules within the thyroid, or to identify functional characteristics of nodule(s)	^{99m}Tc pertechnetate, $^{123}\text{I}/^{124}\text{I}/^{131}\text{I}$ sodium iodide	Patient to avoid foods containing iodine (including sea salt, seafood, cod liver oil, mineral tablets and kelp) for 3 days prior to test. These foods decrease uptake of radiopharmaceutical within thyroid bed. Patient to discontinue thyroid medication for between 3 days and 3 weeks prior to test, depending on specific instructions given by clinician
Parathyroid scan Used to diagnose parathyroid adenomas in patients with primary hyperparathyroidism	^{99m}Tc pertechnetate, ^{201}Tl thallous chloride	This is a two-part test, comprising a thyroid scan which is completed prior to the parathyroid scan. Patient should follow instructions for thyroid test
Tumour imaging Used to differentiate between metabolically active tumours and space-occupying lesions, or for the diagnosis of unknown primary tumours	^{18}F 2-fluorodeoxyglucose (FDG)	Patient to fast for up to 6 hours prior to injection, with only water to be taken. Patients may experience a metallic taste in the mouth immediately after administration. Waiting interval between injection and scan is 30 minutes, scan being performed with a positron emission tomography (PET) camera
Used to diagnose infection and diagnose and stage cancers such as lung, Hodgkin disease lymphomas and neuroendocrine tumours	^{67}Ga gallium citrate	Due to excretion of gallium citrate via the gastrointestinal tract, patients should be given laxatives or encouraged to increase fibre and fluid intake to avoid constipation
Used to diagnose and assess patients with neuroectodermal tumours including pheochromocytomas, neuroblastomas, carcinoid, medullary thyroid cancers and paragangliomas	^{123}I mIBG (meta-iodobenzylguanidine)	Patient must take Lugol's iodine or potassium iodide for 2 days prior to and 3 days after day of administration. mIBG may cause hypertension and is administered slowly over a 10-minute period. On occasions, patients may experience some discomfort at the injection site. This may be relieved by applying heat to the area of discomfort and reducing rate of infusion. For paediatric patients, it is preferable to administer mIBG via a central venous catheter. Some drugs that act on the adrenergic system may interfere with uptake of mIBG
Often used in conjunction with mIBG scans to assist with localization of the primary tumour and sites of metastatic spread in the aforementioned diseases, e.g. neuroendocrine tumours	^{111}In octreotide DTPA-d-Phe-1-octreotide	Patients with insulinoma should have their blood sugar levels monitored before and after injection. An intravenous solution containing glucose should be available in case of hypoglycaemia. Patients should be encouraged to increase fluid and fibre intake to avoid constipation
Sites of infection To identify areas of lymphocyte localization in patients with either acute or chronic inflammatory infections	Labelled white blood cells	50 mL of blood is taken from patient using a 19 G needle. Labelled blood is reinjected after approximately 2 hours, following which patient is scanned later the same day and/or the following day

(continued)

Table 1.3 Radionuclide investigations (*continued*)

Investigation/target organ	Radiopharmaceutical	Procedures and clinical interventions
Gastrointestinal tract		
To determine cause of gastrointestinal bleeding, including Meckel's diverticulum	^{99m}Tc pertechnetate	Patients (usually children) need to fast for 4–6 hours before scan; adults to fast from midnight
Non-imaging studies		
Kidney function		
Measurement of glomerular filtration rate (GFR) provides an assessment of renal function. Often used in renal transplant patients, in compromised renal function due to long-term use of certain drugs (e.g. ciclosporin) or in patients with systemic lupus erythematosus. Oncology patients often have renal function assessed prior to chemotherapy, particularly if regimen includes platinum-based cytotoxic agents	^{51}Cr EDTA (ethylenediamine tetra-acetic acid)	Renal clearance of administered radiopharmaceutical is assessed from residual radioactivity in blood samples taken from patient at either 3 hours, or at 2, 3 and 4 hours post injection. Patient's height and weight are required to enable GFR to be calculated accurately. It is important that no hydration or blood products are commenced during the test as this may alter results of test
Red cell mass/plasma volume		
Often used to diagnose polycythaemia vera in patients with cardiovascular disease	^{125}I human serum albumin, ^{51}Cr or ^{99m}Tc -labelled red blood cells	10 mL of blood is taken from patient using a 19 G needle. Labelled blood is re-injected after approximately 1.5 hours, following which patient's blood is taken at 10-minute intervals for 40 minutes. Patient's height and weight are recorded
Sentinel node localization. Sentinel lymph nodes receive drainage from the breasts (Luini et al. 2005). By undertaking biopsies of these nodes, the surgeon can predict the cancer status of all nodes in the axillary region. This procedure allows for accurate diagnosis of the patient's cancer status, avoiding unnecessary axillary dissection (Schrenk et al. 2005)	^{99m}Tc colloid	0.1–0.2 mL is injected intradermally into the designated area on the breast for location of main sentinel node. Minimum of 1 hour (up to 24 hours) prior to surgical procedure During the procedure all staff must wear their film badges and those handling the specimen must wear finger dosimeters. The theatre door should be labelled with a warning controlled area sign and disposable drapes and gowns should be used. The specimen should be placed in a screw-top container, which is labelled with the radioactive symbol and the details recorded in the log book. The specimen is then stored for 48 hours in a temperature monitored fridge, after which time it is sent to histopathology in the normal way. The radioactive label is removed in histology after 1 week when the specimen is then considered non-radioactive On completion of the procedure, the used drapes, gown and gloves should be placed in a hospital approved clinical waste bag and the environment and waste monitored to ensure no contamination is present. Any contaminated items should be marked radioactive and stored in a secure store until sufficient radioactive decay has occurred. Only then should the warning symbols be removed by the physics department and the waste disposed of as clinical waste
<i>Source: Adapted from Henkin (2006), Peter and Gambhir (2004), Ziessman et al. (2006).</i>		

Common non-imaging studies include investigations into red cell mass and plasma volume, and gastrointestinal tract and renal function (DH 2016).

Principles of care

Radiation protection is more complex than for X-ray procedures because, in addition to the external hazard, there is an internal hazard from contamination arising from contact with the radiopharmaceutical itself or with the patient's body fluids.

Once a patient has been given a radioactive material, they become radioactive themselves; how much and for how long depend on the type and amount of radioactive material used. In the case of diagnostic nuclear medicine, the safety of ward staff nursing these patients can be assured by following very simple advice. The advice regarding therapeutic procedures is more detailed and the nuclear medicine department, Radiation Protection Adviser or Supervisor should always discuss procedures with the ward before the patient is treated (IRMER 2000).

Legal and professional issues

Radiopharmaceuticals are legally categorized as prescription-only medicines (POMs), and, in addition to the standard legislation surrounding the administration of such drugs, are subject to regulations related to their radioactive content. In the UK, a statutory committee called the Administration of Radioactive Substances Advisory Committee (ARSAC) was established to give ionizing radiation advice to health ministers and to manage the certification process for administration of radiopharmaceuticals. This committee issues certificates which authorize individuals to administer radiopharmaceuticals to patients. It also lists the maximum permissible doses of radioactivity that may be administered to adult patients, and appropriately reduced adult doses for children, according to a child's bodyweight or body surface area (HPA 2016).

Pre-procedural considerations

The patient should be physically and psychologically prepared for the procedure so they understand the procedure and give their informed consent (O'Dwyer et al. 2003). The following aspects should be considered prior to the procedure.

Patient considerations

- Pregnant women will generally not be scanned. When essential tests must be undertaken, the patient must sign a consent form and receive a reduced dose of radionuclide. This is to avoid unnecessary irradiation to the abdominal/pelvic region which will include the embryo or fetus (Ionizing Radiation Regulations 1999).
- The person accompanying the patient should not be pregnant, or bring young children or babies with them, so that unnecessary exposure in the time period immediately after the radionuclide administration can be avoided (DH 2016, HPA 2016).
- In women of reproductive age, the possibility of pregnancy must be excluded routinely via a urine test and the patient asked if her menstrual period is late. Patients receiving iodine-131 or any other radioactive agent with a long half-life should not become pregnant for a minimum of 3 months after the procedure (Sharp et al. 1998) to ensure that unnecessary irradiation to the abdomen of a woman who may be pregnant is avoided (HPA 2016).
- If mothers are breastfeeding, then advice from the Radiation Protection Adviser should be sought. Radioactivity can be excreted in breast milk. Therefore, breastfeeding may need to be suspended (HPA 2016) and the mother encouraged to avoid unnecessary cuddling of the child during this time (DH 2016).
- Patients with pain should be provided with effective pain control to ensure they are pain free so that immobility during scan time can be maintained.
- If the patient is incontinent, the test may not go ahead; however, if a decision is made to do so, proceed with caution. Incontinence pads should be worn and universal precautions are to be adopted, to limit the spread of contamination. Disposable gloves and apron should be worn and hand washing performed following patient contact, as these will prevent contamination of staff in close contact with the patient (DH 2016). Urine bags must be emptied regularly to remove the radioactivity from the patient area. Items must be disposed of in hospital approved body fluid and clinical waste.
- Debilitated patients may require prolonged close contact. Nursing staff should share the care of these patients, by regular rotation of staff. This will keep doses to staff as low as possible and avoid prolonged exposure to any one member of staff (DH 2016).
- Patients should keep to a minimum prolonged close contact (less than 1 metre) with anyone who is pregnant.
- Patients should keep to a minimum prolonged close contact (less than 1 metre) with any child under the age of 5 years.
- Patients should pay extra attention to their own personal hygiene, washing their hands thoroughly after each visit to the lavatory.

- Drink plenty of fluids and empty their bladder frequently, as this will hasten the removal of the radioactive tracer from the body (DH 2016, HPA 2016, Sharp et al. 1998).

Ward considerations

Although the amount of radioactivity administered is low, the patient will emit a small amount of radiation for some time after the radioactive tracer has been given. The amount of radioactivity within the patient decreases in two ways. The first way is by the natural physical decay of the radioisotope used, which we cannot change. The second way is by excretion of the radioactive tracer from the patient's body, usually via the urine and occasionally the faeces (HSE 2014, HPA 2016, Vialard-Miguel et al. 2005).

All patients who have been administered a radiopharmaceutical will be issued a yellow wrist or ankle band. The purpose of the yellow band is to act as a visual, easily recognized indicator of the fact that a patient has attended for a nuclear medicine investigation. The band should only be worn on the day of the scan unless the patient is specifically instructed to the contrary and has been given clear radiation protection instructions. Patients wearing a yellow band will also have been issued with a card outlining basic precautions and listing contact telephone numbers if they (or a ward/department) have any queries. When nursing patients who have received a radiopharmaceutical, nurses and other healthcare providers should adhere to the following guidelines.

Patient care

- Nurse in an appropriate controlled area of the hospital designed to manage patients with radioactive sources.
- Encourage their patient to take in plenty of fluid and empty their bladder frequently.
- Wear gloves when emptying catheter bags or bedpans, but dispose of the urine/faeces in the usual way.
- Try to empty catheter bags (if in use) frequently and not allow them to get too full.
- Minimize time spent in close proximity of patients.
- All emergency procedures such as cardiac arrest or deterioration must continue to be provided with adequate safeguards in place such as healthcare professional monitoring, rotation of emergency responders and the ability to manage patients in other settings such as critical care or operating theatres (HPA 2016, Resuscitation Council 2015).

Blood samples and further tests

- Where possible, all blood tests should be performed prior to administration of the radiopharmaceutical.
- Only clinically urgent blood tests may be performed on patients with yellow wrist bands.
- If samples are to be taken from patients with yellow bands, then both the sample and the form *must* have a radioactive sticker placed on them. The pathology department must contact radiation protection to collect and dispose of the sample after testing has been performed.
- Further examinations such as X-ray or CT may be carried out on patients; however it is best practice for the patient to inform the nuclear medicine team of their appointments prior to administration of the radiopharmaceutical (Larkin et al. 2011).

Contaminated sharps or dressings

When removing inserted devices from patients wearing yellow bands, the waste items should be placed in an orange bag or sharps bin (radioactive specific) and taken to the nuclear medicine department.

- These items can then be handed to a member of staff for disposal.
- When handing the item over, please ensure the receiving staff member is told of the patient's details so that it may be disposed of correctly (DH 2013, HSE 2003).



Figure 1.5 Thermoluminescent dosimeter (TLD) badge.

Body fluid and body fluid spillage management

In the event of a patient's incontinence or a spill from a bedpan, catheter bag or other body fluid:

- The soiled linen should be placed in an orange clinical waste bag, and clearly labelled 'Radioactive – Do not dispose'.
- Contact the department of nuclear medicine or Radiation Protection Service to arrange for collection or further advice. It is important to follow local hospital guidelines as local variation may occur (DH 2013, HSE 2003).

Equipment

There are various additional pieces of equipment that are required to safely undertake the procedure. These include lead-lined receptacles and monitoring devices.

Lead-lined equipment

Lead-lined equipment is required to protect the clinician or operator and the environment from radioactive sources.

- **Lead shields.** All syringes containing radiopharmaceuticals should be in a shielded compartment. This is a lead shield to protect the fingers of the operator.
- **Lead-lined disposal bins.** All clinical waste should be disposed of in lead-lined clinical waste and sharps bins. The disposal of this waste must be followed as per hospital policy (DH 2016, HPA 2016).



Figure 1.6 Hand and foot radiation monitor.
Source: Dougherty and Lister (2011).

Monitoring equipment

- **Staff radiation protection.** All staff administering radiopharmaceuticals should be provided with body thermoluminescent dosimeter (TLD) film badges (Figure 1.5).
- **Contamination monitors** to check hands and feet of staff (Figure 1.6). The contamination monitors are required to check the environment at the end of each day or more frequently if a spill occurs. Local hospital guidelines must be followed in the event of a spill of a radiopharmaceutical or contaminated body fluid (HPA 2016).

Procedure guideline 1.2 Unsealed radioactive sources for diagnostic investigations

Essential equipment

- Selection of needles (safety needles may not be appropriate therefore use needles as per local guidelines and specific procedures) and syringes (sizes dependent on volume required)
- Various gauge sizes of cannula
- Alcohol wipes
- Syringe shield
- Lead shield
- Tape and gauze
- Documentation regarding the isotope to be administered
- Radioactive isotope
- Disposable apron and non-sterile gloves
- Thermoluminescent dose (TLD) finger meter
- Film badge
- Sharps bin (radioactive specific)

Pre-procedure**Action****Rationale**

- | | |
|---|---|
| 1 Explain and discuss the procedure with the patient, and, if relevant, with the relative/significant other accompanying the patient. | To ensure the patient is physically and psychologically prepared for the procedure and understands the procedure and gives their informed consent (O'Dwyer et al. 2003, E). |
| 2 Before administering, look at the patient's prescription chart or protocol and confirm patient's identity. | To ensure the correct patient is given the correct radioactive source (NMC 2010b, C). To protect the patient from harm (NMC 2010b, C). |
| 3 Apply the relevant TLD meter and film badge. | To measure radiation doses received by member of staff (Ionizing Radiation Regulations 1999, C). |
| 4 Wash hands with liquid soap and warm water. | To reduce the risk of contamination (DH 2016, C). |
| 5 Apply disposable gloves and plastic apron. | To reduce the risk of contamination (DH 2016, C). |

Procedure

- | | |
|---|--|
| 6 Cannulate patient as per 'Procedure guideline 14.4 Peripheral cannula insertion' in <i>The Royal Marsden Manual of Clinical Nursing Procedures, Ninth Edition</i> . | To ensure venous access is obtained. E |
| 7 Place the empty syringe in a lead syringe shield and attach needle. Place behind the lead body shield. | To reduce exposure to radiation (DH 2016, C ; IRMER 2000, C). |
| 8 Stand behind lead body shield and draw up the prescribed dose of the radiopharmaceutical. | To reduce exposure to radiation (DH 2016, C). |
| 9 Administer the radionuclide intravenously via cannula with cap. There is no evidence to support the use of central venous access devices (CVADs). Please refer to local guidelines. | To administer the radionuclide. E |
| 10 Remove cannula, apply pressure and cover the exit site with gauze and secure with tape. | Prevent any blood loss from skin exit site and possible contamination. E |
| 11 Dispose of all used syringes, needles, and cannula in a designated radioactive sharps disposal bin which is stored within a lead shield. | To contain radioactivity and allow safe disposal (Ionizing Radiation Regulations 1999, C). |
| 12 Remove disposable gloves and wash hands at end of procedure. | To remove any possible radioactive contamination (DH 2005, C ; DH 2000, C). |

Post-procedure

- | | |
|---|--|
| 13 Place a yellow identity bracelet on the wrists of all inpatients and complete information card with the details of when precautions can be discontinued. Give the completed information card to the patient or the nurse accompanying the patient. | The yellow wristband will provide visual warning to inform all healthcare workers of the patient's recent diagnostic investigation. The information card will inform ward staff of restrictions related to managing a patient, as well as when measures that have to be adopted in the event of the patient vomiting or being incontinent can be discontinued (DH 2000, C). The card also states where to obtain help and advice related to the patient's diagnostic investigation. E |
| 14 Sign and complete administration documentation. | To ensure timely and accurate record keeping (NMC 2010a, C). |
| 15 Monitor hands at end of procedure and before leaving the room by using the hand and foot monitor. | To check for possible radioactive contamination (DH 2000, C). |
| 16 Monitor the room for radioactive contamination at the end of each day or if contamination may have occurred. | To establish whether contamination has occurred (DH 2000, C). |

Post-procedural considerations**Immediate care**

As the patient will excrete the radioactive substance, avoid urine, faecal and blood sample collection for laboratories other than nuclear medicine for the first 24 hours. If collection is unavoidable, a radiation warning sticker must be attached to the specimen and request card, and the specimen taken to the laboratory under the supervision of the physics departmental staff. This is to prevent contamination of the laboratory and its staff, as specimens taken within 24 hours of some scans may contain radioactivity (HPA 2016, HSE 2003, Vialard-Miguel et al. 2005). If an

outpatient or inpatient has an acute deterioration and requires additional inpatient or critical care, follow the 'ward considerations' discussed earlier in this chapter with guidance from the physics department (HPA 2016).

Ongoing care

Bone marrow and stem cell harvests should be avoided for 24 hours. Advice should be sought from the physics department as cells may contain radioactivity (HSE 2003, Vialard-Miguel et al. 2005). Seek advice from physics staff if the patient is to undergo a procedure in the operating theatre within 24 hours of a scan in order to prevent theatre equipment from becoming contaminated

with radioactivity. Place soiled bed linen used within the first 24 hours of certain scans, for example bone scan, within an orange plastic bag (radioactive specific) and inform the physics departmental staff for collection (HPA 2016). Other issues concerning the management of patients undergoing radionuclide therapy are discussed in Chapter 5.

Education of patient and relevant others

Patients and relevant others should be provided with education and information leaflets prior to leaving the department. Patient care, considerations and information should also be provided for healthcare professionals from referring hospitals prior to the patient's discharge or transfer (HSE 2006, SNMMI 2016).

Transrectal ultrasound (TRUS) prostate biopsy

Definition

A transrectal ultrasound and prostate biopsy (TRUS Bx) uses an ultrasound probe to visualize the prostate. Once the prostate can be seen, a fine biopsy needle is passed down a probe guide to take small tissue samples from the prostate. The number of tissue samples taken ranges from 2 to 12 depending on local policy and degree of clarification required (Turner et al. 2011).

Anatomy and physiology

The prostate gland has an average volume of 25 mL. It is approximately 3.5 cm long, 4.0 cm wide and 2.5 cm deep from posterior to anterior – about the same size as a walnut (Tortora and Derrickson 2014).

The prostate is an extraperitoneal structure, lying anterior to the rectum and sitting around the neck of the bladder encircling the urethra. It comprises three distinct areas/zones: the central, peripheral and the transition zones, which conform to a cone or inverted pyramid. The base of the prostate lies against the bladder and the apex on the urogenital diaphragm, which is a fibrous supporting ring that also contains the urethra. The gland is surrounded by the prostate capsule and beyond that smooth muscle and connective tissue. Between the prostate gland and the rectum

lies Denonvilliers' fascia – a peritoneal plane or space (Turner and Pati 2010, Turner et al. 2011) (Figure 1.7).

Related theory

As a man ages, the transition zone increases in size due to benign prostate enlargement (BPE) while the central zone atrophies and the peripheral zone remains the same. It is the peripheral zone, however, in which the majority of prostate cancers are found and therefore clinically this is the most important region to target during prostate biopsy.

Transrectal biopsy of the prostate is most commonly undertaken in an outpatient setting. Many thousands of prostate biopsies are undertaken every year throughout the UK. First described by Astraldi in 1937, it remains the gold standard investigation for diagnosing prostate cancer (Turner et al. 2011).

Prostate biopsy specimens

The number of specimens to be collected and the location will depend on the patient's clinical condition. The following should be considered when determining specimen collection:

- Ultrasound does not detect areas of prostate cancer with adequate reliability and therefore targeted prostate biopsies on the basis of ultrasound alone are unproductive. However, occasionally additional biopsies of abnormal areas identified on magnetic resonance imaging (MRI) can be useful (Heidenreich et al. 2014, Siddiqui et al. 2015). On the first biopsy (baseline biopsy) the sample sites should be as far posterior and lateral in the peripheral zone as possible.
- When cancer is suspected a 12 core biopsy protocol should be observed (Heidenreich et al. 2014). However, if the patient has proven or strongly suspected advanced prostate cancer or is part of a clinical trial, limited cores should be taken (2–4 being optimal).
- The 12 core biopsy protocol is as follows (Figure 1.8):
 - right apex lateral × 2
 - right mid lateral × 2
 - right base lateral × 2
 - left apex lateral × 2
 - left mid lateral × 2
 - left base lateral × 2.

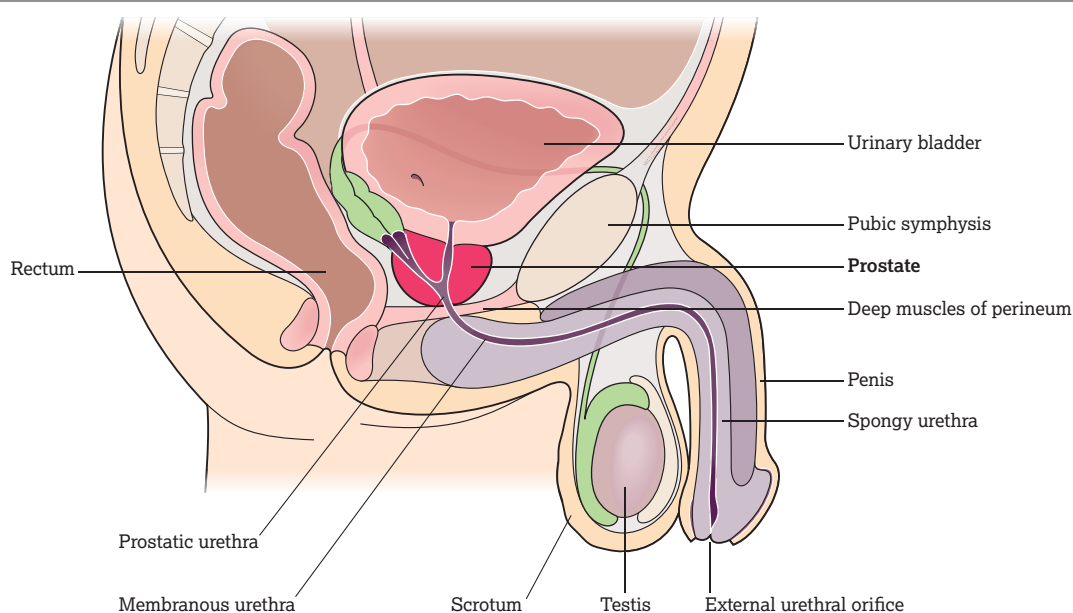
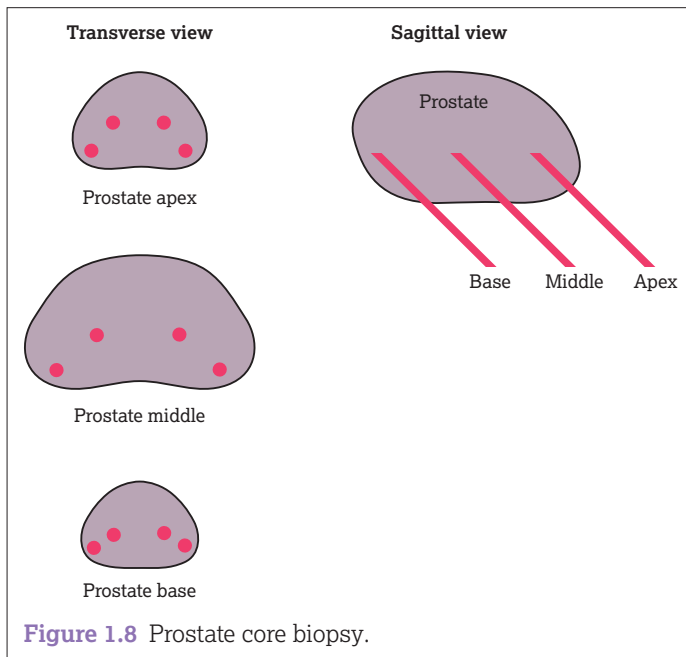


Figure 1.7 The prostate and its zones. *Source:* Adapted from Tortora and Derrickson (2011). Reproduced with permission of John Wiley & Sons.



Evidence-based approaches

Rationale

A prostate biopsy should only be considered and undertaken if it influences the management of the patient. It should be determined on the basis of the PSA level and/or a suspicious digital rectal examination (DRE) and/or suspicious prostate MRI. Factors such as patient age and co-morbidities should also be considered (Batura and Gopal Rao 2013).

Indications

There are many indications for prostate biopsy which include:

- raised PSA level in the absence of urinary tract infection, acute urinary retention or acute prostatitis
- abnormalities identified through DRE or MRI of the prostate
- patients being assessed for radiation failure (i.e. PSA increases post radiotherapy)
- patients on an active surveillance protocol requiring repeat biopsies
- patients with previous histology requiring repeat biopsy (e.g. high-grade prostatic intra-epithelial neoplasia or suspicious but not diagnostic for carcinoma)
- patients on an ethically approved clinical trial (NICE 2014, Turner et al. 2011).

Contraindications

It is important to note that patients with the following risk factors may require special preparation:

- patients on anticoagulation therapy or with coagulation disorders that may interfere with haemostasis and increase the risk of haemorrhage. Low-dose aspirin (75–150mg) is not a contraindication but discontinuation should be discussed with the medical team
- patients with an identified urinary tract infection as the risk of septicaemia may be increased
- patients with an allergy to latex, antibiotics or local anaesthetic
- patients with diabetes mellitus who may be at increased risk of infection
- patients on steroid medication which may increase the risk of infection

- patients who are immunocompromised. It may be necessary to seek advice from other healthcare professionals on complex medical conditions
- patients with urinary obstruction (Giannarini et al. 2007, Lange et al. 2009, Loeb et al. 2013).

There is a lack of agreement in the literature specifying those with an absolute increased risk of complications. It is therefore at the discretion of the person performing the procedure to proceed to biopsy based on local policy and/or professional judgement. However, it has been suggested that certain patient groups should undergo biopsy by a transperineal approach only (Miller et al. 2005). This includes those with:

- prosthetic cardiac valve or prosthetic material used for cardiac valve repair
- congenital heart disease (CHD)
- completely repaired congenital heart defect with prosthetic material or device, whether placed by surgery or by catheter intervention, during the first 6 months after the procedure
- repaired CHD with residual defects at the site or adjacent to the site of a prosthetic patch or prosthetic device (which inhibit endothelialization)
- cardiac transplantation recipients who develop cardiac valvulopathy.

Some patients should be considered for exclusion from biopsy altogether and managed conservatively. This will require local agreement. Such patients are those with:

- previous infective endocarditis
- CHD (dependent on clinical assessment and review)
- unrepaired cyanotic CHD, including palliative shunts and conduits.

Legal and professional issues

The nurse is required to have an intimate understanding of the anatomy and physiology of the male urinary system, factors that affect PSA measurement and other conditions of the urinary system and their management. In addition, the nurse must be competent in DRE and have a thorough understanding of the role of TRUS and possible ultrasound findings as well as familiarization with the possible complications of TRUS and their management (Greene et al. 2015).

For nurse specialists a minimum of 20 cases should be performed under supervision (Greene et al. 2015, Turner et al. 2011, Turner and Pati 2010). The nurse could be trained by any competent healthcare professional but ultimately competence should be assessed by an experienced practitioner, usually a urologist or radiologist. Each practitioner should regularly audit the outcome and management of complications. Examples and guidance for how this can be achieved exist within the published literature (Greene et al. 2015, Turner and Pati 2010).

Consent

At the appointment at which the biopsy is requested, the patient should be counselled about the procedure and a transrectal prostate biopsy information sheet should be given, for example the British Association of Urology Surgeons' Prostate Biopsy patient information leaflet' (BAUS 2017). This information leaflet outlines the procedure in detail including benefits, risks, potential complications and emergency contacts. Patients should be warned of the possible side-effects (Table 1.4) as part of the informed consent process.

It is imperative that the procedure, potential complications, potential outcomes and discomfort to the patient are explained to the patient. Answer questions at a level and pace appropriate to the patient's understanding, culture and background, preferred way of communicating and needs. Both verbal and written consent must be obtained from the patient (DH 2009). The signed consent should be scanned to the patient's electronic records or kept in their clinical notes as a hard copy.

Table 1.4 Possible side-effects of transrectal ultrasound and prostate biopsy

Frequency	Side-effect
Common (greater than 1 in 10)	Blood in urine Blood in semen for up to 6 weeks Blood in stools Urinary infection (up to a 10% risk) Discomfort from the prostate due to bruising Haemorrhage (bleeding) causing inability to pass urine (2% risk)
Occasional (between 1 in 10 and 1 in 50)	Blood infection (septicaemia) needing admission to hospital (2% risk) Haemorrhage (bleeding) needing admission (1% risk) Failure to detect a significant cancer of the prostate
Rare (less than 1 in 50)	Inability to pass urine (retention of urine)
Hospital-acquired infection	Colonization with MRSA (0.9% – 1 in 110 patients) MRSA bloodstream infection (0.02% – 1 in 5000 patients) <i>Clostridium difficile</i> bowel infection (0.01% – 1 in 10,000 patients)

Source: Adapted from BAUS (2017).
MRSA, meticillin-resistant *Staphylococcus aureus*.

It is a legal requirement to seek written consent for transrectal biopsy. The healthcare professional responsible for carrying out the procedure is ultimately responsible for the patient consent for the examination (DH 2009, Turner and Pati 2010).

Consent should be taken using a dedicated consent form in which the following should be discussed with the patient:

- how the biopsy is taken
- the risks and benefits of the procedure
- potential complications of the procedure and whether the risk is major or minor
- the number of cores that will be taken
- if any additional cores will be taken using MRI fusion.

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

- false negative result
- need for repeat biopsy
- cancer diagnosis.

Pre-procedural considerations

General assessment

A general assessment of the patient's fitness for the procedure is required. This is to include the ability to use local anaesthesia, including previous allergies to local anaesthetics. Identify any risk factors for which special precautions may be required. Determine the need for the biopsy and decide whether or not to proceed. If not already done, take a comprehensive health history including presenting complaint, health history, medication, family and social history.

Voiding studies

Before biopsy, the patient should undergo uroflowmetry with post urinary residual measurement. This should be recorded in

**Figure 1.9** Ultrasound machine and probe.

the patient's notes and annotated in the post biopsy letter. If the post void residual urine is >150mL, an alpha-blocker should be considered (Bozlu et al. 2003).

Equipment

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. An ultrasound machine and probe must be available and in working order and used as per manufacturer's guidelines (Figure 1.9). Various needles and biopsy guns are available (Figure 1.10) and should be used as per manufacturer's guidelines.

Emergency equipment

Emergency equipment should be easily accessible in the rare event of a major complication such as uncontrollable bleeding per rectum or per urethra, retention of urine, anaphylaxis or vasovagal syncope.

Pharmacological support

Aerobic or anaerobic organisms may be introduced when performing TRUSBx, the more common being *Escherichia coli*, *Streptococcus faecalis* and *Bacteroides*. 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 (Kapoor et al. 1998, Sieber et al. 1997, Zani et al. 2011).

Currently fluoroquinolones are the antibiotics of choice in transrectal US-guided prostate biopsy. Fluoroquinolones are well absorbed orally and have good prostate tissue levels (Hori et al. 2010, Lange et al. 2009). Evidence suggests that one dose is as effective as multiple-dose prophylaxis (Aron et al. 2000). The



Figure 1.10 Example of TRUS biopsy equipment.

addition of gentamicin or metronidazole is optional (Bootsma et al. 2008).

As a standard, all patients should have a negative midstream urine (MSU) previous to the biopsy. If a negative MSU was obtained more than 4 weeks before the biopsy, a confirmatory dipstick test should be done on the day of the procedure.

There is a clear trend towards an increase in the rates of infectious complications after TRUS biopsy in the past few decades (Loeb et al. 2013, Nam et al. 2013). Accordingly, many authors

reported rising rates of antimicrobial, particularly quinolone, resistance (Feliciano et al. 2008, Williamson et al. 2013). It is therefore important to consider risk factors for pre-biopsy quinolone resistance (Challacombe et al. 2011, Patel et al. 2012, Taylor et al. 2012) such as:

- travel to Asia/Africa/Latin America in the previous 8 weeks
- use of quinolone in the previous 6 weeks
- chronic immunosuppression – chronic obstructive pulmonary disease (COPD), diabetes mellitus or long-term steroids use
- indwelling urinary catheter
- history of recurrent urinary tract infections.

If a patient has one of these risk factors a rectal swab should be considered to screen for quinolone resistance (Liss et al. 2015, Taylor et al. 2012). If this is not available, consider adding intravenous gentamicin 5 mg/kg (based on ideal bodyweight if the patient is obese, i.e. actual bodyweight is 20% higher than ideal bodyweight), 60 minutes before the procedure in this high-risk group of patients (Ho et al. 2009).

Lidocaine 1% is the standard agent for an ultrasound-guided peri-prostatic block. In addition, an intrarectal instillation of local anaesthetic can be done (Raber et al. 2008, Yun et al. 2007) at the discretion of the examiner. However, it should not be used as an isolated method, as it is inferior to the peri-prostatic block (Lee and Woo 2014).

Special recommendations

A cleansing enema before biopsy provides no clinically significant outcome advantage and potentially increases patient cost and discomfort. It is therefore not recommended (Carey and Korman 2001).

Procedure guideline 1.3 Transrectal ultrasound (TRUS) prostate biopsy

Essential equipment

- Biopsy gun
- Long spinal needles (to administer anaesthetic) – 20 cm
- Ultrasound probe cover (condom)
- Specimen pots – pre-labelled
- Lubricating jelly
- Wipes/gauze
- Non-sterile gloves
- Needle guide to accommodate biopsy gun gauge
- Sharps bin

- Pathology sponges
- Pathology cassettes
- Sterile gloves
- Sterile gown

Medicinal products

- Antibiotic prophylaxis – patient specific (if not previously administered)
- Local anaesthetic – lidocaine 1% (10 mL)

Pre-procedure

Action

- 1 Check the environment, equipment and medication to ensure that everything is present for the procedure, including access to relevant personnel and emergency equipment.
- 2 Ask assistant to set up trolley with sterile urology pack and in date sterile equipment.
- 3 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 attach the needle guide without splitting the condom.
- 4 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.
- 5 Greet and accurately identify the patient and introduce yourself and any colleagues present.

Rationale

- To ensure the procedure will take place without delay for the patient and to ensure that the safety of the patient is addressed (Turner et al. 2011, **E**).
- To maintain infection control standards and minimize cross-infection and contamination (RCN 2017a, **C**).
- To ensure the equipment is functioning and ready for use (Turner et al. 2011, **E**).
- To ensure correct identification of the patient and to identify details that might require an adaptation of the procedure (Turner et al. 2011, **E**).
- To reduce patient anxiety and to ensure correct identification of the patient (Turner et al. 2011, **E**).

(continued)

Procedure guideline 1.3 Transrectal ultrasound (TRUS) prostate biopsy (*continued*)

Action

- 6 Take a written consent using a dedicated consent form in which the following should be discussed with the patient:
 - how the biopsy is taken
 - the risks and benefits of the procedure, potential complications of the procedure and whether the risk is major or minor
 - the number of cores that will be taken
 - if any additional cores will be taken using MRI fusion.
- 7 Ensure the patient has removed clothing below the waist and offer a gown.
- 8 Ensure the patient has taken antibiotic prophylaxis as prescribed locally.
- 9 Position the patient correctly for the procedure (left lateral position ensuring that the knees are bent up towards the chest) and ensure their comfort within the constraints of the procedure, taking appropriate action to protect the patient's privacy and dignity throughout.
- 10 Wash and dry hands using a bactericidal soap and apply non-sterile gloves.
- 11 Undertake a digital rectal examination to identify symmetry, size, the presence of nodules, and tenderness and pain associated with the prostate. Careful attention should also be paid to exclude the presence of anal pathology or any other anomalies that may influence the procedure.
- 12 Remove gloves and dispose of them. Wash and dry hands.
- 13 Apply non-sterile gloves and check the local anaesthetic agent to be used then draw up required volume into a syringe and attach the spinal needle ready for administration (the use of intrarectal lidocaine gel is optional).

Rationale

- The healthcare professional responsible for carrying out the procedure is ultimately responsible for the patient consent for the examination (BAUS 2017, **C**; DH 2009, **C**; Turner and Pati 2010, **E**).
- To provide privacy and comfort for the patient. **E**. To minimize the risk of a hospital acquired infection (BAUS and BAUN 2012b, **C**).
- To ensure appropriate steps have been taken to prevent infection (Kapoor et al. 1998, **1b**; Sieber et al. 1997, **C**; Zani et al. 2011, **R1a**).
- The left lateral position is preferred, particularly with an end firing probe, as imaging of the apex is easier and more comfortable for the patient (Vassalos and Rooney 2013, **C**).
- To minimize the risk of infection (Loveday et al. 2014, **C**).
- Any abnormality in shape of the prostate may necessitate additional biopsies to the standard biopsy protocol that is used. However, if the rectum is full of faeces and/or anal pathology is identified, transrectal biopsy is contraindicated (Greene et al. 2015, **C**).
- To minimize the risk of cross-infection (Loveday et al. 2014, **C**). To dispose of clinical waste (DH 2013, **C**; HSE 2003, **C**).
- To minimize the risk of cross-infection (Loveday et al. 2014, **C**). To ensure patient is comfortable. **E**.

Procedure

- 14 Apply lubricating gel to the covered TRUS 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 (Turner et al. 2011, **E**).
- 15 Scan and identify the prostate gland, seminal vesicles and surrounding structures, locating the apex and base of the prostate on the ultrasound image. The prostate volume should be measured in three dimensions. In the transverse view:
 - anterior to posterior (width)
 - height and, in the longitudinal plane,
 - from the bladder neck to the apex (length).

Final volume can be calculated using the formula:
 $H \times W \times L \times 0.52$.

To orientate the operator and to identify areas to biopsy (Greene et al. 2015, **C**).
- 16 Take volume measurements and make note of any abnormalities detected on ultrasound and either print images or store them on the ultrasound machine for future reference.

To provide information that may be useful when discussing treatment options with the patient in the future. **E**.
- 17 Inform the patient that the local anaesthetic is about to be administered.

To reduce patient anxiety (Greene et al. 2015, **C**).
- 18 Introduce the local anaesthetic needle through the biopsy channel of the ultrasound probe until the needle tip can be visualized on the screen in the peri-prostatic tissue.

To promote patient comfort. To reduce pain (Turner et al. 2011, **E**).
- 19 Commence infiltration of the local anaesthetic observing the passage of the fluid throughout the peri-prostatic area.

Ultrasound-guided peri-prostatic block is standard. It does not make any difference whether the depot is apical or basal as long as it is given into Denonvilliers' fascia. In addition, an intrarectal instillation of local anaesthetic can be done (Raber et al. 2008, **R1b**; Yun et al. 2007, **R1b**) at the discretion of the examiner. However, it should not be used as an isolated method as it is inferior to the peri-prostatic block (Lee and Woo 2014, **R1a**).

20 Withdraw the needle and discard into a large 5 litre sharps bin.	To prevent sharps injury (DH 2013, C ; HSE 2003, C).
21 Identify the appropriate locations for the biopsy samples according to clinical need, e.g. MRI findings, DRE findings or confidence in diagnosis of cancer.	To ensure the correct areas are biopsied and minimum number of cores taken to ensure a diagnosis is made (Greene et al. 2015, C).
22 Introduce the biopsy needle along the biopsy channel until the needle tip can be visualized on the screen in the peri-prostatic tissue, adjacent to the target area.	To ensure the correct areas are biopsied and minimum number of cores taken to ensure a diagnosis is made (Greene et al. 2015, C).
23 Inform the patient that the biopsy is about to be taken and warn them of the sound of the biopsy gun (sounds like a staple gun) and commence taking tissue samples.	To ensure patient comfort and to reduce anxiety (Greene et al. 2015, C).
24 Fire the biopsy gun and then withdraw it after firing on each occasion, in order to lay each tissue sample onto a sponge (a maximum of two per sponge). Repeat process. Lay a second sponge on top of the first after two samples have been taken.	Prostate biopsy cores taken from different sites should be sent to the laboratory with the use of sponges and cartridges in separate pots. This ensures that the cores do not become fragmented during transportation to the lab (Heidenreich et al. 2014, C).
25 Ensure that the samples taken are adequate for histopathology by comparing the length of the core with the length of the needle notch.	To ensure the correct length is taken and there is consistency of sampling (Greene et al. 2015, C).
26 Take additional samples only where there is clinical concern, e.g. abnormality found on DRE or seen on ultrasound or MRI.	To ensure the correct areas are biopsied and minimum number of cores taken to ensure a diagnosis is made (Greene et al. 2015, C).
27 Assess the patient's tolerance throughout the procedure and ensure they are happy to continue.	To ensure patient comfort. E .
28 Direct the assisting nurse to place each sponge sandwich into a cassette before inserting into a correctly and accurately pre-labelled sample container containing 10% formalin.	To ensure specimen is labelled correctly (NMC 2010a, C ; WHO 2015, C).
29 Remove the TRUS probe from the patient's rectum and insert prophylactic antibiotic if indicated by local policy.	To minimize the risk of infection (Kapoor et al. 1998, R1b ; Sieber et al. 1997, C ; Zani et al. 2011, R1a).
Post-procedure	
30 Wipe rectum, offer a surgical pad to protect the patients underwear and remove and discard gloves	To promote patient comfort. E .
31 Assist the patient into a sitting position.	To promote patient comfort. E .
32 Assess the patient for any complications and take appropriate action.	To ensure patient safety and comfort. (Greene et al. 2015, C).
33 Recognize the need for immediate management of acute emergencies associated with the procedure and respond appropriately.	To ensure patient safety and comfort (Greene et al. 2015, C).
34 Assess the patient's needs following the procedure and offer any verbal support, as required.	To promote patient comfort. E .
35 Ensure the patient has all required information and medication. Reiterate the possible complications and how they should be managed.	To ensure patient safety and reduce the risk of serious side-effects following the procedure (Greene et al. 2015, C).
36 Assess the patient's fitness for discharge by ensuring patient has voided and there are no other adverse events.	To ensure patient safety (Greene et al. 2015, C).
37 Ensure the ultrasound probe is cleaned in line with local infection control policy.	To ensure the safety of staff and patients. E .
38 Ensure that single-use items and sharps are disposed of and that non-disposable equipment is cleaned and/or sterilized.	To minimize the risk of cross-contamination and infection risks (DH 2013, C ; HSE 2003, C).
39 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 (NMC 2010a, C ; WHO 2015, C).
40 Record the details of the procedure in the patient's record, including details of the local anaesthetic and any medication given.	To ensure patient safety and accurate records for other practitioners who may see the patient (NMC 2010a, C ; WHO 2015, C).

(continued)

Procedure guideline 1.3 Transrectal ultrasound (TRUS) prostate biopsy (continued)

Action	Rationale
41 Ensure that steps are taken to inform any other relevant practitioners of the procedure and plan, e.g. GP.	To ensure all relevant healthcare providers are informed of the procedure and its outcome. E .
42 Make the patient a follow-up appointment to discuss the results of the biopsy (usually 1–2 weeks).	To ensure adequate post-procedure follow-up (Greene et al. 2015, C).
43 Recognize when you need help and/or seek advice from appropriate sources.	To ensure patient safety (Greene et al. 2015, C).

Post-procedural considerations**Immediate care****Management of acute post-biopsy complications**

Patients should be discharged with clear instructions on recognizing post-biopsy complications. Depending on the indication, patients with a severe complication (fever, urinary tract infection, acute bacterial prostatitis) after TRUS-guided prostate biopsy should have a course of antibiotic treatment (i.e. not just antibiotic prophylaxis for the prevention of surgical site infections). Some patients may require admission to hospital, such as those requiring intravenous antibiotics (urosepsis), or require catheter insertion (clot retention). Prompt recognition and initiation of antibiotic and support measures can save lives (Vassalos and Rooney 2013).

Biopsy complications**Acute bleeding – rectum (<2 days 1.3–45%, >2 days 0.7–2.5%)**

A small volume of per-rectal bleeding is expected after the procedure. In the instance of abnormal significant bleeding the procedure should be stopped and transrectal direct finger pressure must be applied. The insertion of a balloon tamponade with a large-bore Foley catheter (50mL saline in the balloon) is the next step (Challacombe et al. 2011). In the case of continuous bleeding, the patient should be admitted for observation and the consultant/urology specialist registrar should be informed.

Acute bleeding – urethra

Spontaneous urethral bleeding is not common but can occur during TRUS biopsy. If the bleeding does not subside, the patient should be admitted and the consultant/urology specialist registrar should be informed. A three-way 18Fr Foley catheter should be inserted, with gentle traction applied over the bladder neck (Rodriguez and Terris 1998).

Haematospermia (1.1–93%)

A small volume of blood in the semen is known as haematospermia. Prostate biopsy is the most common cause of blood in the semen. In the case of very vascular prostates it can take up to 6 weeks for haematospermia to clear up. There is no treatment.

Haematuria

Some degree of haematuria is very common. If the patient has severe haematuria with clot retention, he should be admitted. A 22Fr three-way silicone Foley catheter should be inserted, followed by bladder washout and continuous bladder irrigation with normal saline. In case of severe bleeding, formal washout in theatre may be required (Challacombe et al. 2011).

Urinary retention (0.2–1.7%)

All patients must spontaneously void before being discharged. If a patient complains of abdominal pain with inability to void or has no pain but a full bladder (confirmed on ultrasound), an 18Fr Foley catheter should be inserted. An alpha-blocker, e.g.

tamsulosin 400µg, should be prescribed, and a trial of voiding without catheter should be booked to take place 7–10 days later (Batura and Gopal Rao 2013, Challacombe et al. 2011, Feliciano et al. 2008).

Vasovagal syncope

If the patient enters a pre-syncope state, the procedure should be immediately stopped. The probe should be removed from the rectum and the patient should be positioned in dorsal decubitus with a 30° Trendelenburg (on back, head down) position. Vital signs should be recorded. In case of complete loss of consciousness or sustained instability, the resuscitation or emergency team should be informed (Aydin et al. 2010).

Ongoing care**Post prostate biopsy review appointment**

It is good practice to organize a return appointment for the patient to discuss the results of their biopsy before they have left the department. This will reduce the patient's anxiety caused by waiting for an appointment in the post. Usually this appointment is made 7–14 days after the biopsy to ensure the results are acted on expediently.

Audit

It is essential that the practitioner maintains a record of all procedures undertaken. This includes the review of histology results. This enables the practitioner to provide evidence of good practice and areas for improvement and development (Turner and Pati 2010).

Flexible cystoscopy**Definition**

Flexible cystoscopy is a camera examination used to visualize the lower urinary tract including the urethra (including prostatic urethra), sphincter, bladder and ureteric orifices. Cystoscopy can assist in identifying problems with the urinary tract, such as early signs of bladder cancer, surveillance of bladder cancer, infection, strictures, obstruction, bleeding and other abnormalities. It is also an effective method for removing ureteric stents when they are no longer therapeutically indicated and in some cases treating some bladder abnormalities. The procedure is performed under local anaesthetic with the patient awake and takes place in a dedicated outpatient facility (Kumar and Clark 2016, Tortora and Derrickson 2014).

Anatomy and physiology

The urinary bladder is a muscular, expandable organ, hollow in nature, that is used as a storage and emptying structure for urine. It collects urine excreted by the kidneys, which enters the bladder from the ureters before disposal by urination, the urine exiting the body through the urethra (Marieb and Hoehn 2015) (Figure 1.11).

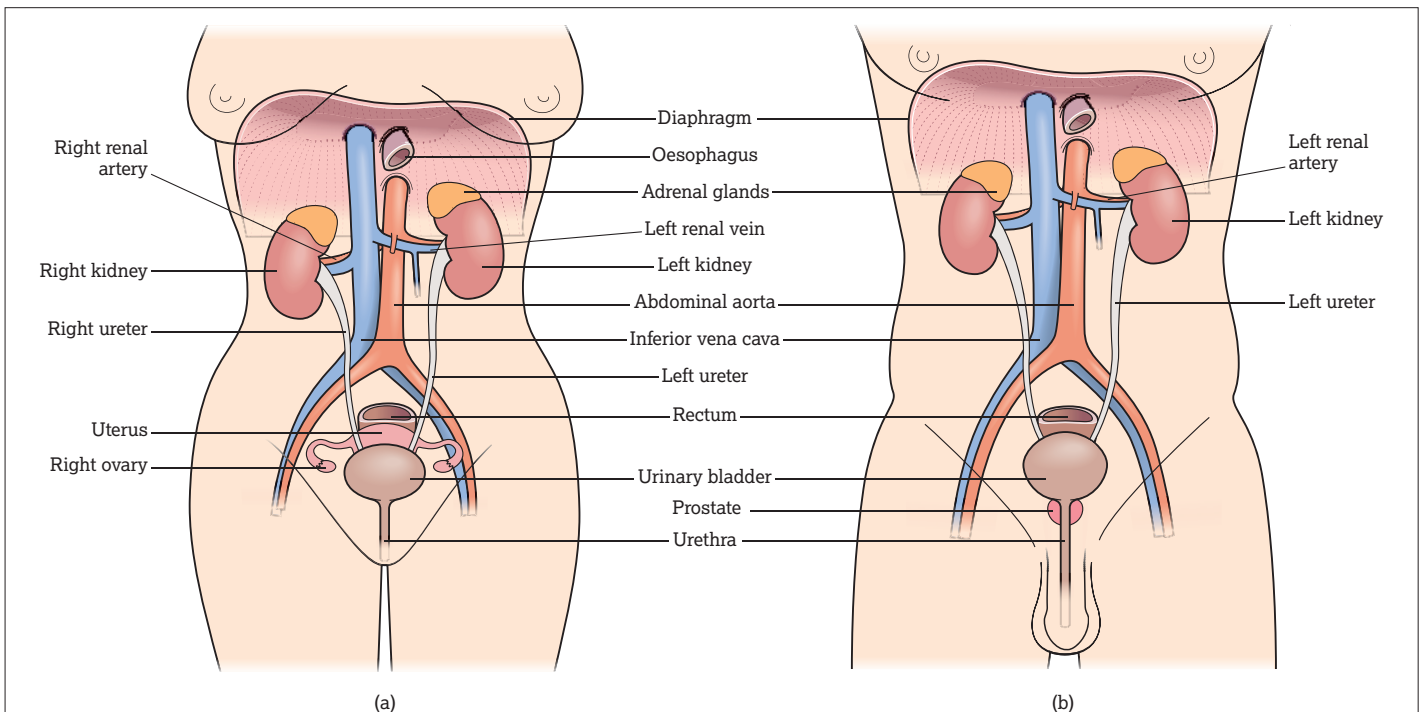


Figure 1.11 (a) Female urinary system. (b) Male urinary system. *Source:* Adapted from Tortora and Derrickson (2011). Reproduced with permission of John Wiley & Sons.

Related theory

Abnormalities of the lower urinary tract

Abnormalities of the lower urinary tract can be identified and in some cases biopsied/treated through flexible cystoscopy. These include:

- bladder cancer
- urinary tract infection
- interstitial cystitis/painful bladder syndrome
- bladder neck/urethral stricture
- prostatic enlargement/occlusion
- bladder stone.

Urinary stents can also be removed using a flexible cystoscope.

Bladder cancer

Most bladder cancers are transitional cell carcinomas (TCC). A minority of bladder tumours are squamous cell carcinomas (SCC). They are broadly categorized into non-muscle invasive (superficial), muscle invasive and metastatic, depending on the extent to which the cancer is invading into the bladder wall (NICE 2015a). Superficial tumours are largely confined to the bladder lining and superficial layers and do not penetrate the muscle layer of the bladder. Deep tumours penetrate the muscular wall of the bladder, and metastatic tumours are present beyond the primary organ (BAUS 2013).

Cancers are graded by their microscopic appearance. The cells of superficial cancers are similar in appearance to normal bladder cells and the tumours are generally slow growing (low grade). High-grade cancers often behave aggressively. Other factors of prognostic importance are: the number of tumours present, the size of the tumours, and their physical characteristics (EAU 2015).

The biopsy information will enable the *staging* and *grading* of the bladder cancer. The grade (Box 1.2) is in accordance with the cells' appearance and rate of growth. The TNM classification of malignant tumours (Table 1.5) describes the stage of a solid tumour according to its tissue involvement. *T* is the size of the original *tumour*, *N* is the nearby lymph *nodes* and *M* is the presence of distant *metastasis* (Brierley et al. 2017).

Box 1.2 WHO grading of bladder cancers

Grading of non-muscle-invasive bladder urothelial cancer

Papillary urothelial neoplasm of low malignant potential (PUNLMP)

Low-grade (LG) papillary urothelial carcinoma

High-grade (HG) papillary urothelial carcinoma

Histological classification for flat lesions

Hyperplasia (flat lesion without atypia or papillary aspects)

Reactive atypia (flat lesion with atypia)

Atypia of unknown significance

Urothelial dysplasia

Urothelial CIS is always high-grade

Source: Adapted from Eble et al. (2004).

CIS, carcinoma *in situ*.

Evidence-based approaches

Rationale

Flexible cystoscopy is undertaken to diagnose or conduct surveillance of cancer. Patient selection is based on locally agreed referral pathways. Commonly this would be through consultant referral or through diagnostic clinics.

Indications

- Referral from outpatient/inpatient clinics.
- Suspicion of a bladder abnormality based on clinical assessment in the outpatient department.
- Abnormal urine cytology.
- Routine bladder surveillance for bladder cancer based on national and local guidelines.
- Diagnostic referral pathways (e.g. for haematuria).
- Consultant referrals.
- Removal of ureteric stents.

Table 1.5 TNM classification of bladder cancer

Stage	Description
T – primary tumour	TX Primary tumour cannot be assessed T0 No evidence of primary tumour Ta Non-invasive papillary carcinoma Tis Carcinoma <i>in situ</i> : ‘flat tumour’ T1 Tumour invades subepithelial connective tissue T2 Tumour invades muscle T2a Tumour invades superficial muscle (inner half) T2b Tumour invades deep muscle (outer half) T3 Tumour invades perivesical tissue T3a Microscopically T3b Macroscopically (extravesical mass) T4 Tumour invades any of the following: prostate, uterus, vagina, pelvic wall, abdominal wall T4a Tumour invades prostate, uterus or vagina T4b Tumour invades pelvic wall or abdominal wall
N – lymph nodes	NX Regional lymph nodes cannot be assessed N0 No regional lymph node metastasis N1 Metastasis in a single lymph node in the true pelvis (hypogastric, obturator, external iliac, or presacral) N2 Metastasis in multiple lymph nodes in the true pelvis (hypogastric, obturator, external iliac, or presacral) N3 Metastasis in common iliac lymph node(s)
M – distant metastasis	MX Distant metastasis cannot be assessed M0 No distant metastasis M1 Distant metastasis

Source: Brierley et al. (2017). Reproduced with permission of John Wiley & Sons.

Contraindications

- If the information can be obtained using an alternative non-invasive approach such as an imaging scan to confirm or refute a diagnosis.
- Acute urinary tract infection – treat infection and reschedule the procedure.
- Warfarin or other anticoagulant therapy (if biopsies or cystodiathermy are required) – these should be discontinued according to patient risk/benefit profile and local guidelines.
- Allergy/intolerance to local anaesthetic agent – the examination should then be performed under general anaesthetic.
- High anxiety/phobia of the procedure – in this circumstance a general anaesthetic would be more appropriate (BAUS 2013).

Legal and professional issues

Flexible cystoscopy is the most commonly performed urological procedure. Nurses with specialist training have been performing this advanced role for several years. In 2000, the British Association of Urological Surgeons set up a working party and first published recommendations in support of nurse cystoscopy for surveillance of bladder cancer (Ellis et al. 2000). In the late 1990s nurse specialists began training to undertake flexible cystoscopy. The role of nurse cystoscopy has developed to encompass surveillance of superficial bladder cancer, diagnostic bladder biopsy,

cystodiathermy and the removal of stents (BAUS and BAUN 2012a, b, Skills for Health 2010a, b, c, d).

Patients should expect that a nurse performing a flexible cystoscopy should be performing at a level of competence equivalent to that of a competent urologist (Cox 2010). Evidence from several UK studies suggests that nurse-led flexible cystoscopy is as effective as doctor-led services in correctly reporting abnormalities (Smith et al. 2015, Taylor et al. 2002). Although some studies suggest that nurse-led services have a greater tendency to over-report abnormalities, other studies suggest that doctors and nurses equally over-report abnormalities (Smith et al. 2015). However it is accepted that experience improves both abnormalities detected and over-reporting of abnormalities (Radhakrishnan et al. 2006).

The nurse cystoscopist

Nurse cystoscopy is increasingly common and several training courses are available in the UK. Training has also been extended to include diagnostic procedures such as biopsy, treatment with cystodiathermy and ureteric stent removal, as well as surveillance. Services are also being developed overseas following the UK model (Osborne 2007). The joint British Association of Urological Surgeons and British Association of Urology Nurses (BAUS and BAUN) guidelines were published in 2012 to guide training and practice.

Training should include all elements of practice as agreed by senior management and consultants and should always include consent training. Continuing professional development for the nurse cystoscopist should include regular updates on this element of practice. The nurse cystoscopist should also participate in regular clinical audit including comparison of accuracy of findings, patient satisfaction and service capacity/waiting times (BAUN and BAUS 2012a, b) to ensure the highest standards of clinical care are being met. It is also important for the nurse to perform regular audit. The audit data are required to reflect on the nurse's own practice and maintenance of competence in accordance with national and local policies and guidelines (BAUS and BAUN 2012a, b, Skills for Health 2010a, b, c, d).

A competent nurse cystoscopist must continue to have access to an experienced, designated urologist for clinical advice and support, and immediate access to a hospital urology team for technical or diagnostic advice (BAUN and BAUS 2012a, b).

Consent

Written consent must be obtained prior to the procedure (NMC 2013). The patient must be informed of the procedure, its risks and potential side-effects. Accurate and legible documentation should be recorded immediately after the procedure, including all the observations and decisions made before, during and after the procedure (NMC 2010a).

Pre-procedural considerations

To prevent an unnecessary invasive procedure, ensure that flexible cystoscopy is indicated and that the results required cannot be achieved by diagnostic imaging. In most cases appropriate diagnostic imaging will precede flexible cystoscopy.

Consideration of concurrent treatment such as chemotherapy, anticoagulants or other medications is required. A confirmation of allergy status must be obtained. In order to exclude a urinary tract infection a dipstick test should be performed prior to a flexible cystoscopy and/or MSU at least one week prior to the procedure. If the patient has an artificial urinary sphincter implanted, this must be deactivated prior to the procedure (BAUN and BAUS 2012a, b).

Equipment

Flexible cystoscopes and stack

As there are several different types of flexible cystoscope (Figure 1.12), it is essential that the practitioner familiarizes



Figure 1.12 Flexible cystoscope.

themselves with the equipment prior to use. A video stack is required to enable visualization and recording (Figure 1.13). Equipment familiarization should include:

- the function, specification and performance characteristics of the equipment to be used in cystoscopy, including how to record and store images
- the impact of equipment controls on the visual image
- the safe operation of cystoscopy equipment
- the importance of timely equipment fault recognition and local procedures for dealing with these
- equipment capabilities, limitations and routine maintenance.

Emergency equipment

Emergency equipment should be easily accessible in the rare event of a major complication. In addition, equipment required for urethral catheterization should be available in the event of a complication such as urinary retention.



Figure 1.13 Video stack.

Pharmacological support

A local analgesic such as a 2% lidocaine gel is inserted topically into the urethra 5–10 minutes prior to the procedure commencing. In males up to 11 mL and in females up to 6 mL are normally prescribed and applied (Peyronnet et al. 2016). If washings are required during the procedure, intravesical sodium chloride 0.9% is used to irrigate the bladder rather than sterile water to improve cell preservation during storage and transfer to the lab (BAUN and BAUS 2012a, b).

Procedure guideline 1.4 Flexible cystoscopy

Essential equipment

- Patient trolley
- Incontinence sheet
- Flexible cystoscope (optical/video)
- Urology sterile pack as determined by local practice, including sterile gauze and sterile forceps
- Procedure trolley
- Non-sterile gloves
- Apron
- Sterile gloves
- Sterile gown

- Sterile drapes
- Chlorhexidine cleansing solution or similar according to local guidelines
- Fluid administration set

Medicinal products

- 2% lidocaine gel (topically into urethra)
- Intravesical sterile water, or sodium chloride 0.9% if washings are required

Pre-procedure

Action

- 1 Check the environment and equipment to ensure that everything is properly prepared for the procedure, including that the irrigation is attached and run through the scope, and awareness of the location and availability of emergency equipment.
- 2 Ask assistant to set up trolley with sterile urology pack and prepare scope.

Rationale

To ensure the procedure will take place without delay for the patient and to ensure that the safety of the patient is addressed (BAUS and BAUN 2012a, b, **C**; Skills for Health 2010a, b, c, d, **C**).

To ensure that the safety of the patient is addressed (BAUS and BAUN 2012a, b, **C**; Skills for Health 2010a, b, c, d, **C**).

To maintain infection control standards and minimize cross-infection and contamination (Fraise and Bradley 2009, **E**; RCN 2017a, **C**).

(continued)

28 Procedure guideline 1.4 Flexible cystoscopy (*continued*)

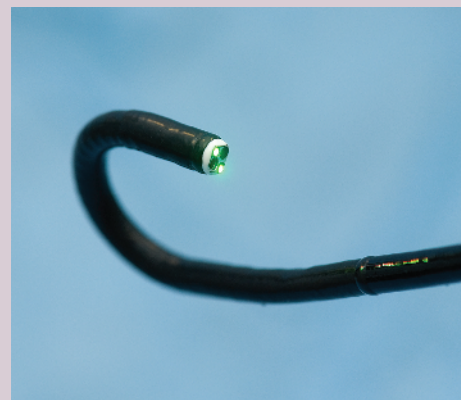
Action	Rationale
3 Read the patient's notes, referral letter, patient history and relevant investigation results and identify any special instructions, investigations or items for which you need to seek advice prior to the procedure.	To ensure that the safety of the patient is addressed (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C).
4 Ensure that pre-procedure criteria have been met: • urine sample tested for infection, the results interpreted and a sample sent for further analysis if required • urine cytology obtained if required • pre-procedure medication has been taken as required such as prophylactic antibiotic • patient has emptied bladder • observations within normal limits • check medications and anticoagulation have been reviewed or withheld.	Requisite pre-procedure tests are performed to ensure patient safety is addressed (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C) and timely sampling of urine. E
5 Accurately identify the patient and introduce yourself and any colleagues present to the patient.	To ensure that the safety of the patient is addressed (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C). To ensure the patient is aware who is present during the procedure. E
6 Assess the patient's suitability for the procedure, including any changes to health since referral, medication or allergy status and seek advice or refer if necessary.	To ensure that the safety of the patient is addressed and to ensure relevant history is recorded (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C).
7 Explain the procedure and potential complications to the patient and accurately answer any questions at a level and pace that is appropriate to: • their level of understanding • their culture and background • their preferred way of communicating their needs.	To ensure informed consent has been obtained and also that patient's needs are appropriately addressed during procedure (DH 2009, C).
8 Ensure the patient's informed consent to the procedure has been given and, if not, obtain it.	To ensure informed consent has been obtained and also that patient's needs are appropriately addressed during procedure (DH 2009, C ; NMC 2015, C).
9 Ask the patient to remove clothing below the waist. Offer a gown to cover the patient.	To provide privacy and comfort for the patient. E . To minimize the risk of a hospital acquired infection (BAUS and BAUN 2012b, C).
10 Assist the patient to position themselves onto an incontinence sheet on the trolley correctly for the procedure (supine), respecting their dignity and ensuring their comfort within the constraints of the procedure. Males lay flat and females with legs apart.	To enable easy passage of the cystoscope (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C) and maintain patient comfort and dignity. E .
11 Wash hands with soap and water and dry, followed by alcohol rub, and apply non-sterile gloves and apron.	To maintain infection control standards and minimize cross-infection and contamination (Fraise and Bradley 2009, E ; RCN 2017a, C).
12 Identify, clean with cleansing solution such as chlorhexidine solution and examine the urethral orifice and surrounding area. In females open the labia, and in males retract the foreskin.	Initial examination of the patient and first findings, appropriate cleansing to minimize cross-infection/contamination (Reynard et al. 2013, E).
13 Insert local anaesthetic gel topically into the urethra, leaving for 5–10 minutes.	To maintain patient comfort E and allow smooth passage of the cystoscope (BAUS and BAUN 2012b, C). Appropriately applied lidocaine gel reduces pain in males during flexible cystoscopy (Aaronson et al. 2009, R1a).
14 Remove gloves and apron and discard in clinical waste.	To ensure correct disposal of clinical waste (DH 2013, C ; HSE 2003, C).
15 Wash hands with soap and water, followed by alcohol rub, and apply sterile gloves and gown.	To maintain infection control standards and minimize cross-infection and contamination (Fraise and Bradley 2009, E ; RCN 2017a, C).
16 Apply sterile drape over patient's lower body.	To maintain infection control standards and minimize cross-infection and contamination (Fraise and Bradley 2009, E ; RCN 2017a, C).

Procedure

- | | |
|---|---|
| 17 Maintain communication with the patient throughout the procedure, monitor and respond to any questions or needs. | To ensure ongoing informed consent (DH 2009, C ; NMC 2015, C); patient comfort, safety and dignity maintained. E |
| 18 Ensure the labia are held open in females or the foreskin is retracted in males. This should be done either by an assistant or with your non-dominant hand. | To ensure thorough and accurate examination (Reynard et al. 2008, E). |
| 19 Introduce the cystoscope into the urethra and advance it gently under direct vision using deflection (Action figure 19a) and inflection (Action figure 19b) (change in angle) of the tip to avoid trauma to the urethral wall and ensure that the correct irrigation fluid is running (sterile water in most cases, normal saline if washings are required to preserve the cells). | To maintain patient safety and comfort. To ensure thorough and accurate examination (Reynard et al. 2008, E). |
| 20 If insertion is difficult, or problems occur, seek advice or decide to terminate the procedure and record your findings. | To maintain patient safety. E |
| 21 Fill bladder sufficiently with irrigation fluid to facilitate systematic examination of the internal structure of the bladder and to identify anatomical landmarks using tip deflection and inflection, instrument rotation and gentle advancement and withdrawal of the cystoscope. | To ensure a thorough and accurate examination (Smith et al. 2012, E) of the bladder (Figure 1.14). |
| 22 Identify all abnormal lesions or structures observed throughout the examination. Record images throughout procedure using the video stack, external printer or software connected to the stack and scope. | To ensure a thorough and accurate examination (Smith et al. 2012, E). |
| 23 Improve visualization, if necessary, by aspirating fluids from the bladder. | To ensure a thorough and accurate examination (Smith et al. 2012, E). |
| 24 Once complete, fully withdraw cystoscope, maintaining irrigation until withdrawal of cystoscope is almost complete. | To ensure cystoscope is completely removed (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C). To maintain patient comfort and safety. E |

Post-procedure

- | | |
|---|--|
| 25 Reassure patient that the examination has been completed. | To maintain patient comfort and safety. E |
| 26 Assist the patient to reposition, wipe surplus lubricant and dry. | To maintain patient comfort and safety. E |
| 27 Remove gloves and dispose of all used single-use equipment. Return cystoscope for washing according to local guidelines. | To maintain infection control standards and minimize cross-infection and contamination (BAUS and BAUN 2012a, b, C ; Fraise and Bradley 2009, E ; RCN 2017a, C ; Skills for Health 2010a, b, c, d, C). |
| 28 Ask the patient to pass urine before leaving the department. | To ensure the patient is able to pass urine (BAUS and BAUN 2012b, C). |

**Action Figure 19a** Cystoscope deflection.**Action Figure 19b** Cystoscope inflection.

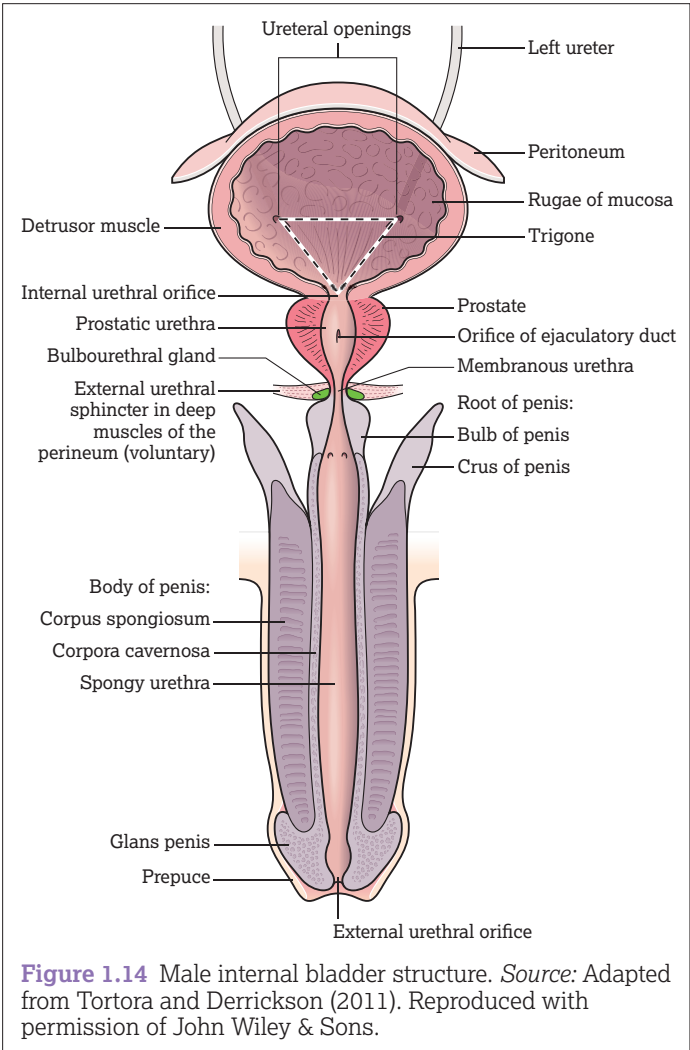


Figure 1.14 Male internal bladder structure. *Source:* Adapted from Tortora and Derrickson (2011). Reproduced with permission of John Wiley & Sons.

Procedure guideline 1.5 Flexible cystoscopy with stent removal

Essential equipment

- Patient trolley
- Incontinence sheet
- Flexible cystoscope (optical/video)
- Urology sterile pack as determined by local practice, including sterile gauze and sterile forceps
- Procedure trolley
- Non-sterile gloves
- Apron
- Sterile gloves
- Sterile gown
- Sterile drapes
- Chlorhexidine cleansing solution or similar according to local guidelines

- Fluid giving set
- Stent grasping forceps

Optional equipment

- Fluid giving set
- 1 litre bag of sterile water/1 litre bag of sodium chloride (if washings required)

Medicinal products

- 2% lidocaine gel (topically into urethra)
- Intravesical sterile water or sodium chloride 0.9% if washings are required

Pre-procedure

Action

Repeat steps 1–16 from Procedure guideline 1.4 Flexible cystoscopy

Rationale

Procedure

- 17 Maintain communication with the patient throughout the procedure, monitor and respond to any questions or needs.

To ensure ongoing informed consent (DH 2009, **C**; NMC 2015, **C**); patient comfort, safety and dignity maintained. **E**

18 Ensure the labia are held open in females or the foreskin is retracted in males. This should be done either by an assistant or with your non-dominant hand.	To ensure thorough and accurate examination (Reynard et al. 2008, E).
19 Introduce the cystoscope into the urethra and advance it gently under direct vision using deflection (Action figure 19a) and inflection (Action figure 19b) (change in angle) of the tip to avoid trauma to the urethral wall and ensure that the correct irrigation fluid is running (sterile water in most cases, normal saline if washings are required to preserve the cells).	To maintain patient safety and comfort. To ensure thorough and accurate examination (Reynard et al. 2008, E).
20 If insertion is difficult, or problems occur, seek advice or decide to terminate the procedure and record your findings.	To maintain patient safety. E
21 Fill bladder sufficiently with irrigation fluid to facilitate systematic examination of the internal structure of the bladder and to identify anatomical landmarks using tip deflection and inflection, instrument rotation and gentle advancement and withdrawal of the cystoscope.	To ensure a thorough and accurate examination (Smith et al. 2012, E) of the bladder (Figure 1.14).
22 Identify all abnormal lesions or structures observed throughout the examination. Record images throughout procedure using the video stack, external printer or software connected to the stack and scope.	To ensure a thorough and accurate examination (Smith et al. 2012, E).
23 Improve visualization, if necessary, by aspirating fluids from the bladder.	To ensure a thorough and accurate examination (Smith et al. 2012, E).
24 Select the grasping forceps and ensure they are working.	To ensure the correct device is selected and avoid adverse events during the procedure (BAUS and BAUN 2012b, C).
25 Visualize and locate the ureteric stent to be removed.	To ensure the correct stent is identified for removal and avoid removal of the wrong ureteric stent if bilateral ureteric stents are <i>in situ</i> (BAUS and BAUN 2012b, C).
26 Insert grasping forceps through the channel of the cystoscope using dominant hand while keeping the cystoscope tip in the straight position.	To ensure damage to the cystoscope does not occur (BAUS and BAUN 2012b, C).
27 Visualize the grasping forceps as they enter the bladder and field of vision.	To ensure the grasping forceps are in the correct position and not opened while within the cystoscope to avoid damage to both devices (BAUS and BAUN 2012b, C).
28 Use the cystoscope controls to orientate the grasping forceps over the ureteric stent.	To ensure the grasping forceps are in the correct position (BAUS and BAUN 2012b, C).
29 Open the jaws of the grasping forceps or instruct an assistant to operate the grasping forceps.	To ensure grasping forceps are operated correctly and safely. E
30 Grasp the stent firmly, ensuring that no mucosa or tissue has been inadvertently gripped.	To enable removal of ureteric stent and avoid damaging bladder (BAUS and BAUN 2012b, C).
31 Withdraw the cystoscope and grasping forceps together from the bladder and urethra under direct vision.	To enable removal of the ureteric stent while minimizing patient discomfort (BAUS and BAUN 2012b, C).
32 If resistance is encountered from the stent, stop the procedure and seek appropriate advice from a senior colleague.	To avoid damage to ureter, bladder and urethra (BAUS and BAUN 2012b, C).
33 Inspect the removed ureteric stent to ensure it is complete.	To ensure the device is completely removed and intact (BAUS and BAUN 2012b, C).

Post-procedure

34 Reassure patient that the examination has been completed.	To maintain patient comfort and safety. E
35 Assist the patient to reposition, wipe surplus lubricant and dry.	To maintain patient comfort and safety. E
36 Remove gloves and dispose of all used single-use equipment. Return cystoscope for washing according to local guidelines.	To maintain infection control standards and minimize cross-infection and contamination (BAUS and BAUN 2012a, b, C ; Fraise and Bradley 2009, E ; RCN 2017a, C ; Skills for Health 2010a, b, c, d, C).
37 Ask the patient to pass urine before leaving the department.	To ensure the patient is able to pass urine (BAUS and BAUN 2012b, C).

32 Procedure guideline 1.6 Flexible cystoscopy with bladder biopsy

Essential equipment

- Patient trolley
- Incontinence sheet
- Flexible cystoscope (optical/video)
- Urology sterile pack as determined by local practice, including sterile gauze and sterile forceps
- Procedure trolley
- Non-sterile gloves
- Apron
- Sterile gloves
- Sterile gown
- Sterile drapes

- Chlorhexidine cleansing solution or similar according to local guidelines
- 1 litre bag of sterile water
- Fluid giving set
- Biopsy forceps
- Specimen container with formalin
- Cystodiathermy checked and in working order

Medicinal products

- 2% lidocaine gel (topically into urethra)
- Intravesical sodium chloride 0.9%

*Pre-procedure***Action****Rationale**

- | | |
|---|---|
| 1 Check the environment and equipment to ensure that everything is properly prepared for the procedure, including that the irrigation is attached and run through the scope, and awareness of the location and availability of emergency equipment. | To ensure the procedure will take place without delay for the patient and to ensure that the safety of the patient is addressed (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C). |
| 2 Ask assistant to set up trolley with sterile urology pack and prepare scope. | To ensure that the safety of the patient is addressed (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C).
To maintain infection control standards and minimize cross-infection and contamination (Fraise and Bradley 2009, E ; RCN 2017a, C). |
| 3 Read the patient's notes, referral letter, patient history and relevant investigation results and identify any special instructions, investigations or items for which you need to seek advice prior to the procedure, including any metal prosthesis. | To ensure that the safety of the patient is addressed (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C). |
| 4 Ensure that pre-procedure criteria have been met: <ul style="list-style-type: none"> • urine sample tested for infection, the results interpreted and a sample sent for further analysis if required • urine cytology obtained if required • pre-procedure medication has been taken as required, such as prophylactic antibiotic • patient has emptied bladder • observations within normal limits • check medications and anticoagulation have been reviewed or withheld. | Requisite pre-procedure tests are performed to ensure patient safety addressed (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C) and timely sampling of urine. E |
| 5 Accurately identify the patient and introduce yourself and any colleagues present to the patient. | To ensure that the safety of the patient is addressed (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C).
To ensure the patient is aware who is present during the procedure. E |
| 6 Assess the patient's suitability for the procedure, including any changes to health since referral, medication or allergy status, and seek advice or refer if necessary. | To ensure that the safety of the patient is addressed and to ensure relevant history is recorded (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C). |
| 7 Explain the procedure and potential complications to the patient and accurately answer any questions at a level and pace that is appropriate to: <ul style="list-style-type: none"> • their level of understanding • their culture and background • their preferred way of communicating their needs. | To ensure informed consent has been obtained and also that patient's needs are appropriately addressed during procedure (DH 2009, C). |
| 8 Ensure the patient's informed consent to the procedure has been given and, if not, obtain it. | To ensure informed consent has been obtained and also that patient's needs are appropriately addressed during procedure (DH 2009, C ; NMC 2015, C). |
| 9 Ensure that the cystoscope is diathermy compatible. | To ensure cystodiathermy is undertaken safely (BAUS and BAUN 2012b, C). |
| 10 Ensure that irrigation fluid is diathermy compatible, for example 1.5% glycine or normal saline. | To ensure cystodiathermy is undertaken safely (BAUS and BAUN 2012b, C). |
| 11 Ask the patient to remove any metal jewellery or to cover with non-conductive tape. | To ensure that the safety of the patient is addressed (BAUS and BAUN 2012b, C). |

12 Ask the patient to remove clothing below the waist. Offer a gown to cover the patient.	To provide privacy and comfort for the patient. E . To minimize the risk of a hospital acquired infection (BAUS and BAUN 2012b, C).
13 Assist the patient to position themselves onto an incontinence sheet on the trolley correctly for the procedure (supine), respecting their dignity and ensuring their comfort within the constraints of the procedure. Males lay flat and females with legs apart.	To enable easy passage of the cystoscope (BAUS and BAUN 2012a, b, C ; Skills for Health 2010a, b, c, d, C) and maintain patient comfort and dignity. E
14 Ensure the patient is not in contact with any metal surface.	To ensure no adverse events occur with subsequent burns while using cystodiathermy (BAUS and BAUN 2012b, C).
15 Prepare the area for the diathermy plate by shaving excessive hair (usually the patient's thigh) while avoiding bony prominences, wet skin, scar tissue, metal prosthesis or tattoos.	To ensure no adverse events occur with subsequent burns while using cystodiathermy (BAUS and BAUN 2012b, C).
16 Wash hands with soap and water and dry, followed by alcohol rub, and apply non-sterile gloves and apron.	To maintain infection control standards and minimize cross-infection and contamination (Fraise and Bradley 2009, E ; RCN 2017a, C).
17 Identify, clean with cleansing solution such as chlorhexidine solution and examine the urethral orifice and surrounding area. In females open the labia, and in males retract the foreskin.	Initial examination of the patient and first findings, appropriate cleansing to minimize cross-infection/contamination (Reynard et al. 2013, E).
18 Insert local anaesthetic gel topically into the urethra, leaving for 5–10 minutes.	To maintain patient comfort E and allow smooth passage of the cystoscope (BAUS and BAUN 2012b, C). Appropriately applied lidocaine gel reduces pain in males during flexible cystoscopy (Aaronson et al. 2009, R1a).
19 Remove gloves and apron and discard in clinical waste.	To ensure correct disposal of clinical waste (DH 2013, C ; HSE 2003, C).
20 Wash hands with soap and water, followed by alcohol rub, and apply sterile gloves and gown.	To maintain infection control standards and minimize cross-infection and contamination (Fraise and Bradley 2009, E ; RCN 2017a, C).
21 Apply sterile drape over patient's lower body.	To maintain infection control standards and minimize cross-infection and contamination (Fraise and Bradley 2009, E ; RCN 2017a, C).

Procedure

22 Maintain communication with the patient throughout the procedure, monitor and respond to any questions or needs.	To ensure ongoing informed consent (DH 2009, C ; NMC 2015, C); patient comfort, safety and dignity maintained. E
23 Ensure the labia are held open in females or the foreskin is retracted in males. This should be done either by an assistant or with your non-dominant hand.	To ensure thorough and accurate examination (Reynard et al. 2008, E).
24 Introduce the cystoscope into the urethra and advance it gently under direct vision using deflection (Action figure 19a) and inflection (Action figure 19b) (change in angle) of the tip to avoid trauma to the urethral wall and ensure that the correct irrigation fluid is running (normal saline if washings are required to preserve the cells).	To maintain patient safety and comfort. To ensure thorough and accurate examination (Reynard et al. 2008, E).
25 If insertion is difficult, or problems occur, seek advice or decide to terminate the procedure and record your findings.	To maintain patient safety. E
26 Fill bladder sufficiently with irrigation fluid to facilitate systematic examination of the internal structure of the bladder and to identify anatomical landmarks using tip deflection and inflection, instrument rotation and gentle advancement and withdrawal of the cystoscope.	To ensure a thorough and accurate examination (Smith et al. 2012, C) of the bladder (Figure 1.14).
27 Identify all abnormal lesions or bleeding areas throughout the examination. Record images throughout procedure using the video stack, external printer or software connected to the stack and scope.	To ensure a thorough and accurate examination (Smith et al. 2012, E).
28 Improve visualization, if necessary, by aspirating fluids from the bladder.	To ensure a thorough and accurate examination (Smith et al. 2012, E).

(continued)

Procedure guideline 1.6 Flexible cystoscopy with bladder biopsy (*continued*)

Action	Rationale
29 Select the diathermy compatible biopsy forceps and ensure they are in working order.	To avoid an adverse event if cystodiathermy is required during the procedure and biopsy forceps are functional (BAUS and BAUN 2012b, C).
30 Insert biopsy forceps through the channel of the cystoscope using dominant hand while keeping the cystoscope tip in the straight position.	To ensure damage to the cystoscope does not occur (BAUS and BAUN 2012b, C).
31 Visualize the biopsy forceps as they enter the bladder and field of vision.	To ensure the biopsy forceps are in the correct position and not opened while within the cystoscope to avoid damage to both devices (BAUS and BAUN 2012b, C).
32 Use the cystoscope controls to orientate the biopsy forceps over the tissue to be sampled.	To ensure the biopsy forceps are in the correct position and not opened while within the cystoscope to avoid damage to both devices (BAUS and BAUN 2012b, C).
33 Open the jaws of the biopsy forceps or instruct an assistant to operate the biopsy forceps.	To ensure grasping forceps are operated correctly and safely. E
34 Close the biopsy forceps jaws, taking an adequate tissue sample.	To provide an adequate specimen for histopathological analysis while minimizing patient discomfort (BAUS and BAUN 2012b, C).
35 While biopsy forceps are closed, pull sharply from the bladder tissue.	To provide an adequate specimen for histopathological analysis while minimizing patient discomfort (BAUS and BAUN 2012b, C).
36 Withdraw the biopsy forceps via the cystoscope channel while keeping the jaws closed, or instruct the assistant to do so.	To ensure the sample is removed (BAUS and BAUN 2012b, C).
37 Deposit all of the tissue sample into the specimen pot or instruct the assistant, making sure the biopsy forceps do not touch the sterile pot.	To ensure the sample is maintained for histopathological analysis (BAUS and BAUN 2012b, C).
38 Clean the forceps between each sample in sodium chloride 0.9%.	To ensure biopsy forceps are clean and ready for additional sampling. E
39 Visualize biopsy sites for excessive bleeding and perform cystodiathermy if required (see Procedure guideline 1.7 Cystoscopy with APC/cystodiathermy).	To minimize the risk of clot retention of urine and haemorrhage (BAUS and BAUN 2012b, C).
40 Repeat steps 32–39 for subsequent samples.	
41 Once complete, fully withdraw cystoscope, maintaining irrigation until withdrawal of cystoscope is almost complete.	To ensure cystoscope is fully withdrawn. E
Post-procedure	
42 Reassure patient that the examination has been completed.	To maintain patient comfort and safety. E
43 Assist the patient to reposition, wipe surplus lubricant and dry.	To maintain patient comfort and safety. E
44 Remove gloves and dispose of all used single-use equipment. Return cystoscope for washing according to local guidelines.	To maintain infection control standards and minimize cross-infection and contamination (BAUS and BAUN 2012a, b, C ; Fraise and Bradley 2009, E ; RCN 2017a, C ; Skills for Health 2010a, b, c, d, C).
45 Label specimens and send to laboratory for histopathological analysis.	To ensure correct identification and correct analysis is undertaken (BAUS and BAUN 2012b, C).
46 Ask the patient to pass urine before leaving the department.	To ensure the patient is able to pass urine (BAUS and BAUN 2012b, C).

Procedure guideline 1.7 Flexible cystoscopy with argon plasma coagulation (APC)/cystodiathermy**Essential equipment**

- Patient trolley
- Incontinence sheet
- Flexible cystoscope (optical/video)
- Urology sterile pack as determined by local practice, including sterile gauze and sterile forceps
- Procedure trolley
- Non-sterile gloves
- Apron
- Sterile gloves
- Sterile gown
- Sterile drapes
- Fluid giving set
- Chlorhexidine cleansing solution or similar according to local guidelines
- Argon plasma coagulation (APC)/cystodiathermy generator: APC/cystodiathermy probe and equipment stack loaded with correct settings and diathermy insulation coating intact (as determined by local practice and manufacturer's guidelines)

Medicinal products

- 2% lidocaine gel (topically into urethra)
- Intravesical sodium chloride 0.9%

Pre-procedure**Action****Rationale**

Repeat steps 1–21 from Procedure guideline 1.6 Flexible cystoscopy with bladder biopsy

Procedure

Repeat steps 22–28 from Procedure guideline 1.6 Flexible cystoscopy with bladder biopsy, then:

- | | |
|---|--|
| 29 Ask the assistant to apply the diathermy plate (patient return electrode). | To ensure no adverse events occur with subsequent burns while using cystodiathermy (BAUS and BAUN 2012b, C). |
| 30 Ask the assistant to move the foot pedals into position for easy use. | To ensure diathermy controls are in safe working reach. E |
| 31 Ask the assistant to connect the wire to the diathermy lead. | To ensure no adverse events occur with subsequent burns while using cystodiathermy (BAUS and BAUN 2012b, C). |
| 32 Insert diathermy wire through the channel of the cystoscope using dominant hand while keeping the cystoscope tip in the straight position. | To ensure damage to the cystoscope does not occur (BAUS and BAUN 2012b, C). |
| 33 Visualize the diathermy wire as it enters the bladder and field of vision advancing past the tip of the cystoscope. | To ensure diathermy is delivered only to the area required (BAUS and BAUN 2012b, C). |
| 34 Position the diathermy wire gently at the area to be treated. | To ensure diathermy is delivered only to the area required (BAUS and BAUN 2012b, C). |
| 35 Push the foot pedals in short bursts until bleeding has ceased or the abnormality is destroyed. | To ensure bleeding is ceased or abnormality is destroyed (BAUS and BAUN 2012b, C). |
| 36 Remove the diathermy wire and hand to the assistant while maintaining asepsis. | To ensure all areas to be treated have been treated successfully (BAUS and BAUN 2012b, C). |
| 37 Repeat steps 34–36 as required. | |
| 38 Ensure all areas have been treated and if complete, remove the cystoscope. | To ensure all areas to be treated have been treated successfully (BAUS and BAUN 2012b, C). |

Post-procedure

- | | |
|---|--|
| 39 Reassure patient that the examination has been completed. | To maintain patient comfort and safety. E |
| 40 Ensure the diathermy controls are moved away and the device is switched off. | To ensure safety of the patient and staff. E |
| 41 Remove the diathermy plate and inspect area, ensuring there are no adverse events such as burns. | To ensure any damage to the skin is identified, treated and documented (BAUS and BAUN 2012b, C). |
| 42 Assist the patient to reposition, wipe surplus lubricant and dry. | To maintain patient comfort and safety. E |
| 43 Remove gloves and dispose of all used single-use equipment. Return cystoscope for washing according to local guidelines. | To maintain infection control standards and minimize cross-infection and contamination (BAUS and BAUN 2012a, b, C ; Fraise and Bradley 2009, E ; RCN 2017a, C ; Skills for Health 2010a, b, c, d, C). |
| 44 Label specimens and send to laboratory for histopathological analysis. | To ensure correct identification and correct analysis is undertaken (BAUS and BAUN 2012b, C). |
| 45 Ask the patient to pass urine before leaving the department. | To ensure the patient is able to pass urine (BAUS and BAUN 2012b, C). |

Problem-solving table 1.2 Prevention and resolution (Procedure guidelines 1.4, 1.5, 1.6, 1.7) (BAUS and BAUN 2012a, b; Skills for Health 2010a, b, c, d)

Problem	Cause	Prevention	Action
Urethral bleeding.	Urethral trauma.	Careful advancement of the cystoscope under direct vision during the procedure.	The procedure should be stopped and direct finger pressure must be applied to clamp the urethra. In the case of continuous bleeding, the patient should be transferred to the recovery area and escalated to the senior clinician (usually the responsible consultant). A three-way 18Fr Foley catheter should be inserted, with gentle traction applied over the bladder neck.
Haematuria.	Underlying abnormality, intra-procedure bladder trauma, bladder biopsy.	Careful advancement of the cystoscope under direct vision during the procedure.	A 22Fr three-way silicone Foley catheter should be inserted, followed by bladder washout and continuous bladder irrigation with normal saline. In case of severe bleeding, formal washout in theatre may be required.
Urinary retention.	Underlying abnormality.	All patients must spontaneously void before being discharged.	If a patient complains of abdominal pain with inability to void or has no pain but a full bladder (confirmed on ultrasound) a 12–18Fr Foley catheter should be inserted on free drainage. A trial of voiding without catheter should be booked to take place in 7–10 days.
Vasovagal syncope.	Acute anxiety/fear.	Addressing patient anxiety pre-procedure, informing patient of what to expect. Recognizing acute anxiety pre-procedure.	Immediately stop the procedure. Remove the scope and position the patient in dorsal decubitus with a 30° Trendelenburg (on back, head down) position. Vital signs should be recorded. In case of complete loss of consciousness or sustained instability, escalate to the emergency response team and inform the lead clinician.
Urinary tract infection.	Contamination or cross-infection.	Adherence to infection control guidelines.	Recognize symptoms and treat according to local guidelines or microbiology result.
Pain.	Urethral trauma.	Use of 2% lidocaine gel.	In case of acute pain, the procedure should be discontinued and if incomplete it should be re-booked under a general anaesthetic. Pain should stop within a short period of the scope being withdrawn. If it does not, systemic analgesia should be administered and further investigations should be requested in discussion with the lead clinician.

Post-procedural considerations

Immediate care

It is imperative that the practitioner recognizes onset of any acute emergencies associated with the procedure and responds appropriately. Ensure the patient is aware of possible post-procedural complications such as infection and the possibility of expected urinary discomfort. Encourage the patient to maintain adequate fluid hydration. Give a full explanation of the results to the patient, allowing time for them to ask questions regarding the preliminary findings, and where appropriate offer support. Prescribe (non-medical prescriber), or supply under a Patient Group Direction, antibiotics or other follow-up therapy if required and provide the patient with information on their administration.

Remind the patient of the information and advice they have already been given with regard to lifestyle and side-effects and who to contact if problems arise. Respond to any questions or requests for further information. It is also important to confirm the details of how the full outcome of the examination will be communicated and of any future appointments and/or referrals (BAUS and BAUN 2012a, b, Skills for Health 2010a, b, c, d).

Documentation

Document the observations and outcomes of the procedure and record all decisions made in the patient record. Ensure that any specimens are labelled with the correct accompanying request forms (NMC 2010a).

Breast diagnostics

Definition

Reliable assessment of breast symptoms and diagnostics is expected to be a rapid, triple-modality approach comprised of clinical (or physical), radiological and histological components. Established good practice dictates that breast diagnosis is completed by a multidisciplinary team. The aim of triple assessment in a rapid setting is to ensure quick referral to oncological teams for treatment, if cancer is diagnosed, but also to promptly reassure patients when they do not have cancer (ABS 2010, Aebi et al. 2011, NICE 2002, NICE 2016).

Anatomy and physiology

The breast is a glandular and secretory organ which has the primary purpose of lactation. It is also a prominent secondary sexual feature. Prior to puberty there is no difference between the male and female breast bud. Commencement of female sex hormones at puberty causes significant development of the female breast tissue (Tortora and Derrickson 2014).

Breast tissue comprises 10–15% epithelial parenchyma, or functional tissue. The remaining tissue is the stroma, or framework tissue, to give it and maintain its form. Breast cancer arises within the functional parenchyma or epithelial cells. Differences in breast size and shape are generally due to the difference in stroma rather than parenchyma.

Breast parenchyma is composed of 15–20 lobes which can each sub-divide into smaller lobules. The lobules are made up of branched tubuloalveolar glands. Each lobe drains into a lactiferous

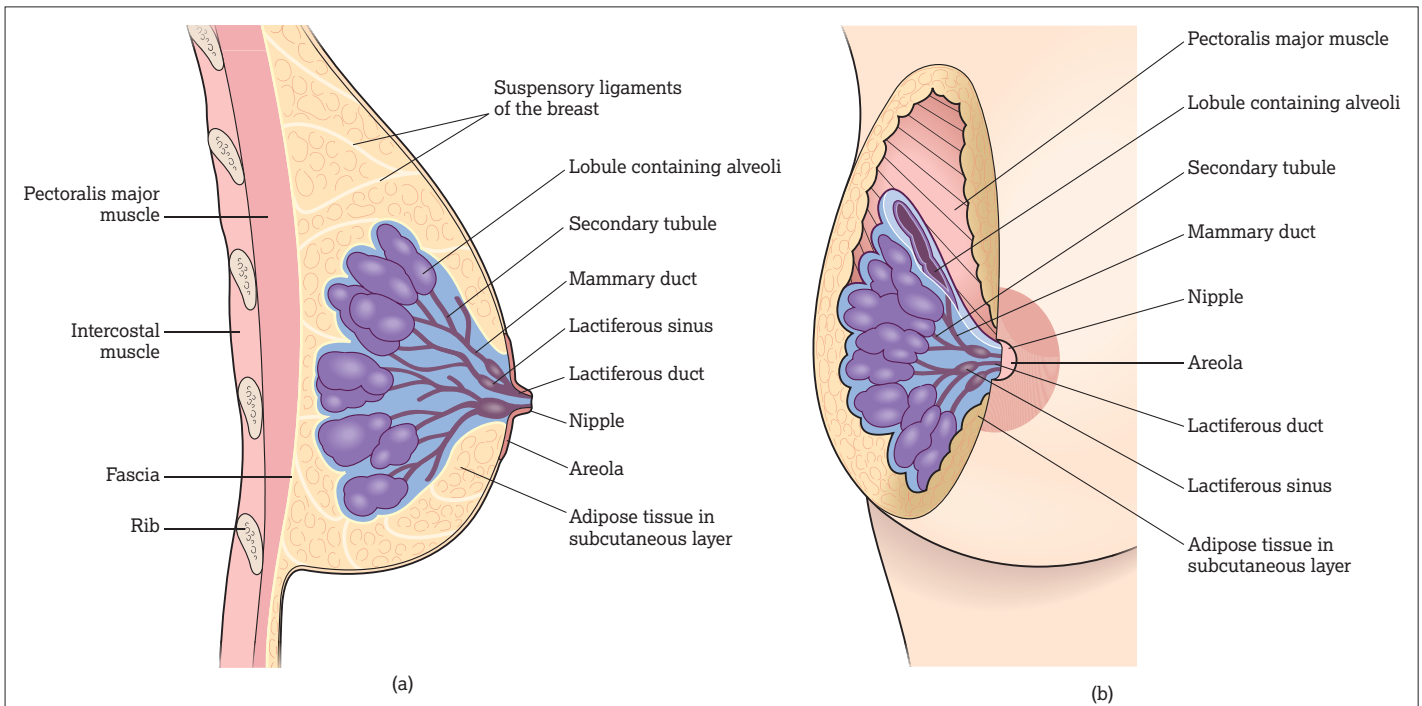


Figure 1.15 (a) Female breast (sagittal section). (b) Female breast (anterior view, partially sectioned). *Source:* Adapted from Tortora and Derrickson (2011). Reproduced with permission of John Wiley & Sons.

duct which runs toward the nipple (Figure 1.15). The lactiferous ducts dilate and coalesce into a lactiferous sinus beneath the areola and then open through a constricted orifice onto the nipple. Breast milk is secreted by the lobular tissue and transported toward the nipple by the breast ducts (Pandya and Moore 2011).

Oestrogen and progesterone both stimulate breast parenchyma during a normal menstrual cycle. Rising oestrogen levels in weeks 1–2 cause proliferation of the ductal system and, following ovulation, the rise in progesterone, synergistically with oestrogen, stimulates the lobular units. These changes give rise to the common breast changes which many women equate with their pre-period state. If no pregnancy ensues, decreasing hormone levels cause regression of this stimulated tissue (Ellis and Mahadevan 2013).

With the onset of menopause, as ovarian tissue ceases to produce high cyclical levels of oestrogen and progesterone, the majority of breast glandular tissue involutes or ceases to be active. Usually more adipose tissue is deposited and the postmenopausal breast is less dense on imaging. Due to this, mammography is more sensitive and specific in the postmenopausal breast.

Related theory

Benign breast disease is a term used to describe a variety of breast changes that are prevalent in the population. This is unsurprising when the stimulatory nature of the menstrual cycle on breast tissue is considered. Benign changes are hugely varied and can be developmental, inflammatory, fibrocystic or neoplastic in nature. They are often proliferative but not atypical in nature. Most can be safely left without intervention once biopsy proven (Guray and Sahin 2006). The most common benign presentations are listed in Table 1.6, related to age. Breast cancer is, however, the most commonly diagnosed cancer amongst women in the UK with 54,800 cases diagnosed per year (Cancer Research UK 2014) and has a high media and social profile (Xu et al. 2016).

Evidence-based approaches

The assessment of breast symptoms is heavily rationalized and covered by the need to ensure that the reported symptom or change is not breast cancer. Local, national and international guidance is clear; in the UK it is produced by the Association of Breast Surgery (ABS 2010) and National Institute for Health and

Care Excellence (NICE 2013). Guidance used in other countries may show some variation in age of screening or follow-up pathways. However there is also a high degree of concordance noted, strengthening the evidence-based approach.

Rationale

The type of diagnostic procedure will vary depending on the clinical presentation of the patient. This may require a patient assessment and clinical breast examination, core biopsy, fine-needle aspiration, punch biopsy or nipple cytology.

Indications

Breast diagnostics are indicated for diagnosis and surveillance of breast changes or disease. The type of diagnostic procedure will vary depending on the clinical presentation of the patient.

Contraindications

The type of contraindication will vary depending on the diagnostic procedure, such as bleeding post biopsy.

Legal and professional issues

Breast diagnostics are increasingly undertaken by advanced nurse practitioners within breast teams. They routinely act as clinicians alongside radiologists, sonographers and pathologists. They will undertake clinical breast examination, instigate appropriate radiological investigations and may obtain tissue or cell specimens. Breast diagnostic techniques include:

- clinical breast examination
- core biopsy
- fine-needle aspiration
- punch biopsy
- nipple cytology.

Where any of these are undertaken by a nurse practitioner or advanced clinical nurse, that nurse should be acting within the scope of his or her professional practice (RCN 2012). Agreement should have been obtained by the employing trust or authority that he or she is competent through local assessment. Clinical assessment, prescription of ionizing radiation in the requesting

Table 1.6 Benign breast changes across ages

		Aberration of normal development and involution (ANDI)		
Age	Normal process	Clinical presentation	Underlying condition	Disease
15–24	Duct and lobule formation	Discrete lump	Fibroadenoma	Giant or multiple fibroadenoma
	Stroma formation	Uneven or excessive breast development	Juvenile hypertrophy Asymmetrical development	Uni- or bilateral macromastia Poland’s syndrome
25–34	Cyclical hormonal effects causing mild breast pain and alterations in size which fluctuate	Exaggerated hormonal effects causing moderate breast pain, nodularity and tenderness Generally cyclical	None	Severe breast pain and tenderness interfering with normal activities Cyclical or non-cyclical in nature Continued nodularity
		Discrete lump	Fibroadenoma or macrocysts	Malignancy (uncommon in absence of family history)
35 onwards	Cyclical hormonal effects causing mild breast pain		Multiple microcysts Sclerosing adenosis Lobular hyperplasia	
			Isolated macrocysts	
			Duct ectasia	
	Lobular involution – microcysts, apocrine change, fibrosis, adenosis Ductal involution	Discrete lumps Nipple discharge Nipple retraction	Ductal hyperplasia Nipple discharge	Periductal mastitis Atypical ductal hyperplasia Multiple papillomata
			Periductal fibrosis Nipple retraction	Discrete lumps requiring biopsy
Normal				

Source: Adapted from Hughes (1991). Reproduced with permission of OUP; permission conveyed through Copyright Clearance Center, Inc.

of mammograms and undertaking tissue sampling all represent advanced nursing competencies.

Clinical breast examination

A clinical breast examination is required to gain information regarding the presenting symptom and patient background. It is also required to visually and palpably assess the breast and axilla in order to inform diagnostic tests required. It is indicated for any patient, male or female with a breast or axillary change, who is referred to a diagnostic breast clinic by a GP or other healthcare professional.

Rationale

A clinical breast examination is required to gain information regarding presenting symptoms and the patient's background to inform the potential diagnostic tests required.

Indication

Presentation with breast symptom or change including:

- lump
- thickening
- change in shape or appearance
- nipple discharge
- focal breast pain.

Contraindication

There are no contraindications to breast examination although inability to lie in the supine position or perform arm manoeuvres will limit the sensitivity of the examination and should be noted in the examination notes.

Procedure guideline 1.8 Clinical breast examination

Essential equipment

- Couch
- Gown
- Screen

Pre-procedure

Action

- 1 Greet patient and introduce self and role and gain consent for procedure.
- 2 Offer chaperone.

Rationale

To put patient at ease and inform of process **E** and gain consent (RCN 2017b, **C**).
Breast examination can be difficult for some women as it is considered intimate (RCN 2016b, **C**).

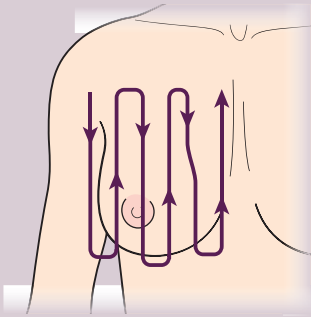
3 Review history of presenting symptom in patient's own words, noting when first noticed, triggering factors, alterations to symptom since first noting, intervening factors.	To establish duration of problem, constancy of symptoms. Breast cancer does not fluctuate but hormonal changes do (ABS 2010, C).
4 Assess menstrual history including: a. age periods started b. number of pregnancies – successful or not c. age of first pregnancy d. use of <i>in vitro</i> fertilization (IVF) e. experience of breastfeeding f. use of contraception g. regularity of periods h. age of menopause i. use of hormone replacement therapy (HRT) j. oophorectomy and/or hysterectomy.	Breast tissue is regulated by female hormones both over a lifetime and in each menstrual cycle. Information regarding oestrogen exposure is important to overall risk and may be pertinent to presenting symptom (ABS 2010, C).
5 Assess family history of breast and/or ovarian cancer.	Family history is a significant risk factor for breast cancer if present and may affect screening recommendations for current assessment and going forward (NICE 2013, C).
6 Assess previous medical history.	Relevant medical and surgical history as well as prescription drugs can be relevant (ABS 2010, C).
7 Assess lifestyle factors – weight, smoking history, alcohol intake.	To establish overall risk of breast cancer as well as other possible causes for symptom (ABS 2010, C).
8 Ask patient to remove upper clothes, including bra, behind curtain or screen. Provide a gown for use.	To enable ease of visible inspection and palpation. E Provide gown to maintain personal dignity (RCN 2008, C).
9 Wash hands with soap and warm water and dry, followed by alcohol rub.	To maintain infection control standards and minimize cross-infection and contamination (Fraise and Bradley 2009, E ; RCN 2017a, C).
Procedure	
10 Ask patient to open gown.	To allow for visual inspection. E
11 While patient is in sitting position with arms relaxed at sides, observe both breasts for contour, regularity, size, skin changes, nipple position and direction.	Malignant changes may attach internally and cause visible skin or shape changes such as tethering, dimpling and in-pulling (Pandya and Moore 2011, E).
12 Ask patient to raise arms together above head and observe movement of breast over chest wall. Check for symmetry and regular contour.	This allows inspection of the lower half of the breast (Pandya and Moore 2011, E).
13 Ask patient to bring hands together in prayer-like stance and push palms together or to put hands on hips and push down and in. Observe for any changes to breast outlines.	Contraction of muscles beneath breast tissue may exacerbate visible changes (Pandya and Moore 2011, E).
14 Ask patient to lie back on couch in supine position.	Breast examination is completed in supine position. E
15 Using the flat of 3 middle fingers, palpate the breast tissue firmly downwards toward the chest wall to assess texture of breast tissue.	Downward pressure should be constant and firm enough to cover superficial, middle and deep layers. E
16 Ensure that the entire breast is covered in a systematic fashion including the tail of tissue toward axilla. It is advised that either a vertical stripe (Action figure 16a), radial spoke (Action figure 16b) or concentric circular pattern (Action figure 16c) is followed. A consistent approach should be employed by the clinician.	A consistent approach increases the likelihood that breast examination is systematic and thorough (Pandya and Moore 2011, E).
17 Examine both breasts equally, starting with the 'normal' breast and finishing by specifically examining the area where a lesion is reported (if applicable).	To ensure an appreciation of what is normal and to allow comparison. To prevent concentrating on reported symptom at risk of missing a further change in a different area. E
18 Inform patient they can get dressed.	To maintain privacy and dignity. E

(continued)

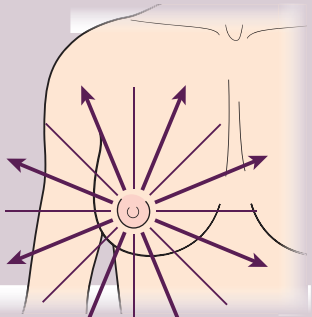
40 Procedure guideline 1.8 Clinical breast examination (continued)

Post-procedure

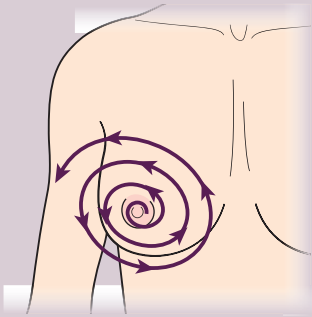
Action	Rationale
19 Annotate findings and assessment on record sheet using the accepted and agreed grading system: a. clinically normal=P1 b. abnormal but no concern=P2 c. uncertain=P3 d. suspicious=P4 e. clinically malignant=P5. Note position of any palpated symptom by clock face and distance from nipple. Supplement with clinical picture.	Being required to describe findings and indicate need for investigation focuses the clinician to produce a result. This has been found to optimize clinical breast examination (Goodson et al. 2010, E ; NMC 2010a, C).
20 Explain findings to patient and need for further radiological tests (as necessary).	To ensure that patient understands what the tests will involve and what to expect. This reduces anxiety and manages expectations realistically. E
21 Accurately complete request forms for mammography and/or breast ultrasound including patient demographics, history of symptoms and result of examination.	To ensure that only required tests are requested depending on patient history and symptoms (RCR 2008, C). To prevent unnecessary radiation exposure (RCR 2008, C).
22 Arrange to see patient with the results of radiological investigations or clearly arrange future follow-up.	To ensure that results are acted upon and patient informed of any decision. E



Action Figure 16a
Vertical pattern.



Action Figure 16b Radial
spoke pattern.



Action Figure 16c
Concentric circular pattern.

Core biopsy

Rationale

The aim of obtaining a core biopsy is to provide an intact histological sample of an area of clinical or radiological concern. Histological assessment of an intact lesion gives the most sensitive and complete result (Chou and Corder 2003) and should be the procedure of choice. In the case of a malignant result it will provide more detailed information to help guide the initial treatment options. It will be undertaken within the breast assessment clinic following clinical and radiological investigation. Clinical and radiological assessment should be completed prior to intervention to gain a tissue sample as this intervention itself may alter the outcome of the radiological and clinical assessment.

Breast biopsies should be guided by radiological imaging (mammogram, ultrasound or MRI) to reduce the need for repeat samples and to increase accuracy of the sample. In this case the procedure is carried out by a radiological consultant, junior doctor or appropriately trained sonographer. It is appropriate to carry

out clinical biopsies, without radiological guidance, in cases of locally advanced lesions and clinically palpably lesions that are not visualized on imaging (Chou and Corder 2003).

Indication

A defined area within the breast or axilla that by clinical or radiological criteria is abnormal.

Contraindication

There is little agreement in research on the absolute need to stop anticoagulants prior to biopsy (Chetlen et al. 2013). Stopping anticoagulant therapy will cause delay and may increase the risk to the patient, depending on the reason for treatment. The latest guidance states that a recent international normalized ratio (INR) check (within the last 5 days or longer if stable) should be available.

- For a core biopsy it is suggested the INR must be <4 although there is little evidence (BSBR 2012).

- If the INR is >4 then warfarin should be stopped for 3 days and restarted on the day of the biopsy.
- Patients on aspirin or clopidogrel do not need to stop treatment (BSBR 2012).

Equipment

Biopsy devices/needles

The biopsy device is a cutting needle with a hollow central cavity that is either integral to a disposable single-use firing apparatus or can be attached to a reusable firing apparatus or 'gun'. The apparatus is pulled back to hold the needle in a cocked position prior to introducing it into the patient. Releasing the firing mechanism launches or throws the needle forward to a specified penetration depth, typically 22 or 15 mm. As the needle moves forward through the anterior tissue it cuts and holds the sample within the hollow central needle space. An example is shown in Figure 1.16.



Figure 1.16 Biopsy device and needle.

Procedure guideline 1.9 Core breast biopsy

Essential equipment

- Procedure trolley
- Sterile dressing pack
- Sterile gloves
- Plastic apron
- Swab saturated with chlorhexidine in 70% alcohol (ChloraPrep), or isopropyl alcohol 70% (ChloraPrep)
- Sterile syringe (2 mL)
- Sterile needles (23 G/25 G)
- 14 G biopsy needle and biopsy gun/apparatus
- Scalpel blade (size 11)
- Sterile iris scissors
- Histology pot
- Histology form
- Sterile gauze
- Steri-Strips™
- Sterile dressing, e.g. Mepore

Additional staff

- This procedure requires an assistant and should not be attempted by a solo practitioner

Medicinal products

- Lidocaine 1% for local anaesthetic

Pre-procedure

Action	Rationale
1 Explain the procedure to the patient.	To ensure that the patient understands the procedure and gives his/her valid consent (RCN 2017b, C).
2 Check that the identity of the patient matches the details on the patient notes.	To ensure that the sample is correctly labelled (RCN 2017b, C).
3 Ascertain whether the patient is allergic to skin cleanser, adhesive plaster or local anaesthetic.	To prevent an allergic skin reaction (NMC 2010b, C).
4 Check patient's medications. The patient should be asked if they are taking anticoagulants.	To ensure any contraindications are considered and appropriate management is in place regarding anticoagulants (BSBR 2012, C ; Chetlen et al. 2013, E).
5 Ask the patient to change into the gown and position the patient on the couch in a position that facilitates access to the site requiring biopsy.	To ensure the patient is comfortable and to ensure safety should the patient feel faint during the procedure. E
6 Carefully wash hands using bactericidal soap and water, dry before commencement. Or decontaminate physically clean hands with alcohol-based handrub.	To minimize risk of infection (RCN 2017a, C).
7 Check all packaging for use-by date. Open and prepare the equipment on the procedure trolley.	To maintain asepsis throughout and check that no equipment is damaged. E
8 Isolate the palpable lesion between fingers.	To enable clinician to localize lesion and assess depth and position. E
9 Apply alcohol handrub and apply sterile gloves.	Sterile gloves form part of aseptic technique. Aseptic technique should be followed for any procedure that breaches the body's natural defences (Loveday et al. 2014, C).

Procedure

- | | |
|---|--|
| 10 Clean the area of patient's skin to be anaesthetized with the locally agreed cleansing solution. | To reduce risk of contamination from skin flora (Gould 2012, E ; Scales 2009, E). |
|---|--|

(continued)

42 Procedure guideline 1.9 Core breast biopsy (*continued*)

Action	Rationale
11 Inform the patient that a local anaesthetic will be administered intradermally and subcutaneously and that it can result in a 'stinging' sensation.	To inform patient and manage anxiety (Rocha et al. 2013, C).
12 Draw up and then inject lidocaine 1% 2–3 cm from lesion.	The local anaesthetic should be injected up to the lesion and backwards along the path of the needle to reduce discomfort (Rocha et al. 2013, C).
13 Check that the area to be incised is numb by asking patient if any pain is felt by touching the skin with a sterile needle prior to the procedure.	To reassure patient that the local anaesthetic works (Rocha et al. 2013, C).
14 Pick up sterile scalpel blade with dominant hand.	Ensure that dominant hand is free and practitioner is in the best position to make incision (Rocha et al. 2013, C).
15 Localize the lesion by holding a small area of skin taut between thumb and forefinger of the non-dominant hand. Then, using the scalpel blade, break the integrity of the dermal layers. Incise scalpel blade to a depth of 5 mm maximum (Action figure 15).	To allow entry of biopsy needle into breast tissue beneath dermal layers (Rocha et al. 2013, C).
16 Withdraw scalpel blade and release skin.	To allow entry of biopsy needle into breast tissue beneath dermal layers (Rocha et al. 2013, C).
17 Pick up 14 G biopsy device with dominant hand and draw back into 'cocked' position.	14 G biopsy needle obtains greater sensitivity than 16 G or 18 G without increasing cost (Rocha et al. 2013, C ; Wallis et al. 2006 C).
18 Introduce the biopsy needle through the puncture site in the dermis and advance toward the palpable lesion while isolating the lesion and fixing between the thumb and finger of the non-dominant hand.	Isolating the lesion with non-dominant hand enables the practitioner to map the position of the lesion and to gauge where the biopsy needle is in relation to it (Rocha et al. 2013, C).
19 Once the biopsy needle is appropriately positioned, at least 2–3 cm away from the lesion but directed at it, release the mechanism which propels the needle forward into the lesion. Ensure that the path of the biopsy needle is running parallel or oblique to deeper structures.	The biopsy apparatus allows for the hollow biopsy needle to be 'fired' into the lesion. If the needle is too close before the apparatus is deployed, the core may be taken from tissue beyond the target lesion. The practitioner must be aware of the length of throw of the biopsy needle. (Rocha et al. 2013, C).
20 Withdraw the needle and ask assistant to apply pressure to wound until no signs of bleeding.	Withdraw the needle in order to access the sample (Rocha et al. 2013, C).
21 Move the biopsy needle above the sample pot containing formalin and draw back the cocking apparatus once to expose the core biopsy. Use sterile needle to move biopsy from needle into the sample pot.	Applying pressure helps to stop bleeding. E Formalin fixes the tissue and preserves cellular architecture and composition ready for subsequent examination (Fox et al. 1985, E).
22 Repeat steps 19–21 to obtain minimum of 4 cores if possible. Angle the biopsy needle through the lesion in different planes to increase representativeness of sample.	Avoid crush artefact of biopsy core. E The number of cores obtained may vary as lesions are not always uniform and a higher number of samples increases the accuracy of the result (Wallis et al. 2006, C).
23 Once the required number of samples is obtained discard the biopsy device/needle in a sharps bin.	To reduce risk of sharps injury (RCN 2013, C).
24 Ensure pressure is correctly being applied by assistant and there is no active bleeding.	To reduce incidence of haematoma post procedure (Rocha et al. 2013, C).



Action Figure 15 Biopsy site skin stretched.

Post-procedure

25 Close sample pot and ensure lid is on securely.	To ensure that sample remains in pot and is uncontaminated (WHO 2015, C).
26 Ensure correct patient identifier label is on the sample pot.	To ensure that the result is ascribed to correct patient. This should be done immediately and by the practitioner (NMC 2010a, C).
27 Inspect the puncture site before applying the dressing.	To ensure that the puncture point has sealed and that bleeding has stopped (Rocha et al. 2013, C).
28 Steri-Strips should be applied to close the wound.	To aid healing of the wound and minimize the risk of infection (Rocha et al. 2013, C).
29 Apply a sterile dressing over the Steri-Strips with pressure to continue compression.	To aid healing of the wound and minimize the risk of infection (Rocha et al. 2013, C).
30 Remove gloves and discard waste in the correct containers, for example sharps into a designated receptacle.	To ensure safe disposal and avoid injury to other members of staff or the public (DH 2013, C ; HSE 2003 C).
31 Complete request form and place sample pot together with form.	To ensure that the result is ascribed to the correct patient. Ensure correct side of body is recorded and that clinical details are correct as this may help pathological interpretation (NMC 2010a, C ; WHO 2015, C).
32 Ask the patient to re-dress.	To ensure dignity and privacy. E
33 Ensure that the patient is comfortable and arrange to be observed for swelling at biopsy site, bleeding through dressing or systematic symptoms such as dizziness or nausea for 30 minutes following injection of local anaesthetic.	To monitor for signs that may indicate adverse reaction to the local anaesthetic such as confusion, respiratory depression and hypersensitivity (Rocha et al. 2013, C).
34 Assess covered biopsy site after 30 minutes for signs of bleeding.	To ensure that the puncture point has sealed and that bleeding has stopped (Rocha et al. 2013, C).

Breast fine-needle aspiration (FNA)**Rationale**

Fine-needle aspiration will provide cells for cytological assessment rather than a block of tissue. As the information available from cytology is less detailed, a biopsy is considered the best approach. However, FNA is performed if the lesion is positioned in such a way that a biopsy may be more hazardous to the patient. An FNA is also the standard pathological investigation for initial assessment of a lymph node. Standard cytological assessment will confirm whether cells are benign or malignant and this is satisfactory for benign outcomes.

Indications

FNA is the second choice for obtaining a pathological sample. It is indicated in the following situations:

- Where the presenting lesion is considered to be a lymph node rather than a breast lesion.
- Where the index lesion is located in a technically difficult area to biopsy.
- Where the biopsy may carry more risk.
- Where the area to be assessed is below the size suitable for a core biopsy.
- If the patient is on anticoagulant therapy with INR outside of range (>4) and said therapy cannot be stopped (BSBR 2012). Patients undergoing an FNA do not need to have INR checked or therapy stopped.

Contraindications

- Position and location of lesion that is inaccessible with FNA.

Procedure guideline 1.10 Breast fine-needle aspiration (FNA)**Essential equipment**

- Procedure trolley
- Sterile dressing pack
- Sterile gloves
- Plastic apron
- Swab saturated with chlorhexidine in 70% alcohol (Chloraprep), or isopropyl alcohol 70% (Chloraprep)
- Sterile syringe (10 mL)
- Sterile needles (23 G/25 G)
- 4 glass slides
- Pencil

- Slide container
- Fixative
- Universal container with normal saline
- Cytology request form
- Sterile gauze
- Sterile dressing, e.g. Mepore

Medicinal products

- 10 mL sodium chloride 0.9% ampoule

Pre-procedure

Action	Rationale
1 Explain the procedure to the patient.	To ensure that the patient understands the procedure and gives his/her valid consent (RCN 2017b, C).
2 Check that the identity of the patient matches the details on the patient notes.	To ensure that the sample is correctly labelled (RCN 2017b, C).

(continued)

Procedure guideline 1.10 Breast fine-needle aspiration (FNA) (continued)

Action	Rationale
3 Ascertain whether the patient is allergic to skin cleanser, adhesive plaster or local anaesthetic.	To prevent an allergic skin reaction (NMC 2010b, C).
4 Check patient's medications. The patient should be asked if they are taking anticoagulants.	To ensure any contraindications are considered and appropriate management is in place regarding anticoagulants (BSBR 2012, C ; Chetlen et al. 2013, E).
5 Ask the patient to change into the gown and position the patient on the couch in a position that facilitates access to the site requiring biopsy.	To ensure the patient is comfortable and to ensure safety should the patient feel faint during the procedure. E
6 Carefully wash hands using bactericidal soap and water, and dry before commencement. Or decontaminate physically clean hands with alcohol-based handrub.	To minimize risk of infection (RCN 2017a, C).
7 Check all packaging for use-by date. Open and prepare the equipment on the procedure trolley.	To maintain asepsis throughout and check that no equipment is damaged. E
8 Use alcohol handrub once again and put on sterile gloves.	Sterile gloves form part of aseptic technique. Aseptic technique should be followed for any procedure that breaches the body's natural defences (Loveday et al. 2014, C).
9 Attach the 10 mL syringe to the sterile 14 G needle and replace onto sterile area.	The syringe is to enable the practitioner to create a vacuum effect. E
Procedure	
10 Clean the area of patient's skin to be anaesthetized with the locally agreed cleansing solution.	To reduce risk of contamination from skin flora (Gould 2012, E ; Scales 2009, E).
11 Palpate and fix the clinical lesion between the fingers of your non-dominant hand.	To enable practitioner to map lesion and better position the needle. E
12 Warn the patient that the needle aspiration is about to be performed.	To manage patient anxiety and expectation. E
13 Introduce the needle into the approximate area of the lesion.	To ensure that cells are retrieved from the correct area (Wright 2012, E ; Fornage et al. 2014, E).
14 Once the needle is inserted, pull back on the syringe approximately 3–4 mL in order to create a vacuum.	The vacuum ensures that cells cut from the lesion by the needle are pulled back into the hollow core of the needle (Wright 2012, E ; Fornage et al. 2014, E).
15 Keeping the vacuum in place, move the needle backwards and forwards through the lesion without removing the needle from the breast entirely.	Repeated passes through the target lesion ensure a higher chance of obtaining representative cells (Wright 2012, E ; Fornage et al. 2014, C).
16 Release the vacuum gently by allowing the syringe to return to normal state.	Vacuum should be released while the needle is still within the breast to stop the obtained cells from being pulled up into the barrel of the syringe. Cells within the barrel of the syringe cannot be transferred to the slide (Wright 2012, E ; Fornage et al. 2014, C).
17 Withdraw needle from breast once vacuum fully released and release skin being held by non-dominant hand.	Withdraw needle in order to release cells onto slide (Wright 2012, E ; Fornage et al. 2014, C).
18 Ensure gauze and pressure are applied to the puncture site by an assistant while you are able to complete procedure away from patient.	To minimize bleeding and bruising (Wright 2012, E ; Fornage et al. 2014, C).
19 In order to get cellular material from needle onto slide, disconnect needle from syringe and fill syringe with air by pulling the plunger back.	To gain air into syringe, which will expel cells from barrel of needle onto slide (Wright 2012, E ; Fornage et al. 2014, C).
20 Reconnect syringe to the needle while ensuring the sharp is facing away from you and you are steadying the needle by the plastic cuff.	To gain air into syringe, which will expel cells from barrel of needle onto slide (Wright 2012, E ; Fornage et al. 2014, C).
21 Push air from syringe back through the needle with needle directed at slide.	To expel cells onto slide (Wright 2012, E ; Fornage et al. 2014, C).
22 Repeat steps 19 and 21 onto 4 slides if there is enough material.	
Post-procedure	
23 Spread cell sample on each slide using a clean slide to apply gentle downward pressure and glide along the stained slide.	To spread cellular material out and achieve a monolayer. Clumping of cells will mask results (Wright 2012, E ; Fornage et al. 2014, C).

24 If 4 good samples appear to have been obtained, 2 should be air dried and 2 should be fixed with formalin.	To achieve clear slides with intact cells for assessment. E
25 Label all slides with patient identifying details, procedure description and date using a pencil.	To ensure results are ascribed to correct patient. Pen will wash off in laboratory work-up so pencil must be used, E (NMC 2010a, C).
26 Place slides into slide container and label the outside of this with patient ID label.	To ensure results ascribed to correct patient (WHO 2015, C).
27 Use needles to draw up sodium chloride 0.9% into the syringe and then to push out sodium chloride into the universal container.	To obtain any cellular material that has been pulled up into barrel of syringe and to clean all material from needle barrel. E
28 Label universal container with patient identifying details, procedure description, location and date/time.	To ensure results are ascribed to correct patient (NMC 2010a, C).
29 Inspect skin wound and apply small sterile plaster.	To ensure that bleeding has stopped and that pressure can be released (Wright 2012, E ; Fornage et al. 2014, C).
30 Remove gloves and discard waste in the correct containers, for example sharps into a designated receptacle.	To ensure safe disposal and avoid injury to other members of staff or the public (DH 2013, C ; HSE 2003, C).
31 Advise patient to remove plaster later that day or the following day.	To manage anxiety and reassure patient. E
32 Ensure arrangements are made for patient to come back for or receive results as per local guidelines.	To manage anxiety and expectations. E
33 Ensure patient has an awareness of possible results expected.	To ensure good communication and manage expectations (ABS 2010, C).
34 Ensure patient can contact appropriate person if they experience any difficulties following the fine-needle aspiration.	To manage anxiety. E

Breast punch biopsy

A punch biopsy is a less invasive method in comparison to a core biopsy. It enables the nurse to take a specimen where the cutaneous (skin) layers are involved.

Indication

- Where the index lesion is involving cutaneous tissue.
- Locally advanced fungating lesions.

Contraindications

- Known sensitivity to local anaesthetic agents.
- Evidence of active infection may delay timing of biopsy unless the area is a fungating lesion which is chronically infected.

Procedure guideline 1.11 Breast punch biopsy

Essential equipment

- Procedure trolley
- Sterile dressing pack
- Non-sterile gloves
- Plastic apron
- Swab saturated with chlorhexidine in 70% alcohol (Chloraprep), or isopropyl alcohol 70%
- Sterile syringe (2 mL)
- Sterile needles (23 G/25 G)
- Punch biopsy instrument (3 or 4 mm)

- Sterile iris scissors
- Histology pot
- Histology form
- Sterile gauze
- Steri-Strips
- Sterile dressing

Medicinal products

- Lidocaine hydrochloride injection BP 1% w/v

Procedure

Action

- 1 Explain the procedure to the patient.
- 2 Check that the identity of the patient matches the details on the patient notes.
- 3 Ascertain whether the patient is allergic to skin cleanser, adhesive plaster or local anaesthetic.
- 4 Check patient's medications. The patient should be asked if they are taking anticoagulants.
- 5 Ask the patient to change into the gown and position the patient on the couch in a position that facilitates access to the site requiring biopsy.

Rationale

- To ensure that the patient understands the procedure and gives his/her valid consent (RCN 2017b, **C**).
- To ensure that the sample is correctly labelled (RCN 2017b, **C**).
- To prevent an allergic skin reaction (NMC 2010b, **C**).
- To ensure any contraindications are considered and appropriate management is in place regarding anticoagulants (BSBR 2012, **C**; Chetlén et al. 2013, **E**).
- To ensure the patient is comfortable and to ensure safety should the patient feel faint during the procedure. **E**

(continued)

46 Procedure guideline 1.11 Breast punch biopsy (*continued*)

Action	Rationale
6 Carefully wash hands using bactericidal soap and water; dry before commencement. Or decontaminate physically clean hands with alcohol-based handrub.	To minimize risk of infection (RCN 2017a, C).
7 Check all packaging for use-by date. Open and prepare the equipment on the procedure trolley.	To maintain asepsis throughout and check that no equipment is damaged. E
8 Position the patient on the couch in a position that facilitates access to the site requiring biopsy.	To ensure the patient is comfortable and to ensure safety should the patient feel faint during the procedure. E
9 Select the area to be biopsied. Commonly selected sites are the most abnormal-appearing site within a lesion or the edge of an actively growing lesion. Position of resultant scar should also be borne in mind.	To obtain a good representative tissue sample and minimize scar effect (Zuber 2002, E).
10 Select the appropriate size punch biopsy instrument. Punch biopsy needles range from 2 to 10 mm. 3–4 mm is usually sufficient for a good sample size.	To ensure that an adequate sample is taken (Zuber 2002, E).
11 Wash hands and put on non-sterile gloves.	To minimize risk of infection (RCN 2017a, C).
Procedure	
12 Clean the area of patient's skin to be anaesthetized with the locally agreed cleansing solution.	To reduce risk of contamination from skin flora (Gould 2012, E ; Scales 2009, E).
13 Inform the patient that a local anaesthetic will be administered and that it can result in a 'stinging' sensation.	To ensure the patient is fully informed and is aware of what to expect (Rocha et al. 2013, C).
14 Draw up lidocaine 1% in 5 mL syringe through 14 G needle.	To ensure the correct preparation. E
15 Inject lidocaine slowly into subdermal tissues.	To minimize pain or discomfort for the patient undergoing a punch biopsy of the nipple or cutaneous breast lesion (Zuber 2002, E).
16 Check that the area to be biopsied is numb by asking patient if any pain is felt when touching the skin with a sterile needle prior to the procedure.	To assess the effectiveness of the local anaesthetic prior to making the incision, to ensure that the procedure is pain free (Rocha et al. 2013, E).
17 When satisfied that the area to be biopsied is anaesthetized, the skin surrounding the biopsy site is stretched with the thumb and index finger of the non-dominant hand.	To stabilize the area before performing the punch biopsy. When the skin relaxes after the biopsy is performed, an elliptical-shaped wound remains. E
18 Warn the patient that the punch biopsy instrument is about to be placed on the skin of the breast/nipple and that they may feel a pushing sensation.	To reduce the risk of the patient moving, and to prepare them for what to expect. E
19 The punch biopsy needle should be held vertically over the skin by the dominant hand and rotated downward using a twirling motion created by the first two fingers on the dominant hand (Action figure 19). Once the instrument has penetrated the dermis into the subcutaneous fat, or once the instrument reaches the hub, it can be removed carefully and removed from the patient. The sample does not come away with the biopsy needle.	To obtain an adequate specimen from the appropriate area (Zuber 2002, E).

**Action Figure 19** Punch biopsy technique.

20 Ensure safe disposal of biopsy needle into sharps container.	To ensure safe disposal and avoid injury to other members of staff or the public (DH 2013, C ; HSE 2003, C).
21 Using the local anaesthetic needle held in the non-dominant hand, raise the cylindrical skin specimen from the biopsy site. The use of forceps is discouraged. Iris scissors held in the dominant hand can be used to cut the specimen free from the subcutaneous tissues. The cut should be made below the level of the dermis.	To retrieve a good, intact sample and to avoid crush artefact or damage to the sample (Zuber 2002, E).
Post-procedure	
22 Place sterile gauze onto the biopsy site and apply digital pressure until bleeding has ceased.	To reduce the risk of leakage and to allow the puncture site to close (Rocha et al. 2013, C).
23 The specimen should then be placed into an appropriate formalin container, and labelled with the patient details, area biopsied, side, date and time.	Formalin fixes the tissue and preserves cellular architecture and composition ready for subsequent examination (Fox et al. 1985, E). To ensure that the specimen is assigned to the correct patient. E
24 Inspect the puncture site before applying the dressing.	To ensure that the puncture point has sealed and that bleeding has stopped (Rocha et al. 2013, E).
25 Steri-Strips should be applied to close the wound.	To aid healing of the wound and minimize the risk of infection (Rocha et al. 2013, E).
26 Apply a sterile dressing over the Steri-Strips with pressure to continue compression.	To aid healing of the wound and minimize the risk of infection (Rocha et al. 2013, E).
27 Remove gloves and discard waste in the correct containers, for example sharps into a designated receptacle.	To ensure safe disposal and avoid injury to other members of staff or the public (DH 2013, C ; HSE 2003, C).
28 Ensure that the patient is comfortable and arrange to be observed for bleeding through dressing or systematic symptoms such as dizziness or nausea for 30 minutes following injection of local anaesthetic.	To monitor for signs that may indicate adverse reaction to the local anaesthetic such as confusion, respiratory depression and hypersensitivity (Rocha et al. 2013, E). To monitor for continued bleeding (Rocha et al. 2013, E).

Nipple discharge smear

A nipple discharge smear is undertaken to exclude underlying breast pathology. Nipple discharge can be physiological. Normal cytology results should show a cellular specimen. The presence of ductal epithelial cells is cause for further investigation.

- nipple discharge is:
 - spontaneous
 - bloodstained
 - unilateral and/or uniductal.
- no target lesion palpable or visible on imaging.

Indications

A cytological smear should be sent if one or more of the following criteria are met:

Procedure guideline 1.12 Nipple discharge smear

Essential equipment

- Fixative
- Apron
- Non-sterile gloves
- 2 glass slides
- Slide container
- Pencil
- Cytology request form

Pre-procedure

Action

- 1 Inform patient that the intention is to try to elicit nipple discharge for specimen.
- 2 Ask patient to remove upper clothes, including bra, behind curtain or screen. Provide a gown for use.
- 3 Wash hands with soap and water, dry hands and apply apron and non-sterile gloves.

Rationale

- To reduce anxieties and manage expectations. **E**
- To enable ease of visible inspection and palpation. **E**
Provide gown to maintain personal dignity (RCN 2008, **C**).
- To minimize risk of infection or cross-contamination (RCN 2017a, **C**).

Procedure

- 4 Gently squeeze the nipple between the thumb and index finger with constant pressure.
 - 5 If discharge is seen, make a note of colour and whether it originates from a single duct or multiple.
- In order to elicit discharge, which will come from ducts immediately behind nipple (Derbis and Scott-Connor 2011, **E**).
- In order to inform overall clinical impression, assist in diagnosis and assist cytologist in their assessment. **E**

(continued)

48 Procedure guideline 1.12 Nipple discharge smear (continued)

Action	Rationale
6 Take a clean slide and smear the discharge onto the slide with a single wiping motion.	To transfer discharge cleanly from nipple to slide (Derbis and Scott-Connor 2011, E).
7 Apply a second clean slide onto the stained slide and apply gentle and constant downward pressure as you glide the clean slide over the stained one.	To achieve monolayer of cells if cells are present. Clumping of cells will obscure results (Derbis and Scott-Connor 2011, E).
Post-procedure	
8 Immediately fix slides with fixative by flooding slide with 95% alcohol solution.	To preserve cell architecture for assessment (Derbis and Scott-Connor 2011, E).
9 Give the patient some tissue to wipe the breast.	To help preserve dignity. E
10 Label the slides with correct patient demographic information, what the slide is of, and which side discharge is from as well as date.	To ensure results are ascribed to correct patient (Derbis & Scott-Connor 2011, E).
11 Remove and dispose of apron and gloves.	To ensure safe disposal and avoid injury to other members of staff or the public (DH 2013, C ; HSE 2003, C).
12 Complete request form.	To ensure results are ascribed to correct patient and to inform cytologist of clinical picture. E
13 Ensure patient is aware of plans to get results.	To manage anxiety and expectations. E

Post-procedural considerations

Immediate care

Observation of possible complications such as bleeding or infection should be monitored (Rocha et al. 2013).

Education of the patient and relevant others

The patient should be given adequate post-procedural instructions, including care of the biopsy site over the initial 4–48 hours. A contact number should also be provided should any complications arise.

Genetic testing

Definition

Genetic testing assesses the risk of cancer for a specific group of patients and their family. Cancer risk management advice is given to individuals and families who are known to have, or are suspected to have, an increased risk of cancer compared with the general population, due to heritable (germline) mutations in their DNA. Genetic testing is currently available for faults in genes that cause an increased risk of breast, bowel, ovarian, uterine and prostate cancer. Genetic tests are also available for rare faults in genes that may increase the risk of kidney, skin (melanoma), pancreatic and thyroid cancer and retinoblastoma. Initially a blood test is taken followed by assessment, history taking and counselling (Cancer Research UK 2016, Kirk 2005, Kumar and Clark 2016).

Related theory

Important genetic concepts and terminology

In order to provide patients with accurate information and appreciate when a referral to the cancer genetic department would be helpful it is essential to understand the difference between germline and somatic genetic testing.

Germline testing. This refers to a genetic test that looks for mutations (harmful variants) in genes that people were born with and that may cause an increased risk of cancer. Germline

mutations are present in every cell of the person's body, including the reproductive cells of the ova and sperm, meaning that such mutations can be passed down from parent to child (inherited) (Balmain et al. 2003). An example of a germline genetic test is a *BRCA1/2* mutation screen undertaken in a breast cancer patient who has a strong family history of breast cancer.

Somatic testing. This refers to a genetic test undertaken on the tumour sample of a cancer patient. This type of test looks at the mutations in genes of the tumour cells. These mutations are specific to the tumour cells, would not be found in normal (non-cancerous) cells in the person's body and would not be passed down from parent to child (Stratton et al. 2009). There will be many mutations within the genes of a tumour sample and these mutations are acquired not inherited. Somatic genetic test results can be used to determine treatment options.

Two examples of common somatic gene tests are:

- *HER2* testing in breast cancer. *HER2* status is used as a prognostic indicator and to plan treatment, for example *HER2*-positive patients will benefit from trastuzumab treatment (Wolf et al. 2013).
- *BRAF* testing in metastatic melanoma. A targeted treatment has been developed which is effective specifically for patients with a *BRAF* mutation in their tumour (Yu et al. 2015).

The genome refers to an organism's complete set of genetic information, including all of the genes. Each genome contains all of the information that organism requires to function. In humans the genome is made up of over 3 billion DNA base pairs and contains over 20,000 genes. Genes make up only approximately 1–5% of the genome. The rest of the DNA is important for regulating the genes and the genome. There is still a lot to learn about how the genome functions (Genomics England 2016).

In the oncology setting the cancer genome refers to the sequencing of the genes within a tumour sample. The catalogue of mutations within a tumour is specific to that tumour, and the range and types of mutations provide information to cancer researchers and to clinicians treating the patient (Stratton et al. 2009).

Understanding genetic terminology

A cancer predisposition gene is a gene in which germline mutations confer highly or moderately increased risks of cancer (Rahman 2014). For the purposes of this chapter this refers to genes in which rare mutations confer high or moderate risks of cancer (>2-fold relative risks) and at least 5% of individuals with relevant mutations develop cancer (Rahman 2014). A mutation is defined as a permanent change in the DNA sequence (Richards et al. 2015) and this change is also called a variant. Colloquially, 'mutation' is often used to describe a disease-causing (pathogenic) variant in a particular gene (e.g. the patient has a *BRCA1* mutation). However, the genes of any individual will contain many variants and most variants are not harmful (Richards et al. 2015).

Variants can be pathogenic, probably pathogenic, variation of uncertain significance (VUS), likely benign or benign. Pathogenic variants, and probably pathogenic variants are disease-causing changes in the DNA sequence. Information about these variants can be taken into account when assessing genetic risk and making healthcare decisions. Benign and probably benign variants are not harmful and would not be taken into account when assessing genetic risk. Variants of uncertain significance are changes in the DNA code that may or may not be harmful, but there is insufficient evidence to understand how the change in the DNA sequence may alter the function of the gene. The presence of a VUS should not change the management of the patient (Richards et al. 2015).

What proportion of cancer is inherited?

All cancer is caused by the accumulation of pathogenic mutations in the DNA within a cell. Genetic mutations may be acquired (occurring during someone's lifetime) or inherited (also called germline mutations). Most cancer occurs as a result of acquired DNA damage, for example in response to environmental factors such as smoking and radiation. These cancers are called 'sporadic' cancers. Only 2–3% of cancers are linked to inherited pathogenic mutations – they are a very rare cause of cancer, overall (Cancer Research UK 2016, Kluijdt et al. 2012). There are specific types of cancer where a small proportion of cases are due to an inherited mutation (Table 1.7).

Most patients with cancer will not require genetic input or testing as most cancers are sporadic. However, it is important to be able to recognize patients who may benefit from a genetics referral, to know how make a referral and to be able to communicate with patients about what to expect at their genetics appointment.

It is also useful to be able to know where to access reliable information about cancer genetics (Kirk 2005).

Rationale

Most germline genetic testing is arranged through a clinical cancer genetics service. The patient's personal history of cancer and their family history of cancer are assessed to determine the likelihood of identifying a germline mutation. If the chance of finding a mutation in a specific cancer predisposition gene or group of genes is significant (usually if there is at least a 10% chance), genetic testing is offered (Jacobs et al. 2014). This information is important for the person undergoing testing as it may inform current or future cancer treatments, preventative options and screening recommendations.

It is also important for the wider family as testing can be carried out in blood relatives to identify who else is at risk and to advise on risk management options. Wherever possible, genetic testing is offered to the patient affected by the cancer, rather than their unaffected relative, in the first instance. If a germline mutation in a cancer predisposition gene is identified, so-called 'predictive' genetic testing can then be offered to the unaffected relatives of the patient (Jacobs et al. 2014) to provide them with genetic information about their risk. It is important that genetic counselling is provided to people considering genetic testing so that a person is informed about all possible outcomes of the genetic test.

Indications

It is important to identify a person who might benefit from genetic services and information. Genetic testing would be undertaken in a person with a strong personal or family history of cancer where the chance of finding a mutation is significant. This is usually if there is at least a 10% chance. Specific clinical features and patterns of cancers in the family that indicate that a genetic referral is warranted are as follows (ACOG 2015, ICR 2016).

In the cancer patient

- Earlier than average age of onset of cancer (e.g. prostate cancer in a man under 50).
- Multiple primary cancers in an individual (e.g. breast and ovarian cancer or bowel and endometrial cancer).
- Bilateral or multifocal disease (e.g. bilateral kidney cancer).
- Specific types of cancer:
 - medullary thyroid cancer
 - triple negative breast cancer

Table 1.7 Proportion of cancer that is inherited

Type of cancer	Population lifetime risk (men)	Population lifetime risk (women)	Proportion of cases estimated to be due to rare inherited mutations
Breast	Rare	1 in 8	5–10% (for women)
Bowel	1 in 14	1 in 19	5–10%
Lung	1 in 13	1 in 17	Not known
Endometrial	n/a	1 in 41	5–10%
Cervical	n/a	1 in 135 (invasive)	Not known
Ovarian	n/a	1 in 52	10%
Prostate	1 in 8	n/a	5–10%
Thyroid	1 in 480	1 in 180	
Medullary thyroid	5–10 in 100 of thyroid cancers		25%
Pancreas	1 in 71		10%
Retinoblastoma	Rare		33%
Melanoma	1 in 54		5–10%

Source: Adapted from Cancer Research UK (2016), Eeles et al. (2014), Leachman et al. (2009); Lu et al. (2007).
n/a, not applicable.

- ovarian, fallopian tube or primary peritoneal cancers
- colorectal cancer with mismatch repair deficiency
- endometrial cancer with mismatch repair deficiency
- retinoblastoma
- adrenocortical cancer
- male breast cancer.

In the cancer patient's family

- Several close relatives from the same side of the family (i.e. related by blood, not marriage) who have been diagnosed with similar cancer or with related cancers (e.g. breast and ovarian or bowel and endometrial cancer).
- One or more close relatives diagnosed at an unusually young age.
- A pattern or more than one case of a less common or rare cancer (e.g. medullary thyroid).
- Pattern of childhood cancers in siblings (Cancer Research UK 2016, Kirk 2005, Kumar and Clark 2016).

Contraindications

- Genetic testing would not be undertaken where the chance of finding a mutation is very low.
- Where a person is uncertain whether they wish to undergo testing.

Legal and professional issues

Genetic tests for cancer predisposition genes should only be requested by health professionals with adequate training in genetic counselling and in interpreting genetic test results. Genetic testing is usually only carried out by clinical geneticists, genetic counsellors and genetic nurses. In some settings genetic tests are ordered by oncologists as part of a patient's diagnostic and treatment pathway, working in close collaboration with a cancer genetics unit.

Genetic competency standards for nurses

The Department of Health commissioned educational guidelines for nurses in 2003 (Kirk et al.), which were revised and updated in 2011 (Kirk et al. 2011a) to establish the skills and knowledge nurses need to have about genetics to be able to benefit their patients. Seven competency standards were agreed as a part of this work (Box 1.3). It is important that nurses identify those who are at risk for or susceptible to genetic-genomic conditions as well as genomic technologies used in the diagnosis and management of diseases such as cancer (Kirk et al. 2011b).

Box 1.3 Genetic testing skills for nurses, midwives and health visitors at registration

- 1 Identify clients who might benefit from genetic services and information (Gaff 2005).
- 2 Appreciate the importance of sensitivity in tailoring genetic information and services to clients' culture, knowledge and language level (Middleton et al. 2005).
- 3 Uphold the rights of all clients to informed decision making and voluntary action (Haydon 2005).
- 4 Demonstrate a knowledge and understanding of the role of genetic and other factors in maintaining health and in the manifestation, modification and prevention of disease expression, to underpin effective practice (Kirk 2005).
- 5 Demonstrate a knowledge and understanding of the utility and limitations of genetic testing and information (Bradley 2005).
- 6 Recognize the limitations of one's own genetics expertise (Benjamin and Gamet 2005).
- 7 Obtain and communicate credible, current information about genetics, for self, clients and colleagues (Skirton and Barnes 2005).

Consent and confidentiality

Clinical information regarding genetic test results and family histories of cancer is relevant to both the cancer patient and their unaffected relatives. There are nationally agreed guidelines for obtaining correct consent for verifying family histories of cancer and sharing genetic test results and for protecting the confidential information of the patient whilst allowing all at-risk relatives to benefit from genetic risk assessments and test results (Royal College of Physicians, Royal College of Pathologists and British Society for Human Genetics 2011). Patients may express concerns about confidentiality. It is important to inform patients that genetic notes are kept separate from the main hospital notes so confidential genetic information about themselves and their relatives is only available to the genetics team (Skirton and Barnes 2005).

Pre-procedural considerations

Assessment and recording tools

A family history can be recorded using a family history questionnaire or by drawing a 'family tree' or 'pedigree' (Figure 1.17). This can either be done on paper or using specialist computer programs designed to collect family history information (Bennett et al. 1995). The patient's family history is an important tool in determining the likelihood of an inherited cancer predisposition in the patient and their family. Where an inherited cancer predisposition is suspected a referral to a genetics unit would be indicated.

Patients are given a family history questionnaire to complete by the genetics team, ideally ahead of their genetics appointments. Information from this questionnaire is recorded on a pedigree and further details about the family history are recorded on the pedigree at the genetics appointment. The patient is asked to provide information about their relatives' names, dates of birth, dates of death and cancer or other significant medical history, and this information is recorded on the pedigree. The genetics team may also ask the patient to provide copies of death certificates or ask relatives to provide written consent to access their medical records (Bennett et al. 1995).

Non-pharmacological support

Patients seen in the cancer genetic clinic are offered information about their cancer risks and presented with options for genetic testing and/or risk management strategies, if appropriate. The genetics team works with the patient to help them make autonomous choices and to adjust to their genetic risk. This communication process may take place over several appointments over several months or consist of one or two appointments. It is important to tailor information to a specific client's personal situation by listening to and acknowledging an individual's prior experience, recognizing that ethnicity, culture, religion and ethical perspectives may influence their ability to utilize information and services. Communication strategies need to be adapted in relation to the individual's level of understanding of genetic issues (Middleton et al. 2005).

Potential benefits of a genetic risk assessment

When speaking to a patient about a cancer genetic referral, explain the reason for the referral and outline what can be expected at the appointment. Patients may be unaware of the benefits of a referral or that a genetic assessment may have significant implications for their relatives. Before a patient is offered genetic testing they will be provided with information about the condition, the chance of a positive result and the implications of a positive result both for themselves and for their family.

For the cancer patient

- Genetic risk assessment provides an assessment of the genetic basis for their cancer diagnosis.
- Assesses genetic risk to advise on long-term cancer surveillance after treatment.

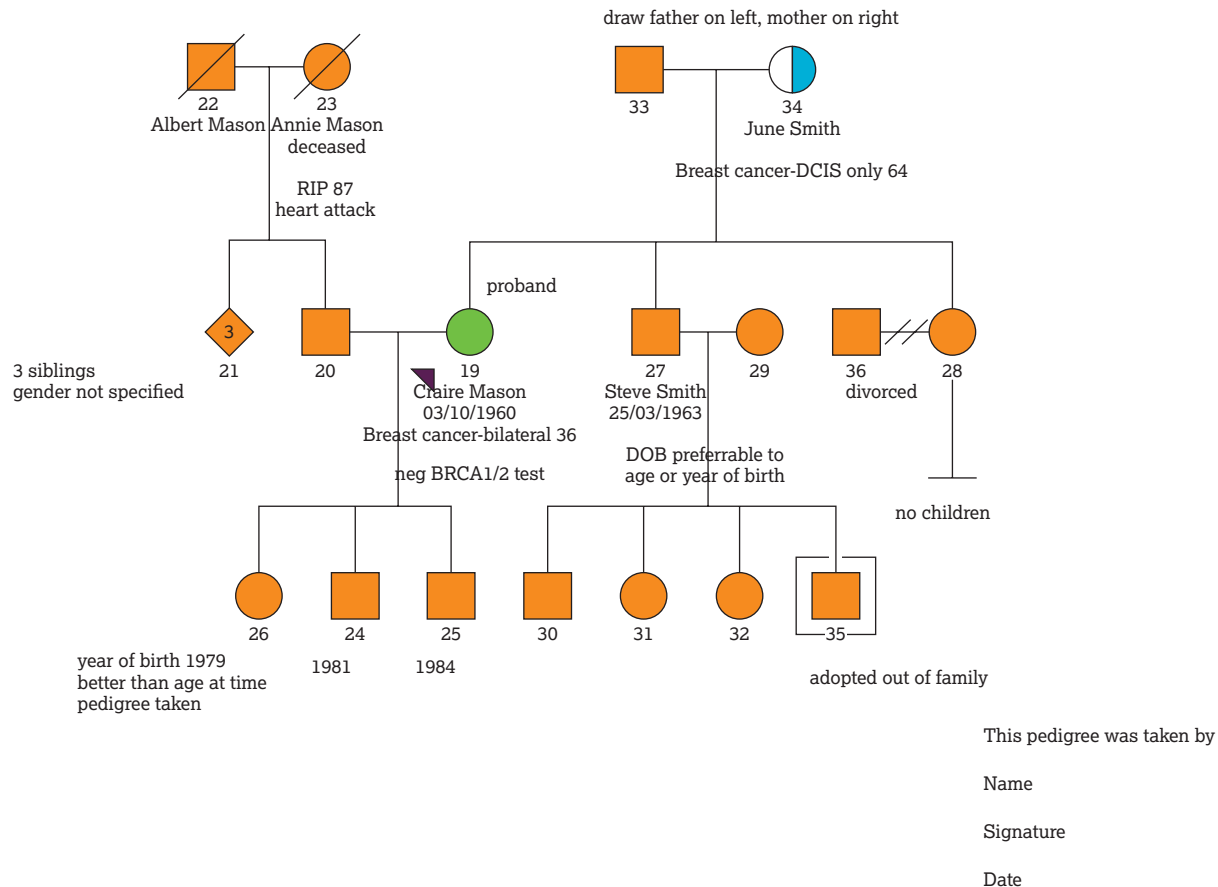
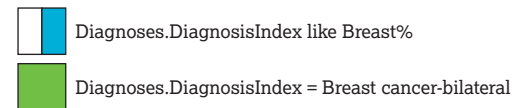
17887

Family File number

03/10/2017

Date pedigree last updated

Key for Symbols

**Figure 1.17** Family tree or pedigree.

- May offer genetic testing for germline mutations.
- Assists targeted treatment of cancer based on presence/absence of a germline mutation.
- Provides risk management options that may include the option of risk-reducing surgery.
- Clarifies cancer risk for offspring, siblings, parents and extended family.

For at-risk relatives

- Genetic risk assessment provides an understanding of how their family history of cancer alters their personal risk of cancer.
- Genetic testing for familial germline mutations may clarify their personal risk of cancer.
- Risk management options may include risk-reducing surgery and/or long-term cancer surveillance.
- Knowledge of a germline mutation may influence treatment planning if an at-risk relative develops cancer in the future.
- Cancer risk for offspring, siblings, parents and extended family is assessed (British Society of Genetic Medicine 2016).

Genetic referrals

It is imperative that any referral is discussed with the patient and they agree to the referral. The genetic testing, which is obtained via

a blood test, may be offered as part of the risk assessment undertaken at the appointment. However it is not always indicated. The results may take several weeks to process depending on the type of genetic test. Genetics centres will usually accept a referral from any healthcare professional. It does not have to be from the GP or consultant. However, it is good practice to discuss the referral with the treating team, and document it in the patient notes. When making a referral the following information should be supplied:

- name and date of birth of patient
- details of cancer diagnosis including age at diagnosis, pathology details, treatment and surgical summary; include a copy of the histopathology report, if possible
- details on medical history including previous diagnoses of cancer or significant illnesses
- brief description of the family history of cancer including the age of initial diagnosis.

Contact details of the regional genetic services in the UK are available on the British Society for Genetic Medicine website. Each centre's website has referral criteria details and contact details for queries prior to referral (British Society of Genetic Medicine 2016).

Genetic testing for inherited cancer syndromes – future practice

It is likely that more germline genetic testing will be offered directly through oncology clinics as well as genetics clinics. Genetic testing is more likely to be offered at the time of a cancer diagnosis as information about a germline mutation in a cancer predisposition gene can be useful in planning cancer treatment including surgery and chemotherapy (George et al. 2016).

The genetic tests offered are likely to change in the future. Patients are currently offered testing for specific 'high-risk' genes only. Genetic technology has improved significantly and it is now faster and easier to screen patients for mutations in many genes at once, rather than one gene at a time. These multigene tests are often called 'panel tests'. Panel tests may include numerous high- and moderate-risk genes that may contribute to cancer risks (Hall et al. 2014, Selkirk et al. 2014).

Although it is now possible to generate a lot of genetic data using these approaches, it is important that the *clinical utility* (whether the gene test provides useful information about diagnosis, treatment, management or prevention of a disease) and *clinical validity* (whether the genetic variant is clearly linked to the presence, absence or risk of a specific disease) of such tests are determined (Easton et al. 2015). For example, the clinical validity and utility of all the genes included in a panel test need to be clearly defined so that the results of the panel test can be accurately interpreted (Hall et al. 2014, Selkirk et al. 2014). Germline and tumour genetic information will become a key feature in the management of oncology patients in the future as new tests and treatments are developed.

Websites

labtestonline

www.labtestonline.org.uk

NHS Livewell: NHS cancer screening

www.nhs.uk/Livewell/preventing-cancer/Pages/cancer-screening.aspx

Ionising Radiation Regulations 1999 (SI 3232)

www.legislation.hmso.gov.uk/si/si1999/19993232.htm

Ionising Radiation (Medical Exposure) Regulations 2000 (SI 1059)

www.legislation.hmso.gov.uk/si/si2000/20001059.htm

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