Consensus Conference on

“Training and Competence Standards in Interventional Pulmonology”

Report of the Consensus Conference on Training and Competence Standards for the Interventional Pulmonology Master Program in Italy

Promoted by the Italian University Master of Florence University

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Introduction

Interventional Pulmonology (IP) is a subspecialty of pulmonary and critical care medicine that focuses on the evaluation and management of thoracic diseases, primarily involving the airways, lung parenchyma, and pleural space, using minimally invasive diagnostic and therapeutic procedures. IP is experiencing a rapid evolution of new technologies, with an emphasis on multidisciplinary care. The diversity of these procedures, and their application in patients with more complex conditions, is leading to the need for more specific training recommendations within this subspecialty. As patient safety and outcomes-based evaluation of clinical practice and procedures have become the priorities, the need for standardization in procedural training, that goes beyond pulmonary and critical care fellowships, must be considered. There is a need to develop training programmes, organized in high volume centres of excellence, with curricula specifically designed to enhance patient safety and improve outcomes, in order to improve trainee education, including by developing validated metrics for their competency assessment. The development of IP has made the training programmes of Specialty Schools no longer sufficient, not just in Italy but elsewhere as well. Over the past 20 years the number and complexity of interventional procedures has increased considerably, leading to recommendations for additional training after Specialty training.

In Specialty training the Core Curriculum envisages the acquisition of competency in basic diagnostic flexible bronchoscopy, but many schools are not even able to perform the entire training programme and we are still lacking objective criteria by which we can assess the competency acquired by trainees who have completed the training. Further, there is no overall programme including complex diagnostic procedures such as endobronchial ultrasound (EBUS), bronchoscopic navigation, thoracoscopy and operative procedures. The more complex interventional procedures are therefore acquired after Specialty training, often once the physicians are active practitioners, through training courses that are different for each professional. And there are no objective criteria to assess and certify the competency achieved by each trainee in the more complex interventional procedures. Modelled on the example of Ultra-Specialty disciplines such as Interventional Cardiology and Digestive Endoscopy, several international projects are underway to establish structured training and certification programmes for IP as well.

In the United States, more than 30 new post-Specialty Fellowships in IP have been established since 2005, each one lasting 1 or 2 years. The Association of Interventional Pulmonology Programme Directors (AIPPD) in collaboration with the American Academy of Bronchoscopy and Interventional Pulmonology (AABIP) and the American College of Chest Physicians (ACCP) have launched a programme aimed at standardizing competencies and training of Interventional Pulmonologists based on the recommendations of the Accreditation Council for Graduate Medical Education (ACGME). In these training settings, the Programme Director is responsible for organizing a structured syllabus, for ensuring the availability of suitable training tools, including simulation models, and for providing expert teaching staff and tutors (including being responsible for the constant assessment of staff performance); s/he will also be required to keep records of trainees’ progress and acquisition of skills, evaluating their performance and keeping a record of complications, as well as being in charge of contacts with other teachers and with Scientific Societies, from whom s/he receives feedback on the quality of training and on the scientific evaluation of teaching methods adopted. For this reason, the Programme Director must devote at least 50% of his/her time to aspects related to training in IP.

The European Respiratory Society (ERS) has also established 2 programmes:
1. HERMES (Harmonising Education in Respiratory Medicine for European Specialists) consisting in a yearly Multiple Choice Questionnaire covering all areas of Pulmonology. The Spirometry teaching programme is the only one that also includes practical training and assessment. The ERS report on this programme is available at www.ersnet.org/hermes.

2. A programme providing professional certification of competence in Bronchoscopy with EBUS, which was introduced in 2016. The aim of this project is to train qualified physicians so that they are able to perform EBUS independently and competently. This three-part training programme will ensure that participants possess all the necessary knowledge and skills required to obtain ERS certification in EBUS.

Fig. 1

Another problem to be addressed relates to the teaching methods. Trainees are for the most part expected to learn through fairly ineffective methods, consisting in students sitting passively listening to frontal lessons, or in the traditional “see one, do one, teach one” method, which offers hardly any theoretical basis and very little practical experience. This is unjustifiable as a teaching programme, since it is well-known that it is highly ineffective from a learning point of view and places the patient at risk of complications when the results are unsatisfactory. Novel education tools such as simulation, flipped classroom models and problem-based learning (PBL) exercises are transforming the traditional approach to knowledge delivery. A gradual progression from theory to practice, using new teaching techniques, including live sessions and simulation, would provide a training setting more suitable for our current need to improve skills and update professionals. The full development of a subspecialty in IP will include the acquisition not only of knowledge and skills, but also of the behaviours and attitudes described in the curriculum, including a high degree of personal and professional maturity, which is based on experience and takes time to acquire. Training programmes should be learner-centred and competence-oriented, as well as being based on a spiral-shaped approach in which the same subject is addressed many times, from new and different perspectives of knowledge, ability, behaviour and attitude, until the trainee has demonstrated a high degree of skill and professionalism. The method proposed is based on a step by step approach, where the trainee undergoes a constant process of maturation and is offered opportunities to improve his/her professional skills. Recent advances in the field of education research have highlighted the need to
standardize both training programmes and evaluation of trainees, based on measurable competency metrics rather than mere volume (i.e. number of procedures performed) or subjective assessments from mentors and supervisors

The Consensus Conference on the professional training and competence standards in Interventional Pulmonology proposes that an agreement be reached on a **Core Curriculum** describing the professional profile of the Interventional Pulmonologist and on the **Training Process** needed in order to achieve a level of competence that enables him/her to perform and manage – both independently and as a team member – all the main issues and procedures in IP. The aim of this document is to guide and support physicians wishing to undertake a gradual and voluntary improvement of their own competencies, and assist those planning and organizing training programmes in IP according to standardized criteria agreed upon by the scientific community.

The **Syllabus** relating to each individual competency provides a detailed description of the knowledge, skills and attitudes required for that specific competency, as well as the teaching methods to be adopted and useful information sources.

The curriculum and the recommendations for the training programme were developed by a group of specialized pulmonologists with proven clinical and teaching experience; they are all teachers of the Master in Interventional Pulmonology of the University of Florence and have benefited from the support of international experts and

The aim of this project and of the Consensus Conference is to:

1. Define the Core Curriculum for an Interventional Pulmonologist and the standard requirements for professional competency qualification
2. Define the training programme Syllabus for the overall professional qualification and for each individual procedure
3. Establish a network of experts in IP, putting together practitioners from universities, hospitals and advanced training centres

The aim of this publication is to provide a practical guide to the organization of training programmes and to the certified evaluation of trainee competency in the different procedures. The intention is to standardize minimum requirements for IP fellowship programmes and Life-long learning (LLL), and to offer them as guiding principles that can be followed on a voluntary basis, not as a strictly binding standard. This publication is in no way intended to limit or diminish the current/future practice of pulmonologists who have not participated in IP fellowship training, nor is it intended to limit patient access to necessary procedures in the absence of a fellowship-trained Interventional Pulmonologist, should those procedures be available through another competent provider.

In this publication there are two sections of Syllabus descriptions: the first (section 4) on the clinical knowledge that the Interventional Pulmonologist must possess, and the second (section 5) on the skills that the Interventional Pulmonologist must master in order to perform the different kinds of procedures. When describing the clinical knowledge required in the treatment of each pathology, the Syllabus also lists the skills the trainee will master, once this knowledge is applied practically. And each Syllabus on the different procedures, that the trainee is required to become competent in, also includes a section on the clinical and technical knowledge that s/he must possess, as well as offering a detailed description of the procedural steps to be followed in the practical training.
1. The core curriculum in interventional pulmonology (IP)

**Programme Requirements for Graduate Medical Education in Interventional Pulmonology**

**Basic requirements**

- University degree in Medicine and Surgery
- Trainee must be qualified to practice as a physician
- Trainee must have completed a Fellowship in Pulmonology or other Fellowship, such as Internal Medicine, Emergency Medicine, Thoracic Surgery and Anaesthesiology and must have worked professionally for at least 5 years in a Respiratory Unit (pursuant to Italian legislation Decree of the President of the Republic no. 484, dated 10/12/97, and Ministerial Decree HEALTHCARE 30-31/01/98 – item 11 of tables – validated without time limits pursuant to Legislative Decree 254, dated 28/07/2000)

The document addresses alternative training programmes and curricula for Fellowships such as Internal and Emergency Medicine, Thoracic Surgery and Anaesthesiology, specifically in relationship to interventional procedures.

**Objectives for the Professional Profile of the Interventional Pulmonologist**


“The Professional Standard defines the structure, the content and the timeline of the training process leading to the acquisition of the skills needed for this professional profile, as well as the criteria according to which the examination for Professional Qualification will be organized. The competences below should be learnt according to a step by step approach during the course of the Pulmonology Fellowship, an IP subspecialty Fellowship and a continuing education or life-long learning programme.

The Interventional Pulmonologist must possess suitable knowledge, practical experience and clinical ability to:

1. Evaluate and manage patients with complex airways, thoracic and pleural disease.
2. Recommend the most appropriate diagnostic and/or therapeutic procedure based on an understanding of accepted indications, contraindications, and additional diagnostic and therapeutic alternatives in the context of safety and timeliness.
3. Demonstrate the ability to obtain an accurate and thorough pre-procedure patient assessment, including the identification of specific risk factors for each procedure.
4. Demonstrate the ability to minimize and manage anticipated and unanticipated complications.
5. Accurately identify, describe, and communicate pertinent procedural findings.
6. Recognize one’s own limitations and the limitations of a particular specialty or institution, and appropriately refer patients to providers who have the required equipment and skill set.
7. Demonstrate personal skills in obtaining informed consent, advanced directives, medical ethics, and communication to patients, families, and referring physicians.
8. Develop an understanding of the required equipment, including maintenance and technical troubleshooting.
9. Continue to contribute to and critically evaluate the scientific literature, specifically participating in research regarding new technologies or techniques specific to IP.
10. Demonstrate the responsible use of resources for diagnostic testing and therapeutic interventions.

11. Obtain the necessary skills to develop and direct a sustainable IP programme.

12. Maintain and review outcomes and compare them with benchmarks, to maintain the highest possible quality of care.

13. Complete training in two primary advanced diagnostic techniques, to include endobronchial ultrasound, and reach threshold numbers with appropriate supervision.

14. Complete training in a minimum of two ablative techniques for therapeutic management of the airway.

15. Complete comprehensive training in the use of both silicone and metallic airway stents, including stent placement, removal, and management of complications”.

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**General Competencies**

**Basic Technical and Professional Knowledge, Skills, Behaviours and Attitudes**

- Epidemiology of the pathologies pertaining to pulmonology
- Bronchopulmonary, pleural and mediastinal anatomy
- Physiology applied to airways obstruction and anaesthesiology procedures
- Knowledge of clinical risk: monitoring and preventing post-procedural (diagnostic and/or interventional) side effects, adverse reactions and complications
- Recording/documenting the process of diagnosis and treatment using the appropriate tools and technologies

**Basic Technical and Instrumental Knowledge, Skills, Attitudes**

- Knowledge of instrumentarium, including maintenance and problem solving tasks
- Correct use of tools and devices appropriate for diagnostic/interventional procedures
- Monitoring and oversight of correct functioning of equipment, devices and tools used
- Management of machines providing mechanical ventilation
- Technological innovation and mastery of new machines (Health Technology Assessment – HTA)
- Procedural quality control management: maintain and produce a comprehensive procedural log that includes underlying diagnosis, outcomes, diagnostic yield, and complications
- Equipment maintenance and procedural suite design
- Occupational Safety and Health Administration (OSHA) and infection control regulations and policies as they pertain to procedural suite design, ventilation, radiation physics and biology, as well as isolation and safety requirements related to the use of X-ray imaging equipment; laser physics and safety

**Medical Knowledge and Skills Specific for IP**

- Knowledge of the basic principles of anatomy, physiology and physics, as they pertain to the practice of IP.
- Thoracic imaging procedures, to include CT, MRI, PET, thoracic ultrasound
- Principles of advanced airway, mediastinal and lung parenchyma imaging enhancement techniques: endoscopic MRI-EMN (Electromagnetic Navigation), radial and convex ultrasound and transthoracic ultrasound
Knowledge of indications, contraindications, limitations, complications, techniques and interpretation of results of those diagnostic and therapeutic procedures integral to the discipline, including the appropriate indication for (and use of) screening tests/procedures, as well as the risks and benefits of alternative procedures.

- Ability to achieve an accurate and in-depth evaluation of the patient, including the identification of specific risk factors for each procedure.
- Evaluate and identify key aspects of a complex situation.
- Formulate diagnosis of specific potential risk and of treatment intensity.
- Choose the most effective intervention strategy based on the patient’s pathology and clinical conditions.
- Correctly identify, describe and communicate the significant outcomes of the procedures.
- Ability to prevent and manage expected and unexpected mechanical complications of interventional pulmonary procedures, which may include:
  - Simple and tension pneumothorax, haemothorax.
  - Airway disruption, perforation, tear.
  - Massive haemoptysis.
  - Refractory hypoxia / respiratory failure.
  - Injury to adjacent organs, e.g. oesophageal perforation during percutaneous dilatational tracheostomy placement.
  - Airway fire.
  - Secondary tracheal stenosis (post tracheostomy) and secondary bronchial/tracheal strictures from laser/EC/mechanical trauma/anastomotic complications.
- Ability to manage semi-intensive respiratory activity.
- Identify, manage and prevent pulmonary infections.
- Recognize one’s own limitations and the limitations of the specialty or facility; refer patients appropriately to facilities possessing suitable instruments and competencies.
- Medical legal issues and informed consent.
### Specific Competence in Interventional Pulmonology

**Part A: Disease-specific basic knowledge requirements**

| Lung cancer and solitary pulmonary nodule (Section 4.1) | • Diagnosis, staging and natural history of thoracic malignancies to include lung cancer, mesothelioma, thymoma, lymphoma  
• Pathology of lung cancer  
• Indications, contraindications, limitations, complications, techniques, and interpretation of results of diagnostic and therapeutic procedures integral to the discipline, including the appropriate indication for and use of screening tests/procedures as well as the risks and benefits of alternative procedures  
• Collaboration among specialists in the management of lung cancer: multidisciplinary thoracic tumour board  
• Undiagnosed mediastinal and hilar lymphadenopathy |
| Malignant and non-malignant central airway disorders (Section 4.2) | • Malignant central airway disorders  
• Non-malignant central airway obstruction due to:  
  o Tracheal/bronchial obstruction secondary to, for example, granulomatosis with polyangiitis, post-intubation/tracheostomy, tuberculosis, sarcoidosis, amyloidosis, recurrent respiratory papillomatosis, broncholithiasis, tracheal/bronchial malacia / excessive dynamic airway collapse secondary to relapsing polychondritis, Mounier-Kuhn syndrome, COPD  
  o Foreign bodies  
  o Vocal cord disorders  
  o Airway complications following airway surgery/lung transplant to include anastomotic strictures/granulation  
  o Airway stent-associated granulation tissue  
  o Extrinsic compression from, for example, goitre, mediastinal cyst, lymphadenopathy  
• Pathophysiology and radiographic interpretation of central airway obstructions  
• Strategy on endoscopic and surgical treatment |
| Interstitial lung diseases and granulomatosis (Section 4.3) | • Classification, epidemiology, aetiology, clinical and endoscopic diagnosis, treatment and follow-up of interstitial lung diseases  
• Radiographic (CT-Scan) interpretation of the main patterns of ILD and granulomatosis  
• Indication for interventional bronchoscopic diagnosis (BAL, transbronchial biopsy and needle aspiration, cryobiopsy) and for surgical biopsy |
| Pulmonary infections (Section 4.4) | • Classification, epidemiology, aetiology, clinical and endoscopic diagnosis, treatment and follow-up of pulmonary infections  
• Radiographic and blood chemistry interpretation of pulmonary infections  
• Indication for interventional diagnosis (BAL, transbronchial biopsy and
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<td>4.5</td>
<td>COPD and Asthma</td>
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<td>COPD</td>
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<td>Pathophysiology, classification, imaging and treatment of severe COPD</td>
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<td>Indications for the endoscopic treatment of emphysema</td>
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<td></td>
<td>Asthma</td>
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<td>Pathophysiology and treatment of severe asthma</td>
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<td>Differential diagnosis of asthma</td>
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<td>Indications for the endoscopic treatment of asthma (thermoplasty)</td>
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<td>Pleural diseases</td>
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<td>Parapneumonic effusion and empyema</td>
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<td>Malignant pleural effusions</td>
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<td>Malignant mesothelioma</td>
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<td>Recurrent non-malignant pleural effusions (chylothorax, hepatic hydrothorax / effusions due to refractory congestive heart failure)</td>
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<td>Pneumothorax</td>
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<td>Pleural fistulas</td>
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<td>Knowledge of differential diagnosis and treatment through non-invasive (radiographic imaging, thoracic ultrasound) and invasive procedures (medical thoracoscopy with parietal pleural biopsy and pleurodesis, pleural catheter placement: chest tube, small bore catheter, and implantable tunneled catheters, percutaneous pleural biopsy, VATS)</td>
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**Part B: Skills in diagnostic and operative procedures**

### Diagnostic procedures (Section 5.1)
- **Flexible bronchoscopy** and basic biopsy techniques: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing
- **Interventional endosonography** (EBUS, EUS, EUS-B): Mediastinal and hilar lymph node sampling using convex endobronchial ultrasound
- **Bronchoscopic navigation**: image-guided or computer-guided diagnostic bronchoscopy for evaluation of parenchymal opacities, of airway invasion vs compression, and to guide biopsy: fluoroscopy, electromagnetic pulmonary navigation, EBUS-radial probe and cryobiopsy.
- **Transthoracic pulmonary biopsy**

### Operative (Therapeutic) procedures (Section 5.2)
- Rigid bronchoscopy with the following associated procedures:
  - Rigid core and mechanical debulking
  - Endobronchial ablative techniques using one or more of the following devices: Laser, Argon plasma coagulation, Electrocautery, Cryotherapy
  - Photodynamic therapy
  - Placement and removal of endobronchial stents (silicone, hybrid, dynamic)
  - Rigid sequential dilatation
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| Sedation in Interventional Pulmonology (Section 5.3) | • Medication administration methods  
• Knowledge and use of sedation medication  
• Treatment of complications |
| Pleural procedures (Section 5.4) | • Thoracic ultrasound to assess and guide interventions in the pleural space  
• Medical thoracoscopy with parietal pleural biopsy and pleurodesis  
• Pleural catheter placement (chest tube, small bore catheter, and implantable tunneled catheters) |
| Paediatric Bronchoscopy (Section 5.5) | • Indications for paediatric bronchoscopy  
• Skilled use of flexible and rigid bronchoscopy  
• Management of complications  
• Operative bronchoscopy for foreign body removal |
| Bronchoscopy in Anaesthesiology and ICU (Section 5.6) | • Bronchoscope intubation in difficult airways  
• Management of endotracheal tubes, double lumen tubes and laryngeal mask  
• Management of tracheostomy tubes  
• Tracheobronchial aspiration to drain secretions  
• Diagnosis of pulmonary infiltrates, VAP and ARDS in ICU  
• Percutaneous dilatational tracheostomy placement and management |
| Bronchoscopy in Thoracic Surgery (Section 5.7) | • Use and integration of interventional procedures in the management of surgical interventions: mediastinoscopy, thoracotomy and lung resection, thoracoscopy and video-assisted thoracoscopy, surgical management of empyema, lung volume reduction surgery, lung transplantation, laryngeal/tracheal resection and reconstruction, tracheoplasty, suspension laryngoscopy, open surgical tracheotomy, pulmonary sequestration, and management of other malformations, cystic lesions, empyema  
• Clinical and surgical staging of lung cancer  
Diagnosis and treatment of surgical complications: loss of airway integrity; anastomotic dehiscence, tracheobronchial/oesophageal fistula, broncho-pleural/alveolar-pleural fistula; management of chest drainage |
| Emergency in Interventional Pulmonology (Section 5.8) | • Knowledge and management of respiratory emergency  
• Bronchoscopic management of massive haemoptysis, foreign body, thoracic trauma, central airway obstructions and lesions, surgical complications  
• Paediatric thoracic emergency |

Note: This model is the result of a process of reflection and systematic reorganization of concepts and practices from experiences in “competence training”, adopted in Europe as a training strategy;
the model is based on European and Italian legislation and on several national/international experiences aimed at identifying common or innovative elements.

2. Modern training and assessment tools for IP

2.1. From the notion of training to the notion of competency

Professional competence in medicine means to make use – on a regular basis and in a sensible manner – of communication, knowledge, technical skills, clinical judgment, emotions, values and critical reflexions in one’s everyday practice in order to enhance the wellbeing of individuals and of the community. Competence therefore includes knowledge (knows), clinical skills and capabilities (knows how to do), personal attitudes and behaviours (knows how to act). Psychologist George Miller, back in 1990, proposed a model for the assessment of clinical competence based on the layers of a virtual pyramid, integrating basic knowledge with clinical skills and personal skills into the actions performed. R. Mehay and R. Burns adapted the Miller triangle to include the knowledge, skills and attitudes domains of learning and thus called it ‘Miller’s Prism’. Dent and Harden have added a 5th level called ‘Mastery’ that sits above ‘Does’ to make the distinction between one who can perform a skill with competence to one who can perform it in a expert or masterful way.

Fig. 2

MILLER’S PRISM OF CLINICAL COMPETENCE (aka Miller’s Pyramid)

it is only in the "does" triangle that the doctor truly performs

Based on work by Miller GE, The Assessment of Clinical Skills/Competence/Performance; Acad. Med. 1990; 65(9); 63-67
Adapted by Drs. R. Mehay & R. Burns, UK (Jan 2009)

It is fundamental that any training session (either in the classroom or in a practical setting), or any programme aimed at updating specialized physicians be capable of involving all three elements (knows, knows how to do, knows how to act) by using the teaching tools and methods that are best suited to the task at hand, and which are capable of ensuring that trainees achieve the level of
2.2. Competency-oriented education

Training in the new and increasingly complex medical technologies calls for a radical change from the traditional teaching practices, which envisaged the transfer of the theoretical knowledge acquired by the trainee directly onto the patient. Such a pattern is nowadays considered both ethically and legally unacceptable, since it can place the patient at risk if the initial stages of the physician’s learning curve have been unsatisfactory. Furthermore, the time a physician would need to learn the technique would risk becoming very long, since not enough procedures are performed on patients to meet the needs of trainee physicians.

Currently most training is provided through methods that are not very effective, consisting in the passive administration of frontal lectures and in the teaching method known as “see one, do one, teach one”, with little theoretical background knowledge and equally little practical experience.

According to the more recent didactic methodologies, training in Interventional Pulmonology should be organized in 5 stages:

1. **Theoretical Stage** with the use of more interactive teaching methods, such as flipped classroom, problem-based learning, live streaming, e-learning and blended learning.
2. **Practical Stage using low and high fidelity simulators** (artificial models, animal models, virtual reality, practical sessions on cadavers).
3. **Practical Stage on patients under supervision** of a tutor, based on the specific learning curve associated with each procedure and on the individual trainee’s predisposition.
4. **Quantitative and qualitative assessment** of acquired competence and final certification.
5. **Life-Long Learning**: continuing professional development is an important part of training programmes, enabling physicians to constantly update their professional competence. It is also a need linked to the physiological loss in performance levels when training opportunities are lacking. An entirely new paradigm, Continuing Professional Development (CPD), has been proposed as a replacement for the existing Continuing Medical Education (CME) system.

Every stage of the learning process can and should be monitored according to specific evaluation criteria and tools (knowledge and skills based assessment). Practice Centres or Boot Camps, where training is provided through a gradual process from theory to practice using live sessions and simulation can provide a form of training that is more in harmony with the new paradigm.
with the current needs for improvement of competencies and continuing professional development.

2.3. Learner-centred classroom model

General Principles
Many studies, both nationally and internationally, have shown that classroom training is more effective when it is interactive, favouring the active involvement of trainees. If the students are the main focus of the training programme (student-centred teaching, as defined by Colt H.), and characteristics such as flexibility, accessibility, capacity to adapt and cultural sensitivity are the basic pillars on which the training activity is constructed, the following aspects of student involvement are stimulated:

- Personal initiative
- Search for solutions
- Use of experimentation
- Observation as a tool leading to theoretical elaboration

In order for training to be able to express its full potential it is also necessary for students to understand clearly the aims of the training and for the overall training programme to be sustainable, in terms of both resource allocation and sufficient generalizability. Learning must be gradual, multidimensional, structured, personalized, stimulating and as evaluable as possible.

For this reason, all methods based on the principle of active learning have the following requirements:

- The method must be agreed upon with students and match their training needs
- The teacher must be transformed into a trainer / facilitator
- A set of rules that all players have agreed upon and which they observe fully, in a context of stringent discipline
- Agreement over the fundamental importance of the “training contract” between trainers and trainees.

A further fundamental element, which will be decisive in ensuring the success of the activities, is the notion of “discovery” which enhances the trainees’ mastery of new knowledge.

Methods and Techniques for the Stage of Theoretical and Classroom Training
Among the tools most useful in providing an interactive learning experience are those that make the most of web-based resources, such as teleconferences, e-books, websites and blogs, Apps, e-learning, learning objects, MOOC-Massive Open Online Courses, etc. These tools can make available in real time, “on demand” and on a vast scale, a huge variety of scientific materials, most of which are constantly updated.

E-learning platforms, the most popular of which is Moodle, allow trainers to organize their lessons and to create interactive systems that can be used in self-evaluation and remote evaluation as well. Massive Open Online Courses (MOOC) are university-level free access courses, organized by major international universities. Then there are web-based structured courses which provide the basic theoretical notions required, including especially those available at www.bronchoscopy.org.
Among the main classroom techniques, the “flipped classroom” (Fielding D) is a method that has been in use for many years, aimed at increasing trainees’ productivity, especially during the hours that the students spend in what is formally defined as the classroom\textsuperscript{32}. In this teaching model, traditional lectures can be provided to students online, so that they can read them in their own time, leaving actual student–teacher contact time for engaging in PBL and enquiry\textsuperscript{21}.

Fig. 4 – Traditional vs. Flipped Classroom - Source: washington.edu

In PBL (Problem Based Learning) the teacher presents a problem to the class and acts as a facilitator or mentor, rather than as the provider of solutions\textsuperscript{33}. In medicine, these exercises help learners gain cognitive, technical and experiential skills in a patient- and learner-centric environment. One such model, the ‘Practical Approach (PA) to Interventional Bronchoscopy’, is based on a four-box format which has been developed to complement traditional learning. This type of PBL helps learners think about the reasons for their actions and elaborate implementation strategies based on background information, relevant literature and personal experience\textsuperscript{34}.

Fig. 5 – The four-box approach for problem-based learning: Fielding, D.I, Maldonado, F. and Murgu, S., Achieving competency in bronchoscopy: Challenges and opportunities, Respirology (2014) 19, 472–482\textsuperscript{21}

<table>
<thead>
<tr>
<th>Initial evaluation</th>
<th>Procedural strategies</th>
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<td>2. Patient's significant comorbidities</td>
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<td>3. Patient's support system (also includes family)</td>
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<td>1. Indications, contraindications and expected results</td>
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<td>4. Respect for persons (informed consent)</td>
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<tr>
<th>Procedural techniques and results</th>
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<tr>
<td>1. Anaesthesia and other perioperative care</td>
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<td>2. Techniques and instrumentation</td>
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<td>3. Anatomic dangers and other risks</td>
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<td>4. Results and procedure-related complications</td>
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<td>Long term management plan</td>
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<tr>
<td>1. Outcome assessment</td>
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<tr>
<td>2. Follow-up tests, visits and procedures</td>
</tr>
<tr>
<td>3. Referrals to medical, surgical or palliative/end of life subspecialty care</td>
</tr>
<tr>
<td>4. Quality improvement and team evaluation of clinical encounter</td>
</tr>
</tbody>
</table>

There are other tools that can support training programmes, including the following:
- **Journal club**, presentations given by groups of students and discussed by all;
- **Case presentations**
- **Research projects (with assessment)**
- **Lessons in small groups**
- **Grand Rounds**, consisting in the presentation of cases and clinical activities to an audience of physicians and students, in the presence of the patient, who can answer questions, or who can be replaced by an actor simulating the patient’s behaviour.
2.4. Hands-on practical training

General principles underpinning training programmes
There is a large component of procedures in Interventional Pulmonology. In training programmes for this discipline practical training is therefore of crucial importance, i.e. practicing the different procedures before being allowed to perform them independently. How successfully this part of the training course is implemented, however, will depend very much on the methods and techniques used, as well as on the assessment and evaluation criteria applied during the course itself. The number of different procedures that all trainees need to become competent in is vast, and this could be risky for patients involved in the practical stage of training courses in Interventional Pulmonology; furthermore, the final assessment assigned to each trainee should not merely list the number of practical procedures performed, but rather provide a means of certifying the trainee’s level of competence.\textsuperscript{15,16}

Training methods and techniques
The concept of “learning by doing” can no longer be considered acceptable, especially when the procedures in question are invasive and risky for patients. Equally, the old approach of “see one, do one, teach one” is no longer sustainable. In recent years a more complex and multi-faceted approach has come into use, centred on the notion “see one, simulate many, do one competently” which can even be extended to include “teach everyone”. This has led to the development of simulation tools capable of enhancing and facilitating practical hands-on learning, as well as extending the opportunity of training to all students.\textsuperscript{35}

Historically, the apprenticeship model has been used to teach trainees how to perform flexible bronchoscopy through practice on patients. Not only does this training model induce learner anxiety, but trainees also take home different experiences, depending on the individual patients and preceptors they encounter.

Leaving the training experience to chance introduces significant variability in the training and can result in some physicians being inadequately trained in basic procedural skills. Although generally considered to be a safe procedure, bronchoscopy can be associated with severe complications, including respiratory failure and death. The presence of trainees during bronchoscopy may lead to increased complications, thereby placing the burden of procedure training on our patients by impacting their comfort and safety. In addition, non-diagnostic procedures resulting in the need for “repeat” procedures may also be considered a specific complication in the training environment. As new techniques are developed, the practicing physician is faced with learning new skills without the opportunity or time for dedicated training or proctored procedures that have clearly defined learning objectives. In recent years linear endobronchial ultrasound with transbronchial needle aspiration (EBUS-TBNA) is a technique that is rapidly changing the bronchoscopic diagnosis of many chest diseases but can be challenging to learn, even for experienced bronchoscopists.\textsuperscript{36} Demand for training is high and may be ideally suited for the use of simulator programmes, which often form a component of the courses.\textsuperscript{37}
Simulation, as a training and learning method for both technical and non-technical skills, offers a wide range of opportunities for practical application in medicine. Training systems using simulation exercises for medical or nursing trainees (or physicians and nurses in LLL) include a number of technological devices and task trainers, ranging from tools relating to specific technical skills to high-fidelity simulators capable of reproducing physiological functions and alterations or multi-systemic pathologies affecting the human body.

2.5. High and low fidelity simulation in IP

Fidelity refers to the realism of something. Within simulation, fidelity refers to two things.

1) The realism of the manikin. These are arbitrarily termed low-, mid/medium- or high-fidelity manikins.

2) The realism of the environment in which the simulation takes place. For participants to fully engage in simulation, they need to willingly suspend their disbelief. One way of helping this is through the fidelity of the environment or simulation suite; making the suite appear like the clinical environment you are trying to emulate is very important. With the development of wireless manikins, it’s now possible to perform in situ simulation, within the practitioner’s own environment. Low fidelity simulation uses inanimate mechanical airway models, into which actual bronchoscopes can be inserted and bronchoscopy skills can be practiced (Fig. 6). Advantages of low fidelity simulation include low cost and the ability to use standard bronchoscope equipment. Disadvantages include reduced realism and the risk of damaging the bronchoscope.

Low fidelity manikins are artificial anatomical models, made in plastic, or made from cadaver parts (either animal or human). Their advantage is undoubtedly that they provide a perfect reproduction of the anatomy, but they do not allow for the reproduction of situations or complications that may occur in a living model, such as respiratory and cardiac movements, coughing, muscle spasm, haemorrhage. To overcome these limitations, and thanks to an increasingly advanced technology, models defined as high fidelity have been introduced. In the field of bronchial endoscopy, for example, high fidelity simulators not only provide a perfect reproduction of the anatomical structure of the bronchial tree and its adjacent structures, they allow practitioners to reconstruct a real life environment including cardio-respiratory movements, coughing and resistance against the introduction of the scope. They further allow for the simulation of clinical scenarios and complications so as to test the trainee’s ability to manage complicated procedures (such as, for example, the removal of foreign bodies) or the management of complications (for example, iatrogenic bleeding or desaturation).

Both groups, low and high fidelity simulators, have advantages and disadvantages, listed in the table below. There is still no evidence to prove that either one or the other type of simulation is superior to the other. So, at present, they are considered complementary.
Low fidelity simulators: physical models
Silicone-based and plastic-based models, such as the Laerdal Airway Management Trainer (Laerdal, Stavanger, Norway) and the Life/form “Airway Larry” (Nasco, Fort Atkinson, WI), consist of a head, upper airway, larynx, and basic tracheobronchial tree. These models can be used for performing laryngotracheal intubation and airway management exercises, including bronchoscopy-guided endotracheal intubation. The CLA Broncho Boy (CLA, Coburg, Germany) AirSim Advance Combo bronchi (© TruCorp® Ltd, Belfast, N. Ireland) also have a torso and/or a detailed tracheobronchial tree (to the level of the first segmental bronchi) and can be used for learning and evaluating rigid bronchoscopy skills. They enable trainees to practice the entire procedure, starting from the insertion of the bronchoscope, through the nose or the mouth, to the inspection of all 19 pulmonary segments. Trainees may use clinical bronchoscopes and other accessories, or disposable tools such as aScope™ 3 (Ambu A/S, Ballerup, Denmark) which is equipped with a smaller screen and a reduced image quality, but is very practical for training programmes, due especially to its low maintenance costs.
A model with a bifurcation (Model TEUS-B) was developed for EBUS-TBNA training. The Ultrasonic Bronchoscopy Simulator (KOKEN CO. LTD, Tokyo, Japan) can be used not only for ultrathin bronchoscope insertion training and transbronchial biopsies, but also for endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) training. ArtiCHEST®trainer (© MIMEDA GmbH, Heidelberg, Germany) is a simulator that offers physicians a wide range of simulation exercises on bronchoscopy procedures, including TBNA and EBUS-TBNA. Accurate s.r.l. (Cesena, Italia) produces several types of simulators for use in Interventional Pulmonology: an ultrasound trainer for thoracentesis and thoracoscopy which allows practitioners to develop and improve their skills in using ultrasound to identify and guide needles and catheters in patients with pleural effusion; an advanced manikin for the management of airways in the adult.

Fig. 7

Ultrasonic Bronchoscopy Simulator
ArtiCHEST®trainer
Low fidelity airway inspection and transbronchial needle aspiration models

KOKEN CO. LTD, Tokyo, Japan  © MIMEDA GmbH, Heidelberg, Germany  Bronchoscopy International (www.bronchoscopy.org).

Fig. 8

Trainer per la Toracentesi Medioscapolare Ecoguidata
Trainer ATLS per il Drenaggio Toracico, Pneumotorace e Tecniche Ecoguidate

Accurate s.r.l., Cesena, Italy  Accurate s.r.l., Cesena, Italy
Simulation on animal model and on cadaver: Simulation on animal models in vivo or on individual organs, such as for example pig lungs, either frozen or preserved under plastic lamination, is extremely useful in all endoscopy procedures. Many institutions have used animal models for airway management courses, bronchoscopy CME courses (for EBUS and Intervventional Pulmonology techniques), and during pulmonary and IP fellowship training. Advantages of wet lab models over computer models include increased realism and giving the learners the opportunity to use the actual bronchoscopy equipment. Disadvantages of the wet lab models are the ethical issues associated with the use of animals for research and education, the cost of the highly trained personnel required to ensure safe and humane handling of the animals, and the potential for damage to the expensive bronchoscopes. There are no publications comparing wet lab simulation with high fidelity and low fidelity simulation for bronchoscop training. There is a need to evaluate the cost/benefit ratio and compliance with national legislation. The use of embalmed human or animal cadavers in the teaching of bronchoscopy has been well documented, and the exercises have been studied by Ram and co-workers who have shown that they allow trainees to develop the psychomotor skills needed to perform a bronchoscopy correctly; they are also useful for physicians who want to keep their skills in practice. But the use of cadaver models does present considerable limitations, essentially in that they are incapable of reproducing the exact situation or the complications of a living being, such as the movements of the cardiorespiratory system, coughing, muscle spasm, haemorrhage. Furthermore, the donor is required to have given his/her consent when still alive and the procedure on cadaver material can only be performed in specifically authorized centres.

High fidelity virtual reality simulators (Task trainer)

A computer-based bronchoscopy simulator that could be used for bronchoscopy training was first described in 1999. This “PreOP Endoscopy Simulator” (HT Medical Systems, Rockville, MD) consists of a proxy flexible bronchoscope, a robotic interface device and a computer with monitor and bronchoscopy simulation software. The learner inserts the proxy bronchoscope into the nasal passage of a robotic interface device, the proximal end of which is shaped to look like a human face. The interface device monitors the movements of the proxy flexible bronchoscope and creates resistance forces, simulating the forces experienced during an actual bronchoscopy procedure. The proxy bronchoscope tracks the manipulations of the bronchoscope (including the tip control lever, suction button, etc.) and the computer software creates computer-generated images of the airway on the monitor to simulate a realistic virtual bronchoscopy experience. These studies confirm that metrics based on computer simulator performance can differentiate between operators of different experience and skill levels, for both basic and complex bronchoscopy procedures. Superior clinical skills are associated with better performance on simulators.

A newer version of the simulator renamed the “AccuTouch Endoscopy Simulator” is now owned and distributed by CAE Healthcare, Montreal, Canada, imported into Italy by Accurate, Cesena. The “EndoVR™ Interventional Simulator” (CAE Healthcare) is a training device for both traditional bronchoscopy and EBUS. The BRONCH Mentor (3D Systems Healthcare, Littleton, Colorado, USA, imported into Italy by M.G. Lorenzatto S.r.l., Venaria Reale, Turin) consists of a hardware platform with a touch screen, a modified bronchoscope and ultrasound endoscope, tools such as an EBUS needle, which are used in the training and evaluation of bronchoscopies. The trainee navigates through the 3D virtual anatomy and the computer generates realistic images in real time, as the trainee guides the bronchoscope through the airways.
Trainees can practice flexible bronchoscopy on dozens of simulated cases, including patient management, inspection of airways, endobronchial and transbronchial tissue sampling, EBUS-TBNA, and much more. There is also a less expensive portable model called Bronch Express. The new European Guidelines on Endoscopic Ultrasound recommend that pulmonologists be competent in both EBUS and EUS, but unfortunately, there is no simulator that includes a software for EUS training. Both the AccuTouch Endoscopy Simulator and the GI-BRONCH Mentor systems have the ability to incorporate gastrointestinal endoscopy modules into the system, which may be advantageous in some centres where cost sharing between departments is possible.

AirwaySkills (Auckland, New Zealand) has recently marketed a less expensive, lighter virtual reality simulator to be used in bronchoscopy training, but the absence of a force-feedback in the interface permits users to advance the tool to its maximum even without a guide. And the absence of a work channel means that it is not ideally suited for Interventional Pulmonology training. Lastly, Surgical Science (Gothenburg, Sweden) is currently developing a software for bronchoscopy to be implemented on their virtual reality simulator EndoSim®.

Among thoracic ultrasound devices, SonoSim® (SonoSim, Inc, Santa Monica, CA, imported into Italy by Emacl s.r.l., Genova) is a simulator that provides good teaching experiences, since it includes an ultrasound diagnosis function based on real pathologies and cases. Some studies confirm that metrics based on computer simulator performance can differentiate between operators of different experience and skill levels, for both basic and complex bronchoscopy procedures. In a recent study we found that trainees with pre-simulation EBUS-STAT scores above 80/100 did not show any significant improvement after virtual reality training, suggesting that this score represents a cut-off value capable of predicting the likelihood that simulation can be beneficial.

Superior clinical skills are associated with better performance on simulators. Studies suggest that learners do acquire skills while practicing on simulators, as assessed by the simulator devices themselves. It has also been demonstrated that short-term learning gain occurs during 1-day introductory bronchoscopy courses with a focus on very specific cognitive information and bronchoscopy technical skill learning.

Some procedures performed during bronchoscopy – such as bronchoalveolar lavage, endobronchial biopsies/brushings, and conventional TBNA – require mastery of a tactile skill, or dexterity, which is difficult to simulate on a computer. TBNA and endobronchial biopsies on high fidelity simulators, in particular, have been found to lack realism. Fortunately, there are alternative low fidelity simulation models with perceived better realism that can be used, until the high fidelity simulator technology improves. Transbronchial biopsy is the bronchoscopy sampling technique most associated with complications.

Bronchoscopy simulation could allow for repetitive practice of low-volume procedures or critical clinical scenarios. It is recognized that simulation scenarios can be created to teach very specific procedural aspects and to provide an element of control until the learner has demonstrated a basic level of competency. After this milestone has been achieved, additional elements of a given scenario can be added to reproduce the real-life distracters that call upon other skills which the learner needs to deploy in order to avoid chaos in a procedure. Examples of critical clinical scenario simulation already in use are wet lab and computer simulation models for practicing the management of patients with massive haemoptysis even in a non-technical skill simulation.
Fig. 9 High fidelity virtual reality simulators (Task Trainers)

**BRONCH Mentor**
3D Systems Healthcare, Littleton, Colorado, USA imported by M.G. Lorenzatto S.r.l., Venaria Reale, Turin

**BRONCH Express**
3D Systems Healthcare, Littleton, Colorado, USA imported by M.G. Lorenzatto S.r.l., Venaria Reale, Turin

**ORSIM®**
Airway Ltd Auckland, New Zealand, imported by Emac s.r.l., Genova, Italy

**EndoVR™ Interventional Simulator**
CAE Healthcare imported by Accurate, Cesena, Italy

**EndoSim®**
Surgical Science (Gothenburg, Sweden)

**Vimedix**
CAE Healthcare imported by Accurate, Cesena, Italy

**SonoSim®**
SonoSim, Inc, Santa Monica, CA, imported by Emac s.r.l., Genova, Italy
Non-Technical Skills (NTS) training

Technical skills are necessary but not sufficient to maintain high levels of performance over time. In 1999, the ACGME identified 6 core competencies residency programs are required to teach: interpersonal and communication skills, professionalism, patient care, systems-based practice, practice-based learning and improvement, and medical knowledge. The Joint Commission in 2011 and 2012 identified failures in communication, human factors, and leadership as the most common issues as root causes in sentinel events. Adverse events in health care have found that many underlying causes originate from failures in non-technical aspects of performance rather than a lack of technical expertise. Non-technical skills are the cognitive and interpersonal skills that underpin effective team work: it is estimated that around 70-80% of healthcare errors can be attributed to a breakdown involving these skills. Non-technical skills are part of the human factors agenda. “Human factors” is an umbrella term which analyses how healthcare professionals interact with everything in their working environment, such as clinical guidelines, policies and procedures, equipment and stress management. Non-technical skills specifically examine the interaction of team members (liveware to liveware). These skills are trained in crew resource management (CRM) courses in civil aviation, oil exploration, nuclear power and recently in anaesthesia, emergency medicine and surgery. Errors more frequently observed in operating theaters were a. Surgeon’s failure to inform anaesthetist, b. Failure to anticipate events during complex procedure c. Failure to monitor other team activities d. Consultant distracted from making a decision by problems reported from another operating theatre, e. Failure to brief own team f. Failure to discuss alternative procedure g. Hostility and frustrations owing to poor team coordination h. Failure to debrief operation to learn from situation i. Failure to establish leadership for operating room team l. Unresolved conflicts between surgical team and anaesthetists. These are errors very common in interventional pulmonology that have to be considered in a comprehensive training programme in IP.

Interdisciplinary emergency clinical simulations are frequently used to educate surgical residents in leadership, teamwork, effective communication, and infrequently performed emergency surgical procedures. Simulations could be conducted in the operating room, intensive care unit, emergency department, ward or simulation center. Examples of these scenarios included a postoperative pulmonary embolism, pneumothorax, treatment of an acute myocardial infarction, gastrointestinal bleeding, anaphylaxis with a difficult airway, fires in the operating room, and pulseless electrical activity arrest. Sessions with a surgical role required the surgical residents to perform a procedure during the session (eg, cricothyrotomy, chest tube, and central venous catheter or access). Nicksa et al. using a SimMan 3GS to educate surgical residents in technical and nontechnical skills to simulate high-risk clinical scenarios, showed a significant improvement of performance after nontechnical skill simulations: communication score increased from 3 to 3.71 ($P = .01$), leadership score increased from 2.77 to 3.86 ($P < .001$), teamwork score increased from 3.15 to 3.86($P = .007$), and procedural ability score increased from 2.23 to 3.43 ($P = .03$). There were no statistically significant improved scores in PGY 2 decision making or situation awareness. A modified Oxford Non-Technical Skills (NOTECHS) scale (score range, 1-4) was used to assess surgical resident nontechnical performance. The session was lasting 15 to 20 minutes. All simulation sessions were followed by 30-minute debriefings with real-time feedback. During the first 10 minutes, the participants reflected on the experience and their thoughts on the simulation; in the remaining 20 minutes, videos were viewed (if available) and the simulation team provided feedback, facilitated discussion, instructed on areas of knowledge as needed, provided insight, and encouraged participant self-reflection. There are very few experiences in Interventional pulmonology but the scenarios are similar to
surgery including emergencies such as bleeding, pneumothorax, foreign bodies, central airways disorders, severe respiratory failure, difficult airways.

**Boot Camp: Practice Centres or Boot Camps**, where training takes place through a gradual process from theory to practice, using live sessions and simulation, may provide a training approach that is more in harmony with current needs to improve competence and continuous professional development⁷⁷. A European model of a Boot Camp is the new facility of IRCAD (Research Institute against Digestive Cancer) in Strasbourg. IRCAD was founded in 1994 within Strasbourg’s University Hospital and it carries out research on digestive cancer as well as developing telematic and robotic systems. The field in which it has especially distinguished itself is training for Minimally Invasive Surgery, within the EITS (European Institute of TeleSurgery). Several years ago IRCAD established a Boot Camp that included other disciplines as well, and provided space to some multinational healthcare product enterprises such as Medtronic-Covidien, Intuitive Surgical and Storz. Another European Centre fully equipped for the simulation in Interventional Pulmonology is the JMC Simulation Unit in Copenhagen: [https://www.rigshospitalet.dk/english/contact-us/Pages/default.aspx](https://www.rigshospitalet.dk/english/contact-us/Pages/default.aspx).

Medical training is changing in Italy, too, and several new simulation centres have been established, to provide training both for students and for specialist practitioners. One of the first Simulation Centres to be opened in Italy is the one at the Mediterraneane Institute for Transplants and Therapies (Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione, ISMETT), based in Palermo. Other Simulation Centres are located in other parts of the country, most of them specialized in Emergency Medicine, Surgery, Interventional Medicine and the Management of the Critical Patient:

- Si.F.A.R.V., the Veneto Region Centre for Simulation and Advanced Training (Centro di Simulazione e Formazione Avanzata della Regione Veneto) [http://www.sifarv.com/](http://www.sifarv.com/)
- The Simulation Centre of the School of Medical and Pharmaceutical Studies, University of Genova (Centro Simulazione Scuola Scienze Mediche e Farmaceutiche, Università degli Studi di Genova) [http://csa.medicina.unige.it](http://csa.medicina.unige.it)
- ICLO Anatomy Simulation Centres (Centri di simulazione per l’Anatomia ICLO, San Francesco di Sales, Arezzo and Verona) [http://www.iclo.eu/Centri di simulazione per la medicina d’Emergenza-Urgenza](http://www.iclo.eu/Centri di simulazione per la medicina d’Emergenza-Urgenza)
- Center for Advanced Simulation in Medicine (Centro per la simulazione avanzata in medicina. Unifi CASM. Firenze)
- SIMANNU (Centro Simulazione Medica Nuoro), Medical Simulation Centre in Nuoro, Sardinia, [http://www.simannu.it/](http://www.simannu.it/)
- International Fatebenefratelli Simulation Centre, Isola Tiberina, Rome (Fondazione Internazionale Fatebenefratelli – Isola Tiberina)
- MESIT, Advanced Medical Simulation Centre, Hub for Research and Innovation Applied to Medical Training (Centro di Simulazione Medica Avanzata e Hub per la Ricerca e l’innovazione Applicata alla Formazione Medica)
- Centre for Simulation in Anaesthesia and Intensive Care, University of Perugia (Centro di simulazione per l’Anestesia e la Terapia Intensiva [http://csma.unipg.it/](http://csma.unipg.it/))
2.6. Assessment tools for accreditation and certification

Competency is deemed acquired when a person can demonstrate his/her proven ability to use knowledge as well as personal, social and methodological skills and abilities, in a situation related to his/her profession or in research, and benefit from such knowledge and skills in further personal and professional development (Table 3).

Ever since the early 20th century (1933) in the United States there has been a system certifying professional know-how and competence: Board Certification. Since 2001 a time limit has been introduced to the validity of this certification, which now needs to be renewed within 6 to 10 years. The aim is to inform patients, protect their safety, improve the quality of healthcare. ACGME (Accreditation Council for Graduate Medical Education) guarantees the quality of the education content of training programmes in every different specialty and subspecialty, as well as the qualitative and quantitative professional standards that every physician is required to achieve and maintain in order to be certified.

There are specific tools that can be used to assess physicians’ basic knowledge (an element of the practitioner’s competencies) and their skills, tools such as the Multiple Choice Questionnaires approved by the Joint Royal Colleges of Physicians Training Board (JRCPTB) and the Objective Structured Clinical Examination (OSCE).

As far as the field of Interventional Pulmonology is concerned, specific validated tools have been developed by AIPPD/AABIP, by Prof. Henry Colt (www.bronchoscopy.org) and by the Copenhagen Centre.

Knowledge assessment

The Multiple Choice Questionnaire elaborated by AIPPD members has shown that it is capable of measuring the ability of physicians to take decisions based on training and practical experience, for in a practical exercise (assessing 4 study groups of first and last year specialty students in Pulmonary and Critical Care Medicine, as well as students and trainers of the additional yearly programme in Interventional Pulmonology) their results yielded statistically significant differences. Of course, in order for assessment tools to be able to evaluate competence in such a highly complex discipline, they must take into consideration all the subjects included in the recommended training curriculum for Interventional Pulmonologists, and this means all the knowledge specifically related to the different pathologies and to the range of procedures, as is shown clearly in the figure below.
Savran and Konge developed and validated a specific theoretical test in endosonography including endobronchial ultrasonography (EBUS) and esophageal ultrasonography (EUS) with real-time aspiration of the lymph nodes.

Quantitative Skill Assessment

As far as procedural skills are concerned, criteria used in the evaluation are both quantitative (volume of procedures performed, including establishing a minimum number) and qualitative (self-evaluation test and evaluation by a supervisor). While the number of performed procedures may rightly be considered an indirect indicator guaranteeing competence, it is also true that different practitioners have different learning curves, i.e., they do learn by performing procedures, but they do so at different speeds. Therefore, absolute numbers, even when they are high, may not be a guarantee of competence from a qualitative point of view.

The assumption, in any case, is that the more a physician performs a procedure, the better he or she will be. However, precise data describing the learning curve for single procedures are difficult to obtain. And, as we have seen, it varies from person to person. It is fundamental that the trainee physician creates her/his own logbook, documenting all cases s/he has observed or assisted with, including pictures and video, as well as the basic case history and biopsy findings. It will then be possible to measure and monitor outcomes and performance quality, and to provide feedback to the trainees’ directly, rather than relying solely on expert opinion, volume requirements, or other surrogate markers. Such a system could be combined with volume requirements and other didactic instruments.
Tab. 2: Summary of published guidelines for numbers of procedures required in IP training

<table>
<thead>
<tr>
<th>Type of procedure</th>
<th>BTS</th>
<th>TSANZ</th>
<th>ERS/ATS</th>
<th>ACCP</th>
<th>AIPO</th>
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<tbody>
<tr>
<td>Flexible bronchoscopy</td>
<td>50*</td>
<td>200/12-20</td>
<td>NR</td>
<td>100/25</td>
<td>100/100</td>
</tr>
<tr>
<td>Rigid bronchoscopy</td>
<td>-</td>
<td>-</td>
<td>20/10-15</td>
<td>20/10</td>
<td>NR</td>
</tr>
<tr>
<td>TBNB</td>
<td>-</td>
<td>20</td>
<td>25/NR</td>
<td>15/10</td>
<td>NR</td>
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<tr>
<td>AFB</td>
<td>-</td>
<td>-</td>
<td>Long learning curve</td>
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<tr>
<td>EBUS</td>
<td>-</td>
<td>-</td>
<td>40/25</td>
<td>50/20</td>
<td>NR</td>
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<td>TTN/A/B</td>
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<td>-</td>
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<td>10 aspirate, 10 core/10</td>
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<tr>
<td>LB</td>
<td>-</td>
<td>-</td>
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<td>NR/30</td>
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<td>-</td>
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<td>15/10</td>
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<td>Airways stents</td>
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<td>PDT</td>
<td>-</td>
<td>-</td>
<td>10/5-10</td>
<td>10/5</td>
<td>NR</td>
</tr>
<tr>
<td>PT</td>
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<td>5/10-20</td>
<td>20/10</td>
<td>NR</td>
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<td>TTOT</td>
<td>-</td>
<td>-</td>
<td>5/5</td>
<td>10/5</td>
<td>NR</td>
</tr>
</tbody>
</table>

Table: Number of supervised procedures needed according to the different societies. The first number represents the minimum training required and the second (when present) the minimum procedures per year required to maintain competency. TBNB: transbronchial needle aspiration, AFB: Autofluorescence bronchoscopy, EBUS: endobronchial ultrasound, TTN/A/B: transthoracic needle aspiration and biopsy, LB: laser bronchoscopy, EES/APC: endobronchial electrosurgery and argon-plasma coagulation, CBCT: endobronchial cryotherapy, EBBT: endobronchial brachytherapy, PDT: photodynamic therapy, PT: percutaneous tracheostomy, TTOT: transtracheal oxygen therapy. *The authors suggest at least 50 procedures under direct supervision and 50 under indirect supervision.

Qualitative Skill Assessment

Competency-based assessments are a prolific area of education research and are increasingly adopted by many training programmes. Validated assessment tools represent the cornerstone of competency-based programmes and allow continuous feedback highlighting improvements and further opportunities for improvement.

The following is a list of workplace-based assessments approved by GMC and JRCPTB, and used in this curriculum:

- mini-Clinical Evaluation Exercise (mini-CEX)
- Case-Based Discussion (CbD)
- Direct Observation of Procedural Skills (DOPS)
- Acute Care Assessment Tool (ACAT)
- Multi-Source Feedback (MSF)
- Multiple Consultant Report (MCR)
- Audit Assessment (AA)
- Patient Survey (PS)
- Teaching Observation (TO)

Workplace-based assessments should be recorded in the trainee’s e-Portfolio.

An objective evaluation of a practitioner’s skills can be done through DOPS (Direct Observation of Procedural Skills). A DOPS is an assessment tool designed to assess the performance of a trainee in undertaking a practical procedure, against a structured checklist. The trainee receives immediate feedback to identify strengths and areas for development. In addition to the general DOPS form available on the JRCPTB website, there are 2 DOPS forms specific to Respiratory Medicine – one for
Two instruments were studied and validated for the assessment of basic bronchoscopy skills: the Bronchoscopy Skills and Tasks Assessment Tool (BSTAT) and the Bronchoscopy Stepwise Evaluation Tool (BSET)\(^90\).

The BSET tests a learner’s knowledge of a series of specific manoeuvres designed to facilitate bronchoscope handling; it comprises a global rating scale and a rating of the proper execution of the specific manoeuvres. The Bronchoscopy Skill Assessment Tool (BSTAT) assesses basic bronchoscopic anatomy knowledge, skill in manoeuvring the bronchoscope through the bronchial tree and ability in performing tasks such as biopsy or bronchoalveolar lavage, and the identification of common airway pathologies.

BSTAT can be found at http://bronchoscopy.org/downloads/tools/BSTAT, is designed to measure the skills of a bronchoscopist performing a diagnostic bronchoscopy and is comprised of 8 sections. The first 2 assess the operator’s knowledge of segmental anatomy, along with his/her ability to enter each segment. One section assesses whether the procedure was performed with the bronchoscope well-centred, avoiding excessive airway wall trauma, and another evaluates the operator’s posture, hand positions and equipment handling. Another section is a measure of how well the operator performs 2 standard manoeuvres (entering RB-4, 5 and 6 and then LB-8, 9 and 10 on demand); the next section asks the operator to perform a standard diagnostic task; the possible tasks include bronchoalveolar lavage (BAL), bronchial brushing, endobronchial lung biopsy, transbronchial lung biopsy or transbronchial needle aspiration. The 2 final sections deal with the recognition of airway secretions and mucosal abnormalities; each consists of reviewing a slideshow of 10 colour bronchoscopic images on a desktop monitor and selecting the correct description for each from a list. The BSTAT has a maximum score of 24 and can also be graded on a letter scale for users familiar with an A–F grading system.

The BSET has been specifically designed to measure performance on the Bronchoscopy Step-by-Step exercises (http://bronchoscopy.org/downloads/posters/StepByStepPoster.pdf). These exercises, elaborated by the same working group, are a series of graded training manoeuvres that direct the learner through the incrementally difficult moves of bronchoscopy; the learner begins by practicing passage through the oral or nasal orifice to the larynx, followed by navigating central, lobar and segmental airways. The BSET is comprised of 2 sections. The Bronchoscopy Global Rating Scale (BGRS) assesses the operator’s general bronchoscopic skills while performing the exercises; it is divided into 4 subsections focusing on bronchoscope manipulation, body posture and hand positions, identification of anatomy and the ability to perform specific exercises. The Bronchoscopy Exercises Rating Scale (BERS) measures the proper performance of each step-by-step exercise; it is divided into 3 subsections, relating to (a) larynx, upper and central airway exercises, (b) lobar bronchial exercises, and (c) segmental bronchial exercises.

The Ontario Bronchoscopy Assessment Tool (OBAT) assesses not only technical proficiency in bronchoscopy but also all clinically relevant aspects of bronchoscopy from pre-procedural planning to post-procedure documentation. The OBAT was designed to be sufficiently brief to be used in a clinical setting and sufficiently simple to be used by experienced clinical teachers with minimal additional training\(^91\).

For more complex procedures, the following DOPS have been validated:

1. EBUS Skill Assessment Tool (EBUS-STAT): This is a 10-section assessment tool incorporating anatomy, equipment handling, and computed tomography and EBUS image interpretation. The EBUS-STAT is a 10-section assessment tool designed to objectively and systematically evaluate the technical skill and relevant knowledge of an operator performing convex-probe
(CP) EBUS-guided TBNA. Created as a component of the Bronchoscopy Education Project, it can be used alone or in addition to other learning tools, reading materials, and simulation-based educational sessions to document the gradual acquisition of knowledge and skills in learners training to become competent EBUS-TBNA operators. The EBUS-STAT can be scored while observing an operator perform CP EBUS-TBNA in a patient or simulated environment. Of the 10 items, items 1 to 7 test technical skill, and items 8 to 10 use a 25-image slideshow to test computed tomography (CT) and EBUS image and pattern recognition, anatomic orientation, and correlation. The first seven items are tested in the procedure suite or simulation centre, whereas items 8 to 10 can be completed using a computer monitor.

(EBUSAT) EBUS Assessment Tool: The assessment tool was developed by a group consisting of two respiratory physicians, a thoracic surgeon, and a professor of medical education, all with considerable experience in performance, teaching, and validation of endoscopic ultrasound and other procedures. The tool was designed according to the original format for “objective structured assessment of technical skills”, in which each item is rated on a scale from 1 to 5, with descriptive anchors in the middle and at the ends, and re-coded into a score from 0 to 4 points. Six items were designed to assess knowledge of the mediastinal anatomy, by requesting the operators to identify six anatomic landmarks: lymph node stations 4L, 7, 10L or 11L, 10R or 11R; the azygos vein; and lymph node station 4R. Four items related to the technical skills necessary to handle the scope and perform TBNA were defined: insertion of the endoscope, positioning of the transducer, use of sheath, and use of needle. Finally, two items were added to allow assessors to give their overall opinion on anatomic orientation and biopsy sampling, respectively.

3. The Endoscopic Ultrasonography Assessment Tool (EUSAT): used in EUS-FNA for mediastinal staging. A study by Konge et al. shows the EUSAT can distinguish operators’ performances according to their level of experience, and the result appears to be reproducible.

4. UGSTAT was validated in 2013. UGSTAT (Ultrasound-Guided Thoracentesis Skills and Tasks Assessment Test) was devised following the Guidelines of the British Thoracic Society as a tool to evaluate the teaching of thoracic ultrasound before clinical practice. It consists of a questionnaire with a score on a scale of 100, which can be administered to learners with different levels of experience in thoracic ultrasound procedures, from beginners to intermediate levels and even to advanced level thoracic ultrasound practitioners.

Other DOPS specific for Interventional Pulmonology currently awaiting validation:
- Bronchoscopy Skills and Tasks Assessment Tool for Transbronchial Lung Biopsy and Transbronchial Needle Aspiration (BSTAT-TBLB/TBNA)
- RIGID-TASC
- Chest tube-STAT
- IBV-STAT

Therapeutical and patient care skills can further be evaluated using the mini-Clinical Evaluation Exercise (Mini-CEX). This tool evaluates a clinical encounter with a patient and its purpose is to provide an indication of competence in skills essential for good clinical care such as history taking, physical examination and clinical judgment. The trainee receives immediate feedback to aid learning. The mini-CEX can be used at any time and in any setting when there is a trainee and patient interaction, and an assessor is available.
The following tools are used to evaluate general skills:

- **Multi-Source Feedback (MSF).** This tool offers a method of assessing generic skills such as communication, leadership, team work, reliability, across the domains of Good Medical Practice. It provides for the objective and systematic collection of performance data and feedback relating to a trainee, derived from several colleagues. ‘Raters’ are individuals with whom the trainee works: they include doctors, administration staff, and other related professionals. The trainee will not see the individual responses given by raters; the results will be given to the trainee by his/her Educational Supervisor.

- **Case-Based Discussions (CbD).** This tool assesses the performance of a trainee in his/her management of a patient; the aim is to provide an indication of competence in areas such as clinical judgment, decision-making and application of medical knowledge in relation to patient care. It also serves as a method to document conversations about – and presentations of – cases by trainees. The CbD should include discussion on a written record (such as written case notes, out-patient letter, discharge summary). A typical exchange might occur when presenting newly referred patients in the out-patient department.

- **Patient Satisfaction Questionnaire (PSQ).** This tool provides an evaluation of a learner’s professional competence as perceived by patients. It gives information on the learner’s communication and relational skills, and on the patient’s perception of the learner’s professional competence.

The Respiratory Medicine SAC has suggested that evaluations should be carried out as follows:

- A minimum of 6 mini-CEX and/or CbD per year of training, as educational tools helping trainees achieve the competencies required for the particular stage of training
- At least 2 MSFs, one at the beginning and one near the end of training
- Six bronchoscopy DOPS during the four year single specialty training in Respiratory Medicine. Seven bronchoscopy DOPS during the five year dual training programme in Respiratory Medicine and GIM.
### Tab. 3: KNOWLEDGE & SKILLS ASSESSMENT STRATEGIES

- It is assumed that the number of procedures performed is an indirect indicator of the “core competence” achieved.
- Practitioners learn procedures at different speeds, i.e. each has a different learning curve; in some physicians, absolute numbers, even when they are high, may not be a guarantee of acquired competence.
- Skills may be assessed objectively by means of DOPS.
- In any case, if and when this is possible, the training curriculum should envisage a minimum number of procedures to be performed during the training course (below which competence is not considered achieved).

### OVERALL QUALITY ASSESSMENT OF COMPETENCE IN MEDICINE

- MCQ (multiple choice questionnaires)
- Case-based questionnaires, on appropriate decisions
- DOPS
- Assessment of manoeuvres on manikin
- Assessment of procedures under supervision

### 2.7. Transition from training to practice on patients

Transition to practice (TTP) programmes were developed in the field of general surgery in order to provide a 1-year experience to post-specialty physicians enabling them to develop their independent decision-making processes, so that they can become autonomous in performing operative procedures, and so they can acquire practical management skills; the programmes also offer them the opportunity to benefit from periodical reviews of their performance and their clinical outcomes. At present newly qualified specialists in surgery have less confidence in their ability to perform surgical procedures and do not feel fully competent in performing many common procedures in an entirely independent manner. The key elements of this post-specialty experience are: to ensure the learner can act independently; to guarantee the presence of a senior surgeon acting as mentor, to ensure clinical responsibility; to provide a flexible programme based on the evaluation of past experience and future objectives; to enable trainees to acquire practical skills and clinical outcome measurements.

### 2.8. Continuous professional development (CPD) or Lifelong learning

Continuing education is part of a training process that is intended to offer practitioners an ongoing and gradual maturation. It is also necessary, since a professional who does not undergo in-service training updates will experience a loss in performance levels. An entirely new paradigm of continuous professional development (CPD) has been proposed, as a replacement for the conventional continuing medical education (CME) model. CPD includes several distinct characteristics. It focuses on lifelong learning that is based on the needs of individuals, as opposed to the needs of large learner groups, and involves the use of a range of learner-driven and learner-centred education and training methods. CPD is offered in venues that extend beyond
traditional lecture halls and conference rooms, and uses a variety of learning formats and blended methods to achieve optimal results.

Clinical practice locations and simulated environments are well suited to the delivery of CPD. Furthermore, CPD is more comprehensive in scope than traditional CME, and can be used to address not just the clinical domain but also to practice management, leadership, teamwork, administration, and a host of other professional activities. Another important approach that can be used to offer practicing surgeons effective education and training involves the use of practice-based learning and improvement (PBLI).

Teaching tools are different from those used in initial training experiences. They focus on the learner’s individual experience and facilitate his/her autonomous discovery of new knowledge, the importance of which was demonstrated in aviation training experiences.96

Tab. 4:

<table>
<thead>
<tr>
<th>THEORETICAL/PRACTICAL TRAINING METHODS IN INTERVENTIONAL PULMONOLOGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Handbooks and atlases on the mediastinal anatomy, including instructions on tissue sampling procedures</td>
</tr>
<tr>
<td>• Theoretical lessons (using Flipped classroom and Case discussion methods) on: indications, contraindications, instrumentarium, organization of the endoscopy room, description of procedures</td>
</tr>
<tr>
<td>• Live sessions</td>
</tr>
<tr>
<td>• e-learning and e-mobile learning: Multimedia resources</td>
</tr>
<tr>
<td>• Theoretical/practical course on methods organized in the centres that implement the methods being taught and which can offer trainees practice on simulator systems</td>
</tr>
<tr>
<td>• Training supported by virtual reality simulation on: knowledge of anatomy, acquiring manual dexterity in bronchoscopy and tissue sampling procedures, examination of clinical cases (GI BronchMentor, BronchPilot i-Pad, Simbionix Express, EndoVR Accurate, Ultrasonic Bronchoscopy Simulator)</td>
</tr>
<tr>
<td>• Use of manikins and plastic models in simulating procedures in order to learn and improve coordination (using video systems for tutoring and the most recent disposable bronchoscopes)</td>
</tr>
<tr>
<td>• Simulation on artificial lymph nodes</td>
</tr>
<tr>
<td>• Simulation on animal models in vivo or on individual organs, such as porcine lung, fresh, frozen or preserved under plastic lamination.</td>
</tr>
<tr>
<td>• Training on patients under supervision, until trainees have achieved both quantitative and qualitative competency</td>
</tr>
<tr>
<td>• Attending sessions in the endoscopy room</td>
</tr>
<tr>
<td>• Continuing education by means of national and international publications</td>
</tr>
<tr>
<td>• Online training</td>
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<tr>
<td>• Taking part in clinical risk audits</td>
</tr>
</tbody>
</table>
Tab. 5: Quantitative and qualitative assessment of procedures in IP

<table>
<thead>
<tr>
<th>PROCEDURE TYPE</th>
<th>QUANTITATIVE ASSESSMENT WITH LOGBOOK (MINIMUM VOLUME)</th>
<th>QUALITATIVE ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flexible bronchoscopy and basic sampling technique</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Diagnostic bronchoscopy with biopsy | 100 | MCQ  
  - Case-based Questionnaire  
  - Simulated assessment  
  - DOPS: B-STAT, B-SET  
  - Video or direct supervision of procedure with the patient |
| TBNA | 25 (ACCP, ERS/ATS)  
  20 (TSANZ) | MCQ  
  - Case-based Questionnaire  
  - Simulated assessment  
  - DOPS: B-STAT, B-SET  
  - Video or direct supervision of procedure with the patient |
| Interventional endosonography (EBUS, EUS, EUS-B) | | |
| EBUS-TBNA | 50 procedures, after at least 100 flexible bronchoscopies and 5 TBNAs  
  40 ETS-ERS  
  50 Chest | MCQ  
  - Case-based questionnaire  
  - DOPS (EBUS-STAT, EBUS SAT)  
  - Assessment on patient:  
    - Balloon and needle set-up in all cases  
    - Ability to pass scope through vocal cords in ±90% of cases  
    - Ability to image lymph node in question in ±90% of cases  
    - Ability to pass TBNA needle through wall of trachea/bronchus into node in ±80%  
    - Sensitivity for carcinoma in ±75% of cases  
    - Typical procedure time: 30–40 min  
  - ERS-EBUS Certification Methodology [www.ersnet.org](http://www.ersnet.org) based on verification of pre-requisites and registration, supervised training in home institution, completion of 20 procedures and 3 video procedures. |
| EUS-FNA and EUS-B-FNA | 20 (ERS)  
  36+12 ([Gastrointest Endosc.](http://gastrointestendosc.2010Jan;71(1):64-70, 70.e1)) | MCQ  
  - Case-based questionnaire  
  - DOPS (EUSAT) see appendix  
  - EBUS-EUS training programme ([www.ersnet.org](http://www.ersnet.org))  
  - Assessment on patient:  
    - Ability to visualise lymph node in question |
in ±90% of cases
- Ability to pass TBNA needle through wall of oesophagus into node in ±80% of cases
- Sensitivity for carcinoma in ±75% of cases
- Typical procedure time: 30–40 min

**Bronchoscopic navigation:** Image-guided or computer-guided diagnostic bronchoscopy for the evaluation of parenchymal opacities, of airway invasion vs compression, and to guide biopsy

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Details</th>
</tr>
</thead>
</table>
| **RADIAL PROBE** | 20 MCQ
- Case-based questionnaire
- DOPS: Creation of a specific STAT (similar to EBUS-STAT) |
| **Electromagnetic pulmonary navigation and virtual bronchoscopy navigation** | 20 MCQ
- Case-based questionnaire
- DOPS: Creation of specific STAT (like EBUS-STAT) |
| **Transthoracic pulmonary biopsies** | 10 TTNA (Chest) MCQ
- Case-based questionnaire
- DOPS |
| **Cryobiopsy** | Trainee shall be in attendance on at least 10 procedures performed by expert bronchoscopists (ACCP)
- Trainee shall perform directly, as first operator, at least 10 procedures under supervision of an expert bronchoscopist
- Trainee shall be in attendance on a session with a major complication of bleeding and tension pneumothorax MCQ
- Case-based questionnaire
- DOPS on simulator and patient (cooperation among bronchoscopists, anaesthetists, nursing staff) |

**OPERATIVE BRONCHOSCOPY PROCEDURES**

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Details</th>
</tr>
</thead>
</table>
| **Rigid Bronchoscopy** | 20 ATS/ERS 20 ACCP MCQ
- Case-based questionnaires
| **LASER** | 20 ATS/ERS 15 ACCP MCQ
- Case-based questionnaires
| **ELECTRO/APC** | 10 ATS/ERS 15 ACCP MCQ
- Case-based questionnaires
<table>
<thead>
<tr>
<th>Technique</th>
<th>Training Requirements</th>
<th>Assessment Tools</th>
</tr>
</thead>
</table>
| **CRYO**                                      | • 10 ATS/ERS  
• 10 ACCP                                                           | • MCQ  
• Case-based questionnaires  
• DOPS (RIGID TASC, Ann Am Thorac Soc. 2016 Apr;13(4):502-11) on simulator, animal and patient |
| **STENT**                                     | • 10 ATS-ERS  
• 20 ACCP                                                           | • MCQ  
• Case-based questionnaires  
• DOPS (RIGID TASC, Ann Am Thorac Soc. 2016 Apr;13(4):502-11) on simulator, animal and patient |
| **Endoscopic Lung Volume Reduction Treatment (ELVR)** | Unknown                                                                 | • MCQ  
• Case-based questionnaires  
• DOPS |
| **Thermoplasty**                              | Unknown                                                                 | • MCQ  
• Case-based questionnaires  
• DOPS |
| **Sedation in IP**                            | Unknown                                                                 | • MCQ  
• Case-based questionnaires  
• DOPS |
| **Pleural procedures**                        | **Thoracic ultrasound**  
• 100 clinical examinations with chest ultrasound  
• 10 echo-guided thoracentesis  
• 5 echo-guided insertions of chest tube | • Questionnaires MCQ  
• Case-based questionnaires, with decision-making process  
• Assessment tools (UGSTAT, TUBE-iCOMPT) |
|                                              | **Pleural drainage**  
• 5 – 7 drainages under supervision | • MCQ  
• Case-based questionnaires, including evaluation of correct decision-making  
• DOPS (e.g. UGSTAT and EUTAT) |
|                                              | **Thoracoscopy and talc poudrage**  
• 20 (Fielding) | • MCQ  
• Case-based questionnaires, on appropriate decision-making  
• DOPS |
| **Paediatric bronchoscopy**                   | **Paediatric bronchoscopy**  
• 50 (once trainee has achieved competency in adults) | • MCQ  
• Case-based questionnaires, on appropriate decisions  
• DOPS with flexible and rigid bronchoscope on manikin and patient |
| **Bronchoscopy in anaesthesiology and Intensive Care Unit (ICU)** | **Bronchoscopy in anaesthesiology and ICU**  
• Bronchoscopy: 100  
• Difficult intubation: unknown  
• Tracheostomy: 3 procedures for every type of percutaneous tracheostomy performed | • MCQ  
• Case-Based Questionnaire  
• Simulated assessment  
• DOPS |
<p>| <strong>Bronchoscopy in thoracic surgery</strong>          | | |</p>
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>MCQ, Case-based questionnaires, DOPS for flexible and rigid bronchoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchoscopy in thoracic surgery</td>
<td>• For Interventional Pulmonologists: See section: “Flexible bronchoscopy”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• For Thoracic Surgeons (ABTS): 40 bronchoscopic procedures (30 simple diagnostic procedures and 10 therapeutic procedures).</td>
<td></td>
</tr>
<tr>
<td>Bronchoscopy in lung transplantation</td>
<td>• See section: “Flexible bronchoscopy”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• To reach the specific competence for lung transplantation the learning curve is longer (20% more).</td>
<td></td>
</tr>
<tr>
<td>Emergency in IP</td>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>Emergency in IP</td>
<td>Unknown</td>
<td></td>
</tr>
</tbody>
</table>
3. Interventional Pulmonology Fellowships: Description of a network for training and simulation in IP

Interventional Pulmonology (IP) fellowships should provide advanced level training after completion of a standard fellowship in pulmonary medicine, to ensure that a fellow may acquire competency in the subspecialty and have sufficient expertise to act as an independent professional and expert provider of complex and advanced interventional procedures. This document outlines the minimum core knowledge and procedural skills deemed essential to the practice of IP, and specifies a minimum didactic and experiential exposure required of IP fellowship training programs. The specialty education of physicians enabling them to practice independently is based on experience, and necessarily occurs within the context of the healthcare delivery system. Hands-on practice with simulators is essential before performing interventional procedures on the patients but developing the skills, knowledge, and attitudes leading to proficiency in all the domains of clinical competency requires that the resident and/or fellow may shoulder personal responsibility for the care of individual patients. For the resident and/or fellow, the essential learning activity is interaction with patients under the guidance and supervision of faculty members who give value, context, and meaning to those interactions. For several years in Italy (Florence) there has been a 1-year University 2nd-level Masters course in Interventional Pulmonology during which the trainee is expected to collect 63 University credits (CFU) over a period of about 10 months: the aim of this Master is to provide a structured training in Interventional Pulmonology, dovetailing it to international standards. This Master offers students the core knowledge and skills needed by the Pulmonologist in order to achieve the professional competence envisaged in this publication. As the numbers of procedures required to achieve competence is beyond the possibility of a single center, a perfect integration and cooperation between Hospital and University Centres would allow the programme to train professional Interventional Pulmonologists in a more structured and effective manner. Certified Hospital Centres have the knowledge base, skills, attitudes, cases and series of patients; while University Centres have the teaching approach, the attitude to research, and the institutional task of certifying competence. For they certify the competence needed to practice as a physician, a nurse, a technician, and the competence to practice in a specialty and in superspecialties, such as IP. A network of University Centres, which are members of an inter-University project network, and Hospital Centres working in conventions with universities could collaborate in training programmes for fellowships and to establish a theoretical/practical structured curriculum aimed at the professional qualification of an Interventional Pulmonologist. In those same centres it would be possible to offer continuing education (Lifelong learning) experiences, where the activity of students could be organized and kept on record, providing simulation and live patient training experiences, until the learners have reached the required volume of procedures and they can be certified as having achieved the competency and thereby authorized to practice professionally without supervision. The educational program of the Certified Course or Master in interventional pulmonology must be at least 12 months in length but should last more depending on the time needed for every student to achieve competency.

Following the model of airline pilot training, every practitioner would have his/her own Logbook, the Interventional Pulmonologist’s personal Flightbook, where s/he could record every individual procedure s/he has performed, every training course attended, including intermediate and final assessments of his/her competence, during initial stages, during Master’s and during his/her professional career. Every activity would thus be approved and certified by the Director of the accredited Centre, based on agreed criteria. The Master’s diploma would then be described as
having been “awarded as certified by the Board of Directors” (for ex., Master certified by the Interventional Pulmonology Study Group of Master). Every course on individual subject matters may apply to be granted the Board’s formal approval and thus become a qualification that can be added to one’s CV, either as part of one’s Master’s certificate, or as continuing education. The practicing physician can therefore be awarded either a Master’s degree or a Master’s plus a validation of the activities performed, including a quantitative and qualitative assessment of his/her competences in different procedures. The physicians included in the database can access the website, will receive a newsletter, can discuss clinical cases online, can register to attend teaching activities and simulation exercises at the Centres, take part in Practice Centres or Boot Camps. After having been awarded a Master’s degree, the physician may continue to record in his/her logbook the procedures performed in his/her professional practice.

The Hospital Centres included in the programme must be competent in most IP procedures, and should enter into agreements with other Centres to cover all procedures. All senior physicians who participate in the Consensus Conference may be invited to become members of the Board. The participating institutions must have a sufficient number of faculty with documented qualifications to instruct and supervise all fellows. A minimum of two faculty members are required, one of which is the Programme Director and the other is designated as Key Clinical Faculty. The faculty must devote sufficient time to the educational programme to fulfil their supervisory and teaching responsibilities and demonstrate a strong interest in the education of fellows. The physician faculty must possess qualifications judged acceptable by the Joint IP Fellowship Review Committee. Physician faculty may practice associated specialties such as Pulmonary Medicine or Thoracic Surgery; however, they must be actively engaged in the practice of IP, maintain a regular supervisory responsibility for the IP fellow(s) and maintain board certification in the area of subspecialty.

Each of the following services must be present at the primary clinical site: IP laboratories or suites, each provided with fluoroscopic equipment, digital imaging, recording devices, and resuscitation equipment. The primary clinical site must be capable of providing the following: active thoracic surgery, ENT head and neck surgery, radiation oncology, and thoracic oncology programmes; surgical and medical intensive care units; anatomic and cyto-pathology programmes; and diagnostic radiology programmes.
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4. SYLLABUS DESCRIPTIONS:
Basic knowledge requirements for IP

4.1 Lung cancer and solitary pulmonary nodule

**Introduction**
Despite considerable progress in screening, diagnostics and treatment, lung cancer remains the leading cause of cancer death in men and women in the United States, with a 16% overall 5-year survival rate. Pulmonologists play a central role in lung cancer screening, diagnosis, staging and treatment decisions, thanks especially to innovative technologies such as EBUS and navigation, with new treatments based on histology and mutation analysis, and novel approaches like stereotactic body radiotherapy. Pulmonologists can play pivotal roles in the development and implementation of algorithms for lung cancer diagnosis and treatment. Specifically, they are involved in the interpretation of clinical and radiographic findings, as well as in the performance of interventional procedures, such as bronchoscopy, endobronchial ultrasound (EBUS), thoracentesis and medical thoracoscopy. The samples collected through these procedures are essential in establishing diagnoses and staging, and for providing adequate specimens that can guide targeted and personalized therapies.

**Knowledge & Skills**

<table>
<thead>
<tr>
<th>Knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Epidemiology and clinical manifestations</td>
</tr>
<tr>
<td>• Pathology classification (WHO)</td>
</tr>
<tr>
<td>• TNM Classification of malignant tumours (8th edition American Joint Committee on Cancer – AJCC)</td>
</tr>
<tr>
<td>• Role of screening and early diagnosis</td>
</tr>
<tr>
<td>• Diagnosis, staging and natural history of thoracic malignancies, including: lung cancer, mesothelioma, thymoma, mediastinal tumours and lymphoma, metastatic tumours, tracheal cancers, other chest tumours</td>
</tr>
<tr>
<td>• Evaluation, diagnosis and management of pleural disease, including: malignant pleural effusion, recurrent pleural effusion</td>
</tr>
<tr>
<td>• Differential diagnosis of central and peripheral tumours</td>
</tr>
<tr>
<td>• Tests for diagnosis and staging</td>
</tr>
<tr>
<td>o Non-invasive (imaging): X-ray, CT scan, PET</td>
</tr>
<tr>
<td>o Invasive: bronchoscopy for biopsy, brushing, blind and guided transbronchial needle aspiration (TBNA, EBUS-TBNA, EUS: interventional endosonography), electromagnetic pulmonary navigator (EMN), fluoroscopy, radial EBUS, transthoracic needle aspiration and needle biopsy, thoracoscopy and mediastinoscopy</td>
</tr>
<tr>
<td>• Treatments for lung cancer and mesothelioma:</td>
</tr>
<tr>
<td>o Bronchoscopic and surgical treatment</td>
</tr>
<tr>
<td>o Basic principles of radiotherapy to include brachytherapy</td>
</tr>
<tr>
<td>o Basic principles of chemotherapy as they apply to thoracic malignancies</td>
</tr>
<tr>
<td>o Palliative treatments</td>
</tr>
<tr>
<td>• Know and manage co-morbidity, complications, paraneoplastic syndromes and other conditions influencing the outcome</td>
</tr>
<tr>
<td>• Communication with the patient about treatment options</td>
</tr>
<tr>
<td>• Medical legal issues</td>
</tr>
</tbody>
</table>
### Core Basic Skills
- Interpretation of imaging tests (X-ray, CT scan, PET)
- Interpretation of anatomic pathology and molecular test results
- Organization of sequential procedures
- Provide management and leadership within the lung cancer multidisciplinary team, including playing a role in primary prevention (smoking cessation, screening, diagnosis and staging, clinical and pathophysiological pre-treatment evaluation, histological characterization of the tumour, follow-up, management of respiratory co-morbidities, pleural effusion, respiratory failure) and in managing the side effects of treatment.
- Basic bronchoscopy and interventional procedures

### BEHAVIOURS AND ATTITUDES
- Recognise the importance of relieving physical, psychological and spiritual suffering
- Ability to work as a member of a multidisciplinary team
- Ability to break bad news sensitively but honestly
- Ability to discuss the ethics of prolonging life and to help the patient weigh this up against quality of life
- Ability to communicate sensitively and empathically, but with honesty, with patient, family, friends and carers
- Recognise the importance of audits

### ASSESSMENT OF “CORE COMPETENCES”

<table>
<thead>
<tr>
<th>Qualitative Assessment</th>
<th>Outcome Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>• MCQ</td>
<td>• Evaluation of time to diagnosis: from 4 to 6 weeks for diagnosis and staging</td>
</tr>
<tr>
<td>• Case-based questionnaire</td>
<td>• Evaluation of the lung cancer multidisciplinary team</td>
</tr>
</tbody>
</table>

### Recommended Literature
2. Diagnosis and Management of Lung Cancer, 3rd ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines May 2013; 143(5_suppl)


Multimedia resources
### 4.2 Malignant and non-malignant central airway disorders

**Introduction**

The management of central airway obstructions (CAO) is challenging and requires a multidisciplinary team approach: this requires the involvement of a pulmonologist, medical and radiation oncologist, anaesthetist, ENT specialist, thoracic surgeon and interventional bronchoscopist. CAO management is largely dependent on the initial presentation. More than half of all procedures performed for an airway obstruction are done as urgent care and emergency procedures. Significant airway obstruction presenting with imminent suffocation requires immediate action to promptly and effectively re-establish and secure a patent airway and relieve the obstruction. This is often achieved with rigid bronchoscopy plus a thermal modality of therapy (e.g., endobronchial laser). Since these patients usually present in acute conditions, investigations that would normally be carried out as routine preliminary tests (e.g., high-resolution CT, pulmonary function tests), including a flexible bronchoscopy procedure for diagnostic purposes, are not performed initially. If there is any doubt regarding the stability of the airway in a severe obstruction case, rigid bronchoscopy is the procedure of choice as it ensures a secure airway, enabling oxygenation and ventilation. It also serves as a therapeutic tool for rapid stenosis dilatation. The establishment of a secure airway may require endotracheal intubation or rigid bronchoscopy. In patients with severe proximal upper airway obstruction, urgent cricothyroidotomy or tracheotomy are the procedures of choice. The Interventional Pulmonologist is pivotal in the diagnosis and urgent (often definitive) treatment of CAO.

### Knowledge & Skills

#### Knowledge

- Anatomy and physiology of central airways
- Dynamic flows
- Epidemiology, symptoms and classification of malignant central airway disorders
- Epidemiology, symptoms and classification of non-malignant central airway obstruction due to:
  - Tracheal/bronchial obstruction secondary to, for example, granulomatosis with polyangiitis, post-intubation/tracheostomy, tuberculosis, sarcoidosis, amyloidosis, recurrent respiratory papillomatosis, broncholithiasis, tracheal/bronchial malacia (TBM), excessive dynamic airway collapse (EDAC) secondary to relapsing polychondritis, Mounier-Kuhn syndrome, COPD
  - Foreign body
  - Vocal cord disorders
  - Pseudomembranes
- Airway complications following airway surgery/lung transplant, including anastomotic strictures/granulation
- Airway stent-associated granulation tissue
- Extrinsic compression from, for example, goitre, mediastinal cyst, lymphadenopathy
- Epidemiology, symptoms, classification, dynamic imaging and endoscopy of TBM and EDAC (e.g. FEMOS classification)
- Strategy for endoscopic and surgical treatment
- Pharmacological, endoscopic and surgical treatment of tracheo-bronchial stenosis and lesions

#### Core Basic Skills

- Pathophysiology and radiographic interpretation of central airway obstructions (CT scan, PET)
- Interpretation of endoscopic images of lesions (intraluminal, extraluminal, mixed) and evaluation of the lumen’s residual patency as well as extent of stenosis.
- Initial stabilization and decision regarding urgency and emergency
- Selection of the appropriate approach depending on: acuteness of presentation, underlying cause and type of lesion, patient stability, the patient’s general, cardiac, and pulmonary status, quality of life, overall prognosis, physician’s expertise, and the technology available
- Decision regarding endoscopic or surgical approach
- Basic bronchoscopy and interventional procedures with rigid bronchoscopy and thermal modalities (laser, electrosurgery, Argon Plasma Coagulation – APC, cryotherapy) and non-thermal endoscopic airway procedures (brachytherapy, photodynamic treatment, microdebrider, airway dilatation, stenting)
- Diagnostic choice based on clinical context (see section 5)

**BEHAVIOURS AND ATTITUDES**
- Recognise the need to relieve physical pain
- Ability to discuss ethical consequences of prolonging life

**ASSESSMENT OF “CORE COMPETENCES”**

<table>
<thead>
<tr>
<th>QUALITATIVE ASSESSMENT</th>
<th>OUTCOME ASSESSMENT</th>
</tr>
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<tbody>
<tr>
<td>MCQ</td>
<td>Clinical outcomes (improvement in symptoms, quality of life and survival) and complications</td>
</tr>
<tr>
<td>Case-based questionnaire</td>
<td>Multidisciplinary team decisions</td>
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</table>

**Recommended Literature**

4.3 Interstitial lung diseases and granulomatosis

Introduction

Advances in the field of high-resolution computed tomography (HRCT) have led to major changes in the approach to idiopathic interstitial pneumonia (IIP) diagnosis; this has considerably reduced the need for surgical lung biopsies in the majority of patients. Challenges in establishing a diagnosis occur in patients with an HRCT pattern of ‘possible usual interstitial pneumonia’ (UIP). Recent studies have shown that, unlike conventional transbronchial biopsy (TBB), TBB using a cryoprobe (also known as cryobiopsy) is a viable technique, providing a less invasive method of obtaining histopathological specimens, accompanied by lower morbidity and mortality than surgical lung biopsy. The role of cryobiopsy in the diagnostic algorithm of idiopathic pulmonary fibrosis (IPF) and of a differential diagnosis relative to other interstitial lung diseases (ILDs) is unclear; further, its potential advantages have not yet been verified in a cost-benefit analysis.

KNOWLEDGE & SKILLS

Knowledge

- Classification, epidemiology, etiology, clinical and endoscopic diagnosis, histopathological characteristics, treatment and follow-up of infiltrative lung diseases and pulmonary granulomatosis (i.e. sarcoidosis)
- Radiographic interpretation of the main patterns of ILD and granulomatosis
- Differential diagnosis and diagnostic algorithm through clinical examination, respiratory function, imaging and pathology
- Indications for interventional bronchoscopy diagnosis (bronchoalveolar lavage, transbronchial biopsy with needle aspiration, cryobiopsy) and for surgical biopsy
- Knowledge of bronchoscopic and surgical procedures for the diagnosis of ILD
- Thorough knowledge of bronchoscopic cryobiopsy
- Pharmacological and non-pharmacological treatment
- Management of follow-up and indications for transplantation
- Complications of ILD, in particular respiratory failure

Core Basic Skills

- Interpretation of the different radiographic patterns of ILD
- Management of diagnostic pathway of IIP and granulomatosis, especially for interventional procedures: bronchoalveolar lavage (BAL), transbronchial biopsy (TBB) and needle aspiration (TBNA, EBUS-TBNA), cryobiopsy.
- Performance and interpretation of spirometry and other appropriate lung function tests
- Clinical and therapeutic management of ILD
- Capacity to manage and work within a multidisciplinary team (MDT), in collaboration with radiologist, pathologist, thoracic surgeon, internist and rheumatologist
- Basic bronchoscopy, BAL and TBB

BEHAVIOURS AND ATTITUDES

- Awareness of need to involve patient in management decisions, particularly with regard to risk/benefits of treatment and “ceiling of care” in relation to mechanical ventilation
- Awareness of need to inform patient, where appropriate, of prognosis
- Awareness of need for patient/carer support in poorer prognosis pathologies
- Awareness of need to relieve symptoms where disease course cannot be beneficially affected
- Awareness of possible role for palliative care team
- Recognise potential role for MDT approach to management
## THEORETICAL/PRACTICAL TRAINING AND CORE COMPETENCES ASSESSMENT METHODS

### QUALITATIVE ASSESSMENT
- MCQ
- Case-based questionnaire
  For skills see section 5.1

### OUTCOME ASSESSMENT
- Clinical outcome

### Recommended Literature


### 4.4 Pulmonary infections

**Introduction**

Fibre-optic bronchoscopy (FOB) has been shown to be of considerable diagnostic value in opportunistic pulmonary infections occurring in immunocompromised patients, including HIV positive patients and tuberculosis (TB). The initial diagnostic approach to suspected cases of pulmonary TB consists in demonstrating the presence of *mycobacterium tuberculosis* bacilli in stained smears of sputum. Many patients exhibiting the clinical and radiographic features of pulmonary TB have negative sputum smears, even if the examination is repeated on several occasions; and their sputum culture for acid-fast bacilli (AFB) may also turn out to be negative. Smear-negative TB cases are defined as those in which the patient presents with: 1. at least two negative sputum samples; 2. X-ray findings suggesting TB; 3. no clinical response to treatment with antimicrobial agents (except fluoroquinolones); or any combination of these three. In cases in which it is impossible to collect spontaneous sputum, or in which smear microscopy results are negative, induced sputum or bronchoscopy with collection of BAL specimens, with or without transbronchial biopsy (TBB), can be used. Pulmonologists must possess a specific competency to undertake the specialist assessment and management of patients with TB or other microbial diseases (OMD). Trainee must have knowledge of management of multi-drug resistant (MDR) TB, including use of negative pressure rooms.

**KNOWLEDGE & SKILLS**

#### Lower respiratory tract infections (LRTI)

- Classification, local and global epidemiology, etiology, clinical and endoscopic diagnosis, treatment and follow-up of pulmonary infections: acute bronchitis, exacerbation of chronic obstructive pulmonary disease (COPD), bronchiectasis, community-, hospital- or ventilator-associated pneumonia (CAP, HAP, VAP), opportunistic lung infections
- Radiographic interpretation of pulmonary infections
- Differential diagnosis of pulmonary infections
- Indications for interventional diagnosis (bronchoalveolar lavage, transbronchial biopsy and needle aspiration)
- Management of patients with pulmonary infections, including oxygen therapy, intravenous fluids and other supportive care
- Management of critical phases of pulmonary infections
- Diagnostic and therapeutic algorithm, and related invasive and non-invasive tests
- Indications and contraindications for interventional procedures (bronchoscopy, bronchoalveolar lavage, bronchial and transbronchial biopsy)

#### TB and MDR-TB

- Classification, local and global epidemiology, etiology, clinical and endoscopic diagnosis, treatment and follow-up, and symptomatology of TB and MDR-TB
- WHO and ERS guidelines on TB and MDR-TB
- Infection control
- Diagnostic and therapeutic algorithm, and related invasive and non-invasive tests
- Indications and contraindications for interventional procedures (bronchoscopy, bronchoalveolar lavage, bronchial and transbronchial biopsy, pleural aspiration, thoracoscopy)
- Management of MDR-TB, including use of negative pressure rooms
### Core Basic Skills

- Indications for endoscopic and surgical treatment
- Relevant guidelines including contact tracing, screening and vaccination programmes
- Interpretation of the different radiographic signs of infections in CT scans and PET
- Interpretation of blood and serological tests
- Clinical and therapeutic management of pneumonia and TB
- Management of critical stage of disease
- Prevention of contamination
- Pharmacological and surgical management of pulmonary abscess
- Indications and contraindications for diagnostic bronchoscopy procedures: bronchoalveolar lavage (BAL), transbronchial biopsy (TBB) and needle aspiration (TBNA), protected sheath, thoracic ultrasound, thoracoscopy
- Performing basic bronchoscopy and related procedures (BAL, TBB, protected sheath)
- Organization and management of contact tracing, appropriate use of isolation precautions and negative pressure rooms

### Behaviours and Attitudes

- Recognise the importance of primary care and respiratory specialist nursing staff in patient management
- Recognise the importance of methods to achieve compliance with treatment
- Recognise the importance of contact tracing; know one’s own role in this and know how to lead in getting contact tracing services organised and implemented
- Recognise the importance of immigration screening and know one’s own role in this
- Recognise and act upon public health aspects of care
- Communication skills with patients, family, carers and contacts

### Theoretical/practical training and core competences assessment methods

#### Qualitative Assessment

- MCQ
- Case-based questionnaire on appropriateness of interventions

#### Outcome Assessment

Clinical outcome

### Recommended Literature

22. Dheda K, Migliori GB. The global rise of extensively drug-resistant tuberculosis: is the time
# 4.5 COPD and Asthma

## Introduction
COPD. Chronic obstructive pulmonary disease (COPD) is a progressive condition comprising a constellation of disorders from chronic bronchitis, airflow obstruction through to emphysema. The standard of care is based on a combination of: smoking cessation, pharmacological treatments, oxygen therapy and pulmonary rehabilitation. However, the more advanced stages of COPD are challenging to manage. In the management of these cases, our current standards of care do not adequately control patient symptoms nor do they halt their progressive decline. For the emphysema phenotype, lung volume reduction surgery (LVRS) has shown a beneficial effect in selected patients, but is counterbalanced by the morbidity experienced by some patients. International guidelines, i.e. GOLD, recommend endoscopic lung volume reduction (ELVR) in patients with severe emphysema. Bronchoscopic volume reduction technologies have been developed to improve the clinical situation of emphysema patients. The basic knowledge required to achieve competence in this field involves knowing the correct indications for these procedures and mastering the skills to perform procedures using current and emerging technologies.

ASTHMA. Bronchial thermoplasty is a new interventional procedure that was approved by the US Food and Drug Administration (FDA) for asthma in April 2010, for patients aged 18 years and older “whose severe and persistent asthma is not well-controlled with inhaled corticosteroids and long-acting beta agonist medications.” The basic knowledge required to achieve competence in this field is the ability to manage severe asthma, to perform a correct procedure and manage the follow-up, in which some complications are to be expected.

## KNOWLEDGE & SKILLS

**Knowledge**
- **COPD**
  - Pathophysiology, classification and treatment of severe COPD
  - Pulmonary function testing
  - Imaging of emphysema with Quantitative CT and Fissure integrity, 3D systems (i.e. Strat-)
  - Indications for endoscopic treatment of emphysema
  - Bronchial anatomy
  - Knowledge of tools and procedures used in endoscopic lung volume reduction treatment (unidirectional valves, coils, thermal vapour, sealants, Chartis system)

- **Asthma**
  - Pathophysiology, diagnosis and treatment of severe asthma
  - Differential diagnosis of severe asthma (COPD, foreign bodies, other bronchial obstructions)
  - Pulmonary function testing
  - Indications, contraindications and complications of treatment of asthma with thermoplasty
  - Bronchial anatomy
  - Physics and technological principles of thermoplasty
  - Knowledge of the methodology of thermoplasty and related protocols (bronchial mapping, hospital setting)

**Core Basic Skills**
- **Asthma: (see section 5.2.3)**
  - Ability to take a relevant, focused history; to elicit relevant physical signs, formulate a differential diagnosis, plan appropriate further investigations and formulate an appropriate management plan
  - Perform and interpret spirometry and other appropriate lung function tests
  - Management of options for severe and steroid-resistant asthma, including indication to treatments such as thermoplasty
  - Management of asthma exacerbations and near fatal asthma, including intensive treatment
- Perform basic bronchoscopy and related procedures: bronchoalveolar lavage (BAL), transbronchial biopsy (TBB), protected sheath
- Administer and monitor conscious sedation

**COPD and Endoscopic Lung Volume Reduction (ELVR, see section 5.2.2)**
- Ability to take a relevant, focused history; to elicit relevant physical signs, formulate a differential diagnosis, plan appropriate further investigations and formulate an appropriate management plan
- Perform and interpret spirometry and other appropriate lung function tests
- Interpret imaging studies (CT scans and 3D images)
- Management of options for severe COPD and co-morbidities, including indication to treatments such as ELVR
- Management of COPD exacerbations, including intensive treatment for respiratory failure and end-stage disease
- Management of ELVR complications, such as thoracic drainage for pneumothorax in emergency, and haemoptysis
- Perform basic bronchoscopy and ELVR related procedures, including Chartis (see section......)
- Administer and monitor conscious sedation

**BEHAVIOURS AND ATTITUDES**
- Recognise the importance of taking a detailed history to determine factors contributing to poor asthma control
- Recognise the importance of checking inhaler technique and treatment compliance
- Recognise asthma as a chronic condition requiring ongoing care in the appropriate (primary/secondary/tertiary) care setting
- Ability to establish a trusting doctor-patient relationship
- Recognise the importance of appropriately trained nurses and other healthcare professionals in long-term care

**THEORETICAL/PRACTICAL TRAINING AND CORE COMPETENCES ASSESSMENT METHODS**

**QUALITATIVE ASSESSMENT**
- MCQ
- Case-based questionnaires, on appropriate decisions

**OUTCOME ASSESSMENT**
- Clinical outcome

**Recommended Literature**

**Asthma:**

1. GINA guidelines available at [www.ginasthma.org](http://www.ginasthma.org)


**COPD:**


# 4.6 Pleural disease

## Introduction

Pleural effusion, pneumothorax, and pleural thickening are frequently encountered in pulmonary practice, accounting for an annual incidence of more than 1.5 million cases in US. Although the radiographic and ultrasonographic detection of pleural abnormalities may be obvious, determination of a specific diagnosis can often represent a challenge. Since pleural effusions can develop as the result of over 50 different pleuropulmonary or systemic disorders, determining the cause of a pleural effusion can be greatly facilitated by the analysis of the pleural fluid obtained during an ultrasound guided thoracentesis. A presumptive diagnosis, based on the pre-thoracentesis clinical impression, can be substantiated by the pleural fluid analysis in more than 50% of the patients. Even with a non-diagnostic thoracentesis, pleural fluid analysis can be useful in excluding other possible causes, such as infection, or guiding subsequent diagnostic studies. Invasive procedures such as ultrasound/CT-guided pleural biopsy or medical thoracoscopy can be useful in every case of undetermined etiology.

The knowledge of the etiology and of the management of primary and secondary spontaneous pneumothorax is mandatory in an interventional pulmonology training program, while the medical or surgical treatment of the recurrence is still matter of discussion.

## KNOWLEDGE & SKILLS

### Knowledge

- Anatomy and pathophysiology, cytology of pleural fluid, difference between transudates and exudates
- Classification, epidemiology, etiology, clinical diagnosis, histopathological characteristics, treatment and follow-up of pleural diseases: parapneumonic effusion and empyema, malignant pleural effusions, malignant mesothelioma, recurrent non-malignant pleural effusions (chyllothorax, hepatic hydrothorax/effusions due to refractory congestive heart failure), pneumothorax, pleural fistulas
- Knowledge of differential diagnosis and treatment through non-invasive (anamnesis and physical examination, pleural ultrasound, CT scans) and invasive procedures (medical thoracoscopy with parietal pleural biopsy and pleurodesis, pleural catheter placement: chest tube, small bore catheter, and implantable tunnelled catheters, percutaneous pleural biopsy, video-assisted thoracoscopic surgery − VATS)
- Know when drainage of a pleural effusion is appropriate, including safety aspects of chest drain insertion
- Knowledge of chest drain management, including in-dwelling pleural catheters
- Knowledge of all treatments for pleural effusion
- Knowledge of chemical pleurodesis
- Knowledge of the role of surgery in the management of pleural effusions
- Classification, epidemiology, etiology, clinical diagnosis and treatment of pneumothorax
- Knowledge of differential diagnosis and treatment of pneumothorax through non-invasive (anamnesis and physical examination, pleural ultrasound, CT scans) and invasive procedures (thoracic aspiration, pleural catheter placement: chest tube, small bore catheter, medical thoracoscopy, pleurodesis, VATS, thoracotomy)

### Core Basic Skills

- Management of pleural effusion and pneumothorax using the appropriate diagnostic and therapeutical algorithm
- Interpretation of chest X-rays, ultrasound and CT scans
- Pleural fluid aspiration
- Insertion of chest drains, including ‘seldinger’ drains (mandatory) and large bore ‘surgical’ drains (optional)
- Local anaesthetic (medical) thoracoscopy (optional)
### Behaviours and Attitudes
- Ability to recognise, when appropriate, the urgency of the situation and to expedite management appropriately
- Ability to explain the possible causes to the patient and relatives/carers, and to outline the investigation and management plan
- Ability to communicate with skill and sensitivity in breaking bad news, where appropriate
- Ability to involve the multidisciplinary/palliative care team, where appropriate

### Theoretical/Practical Training and Core Competences Assessment Methods

#### Qualitative Assessment
- MCQ
- Case-based questionnaire
For skills assessment see section:

#### Outcome Assessment
- Clinical outcome

### Recommended Literature

### Multimedia Resources
12. Pleural-HUB: [https://www.facebook.com/groups/pleural.hub/](https://www.facebook.com/groups/pleural.hub/)
5. SYLLABUS DESCRIPTIONS: Basic procedural skills

5.1 Diagnostic procedures

5.1.1 Flexible bronchoscopy and basic sampling technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing

Introduction

Diagnostic bronchoscopy and tissue sampling techniques using forceps (biopsy) or needle aspiration (TBNA), all performed with a flexible bronchoscope, are the basic elements of any interventional procedure. A physician’s competence with these procedures needs to be acquired through a specialization or fellowship in Respiratory Diseases and maintained by continuous practice. This section lists the indispensable knowledge and skills that any physician must possess if s/he is to perform these procedures; it also lists the theoretical and practical training methods to be applied, as well as the assessment criteria to be followed in evaluating a practitioner’s competence.

Trainees will acquire a thorough knowledge of thoracic anatomy and become skilled in the interpretation of thoracic imaging (CT with contrast medium and PET), after which they will be given a theoretical and practical training course on virtual reality simulators, on animal or cadaver models, the effectiveness of which has been fully demonstrated by scientific studies. Specific DOPS tests have been developed for a qualitative evaluation of procedures on simulators, on animal models and on the patient, B-STAT and B-SET.

Indications for the procedure

GROUP 1: INDICATIONS WITH STRONG EVIDENCE

- Pulmonary lesions observed at CT scan (consolidation, atelectasis, masses, localised hyper-transparency), located in central areas (reachable with the flexible bronchoscope);
- Staging of lung cancer (evaluation of the endobronchial extension of the tumour and/or transbronchial needle aspiration of enlarged lymph nodes; pre-operative evaluation; restaging after therapy);
- Mediastinal lesions or masses (evaluation of compression of the airways; transbronchial needle aspiration for diagnosis);
- Presence of atypical cells in the cytological examination of the sputum;
- Clinical or CT scan suspicion of tracheal stenosis;
- Clinical or CT suspicion of endobronchial foreign body;
- Clinical suspicion of bronchopleural or tracheal/broncho-oesophageal fistula;
- Thoracic trauma, when there is a suspicion of airways obstruction (blood clots, foreign bodies, secretions) or airways rupture (haemoptysis, mediastinal and/or subcutaneous emphysema);
- Infiltrative lung diseases (to perform bronchoalveolar lavage and/or transbronchial lung biopsy, according to the indications provided by high resolution CT scan);
- Suspicion of mucociliary dyssinesia syndrome (to perform mucosal biopsies for electron microscope study);
- Evaluation of patients with tracheal cannula, before decannulation.

GROUP 2: INDICATIONS WITH SPECIFIC TIMING AND MODALITY OF PERFORMANCE OF BRONCHOSCOPY

- Chronic cough;
- “Non-resolving” or “Slow-resolving pneumonia”;
- Dyspnoea of unknown origin;
- Haemoptysis;
- Pleural effusion of unknown origin;
- Vocal cord or diaphragm paralysis;
- Peripheral lung lesions and pulmonary nodules;
- Staging of oesophageal cancer;
- Staging of thyroid cancer.

<table>
<thead>
<tr>
<th>KNOWLEDGE &amp; SKILLS</th>
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<tbody>
<tr>
<td><strong>Prior Experience Requirements</strong></td>
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<table>
<thead>
<tr>
<th>Knowledge</th>
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</thead>
<tbody>
<tr>
<td>- Diagnostic and therapeutic algorithm of lung cancer and other respiratory diseases (see sections 4.1 – 4.6)</td>
</tr>
<tr>
<td>- Normal, variant and abnormal bronchial anatomy, and relationships of bronchial tree to other important intra-thoracic structures (mediastinum, and other)</td>
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<tr>
<td>- Thoracic imaging (CT Scan, PET)</td>
</tr>
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<td>- Full working knowledge of all the equipment involved; organization of the endoscopy room (structural, technological and organizational requirements)</td>
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<tr>
<td>- Indications and contraindications for fibre-optic bronchoscopy (including recommendations for the suspension of antiaggregant and anticoagulant therapies) and risk/benefit analysis of the procedures</td>
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<tr>
<td>- Sensitivity, specificity, accuracy and limitations of diagnostic procedures with bronchoscopy</td>
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<tr>
<td>- Special indications for intensive care and emergency settings</td>
</tr>
<tr>
<td>- Safe sedation and local anaesthesia for fibre-optic bronchoscopy (see section...) and technique of monitoring and intensive support</td>
</tr>
<tr>
<td>- Techniques of fibre-optic bronchoscopy (endobronchial biopsy, brushing, bronchial washing, BAL, TBNA, transbronchial biopsy) and knowledge of main types of forceps and needles</td>
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<tr>
<td>- Methods for preparing cytology and histology samples (slides, cell block, clot core)</td>
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<tr>
<td>- Basic knowledge of cytology and Rapid On Site Evaluation (ROSE)</td>
</tr>
<tr>
<td>- Be acquainted with more advanced diagnostic and therapeutic bronchoscopic techniques, including TBNA, EBUS, fluoroscopy, navigator, diathermy, laser, photodynamic therapy, cryotherapy, endobronchial radiotherapy and stent placement (knowledge only required)</td>
</tr>
<tr>
<td>- Risk management and prevention</td>
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<td>- Relevant guidelines</td>
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<tr>
<td>- Infection control/safety at work issues</td>
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<td>- Disinfection and tracking of the equipment</td>
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<table>
<thead>
<tr>
<th>Core Basic Skills</th>
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<tr>
<td>- Expertise in the clinical evaluation and management of the main respiratory diseases and active participation in the multidisciplinary team – including radiologist, oncologist, thoracic surgeons etc. – in making the best diagnostic decision</td>
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<tr>
<td>- Interpretation of imaging exams and correlation between imaging and endoscopy</td>
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<td>- Correct procedure selection based on indications</td>
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<tr>
<td>- Be competent to safely perform fibre-optic bronchoscopy via nasal and oral route: o  Introduction of bronchoscope and examination to subsegmental level</td>
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- Advanced diagnostic and therapeutic bronchoscopic techniques (only knowledge of these is required; although some trainees may gain practical experience as well)
- Safe administration of local anaesthetic including appreciation of potential toxicity (competence)
- Safe administration of intravenous sedation and how to reverse excessive sedation (competence)
- Appropriate monitoring for each procedure, provided in collaboration with nurses and anaesthetist
- Manage bronchoscopy in the patient with respiratory failure using NIV or other ventilation devices
- Communication with the patient before, during and after the procedure
- Prevention and management of any complications arising during the procedure (bleeding, pneumothorax, cardiac and respiratory complications) in collaboration with the team
- Manage correctly the retrieval and processing of cyto-histological specimens
- Performing and interpretation of Rapid On Site Evaluation (ROSE) (optional)
- Manage disinfection and tracking of equipment
- Interpretation of results and reporting
- Re-evaluation of the patient and follow-up
- Informed consent and proper explanation of risks and benefits.

<table>
<thead>
<tr>
<th>Procedural Steps for Practical Training (Check list)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Before beginning the procedure, check that all equipment is functioning regularly and is properly prepared: bronchoscope, accessories for sampling, interfaces and devices for oxygenation and ventilation</td>
</tr>
<tr>
<td>• Preparation and correct positioning of the patient, local anaesthesia and sedation, monitoring</td>
</tr>
<tr>
<td>• Performing the bronchoscopy on patient under conscious or deep sedation with assistance of anaesthetist</td>
</tr>
<tr>
<td>• Handling the bronchoscope</td>
</tr>
<tr>
<td>• Nasal and oral approach</td>
</tr>
<tr>
<td>• Inspection of the vocal cords and tracheobronchial tree and choice of sampling technique:</td>
</tr>
<tr>
<td>o Bronchial washings and lavage</td>
</tr>
<tr>
<td>o Tracheobronchial biopsies</td>
</tr>
<tr>
<td>o Transbronchial biopsies (TBB): radiographic evaluation and choice of pertinent bronchus</td>
</tr>
<tr>
<td>o Bronchoalveolar Lavage (BAL)</td>
</tr>
<tr>
<td>o TBNA and EBUS/TBNA</td>
</tr>
</tbody>
</table>

**ENDOBRONCHIAL BIOPSY:** This procedure is performed for visible airway abnormalities, most commonly in the diagnosis of suspected lung cancer. Once again, radiology should be available to plan where sampling should occur. There are several types of forceps that can be used for biopsies: the most common are alligator or open cup forceps. Studies have not demonstrated any advantage of one type of forceps over the other in diagnostic yield.

  o The bronchoscope should be advanced until the endobronchial lesion is visualised
  o Secure the bronchoscope in this position so that the abnormality can be fully visualised, then advance the forceps in the closed position through the working channel of the bronchoscope
  o Once the forceps is visualised at the distal end of the bronchoscope, the forceps can be opened
  o While keeping the bronchoscope still, the forceps should be advanced in the open position towards the abnormality
  o Once the target is reached, the forceps should be closed trapping as much tissue
as possible
- The forceps should be retracted and removed from the working channel of the bronchoscope
- A "tugging" sensation may be felt whilst retracting the forceps
- Once the sample has been removed from the forceps, it should be reinserted into the working channel and the procedure repeated 5-6 times

**TRANSBRONCHIAL LUNG BIOPSY (TBLB):** This procedure is performed via flexible bronchoscopy, to aid the diagnosis of parenchymal lung disease. Accurate radiographic imaging is essential to guide the bronchoscopist to the lung parenchyma with the greatest potential diagnostic yield in non-diffuse interstitial disease. Unlike endobronchial biopsy this procedure can be performed "blind", without direct visualisation of the lesion but is recommended to perform this procedure with radiographic guidance (fluoroscopy).
- After inserting the forceps into the working channel of the bronchoscope until its distal tip is just visible the bronchoscope is advanced as far as possible into the area of the lung to be biopsied
- The forceps is then advanced as far as possible (if blind, a pleural pain should be elicited)
- At this point the forceps is retracted 1-2 cm to avoid a biopsy of the pleura. Instruct the patient to breathe in, deeply and slowly. The forceps is then opened during inspiration. This procedure is specific for Interstitial Lung Diseases.
- Instruct the patient to breathe out slowly; while the patient is breathing out, the forceps is advanced and closed
- The forceps is then gently removed and the sample retrieved. Warning: Do not take the biopsy if the patient experiences pain when forceps is pulled back or removed, since this may signal that pleura may have been caught in the forceps. If this occurs, open the forceps and remove without biopsy
- The procedure is repeated a further 5-6 times. Clinical Tip: While performing a TBLB, the patient’s co-operation is necessary. Since patients should be able to follow commands, a light sedation is recommended

**TRANSBRONCHIAL BIOPSY (TBB):** fluoroscopy should be employed with transbronchial biopsy in cases of localized or focal parenchymal lung disease. The use of fluoroscopy during transbronchial biopsy has been shown to increase the diagnostic yield in focal lesions, though it has not been found to provide a comparable benefit in diffuse lung diseases such as sarcoidosis. The number of biopsy specimens required for optimal diagnostic yield has been reported as being between 4 and 10. The 2013 BTS Guidelines recommend that at least five samples should be obtained in cases where endobronchial tumour is visible and that at least five or six samples should be obtained in cases of interstitial lung disease.

**BRONCHOALVEOLAR LAVAGE (BAL):** This procedure is performed via flexible bronchoscopy and is useful in the diagnosis of pulmonary infections; it may also be useful in the diagnosis of parenchymal lung disease. The site of BAL should be chosen with radiographic guidance.
- Once the site for BAL has been chosen, the bronchoscope should be advanced until the desired site is reached; in diffuse parenchymal disease, middle lobe or lingula should be chosen, due to an easier retrieval.
- The bronchoscope should then be wedged in to a position where the lumen of the bronchus is occluded by the bronchoscope
- While the bronchoscope is in this position, normal saline (at room temperature) is instilled through the bronchoscope, with a total volume that is between 100 and 300 ml and divided into three to five aliquots
- Low-pressure suction should then be applied to retrieve the sample. The aim is to
apply enough suction to retrieve the sample without causing airway collapse.
  o To ensure an adequate sample is retrieved it is useful to have tubing with several
    containers in series attached to the suction pump.
  o Some centres employ a syringe to retrieve the sample from the same port through
    which the saline is instilled.

- **ENDOBRONCHIAL BRUSH**: This procedure is performed to collet cytology samples in areas of
  abnormal mucosa or endobronchial lesions. Although no evidence exists to suggest which
  procedure should be performed first, we recommend that endobronchial biopsies are
  performed prior to brushings.
  o Once the area of abnormality is detected, the bronchial brush is inserted through
    the working channel of the bronchoscope in its retracted position, inside its
    protective sheath.
  o Once the bronchial brush is visualised at the distal end of the bronchoscope, the
    brush can be pushed out (opened).
  o The brush is then advanced towards the lesion and moved back and forth over
    the lesion several times.
  o The brush is then retracted into its sheath (closed) and removed from the working
    channel.
  o The procedure is repeated.
  o Alternatively, to minimize sample loss, the brush can be retract without being
    withdrawn inside the operating channel, but extracting it in its entirety.

- **TRANSBRONCHIAL NEEDLE ASPIRATION (TBNA)**:
  o Insert the needle catheter through the working channel of the bronchoscope, keeping
    the bevel of the needle protected inside the metal hub and keeping the scope as
    straight as possible.
  o Extend the catheter out of the working channel with the scope in a neutral forward
    viewing position, in the central airways.
  o The needle is extended, locked in place and withdrawn until only the very distal tip of
    the needle is visible through the bronchoscope; then the needle is anchored at the
    target site.
  o Using either the jabbing, piggy-back, the hub-against-the-wall, or the cough
    method, push the needle through the tracheobronchial wall to its fullest extent, at an
    angle as near to 90 degrees as possible. All of these techniques can be used singly or
    in combination to insert the needle through the tracheobronchial wall.
  1. **“JABBING”:** after the scope is fixed at the nose or the mouth by an assistant, the
     needle is thrust through the inter-cartilaginous space with a quick, firm jab.
  2. **“PUSHING or PIGGY-BACK”:** after the needle tip contacts the mucosa at the
     puncture site, the catheter is advanced until the hub is visible. Then the catheter is
     fixed in relation to the scope at the proximal insertion port, using the right hand
     fingers (for right-handed operators), and the scope is pushed forward at the distal
     end, close to the nose, by the left hand. The bronchoscope and catheter are
     actually pushed forward as a single unit until the entire needle penetrates the
     tracheobronchial wall.
  3. **“HUB-AGAINST-THE-WALL”:** with the needle retracted, the distal end of the
     catheter (the metal hub) can be placed directly in contact with the mucosa and held
     firmly; then the needle is pushed in and locked. Usually the needle will penetrate
     through the tracheobronchial wall.
  4. **COUGH METHOD**: a patient’s cough may facilitate the needle’s penetration.
     o Apply suction at the proximal end of the needle using a 20- to 50-cc syringe.
     o Cytology specimen is obtained by applying suction and agitating the catheter at its
proximal end. Histology specimen is obtained by moving the needle to and fro, 3 to 4 mm, while applying suction.
- Release the suction.
- Remove the needle from the tracheobronchial wall.
- Pull the needle back into the catheter.
- Remove the catheter from the working channel of the scope in a single smooth motion and collect the specimen.
- Evaluation of the adequacy of the specimen, preparation of slides, cell block and ROSE in collaboration with the pathologist
- Management of complications and follow up

<table>
<thead>
<tr>
<th>Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hands-on Practical TRAINING</strong></td>
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<tr>
<td><strong>GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES:</strong> see page....</td>
</tr>
<tr>
<td><strong>SPECIFICALLY FOR BRONCHOSCOPY:</strong></td>
</tr>
<tr>
<td><strong>Simulation:</strong></td>
</tr>
<tr>
<td>- Manikins and plastic models for endoscopy simulation in order to learn and improve trainees’ coordination. For bronchoscopes, use video tutoring systems and the most recent type of disposable bronchoscopes</td>
</tr>
<tr>
<td>- Animal models in vivo or single organs, e.g. fresh or frozen porcine lungs, or preserved under plastic lamination. A chest cavity simulator connected to a negative pressure can also be useful (such as ArtiCHEST®trainer or custom-made cages)</td>
</tr>
<tr>
<td>- Virtual reality simulation in order to learn the anatomy, to enhance manual dexterity in bronchoscopy and tissue sampling techniques, simulated clinical cases (e.g. BRONCH Mentor, ORSIM®, EndoVR ™ Interventional Simulator)</td>
</tr>
<tr>
<td>- Non-technical skills for teamwork and management of complications (difficult airways, bleeding, pneumothorax, respiratory and cardiac failure)</td>
</tr>
<tr>
<td>- Self-regulated and independent training with simulators</td>
</tr>
<tr>
<td><strong>Performing in the patient:</strong></td>
</tr>
<tr>
<td>- Initially the trainee will be an observer until s/he is formally assessed as being competent. Subsequently s/he will perform bronchoscopy under supervision, and gradually increasing independence as training progresses</td>
</tr>
<tr>
<td>- Trainees should not perform bronchoscopy unsupervised until their educational supervisor has assessed them as being competent to do so and signed them off</td>
</tr>
<tr>
<td>- Trainees should not perform any advanced diagnostic or therapeutic bronchoscopic techniques unless formally assessed and certified as competent to do so by educational supervisor</td>
</tr>
<tr>
<td>- Participate in clinical risk audits</td>
</tr>
<tr>
<td>- Length of course: during the fellowship: 6-12 months;</td>
</tr>
<tr>
<td><strong>QUANTITATIVE ASSESSMENT WITH LOGBOOK (MINIMUM VOLUME)</strong></td>
</tr>
<tr>
<td><strong>Minimum no. of procedures:</strong></td>
</tr>
<tr>
<td>- Diagnostic bronchoscopy with biopsy: 100</td>
</tr>
<tr>
<td>- TBNA: 25 (ACCP, ERS/ATS), 20 (TSANZ)</td>
</tr>
</tbody>
</table>
**QUALITATIVE ASSESSMENT**

- MCQ
- Case-based Questionnaire
- Simulated assessment
- DOPS: B-STAT, B-SET
- Video or direct supervision of procedure with the patient

**OUTCOME ASSESSMENT**

- Evaluation of diagnostic yield and complications: at least 85% diagnostic sensitivity for biopsies;
- Operators shall ensure that sufficient diagnostic material is obtained to allow phenotyping and genotyping of tumours where appropriate (ROSE)

**Competence maintenance (by LOGBOOK)**

- Diagnostic bronchoscopies: 50/year
- TBNA: 10/year (ACCP)

**Recommended Literature**

5.1.2 Interventional endosonography (EBUS, EUS, EUS-B)

5.1.2.1. EBUS–TBNA
Endobronchial Ultrasound-Guided Transbronchial Needle Aspiration

Introduction

Introduced in 2003, this method of sampling mediastinal and hilar lymph nodes has rapidly gained popularity and become widely used because of its strong safety profile and high diagnostic yield. It is not only useful in the staging of known carcinomas, but also in that it allows for a diagnosis performed on the basis of original tissues in patients with lung masses. A dedicated bronchoscope is used, which incorporates an ultrasound tip for real-time imaging of nodes adjacent to the bronchial/tracheal wall. It also utilizes a dedicated TBNA needle with dedicated biopsy channel. This needle is passed into the node in question and can be visualized in real time as samples are taken. Seven well-described anatomical sites can be sampled, as is required for standard TBNA. This method, therefore, builds on the previous technique of ‘blind’ TBNA, which has been shown as safe for over 20 years. The new design of the EBUS-TBNA scope improves the ability of the TBNA needle to enter lymph nodes through the bronchial wall. Studies comparing it to ‘blind’ TBNA show that real-time ultrasound imaging improves results, particularly when the node is small and located in less commonly biopsied sites. Even in more commonly biopsied sites, such as the subcarinal region, the operator’s confidence is enhanced by the fact that the needle’s position is known at all times. Mediastinal staging is critical in many lung cancer patients; Accuracy of convex probe TBNA in lung cancer staging is exceptionally high, and in controlled studies exceeds that for PET scan and CT. The ACCP guidelines 2013, 3rd edition of Diagnosis and Management of Lung Cancer recommendes in patients with high (and moderate) suspicion of N2,3 involvement a needle technique (endobronchial ultrasound [EBUS]-needle aspiration [NA], EUS-NA or combined EBUS/EUS-NA) over surgical staging as a best first test if available adequate technology and appropriate experience and skill of the operators.

Typical sensitivity for malignancy in a large number of studies is 90–95%. The method has been shown in numerous studies to be an effective and simple way of obtaining tissue even for the histological diagnosis of sarcoidosis, with yields of over 85% in patients with suspicious radiology. It thereby reduces the need for transbronchial lung biopsy and indeed, when used in combination with transbronchial lung biopsy (TBLBx), has been shown to significantly improve the yield.

This is a highly complex procedure: first-level competence must be a requirement for admission to training.
Trainees must possess a perfect knowledge of anatomy and be fully competent in imaging interpretation (CT with contrast medium and PET), and shall have completed a practical training on virtual reality simulators whose effectiveness has been demonstrated by scientific studies, on both animal and cadaver models. Specific DOPS tests have been developed for the overall qualitative evaluation of training practice on simulators, animal models and on patients: the EBUS Skill Assessment Tool (EBUS-STAT) and EBUS Assessment Tool (EBUSAT).

Indications for the procedure

- Diagnosis of mediastinal/hilar nodes in patients with lung masses, either as the first means of making a tissue diagnosis or as the means of staging a known cancer
- Diagnosis of other isolated mediastinal masses
- Confirmation of sarcoidosis in patients with bilateral mediastinal/hilar nodes, either as a sole method or in combination with transbronchial lung biopsy
- Tumour near oesophagus and tracheobronchial tree
- Staging of non-small-cell lung cancer (NSCLC) according to American College of Chest Physicians (ACCP) guidelines
- Restaging after neoadjuvant treatment
## Suspected tumoral invasion of mediastinum

### Knowledge & Skills

#### Prior Experience Requirements
- Trainee must have completed training described in sections on “Lung cancer” and “ Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” and have performed:
  - 100 flexible bronchoscopies, with demonstrated competence
  - 5 standard TBNA's

#### Knowledge
- Anatomy and imaging (CT scan, PET) of mediastinal lymph nodes and correlation with ultrasound bronchoscopy
- Understand node landmarks for standard TBNA, as well as nodal maps of the International Association for the Study of Lung Cancer (IASLC) guidelines (see references)
- Understand key anatomical relations at each of the seven commonly biopsied sites
- Diagnosis and staging of NSCLC and role of EBUS/TBNA in the staging algorithm (see section 4.1)
- Organization of endoscopic suite and knowledge of the equipment for the performance of EBUS/TBNA on patient under moderate and deep sedation
- Strategy of systematic approach and selective approach
- Indications, contraindications and risk/benefit ratio of EBUS/TBNA, EUS-B-TBNA and EUS/TBNA
- Equipment for EBUS/EUS: ultrasound bronchoscopes, ultrasound machine and different-sized needles
- Physics and principles of ultrasound (see section “Thoracic ultrasound”]
- Technique for collecting cytology and histology specimens; types and sizes of needles and guide systems
- Basic knowledge of cytology: technique of rapid staining and reading of slides for a Rapid On Site Evaluation (ROSE)
- Alternative sampling methods (i.e. mediastinoscopy)
- Risk management, informed consent and medical legal issues

#### Core Basic Skills
- Active participation in the multidisciplinary team with radiologists, pathologists, oncologists, thoracic surgeons
- Decision on systematic versus selective approach
- Sedation and oxygenation techniques, and management of related complications
- Clinical and radiographic (CT scan and PET) evaluation of the patient and her/his comorbidities; risk evaluation and management of difficulties and complications
- Radiographic/endoscopic correlations
- Competent use of ultrasound device
- Endoscopic finding of the landmarks of tracheobronchial node stations
- Ability to visualise with EBUS mediastinal lymph nodes and vessels and their anatomic relationship
- Competent use of different sizes and types of needles and other accessories (balloons) and ability to pass TBNA needle through wall of trachea/bronchus into node
- Management of the needle specimens
- Interpretation and reporting of test findings: size, shape, margins, echogenicity, presence of internal hypoechoic zones due to the presence of necrosis, elastography
- Prevention and management of procedure-related complications

#### Procedural Steps for Test technique
- Insertion of endoscope through upper airways and vocal cords, bearing in mind the correct angles providing different endoscopic visualisations
- Presentation of main lymph nodes (2, 4, 7, 10, 11) and vascular stations and their relationship
### Practical Training (Check list)

  1. Advance EBUS needle through the working channel with scope in neutral position
  2. Secure needle assembly by sliding the flange, locking it in place
  3. Release the sheath screw
  4. Advance and lock the sheath when it is visualised at the top right-hand corner of the monitor
  5. Locate the target lymph node to be sampled using US imaging
  6. Release the needle guard
  7. Advance the needle using the quick “jab” method
  8. Visualise needle entering target node with US
  9. Move the stylet in and out a few times to dislodge debris within the needle
  10. Withdraw the stylet
  11. Attach suction syringe to the needle
  12. Apply suction
  13. Move the needle back and forth within the node >10 times
  14. Release suction
  15. Retract the needle into the sheath
  16. Secure the needle guard
  17. Unlock the needle assembly
  18. Remove the needle and sheath; collect the specimen

- Correct placing of specimen on slide and cell block
- Preparation and interpretation of ROSE

### Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”

**Hands-on Practical TRAINING**

**GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES:** see page 30

**SPECIFICALLY FOR EBUS- TBNA:**

- Task trainer with low fidelity simulation: plastic and animal models, live animals and cadaver (Ultrasonic Bronchoscopy Simulator with EBUS and needle routinely used for patient)
- High fidelity with virtual reality to learn the anatomy and the manual dexterity required for bronchoscopy and sampling procedures, simulated clinical cases (BRONCH Mentor, BronchPilot EBUS-TBNA, BRONCH Express, EndoVR™ Interventional Simulator, Ultrasonic Bronchoscopy Simulator). The simulator is useful when EBUS-STAT score is > 80/100
- Observe the procedure directly or with live sessions (Endosc Ultrasound. 2015 Jan-Mar;4(1):4-9)
  - “Pattern recognition”: Learn to recognize anatomic landmarks by observing the procedure when performed by an experienced colleague in the clinical setting or on a simulator.
  - “Handling of the endoscope”: Learn to insert the endoscope and to produce the pictures, which is much more difficult than watching an experienced practitioner performing the procedure.
  - “How to take biopsies”: Learn to position the transducer correctly and to use a sheet and the needle.
  - Learn step by step, beginning from the six EBUS landmarks (Stations 4L, 7, 10L, 10R, 4R, Azygos vein)
- An EBUS-EUS training programme and certification in 3 step is available by European Respiratory society (ERS): theoretical teaching and simulation, active clinical observation, final assessment after 20 procedures, 3 videos (www.ersnet.org)
<table>
<thead>
<tr>
<th><strong>QUANTITATIVE ASSESSMENT WITH LOGBOOK (MINIMUM VOLUME)</strong></th>
</tr>
</thead>
</table>
| **NUMBER OF PROCEDURES:** 
  • 50 procedures, after at least 100 flexible bronchoscopies and 5 TBNAs (23 in the ERS programme after 2 days of simulation) |

<table>
<thead>
<tr>
<th><strong>QUALITATIVE ASSESSMENT</strong></th>
</tr>
</thead>
</table>
| • MCQ  
• Case-based questionnaire  
• DOPS (EBUS STAT, EBUS SAT)  
• Assessment on patient:  
  o Balloon and needle set-up in all cases  
  o Ability to pass scope through vocal cords in ±90% of cases  
  o Ability to image lymph node in question in ±90% of cases  
  o Ability to pass TBNA needle through wall of trachea/bronchus into node in ±80%  
  o Typical procedure time: 30–40 min  
• ERS-EBUS Certification Methodology [www.ersnet.org](http://www.ersnet.org) based on verification of pre-requisites and registration, theoretical interactive session, simulation training, supervised training in home institution, completion of 20 procedures and 3 video procedures. |

<table>
<thead>
<tr>
<th><strong>OUTCOME ASSESSMENT</strong></th>
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</table>
| Diagnostic yield: Diagnostic samples containing sufficient material for molecular testing required for treatment guidance.  
• Comparison with pathology staging  
• Sensitivity for carcinoma in ±75% of cases  
• Safety (< 1% - bleeding, pneumothorax, infections) |

<table>
<thead>
<tr>
<th><strong>Competence maintenance (by LOGBOOK)</strong></th>
</tr>
</thead>
</table>
| **No. of procedures/year** 
• 20/year  
• Re-evaluation |

<table>
<thead>
<tr>
<th><strong>Recommended Literature</strong></th>
</tr>
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**Multimedia resources**

**5.1.2.2. EUS-FNA and EUS-B-FNA**

**Endoscopic Oesophageal Ultrasound**

<table>
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<th>Introduction</th>
</tr>
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<tbody>
<tr>
<td>Endoscopic ultrasound (EUS) with fine needle aspiration (EUS-FNA) of mediastinal lymph nodes (LN) through the wall of the oesophagus has been performed in the last decade by pulmonologists for the diagnosis and staging of lung cancer, and for the diagnosis of granulomatous diseases.</td>
</tr>
</tbody>
</table>

**EUS-FNA.** Similarly to EBUS, EUS is performed with a “dedicated” echoendoscope, allowing real-time visualization of fine needle aspiration (FNA), usually used in the past by gastroenterologists and cardiologists. Different linear EUS scopes are available, presenting with an oblique viewing direction of 40°, a scanning range of 100° to 180°, a frequency range of 5-12 MHz, a 3.7-3.8mm diameter integrated working channel with elevator, a bending capability of up/down (130°-160°/90°-160°) and left/right (90°-120°/90°-120°), all incorporating colour and power Doppler. Procedure is performed with the patient lying on his/her left side, and it begins once the patient is adequately sedated, either under **mild sedation with midazolam, or under deep sedation with anaesthesia care, based on the internal structure organization. The instrument is introduced through the mouth** (through the use of a mouthpiece), and pushed gently until the gastric wall can be individualized at ultrasound, at the level of the left hepatic lobe, which presents cranially the hepatic vein flowing into the inferior vena cava. Through the introduction in the operating channel of the echoendoscope of a 22 gauge needle (also available 19, 21 and 25 gauge needles) placed in suction, EUS-FNA can be performed under real-time ultrasound guidance. The risk of infection or bleeding is negligible, complications are rare, and no mortality has been reported. EUS-FNA allows easy access to the subcarinal region 7, to the left paratracheal region (4L), and partially to the left hilar region (10L). It also allows evaluation of the lower mediastinum including paraesophageal region 8, and pulmonary ligament region 9. Detection of region 5 is also possible if lymph nodes are considerably enlarged, whereas in small lymph nodes EUS-FNA might be more difficult or impossible into this region, due to interposition of the pulmonary artery/aorta. The para-aortal lymph nodes (station 6) are even more difficult to sample, due to the proximity of the large mediastinal vessels. For this region, a transaortic approach using a 25G-needle may be used only in selected cases, and with only one puncture. Due to the anatomy of the oesophagus, which is located behind and to the left of the trachea, EUS-FNA is not recommended for the right-sided paratracheal and hilar located LN (2R, 4R, 10R), since their visualisation is prevented by the air contained in the trachea. Importantly, EUS-FNA is also capable of detecting metastatic disease in subdiaphragmatic sites, such as the left adrenal gland, celiac lymph nodes, and the left lobe of the liver. |

**EUS-B-FNA.** The EUS-B-FNA (transesophageal bronchoscopic ultrasound-guided fine-needle aspiration) consists in the mediastinal lymph node evaluation and sampling by the introduction of an EBUS bronchoscope into the oesophagus instead of into the airways. Differently from EUS, for EUS-B, the flexible EBUS endoscope is inserted and advanced through the esophagus with the patient lying in the supine position (and not lying on the left side as for the EUS procedure). EUS-B-FNA might increase the diagnostic utility of EBUS-TBNA by further coverage of mediastinal LN stations and access to subdiaphragmatic site lesions. EUS-FNA and EUS-B-FNA procedures require a skilled endoscopist with specific experience and suitable equipment. The challenge to mastering EUS (and EUS-B) is not the sampling, but rather learning to understand mediastinal anatomy from an oesophageal perspective, and relating the various lymph nodes to the vascular structures and the lymph node map. The integration of the two techniques, EBUS-TBNA and EUS-FNA (EUS-B-FNA), significantly improves sensitivity in detecting mediastinal nodal metastases, reducing the need for surgical staging procedures. International guidelines recommend at present endosonography with fine-needle aspiration as first diagnostic step for mediastinal nodal staging in non-small-cell lung cancer,
and combined endosonographic procedures are now the new gold standard when performed by an experienced operator.

Compared to EBUS-TBNA, EUS-FNA has the advantage of being comparably well tolerated with lower doses of anaesthetics and sedatives, shorter procedure time, less oxygen desaturation, less coughing; further, it offers greater scanning angles (150-180° as against 50-60°), better imaging with a higher resolution and better visualisation of very small structures, with the transducer in close contact with the target, enabling desufflation to make the lumen virtual, with no interposed cartilage between needle and target; the presence of the elevator makes the needle more manoeuvrable, including the option of using 19G needles.

### Indications for the procedure

| • Suspected lung cancer                                                                 |
|   o Enlarged mediastinal lymph nodes                                                   |
|   o FDG-PET-positive mediastinal lymph nodes                                           |
|   o Primary lung tumour adjacent to oesophagus (EUS) or to the airways (EBUS)          |
| • Staging of NSCLC                                                                      |
|   o Mediastinal staging (regardless of nodal size at CT)                               |
|   o FDG-PET-positive mediastinal lymph nodes                                           |
|   o Enlarged (short axis >10 mm)                                                       |
|   o FDG-PET-negative mediastinal lymph nodes                                           |
|   o Mediastinal restaging after neoadjuvant treatment (chemotherapy)                   |
|   o Suspected mediastinal tumour invasion (T4)                                          |
|   o Suspected left adrenal or celiac lymph node metastasis (EUS)                        |
| • Evaluation of mediastinal masses                                                     |
|   o Solitary (multiple) solid mediastinal masses                                       |
|   o Suspected mediastinal metastases of extrathoracic tumours                          |
| • Mediastinal lymphadenopathy of unknown origin                                         |
|   o Suspected granulomatous disease (sarcoidosis, tuberculosis)                         |
|   o Suspected lymphoma                                                                  |
| • EUS with real-time guided fine needle aspiration using the EBUS scope (EUS-B-FNA) can reach the following locations that are relevant to lung cancer diagnosis and staging (Endoscopy 2015; 47(06): 545-559): |
|   o lung tumours close to the oesophagus                                               |
|   o mediastinal lymph nodes in stations 2 L, 4 L (high and lower left paratracheal nodes) |
|   o station 7 (subcarinal node)                                                        |
|   o stations 8 and 9 (nodes located in the lower mediastinum)                          |
| and structures below the diaphragm, retroperitoneal lymph nodes close to the aorta and the celiac trunk, and tumours in the left liver lobe and the left adrenal gland |

### Knowledge & Skills

#### Prior Experience Requirements
- Trainees must have completed training as described under “Lung Cancer” and “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” and EBUS-TBNA.
- 100 flexible bronchoscopies with demonstrated competence
- 5 standard TBNA as “EBUS-TBNA”

#### Knowledge
- See section “EBUS-TBNA”
  - Anatomy and imaging (CT scan, PET) of mediastinal lymph nodes and correlation with ultrasound bronchoscopy
  - Understand node landmarks as well as nodal maps of the International Association for the Study of Lung Cancer (IASLC) guidelines (see references)
- Key anatomical relations for: liver, aorta, left adrenal gland, stations 7, 4L, 2L, 5, 8 and 9
- Diagnosis and staging of NSCLC and role of EBUS, EUS and EUS-B in the staging algorithm (see section 4.1)
- Organization of endoscopic suite and knowledge of the equipment for the performance of EUS/EUS-B on patients under moderate and deep sedation
- Strategy of systematic versus selective approach
- Indications, contraindications and risk/benefit ratio of EBUS-TBNA, EUS-FNA and EUS-B-FNA
- Equipment for EBUS/EUS: ultrasound endoscopes, ultrasound machine and different-sized needles
- Physics and principles of ultrasound (See section “Thoracic ultrasound”)
- Technique for collecting cytology and histology specimens; types and sizes of needles and guide systems
- Basic knowledge of cytology: technique of rapid staining and reading of slides for a Rapid On Site Evaluation (ROSE)
- Alternative sampling methods (i.e. mediastinoscopy)
- Risk management, informed consent and medical legal issues

### Core Basic Skills
- See section on “EBUS-TBNA”
- Active participation in the multidisciplinary team with radiologists, pathologists, oncologists, thoracic surgeons
- Decision on systematic versus selective approach with EBUS and EUS
- Sedation and oxygenation techniques, and management of related complications
- Clinical and radiographic (CT Scan and PET) evaluation of the patient and her/his comorbidities; risk evaluation and management of difficulties and complications
- Radiographic/endoscopic correlations
- Competent use of the ultrasound device (see Thoracic ultrasound)
- Endoscopic finding of the landmarks of oesophageal nodes and vessels, intrathoracic and extrathoracic lesions
- Ability to visualise mediastinal lymph nodes and vessels and their anatomic relationship
- Competent use of different sizes and types of needles and other accessories and ability to pass FNA needle through wall of oesophagus into node
- Management of the needle specimens
- Interpretation and reporting of test findings: size, shape, margins, echogenicity, presence of internal hypoechoic zones due to the presence of necrosis, elastography
- Prevention and management of procedure-related complications
- Ability to competently manoeuvre the ultrasound endoscope and EBUS inside the oesophagus

### Procedural Steps for Practical Training (Check list)
- See also section on EBUS-TBNA

**Test technique**
- Liver (landmark I): introduce the endoscope into the oesophagus and slide it down below the diaphragm. Turn the endoscope counter clockwise to find the left liver lobe.
- Aorta (landmark II): turn the endoscope clockwise and find the aorta with the celiac trunk and the superior mesenteric artery
- The left adrenal gland (landmark III): turn the endoscope further clockwise, move the transducer a little upwards to find the left adrenal gland (it resembles a small bird, a seagull) close to the upper pole of the left kidney.
- Station 7 (landmark IV): retract the endoscope to the mediastinum and find station 7 below the carina close to the left atrium and the right pulmonary artery.
- Station 4L (landmark V): retract the endoscope a few centimetres, turn counter clockwise
and find station 4L between the aortic arch and the left pulmonary artery (the vessels resemble the ears of Mickey Mouse).

- Positioning of the transducer and biopsy sampling, according to the 18 procedural steps described by Mehta:
  1. Advance EUS needle through the working channel with scope in neutral position
  2. Secure needle assembly by sliding the flange, locking it in place
  3. Release the sheath screw
  4. Advance and lock the sheath when it is visualized at the top righthand corner of the monitor
  5. Locate the target lymph node to be sampled using US imaging
  6. Release the needle guard
  7. Advance the needle using the quick “jab” method
  8. Visualize needle entering target node with US
  9. Move the stylet in and out a few times to dislodge debris within the needle
  10. Withdraw the stylet
  11. Attach suction syringe to the needle
  12. Apply suction
  13. Move the needle back and forth within the node >10 times
  14. Release suction
  15. Retract the needle into the sheath
  16. Secure the needle guard
  17. Unlock the needle assembly
  18. Remove the needle and sheath; collect the specimen
- Correct sampling of the specimen on slide and cell block
- Preparation and interpretation of ROSE

<table>
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<tr>
<th>Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”</th>
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</table>

**Hands-on Practical TRAINING**

**GENERAL THEORETICAL AND PRACTICAL TRAINING METHODS COMMON TO ALL PROCEDURES:**
see page 30

**SPECIFICALLY FOR EUS-B-TBNA and EUS-FNA:**
- **Observation and live sessions:** recognise anatomical landmarks and mediastinal vessels by observing the procedure (liver, aorta, left adrenal gland, stations 7, 4L, 4R)
- **Simulation in plastic and animal models:** learn to insert the endoscope and to “produce” the pictures, which is much more difficult than watching an experienced examiner performing the procedure. The final task relates to the correct positioning of the transducer, proper use of the needle sheath and correct handling of the needle when taking fine needle aspirates. At the moment there are no commercially available virtual reality simulators for mediastinal EUS-FNA.
- After passing a simulation-based test the trainee should perform his/her initial endosonography procedures in patient.
- **EBUS-EUS training programme (www.ersnet.org)**

<table>
<thead>
<tr>
<th>QUANTITATIVE ASSESSMENT WITH LOGBOOK (MINIMUM VOLUME)</th>
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</table>

Minimum number of procedures:
20 (ERS), 36+12 (Gastrointest Endosc. 2010 Jan;71(1):64-70, 70.e1).

- MCQ
- Case-based questionnaire
### QUALITATIVE ASSESSMENT
- DOPS (EUSAT) see appendix
- Assessment on patient:
  - Ability to visualise lymph node in question in ±90% of cases
  - Ability to pass TBNA needle through wall of oesophagus into node in ±80% of cases
  - Sensitivity for carcinoma in ±75% of cases
  - Typical procedure time: 30–40 min
- EBUS-EUS training programme ([www.ersnet.org](http://www.ersnet.org))

### OUTCOME ASSESSMENT
- Diagnostic yield: Diagnostic samples containing sufficient material for molecular testing required to guide treatment.
- Comparison with pathology staging
- Safety (< 1% - bleeding, pneumothorax, infections)

### Competence maintenance (by LOGBOOK)
- No. of procedures/year:
  - 12 procedures/year

### Recommended Literature
10. Jenssen C, Annema JT, Clementsen P, Cui XW, Borst MM, Dietrich CF. Ultrasound techniques in the evaluation of the mediastinum, part 2: mediastinal lymph node anatomy and diagnostic reach of ultrasound techniques, clinical work up of neoplastic


### 5.1.3 Bronchoscopic navigation

Image-guided or computer-guided diagnostic bronchoscopy for the evaluation of parenchymal opacities, of airway invasion vs compression, and to guide biopsy: radial probe, pulmonary navigation and cryobiopsy.

#### 5.1.3.1. Radial EBUS

**Introduction**

EBUS miniprobe is a procedure used to collect samples of localized lesions beyond the view of the bronchoscope. It is used in conjunction with the reconstruction provided by CT scans and assisted by fluoroscopy during the procedure. It is therefore an improved way of performing a transbronchial lung biopsy of a peripheral lesion. Many bronchoscopy units perform procedures for such lesions only using a bronchial washing or X-ray fluoroscopy guided biopsy, with a diagnostic yield of about 40%. Comparative studies have shown the improved diagnostic yield of adding EBUS miniprobe, compared with fluoroscopy alone. The miniprobe can be used to sample lesions in distal bronchi, bronchioles and alveoli. Lesions that are angiocentric, such as metastases, tend to have a lower yield. The sensitivity for primary malignancy is >70%. Some parts of the lung are less easy to access with any form of transbronchial lung biopsy, and this is true for miniprobe EBUS in the left upper lobe. A wide range of localized infectious and inflammatory lesions can also be sampled using miniprobe EBUS. The techniques for miniprobe EBUS are the same as those currently used for sampling peripheral lesions with fluoroscopy. There are two additional aspects to training practitioners for this technique: first, the use of the plastic guide sheath through which the miniprobe is passed; second, when the probe enters a lesion, an ultrasound image is displayed in real time. During the procedure, the image is used primarily to confirm that the lesion has been localised, and interpretation of the image is used simply to show that there is a circumferential ultrasound shadow corresponding to a lesion, as opposed to uninvolved lung surrounding the miniprobe. An important aspect of the miniprobe technique with the use of the guide sheath is the very low complications rate, compared with standard transbronchial lung biopsy. With this technique, bleeding and pneumothorax are around ±1%, whereas they are about five times higher (±5%) in standard transbronchial lung biopsy, including reports of major bleeding.

**Indications for the procedure**

Biopsy of peripheral lung lesions (either masses or localized segmental infiltrates) beyond the view of the bronchoscope.

**Knowledge & Skills**

#### Prior Experience Requirements

Trainees must have completed training as described in sections on “Lung cancer” and “Flexible bronchoscopy and basic biopsy technique” and “EBUS-TBNA”

- >10 standard transbronchial lung biopsies, having achieved competency in this technique, including familiarity with fluoroscopy X-ray
- 100 flexible bronchoscopies with competency in all types of biopsy

#### Knowledge

See section on “Lung cancer and pulmonary solitary nodule” and “EBUS-TBNA”

- Guidelines for pulmonary nodules (see section 4.1 “Lung cancer”)
- Pulmonary and bronchial anatomy and radiographic anatomy: ability to recognise normal positions of the ten segmental bronchi on the right and nine on the left
- Fluoroscopy
- Indications and contraindications and risk/benefit ratio of radial EBUS
### Core Basic Skills

- Sensitivity, specificity, accuracy and limitations of radial EBUS
- Radial EBUS technology and interpretation with ultrasound

### Procedural Steps for Practical Training (Check list)

- Competency in flexible bronchoscopy (see section on “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”)
- Ability to localize the lesions in relation to the segment involved in CT scan
- Ability to guide the probe to the involved segment and lesion
- Ability to interpret the position of the probe in relation to the peripheral lesion
- Ability to distinguish anatomic structures and pathologic lesions in endosonography
- Use of the plastic guide sheath through which the miniprobe is passed
- Management of specimens for cytology, histology and molecular tests
- Prevention and management of possible complications (bleeding, pneumothorax, infections)

### Procedural steps:

1. Preparation of miniprobe, biopsy forceps and brush in all cases
2. Print out bronchoscopic picture of the relevant lobe, labelling all segmental branches up to fifth order where possible and labelling the branch where the probe was passed to give entry to the lesion: data to be recorded in the Logbook
3. Enter the lesion to obtain an ultrasound image (either central or peripheral); possible in 75% of cases of lesions >2 cm
4. Take pictures of the EBUS image and attribute an EBUS score (I/II/III) before obtaining the histological report
5. Fit the plastic sheath to the miniprobe before the procedure; once the probe has entered the lesion, the probe is removed, while the sheath is left in place.
6. Biopsy forceps and TBNA are passed through this sheath to collect the samples. In fact, this makes the whole process of doing the transbronchial biopsy easier because there is no need to re-localize the lesion each time
7. Interpretation and reporting of test results

**Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”**

### Hands-on Practical Training

**GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES:** see pag 30

**SPECIFICALLY FOR RADIAL EBUS**

- Radiology training with interpretation of chest CT scans and relationship between airways and lesions (X-rays)
- Attending courses on the method in Specialized High Volume Centres
- Observation of procedures in order to gain theoretical competence
- Performance of the procedure on plastic (Ultrasonic Bronchoscopy Simulator) and animal models (at least 30 procedures)

### Quantitative Assessment with Logbook (Minimum Volume)

- Minimum no. of procedures: 20

- MCQ
- Case-based questionnaire
### Qualitative Assessment
- DOPS: Creation of a specific STAT (similar to EBUS - STAT)

### Outcome Assessment
- Correlation between the image and the final histology in >75% of cases (data to be recorded in the Logbook)
- Sensitivity for malignancy: 60–70%
- Typical procedure time: 30–40 min
- Safety: < 1% bleeding, pneumothorax, infections

### Competence Maintenance (by Logbook)
- **No. of Procedures/Year:**
  - 20

### Recommended Literature
5.1.3. Bronchoscopic navigation

5.1.3.2. Electromagnetic pulmonary navigation and virtual bronchoscopy navigation

Introduction

Electromagnetic navigation bronchoscopy (ENB) is an emerging endoscopic technique for the diagnosis of peripheral lung lesions. ENB provides navigational assistance, with the addition of the possibility of steering, to localize and sample peripheral pulmonary lesions. Options for non-surgical tissue diagnosis of the peripheral nodule include CT scan-guided transthoracic needle biopsy (TTNB) and fluoroscopy-guided bronchoscopy, endobronchial ultrasound (EBUS), ENB, and virtual bronchoscopy navigation (VBN). The sensitivity of fluoroscopy-guided bronchoscopy with transbronchial biopsy (TBB) in identifying malignant nodules measuring >2cm in diameter ranges from 5% to 76% (median, 31%). The likelihood of obtaining a specific benign diagnosis is even lower. However, the presence of an air bronchogram in a pulmonary nodule is associated with a higher diagnostic yield, especially if this provides a specific road map to the bronchial location. The sensitivity of ENB-guided TBB for the identification of malignancy in peripheral lung lesions has a range between 44% and 75%, including four studies that described results for nodules measuring >2cm. In those studies the risk of pneumothorax ranged from 0% to 7.5% (median, 2.2%). ENB combines a virtual navigation system with steerable devices. The heart of the electromagnetic system is the locatable guide (LG) and the magnetic locator board that is placed under the patient’s mattress. The LG is incorporated into the tip of a 130-cm-long, 1.9-mm-diameter flexible catheter (serving as an extended working channel, or EWC); once placed in the desired location, using the navigation system for guidance, this EWC creates an easy access for bronchoscopic accessories. It is placed in an electromagnetic field created by the locator board. ENB is a two-stage process: pre-procedure planning and the actual procedure itself. Digital Imaging and Communication (DICOM) data are uploaded to a planning computer, via the network or compact disk. The planning screen consists of four windows, each of which can display axial, sagittal or coronal views, as well as a virtual bronchoscopic animation and three-dimensional bronchial tree. The bronchoscopist outlines the target and then establishes landmarks along the bronchi, leading to the target lesion. The planned path can then be viewed via virtual bronchoscopic animation, allowing the operator to see precisely which sequence of airways leads to the lesion. Selective cannulation of bronchi is possible with a specialized cannula housed in an EWC, also passed through the working channel. The proximal end houses a “steering wheel” that allows deflection of the distal tip in one of eight directions; the distal end contains the LG, whose position is tracked through an electromagnetic field encompassing the patient’s chest with the assistance of three location pads placed on the patient’s chest. The computer provides instructions on how and when to turn the “steering wheel” and advance the catheter to reach each landmark along the pathway and eventually reach the target lesion. Once the LG is near the target lesion and aligned to it, the EWC is left in place while the LG is withdrawn and replaced by the biopsy instruments. Virtual bronchoscopy navigation (VBN) is a method in which the bronchoscope is guided along the bronchial route to a peripheral lesion using virtual bronchoscopy images without the use of a steerable device. EMN and VBN are a highly complex procedure: first-level competence must be a requirement for admission to training. Trainees must possess a perfect knowledge of anatomy and be fully competent in the interpretation of imaging (CT with contrast medium and PET) and have a thorough knowledge of navigation technology in all its complexities. Practical training can be performed on animal, cadaver or plastic models.

Indications for the Procedure

ENB is a bronchoscopic technique with both diagnostic and therapeutic applications:
- Diagnosis of pulmonary peripheral lesions (PPLs)
- Sampling from mediastinal lymph nodes
- Marking of PPLs to identify the location of the lesion and the resection range in thorascoposcopic surgery (tattooing guides VATS pulmonary resection)
- Insertion and fixation of radiosurgical fiducial markers for the set-up and tracking of a lung tumour during radiation therapy - Stereotactic Body Radiation Therapy (SBRT): when treating lesions within the lung where structures are in constant motion, fiducial markers allow for more precise targeting to maintain defined margins and preserve healthy tissue
- Catheters for brachytherapy

<table>
<thead>
<tr>
<th>Prior Experience Requirements</th>
<th>Knowledges &amp; Skills</th>
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</thead>
<tbody>
<tr>
<td>Trainee must have completed training described in sections on “Lung cancer” and “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” and have performed:</td>
<td></td>
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<tr>
<td>o 100 flexible bronchoscopies, with demonstrated competence</td>
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<tr>
<td>o 5 standard or fluoroscoppt-guided TBB</td>
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Knowledge

- See section “Lung cancer” and “Radial EBUS”
- Guidelines for pulmonary nodules (see section 4.1 – Lung cancer)
- Pulmonary and bronchial anatomy, as well as radiographic anatomy: ability to recognise normal positions of the ten segmental bronchi on the right and nine on the left
- Fluoroscopy
- Indications, contraindications and risk/benefit analysis of electromagnetic navigation (EMN)
- Sensitivity, specificity, accuracy and limitations of EMN; Pre-test probability of malignancy of the nodules
- Characteristics of ENB and VBN hardware and software
- Standard high quality CT scan criteria for EMN
- EMN and accessories’ technology (Edge™ firm tip navigation catheter, GenCut™ core biopsy system, aspirating needles and pre-marked aspirating needles, cytology brush, needle-tipped cytology brush with aspirating port, triple needle cytology brush, biopsy forceps)
- Surgical and stereotactic radiosurgical treatment of peripheral nodules

Core Basic Skills

See section “Radial EBUS”
- Competency in flexible bronchoscopy (see section “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”)
- Localize the lesions in relation to the segment involved in CT scan
- Ability to use the EMN software for the planning of ENB procedures:
- Ability to perform the procedure
- Management of specimens for cytology, histology and molecular tests

Procedural Steps for Practical Training (Check list)

SuperDimension Planning software:
1. Upload the patient study in the appropriate DICOM format
2. Mark registration points
3. Review 3D map
4. Mark target
5. Plan pathway + Add a new pathway
6. Mark the affected area, towards which navigation is targeted. Registration points are marked at the main carina, right upper lobe carina, right middle lobe, right lower lobe, left
upper lobe and left lower lobe: these are used to match the patient to the scan. More recent software allows the system to automatically perform the registration and match the patient to the scan. A route to the area can either be planned manually or suggested by the software.

7. Export the Plan via USB

Instructions: create a 3D map of the airways: the planning screen consists of four panels showing axial, coronal and sagittal CT views, and either a reconstructed 3D bronchial tree or virtual endobronchial view; functions such as zoom, pan, distance measurements, contrast, brightness and window level are accessible through a toolbar. Mark the affected area, towards which navigation is targeted. Registration points are marked at the main carina, right upper lobe carina, right middle lobe, right lower lobe, left upper lobe and left lower lobe: these are used to match the patient to the scan. More recent software allows the system to automatically perform the registration and match the patient to the scan. A route to the area can either be planned manually or suggested by the software.

Performing the ENB procedure on a model or patient

1. Preparing system and patient (location board, three location pads and set-up of the patient)
2. Preparing the navigation catheter and the LG
3. Making a manual registration
4. Navigation in the central airway
5. Navigation in the peripheral airway
6. Preparing for a biopsy: once the LG tip is aligned with and in close proximity to the target lesion the EWC is locked onto the bronchoscope, the LG is removed, leaving in place an EWC through which a biopsy forceps or other tools can be inserted and used

- Instructions: Ability to perform the procedure:
  - setting up the bronchoscopy suite and patient. Consistent bronchoscopy suite set-up is imperative as metal objects and/or mobile communications devices within one meter of the electromagnetic field will reduce system accuracy. The location board is placed underneath the patient's mattress ensuring that the region of interest is encompassed within an imaginary rectangular prism extending 50 cm above the location board. Three location pads are placed in a triangular configuration on the patient’s chest to enable precise tracking of the LG through the electromagnetic field.
  - Insertion of the catheter through a therapeutic bronchoscope; each of the points are marked in the registration phase is marked with the catheter (newer versions of the software may make this step unnecessary); as the locator probe is passed through the bronchial tree it is able to send back information, so that the system can match it to the information contained in the CT scan without the need for specific registration points. Either general anaesthesia or conscious sedation may be used.
  - Navigation and biopsy. In the final navigation phase, a steerable catheter is used to navigate to the lesion. The system displays a multiscreen view. The navigation is performed using a specially designed LG. It can be rotated 360 degrees using the small dial on the neck of the catheter. Then, by pulling the neck back, it is flexed in the direction indicated by the arrow on the catheter. The setting of the directional steerable guide inside the catheter is shown in the lower right portion of the navigation screen by arrows seen in the orange circle. Progress is followed by the relative locations of the purple dot. Thus, the LG is steered through the tracheobronchial tree until the target is reached. Once the LG tip is aligned with and in close proximity to the target lesion, the EWC is locked onto the bronchoscope, the LG is removed, leaving in place an EWC through which a biopsy forceps or other tools can be inserted and used.
12. Management of specimens for cytology, histology and molecular tests
13. Rapid On-Site Evaluation (ROSE)

**Theoretical and Practical Training: Resources and Assessment Tools for “CORE COMPETENCES”**

**Hands-on Practical Training**

**General Theoretical and Practical Training Common to all Procedures:** see page 30

**Specifically, for Endobronchial Navigation Systems:**
- Theoretical lessons and practice on imaging of pulmonary nodules and the mediastinum
- Practical session and simulation with planning software
  - Theoretical lessons and practice with EMN and VPN systems and software
  - Basic training on the use of the navigation system
  - Simulation training for use of EMN and VPN with manikin or animal/cadaver lungs: artificial target could be prepared with injectable substances (injected either bronchoscopically or transthoracically), visible by chest CT, echogenic EBUS radial probe, aqueous solution of 10% (by weight) bovine skin gelatine (Sigma-Aldrich, St Louis, MO), 2% agar (Sigma-Aldrich), and 0.1% iodinated contrast (Optiray 350, Mallinckrodt, St Louis, MO), heated to 90° C during mixing and maintained as a solution at 45° C to 50° C before injection. Approximately 5 to 7.5mL of this solution is used for each artificial tumour target.

**Quantitative Assessment with Logbook (Minimum Volume)**

- No. of procedures: 20

**Qualitative Assessment**

- MCQ
- Case-based questionnaire
- DOPS: Creation of specific STAT (like EBUS-STAT)

**Outcome Assessment**

- Correlation between the image and the final histology in >75% of cases: to be recorded in the Logbook
- Sensitivity for malignancy: 60–70%
- Typical procedure time: 30–40 min
- Safety: < 1% - bleeding, pneumothorax, infections

**Competence Maintenance (by Logbook)**

- No. of procedures/year: n.d.

**Recommended Literature**


5.1.3.3 Transthoracic pulmonary biopsies

**Introduction**

Transthoracic needle aspiration (TTNA) and core biopsy are both minimally invasive procedures in which samples are obtained through the skin, using a fine-bore hollow needle or coring needle. These biopsy needles are typically 15 cm in length and 18- to 25-gauge in diameter. They may be aspirating or core biopsy needles. Ultrasound, fluoroscopy or CT for localizing non-palpable lesions and confirming accurate placement of the biopsy needle are also needed. Cytology slides and fixatives along with specimen containers for core biopsies and culture samples are needed, as are small-bore (8F to 12F) catheters or chest tubes to treat large or symptomatic pneumothoraces.

Options for non-surgical tissue diagnosis of the peripheral nodule include CT scan-guided TTNA, fluoroscopy-guided bronchoscopy, endobronchial ultrasound (EBUS), electromagnetic navigation bronchoscopy (ENB), and virtual bronchoscopy navigation (VBN). For physicians who choose to pursue non-surgical biopsy, the decision to perform CT scan-guided or ultrasound-guided TTNA, conventional bronchoscopy or bronchoscopy guided by EBUS, ENB, or VBN will depend on a number of factors. CT scan-guided TTNA is preferable for nodules located near the chest wall or for deeper lesions, provided that there is no need to go through the fissures and there is no surrounding emphysema. Ultrasound-guided TTNA requires contact between the lesion and the costal pleura. Bronchoscopic techniques are preferable for nodules ≥2 cm located near a patent bronchus, or in individuals at high risk for pneumothorax following TTNA. In most other situations, operator experience should guide the decision.

This is a highly complex procedure: a specific knowledge of pulmonary nodule diagnostics (see section on “Lung cancer”) is a pre-requisite for admission to training in this procedure.

Trainees must possess a perfect knowledge of anatomy and be fully competent in the interpretation of imaging (CT with contrast medium and PET). Practical training can be performed on animal, cadaver or plastic models.

<table>
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<th>Indications for the Procedure</th>
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<td>• Diagnosis of pulmonary peripheral lesions (PPLs)</td>
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<td>• Sampling from anterior and posterior mediastinal lymph nodes</td>
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<td>• Thoracic wall lesions</td>
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<td>• Pleural thickening or masses</td>
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<td>• Other thoracic lesions accessible percutaneously</td>
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**Knowledge & Skills**

**Prior Experience Requirements**

- Having completed the training for “Lung cancer” and “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”

**Knowledge**

- In-depth knowledge of:
  - See section on “Lung cancer” and “Bronchoscopic Navigation”
  - Guidelines for pulmonary nodules (see section on “Lung cancer”)
  - Guidelines on benign pulmonary diseases, i.e. diffuse lung diseases (see section 4.3: Interstitial lung diseases and granulomatosis)
  - Pulmonary and bronchial anatomy and radiographic anatomy
  - Radiographic characteristics of peripheral lesions
  - Equipment: aspiration needles of the appropriate length, gauge (18-25) and design (cutting versus non-cutting), based on the sample required; 2) radiographic or ultrasound guidance to locate the lesion and guide needle placement; 3) supplies to prepare the specimen; 4) pneumothorax drainage catheter/tube; 5) cardiac and oxygen saturation
- Indications and contraindications (functional, haemodynamic, coagulative, anatomic) and risk/benefit analysis of TTNA:
- Sensitivity, specificity, accuracy and limitations of TTNA, pre-test probability of malignancy of the nodules
- Safe sedation and local anaesthesia for fibre-optic bronchoscopy (see ...); monitoring and intensive support techniques
- Methods of preparation of cytology and histology samples (slides, cell block, clot core)
- Basic knowledge of cytology and Rapid On-Site Evaluation (ROSE)
- Complications of TTNA and how to manage them: bleeding, pneumothorax, haemothorax due to involvement of intercostal artery, gas embolism. The incidence of pneumothorax is 20-40%, and 50% of those with pneumothorax require chest tube placement.
- Treatments for lung cancer and mesothelioma: surgical treatment, basic principles of radiotherapy and chemotherapy as they apply to thoracic malignancies

### Core Basic Skills

- Clinical-radiographic evaluation of the lesions
- Evaluation of comorbidities, of limitations and difficulties in performing the procedure
- Expertise in the clinical evaluation and management of the principal respiratory diseases; active participation in the multidisciplinary team, together with radiologist, oncologist, thoracic surgeons, etc. in order to take decisions on the best diagnostic choice.
- Management and monitoring of the patient during the procedure, with full collaboration between pulmonologist, anaesthetist, nurses and pathologist
- Performing thoracic ultrasound (see section... Thoracic ultrasound)
- CT localization of PPLs
- Safe administration of local anaesthetic, including appreciation of potential toxicity
- Communication with the patient before, during and after the procedure
- Prevention and management, in collaboration with the entire team, of any complications arising during the procedure (bleeding, pneumothorax, cardiac and respiratory complications)
- Correct performance of fine needle aspiration (FNA), with ultrasound and CT guidance
- Skilled use of available sampling technique, using needles of different sizes
- Manage correctly the acquisition and processing of cytology and histology specimens
- Manage disinfection and tracking of the equipment
- Interpretation and reporting of findings
- Re-evaluation of patient and follow-up
- Informed consent and proper explanation of risks and benefits.

### Procedural Steps for Practical Training

(Check list)

- CT assessment to identify the lesion and its anatomical relationships with vessels, nerves and fissures
- Choice of technique: TTNA performed under ultrasound or CT scan guidance, or transbronchial biopsy.
- Preparation, correct positioning of the patient (prone/supine, arm in adduction/abduction), premedication, local anaesthesia
- Peri-lesional sterile field
- Cardiorespiratory monitoring
- If using CT, the following are the sequential procedural steps:
1. Perform a scout CT scan at CFR (expiration)
2. 3D reconstruction
3. Evaluation of changes according to in/expiration
4. After local anaesthesia (with lidocaine 1-2%) is administered insertion of a 19 G needle, following the needle’s path with the patient in temporary apnoea
5. Needle aspiration / plug insertion to prevent pneumothorax
6. Radiographic check-up
7. Management of the specimens on slides, formalin/alcohol
8. Rapid On-Site Evaluation (ROSE), preferably by a cyto-pathologist
   - Prevention and control of possible complications:
     8. Symptomatic pneumothorax > 2 cm: insertion of a chest drain
     9. Asymptomatic patient with pneumothorax < 2 cm: hospitalise patient, repeat X-ray after 24 hours.

9. Manage bleeding and haemothorax with reduction of HB: hospitalise patient
10. Interpret and report findings

### Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”

**Hands-on Practical TRAINING**

**GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES:** see page 30

**SPECIFICALLY FOR TRANSTHORACIC PULMONARY BIOPSIES:**
- Live sessions and discussion of clinical cases
- Theoretical and practical courses on the methods implemented by the training centres equipped with simulation systems
- Practical sessions on simulation manikins
- Practical sessions with thoracic ultrasound simulation systems (SonoSim®, Vimedix) to learn anatomy
- To assist and perform under supervision diagnostic biopsy procedures
- To train on patients under supervision, preferably with radiologist (TTNA) and pathologist on site (complications are frequent)

**QUANTITATIVE ASSESSMENT WITH LOGBOOK**

#### No. OF PROCEDURES:
10 TTNA Chest 10 (Ernst): Trainees should first practice on inanimate objects, and they should perform 5-10 supervised procedures before attempting this procedure alone.

**QUALITATIVE ASSESSMENT**
- MCQ
- Case-based questionnaire
- DOPS

**OUTCOME ASSESSMENT**
- Diagnostic yield: TTNA/B has an overall diagnostic sensitivity of 68-96%, a specificity of < 100%, and an accuracy of 74-96% in lesions of all sizes. In smaller lesions, its diagnostic accuracy is lower
- Evaluation of the quality of the specimen
- Complications
### Competence maintenance (by LOGBOOK)

<table>
<thead>
<tr>
<th>No. OF PROCEDURES/YEAR:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 5-10/year (CHEST)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recommended Literature</th>
</tr>
</thead>
</table>

**Multimedia resources**

# 5.1.3.4. Cryobiopsy

## Introduction

Transbronchial (TBL) cryobiopsy has been shown in the last decade to potentially represent an “innovative application” of an “old procedure” for the histologic diagnosis of diffuse interstitial lung diseases (DILDs). Thus, the technique of TBL cryobiopsy is now adopted for diagnostic purposes, transbronchially in peripheral airways to sample lung parenchyma, whereas this same technique was traditionally employed for therapeutic purposes, essentially for the management of malignant obstruction of central airways.

TBL cryobiopsy was introduced for the first time for the diagnosis of DILDs in 2009 by a paper published by a group of German authors, Babiak et al, who had the initiative of the new application for this procedure. This study, together with subsequent several studies conducted worldwide have shown that TBL cryobiopsy is feasible, it allows to obtain large lung parenchymal specimens (3 times larger than “classic” transbronchial biopsies), characterized by unaltered and artefact-free morphology, and it represents a safe and poorly invasive diagnostic tool for the histologic diagnosis of ILDs. Data from the updated literature, also including recent systematic reviews, show that more than 700 patients with DILDs underwent TBL cryobiopsy worldwide, showing a diagnostic yield up to 84% for DILDs patterns presenting without a definite UIP-pattern at HRCT of the thorax. Complications might be higher than for “classic” transbronchial biopsies (TBLB), and they include pneumothorax with an incidence of 10% to 20% depending on different studies (6% for TBLB), endobronchial bleeding with 21% (10% for TBLB), but without severe bleeding, and a mortality of 0.5% with a total of 3 cases (no reported death for TBLB). As compared to surgical lung biopsies, although any prospective comparative study is available, the advantages of TBL cryobiopsy are represented by the less invasivity, the shorter time of hospitalization, the lower mortality (0.5% vs 2.3%), and a potential economic benefit in terms of cost saving. The disadvantage is still represented by a lower diagnostic yield, with 84% for TBL cryobiopsy and 91-98% for surgical lung biopsy. However, the role of cryobiopsy in the diagnostic algorithm of the differential diagnosis of DILDs is still unclear, and an international consensus on its diagnostic role is needed. This is a complex procedure requiring to be performed by endoscopists working in specialized centres with specific knowledge of DILDs, and a multidisciplinary approach, which represent prerequisites for admission to training in this procedure (see section on “Interstitial lung diseases and granulomatosis”).

Few papers have been published on the use of TBL cryobiopsy other than for diagnosis of DILDs, e.g. on the role of radial EBUS-guided TBL cryobiopsy in the diagnosis of peripheral lung lesions, pulmonary parenchymal lymphoma, and for histopathologic evaluation of lung allografts.

## Indications for the Procedure

- Interstitial lung disease
- Lung transplantation rejection
- Pulmonary malignancy

## Knowledge & Skills

- Having completed the training described in the sections on “Interstitial lung diseases and granulomatosis” and “Flexible bronchoscopy and basic biopsy technique”

## Prior Experience Requirements

In-depth knowledge of:
### Knowledge
- Guidelines for diagnosis and treatment of interstitial lung disease (see Interstitial lung disease and granulomatosis)
- Pulmonary and bronchial anatomy and radiographic anatomy, including anatomic variants: ability to recognise the normal positions of the ten segmental bronchi on the right and nine on the left
- Fluoroscopy
- Indications, contraindications and risk/benefit analysis of cryo-transbronchial biopsy in DILDs
- Sensitivity, specificity, accuracy and limitations of cryobiopsy
- Conditions that increase the risk of complications
- General anaesthesia for rigid bronchoscopy
- Complications that may arise: devices and procedures to manage the complications (Fogarty)
- Equipment for flexible and rigid bronchoscopy (see section “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” and “Rigid bronchoscopy”)
- Equipment and devices to be used in cryobiopsy
- Sampling methods for the different types of cryoprobe and guidance systems

### Core Basic Skills
- Competency in flexible and rigid bronchoscopy (see section “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” and “Rigid bronchoscopy”)
- Active participation within the multidisciplinary team, together with radiologists, pathologists, thoracic surgeons
- Techniques of sedation and oxygenation; management of related complications
- Clinical and radiographic (CT scan and PET) evaluation of the patient, comorbidities, risks and management of difficulties and complications
- Radiographic/endoscopic correlations
- Competency on the use of fluoroscopy to guide the procedures of cryo-transbronchial biopsy.
- Management of possible complications such as endobronchial bleeding and tension pneumothorax (see section “Emergency in IP” and “Pleural drainage”)
- Management of histology samples
- Post-procedural management

### Procedural Steps for Practical Training (Check list)

<table>
<thead>
<tr>
<th>Technique and performance of the procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Trainee shall act in collaboration with the team of physicians and nurses; and shall decide on the strategy to be implemented before performing the procedure (goals, procedures, duration and possible complications)</td>
</tr>
<tr>
<td>- Before beginning the procedure, trainee shall choose the equipment and check that every item is properly functioning and correctly prepared for the procedure, including all related devices, invasive and non-invasive ventilation support. In particular, s/he shall test the cryoprobe with saline before the procedure. And execute the following steps:</td>
</tr>
<tr>
<td>- Preparation, proper positioning of the patient, pre-medication, monitoring</td>
</tr>
<tr>
<td>- It is highly recommended that the procedure is performed with rigid bronchoscopy/oral endotracheal tube:</td>
</tr>
<tr>
<td>- Rigid bronchoscopy:</td>
</tr>
<tr>
<td>- Patient is deeply sedated with intravenous propofol and remifentanyl and intubated with a rigid bronchoscope; oxygen is administered continuously, and spontaneous breathing is maintained during the procedure.</td>
</tr>
<tr>
<td>- An explorative bronchoscopy with a flexible bronchoscope inside the rigid bronchoscope is performed. Prior to the procedure, the most affected segment will have been determined based on imaging studies (HRCT). This is the segment to sample. Ideally, two</td>
</tr>
</tbody>
</table>
- Different lobes on the same side should be sampled.

- Before performing the biopsies, it is recommended to prophylactically insert a Fogarty balloon (4 or 5 F), placed in the lobar bronchus near the biopsy segment and routinely inflated after sampling, to minimize the consequence of haemorrhage. Keep the rigid suction tube ready, so it can be introduced inside the rigid bronchoscope, if needed.

- A flexible cryoprobe (ERBE Elektromedizin GmbH, Tübingen, Germany), 90 cm long and 2.4 mm in diameter (or 1.9 mm), is introduced through the working channel of the bronchoscope under fluoroscopic guidance, till it reaches a sub-segment that allows the probe to be perpendicular to the chest wall: this allows the operator to ensure that the distance from the wall stays at 1 cm, in order to avoid to be too peripheral (pneumothorax) or too central (bleeding).

- Once brought into position, the probe is cooled with carbon dioxide (CO₂) to decrease the temperature of the probe’s tip to approximately -89°C (the real obtained temperature in the lung is -52°C) for approximately 4-6 seconds, and then the entire bronchoscope is retracted with the frozen lung tissue attached to the probe’s tip.

- The frozen specimen is thawed in saline and fixed in formalin. The optimal number of obtained samples is between 2 and 4 biopsies. The specimens are fixed in 4% formalin and embedded in paraffin, and then stained with haematoxylin-eosin (H&E) and periodic-acid Schiff (PAS).

- A second operator, using a second bronchoscope, will keep airways under control, while the first operator thaws the biopsy specimen in saline and then transfers it and fixes it in formalin.

### Theoretical and Practical TRAINING: Resources and Assessment Tools of the “CORE COMPETENCES”

**Hands-on practice TRAINING**

**GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES:** see page ............

**SPECIFICALLY FOR CRYOBIOPSIES:**
- Video and other multimedia resources
- Live sessions and case reports
- Task trainer simulation and non-technical skill simulation for the training on how to manage complications within the multidisciplinary team, including anaesthetist and nurses
- Training on animal models and cadaver
  - Training on patient, under supervision

**QUANTITATIVE ASSESSMENT WITH LOGBOOK (MINIMUM VOLUME)**
- Trainee shall be in attendance on at least 10 procedures performed by expert bronchoscopists (ACCP)
- Trainee shall perform directly, as first operator, at least 10 procedures under supervision of an expert bronchoscopist
- Trainee shall be in attendance on a session with a major complication of bleeding and tension pneumothorax

**QUALITATIVE ASSESSMENT**
- MCQ
- Case-based questionnaire
- DOPS on simulator and patient (cooperation among bronchoscopists, anaesthetists, nursing staff)

**OUTCOME ASSESSMENT**
- Percentage of biopsies taken every procedure.
- Percentage of complications, in all procedures
- Outcome of complications
<table>
<thead>
<tr>
<th>Competence maintenance (by LOGBOOK)</th>
<th>No. of PROCEDURES/YEAR:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5 – 10 procedures/year</strong></td>
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<tr>
<th>Recommended Literature</th>
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</table>
## 5.2 Operative bronchoscopy procedures

### 5.2.1 Rigid bronchoscopy, ablative procedures and stents

**Introduction**

**RIGID BRONCHOSCOPY.** First performed by Gustav Killian in 1897, rigid bronchoscopy was initially used primarily for foreign body removal, although it was soon extended to diagnostic indications. The instrument consists of a straight hollow metal tube, which (for adult use) is approximately 40 cm long, and 7 to 13.5 mm in diameter.

The distal end is bevelled, to allow for easier passage through the vocal cords and through stenotic areas; this also provides a chisel action to allow resection of tumour from the airway wall. The distal portion of the bronchoscope has side holes to provide ventilation. It is similar to a tracheoscope, which however is shorter and has no side holes. The intrinsic advantages of the rigid bronchoscope over the flexible bronroscope lie in (1) its inherent rigidity, (2) its ability to serve as an instrument providing ventilation, and (3) in the size of its operative lumen, which allows the passage of instruments such as large forceps, large channel aspirators, telescopes, stents, and laser fibres or coagulation devices. The combination of visualization, therapeutic manipulation of the airway, and simultaneous ventilation is of particular value in situations where there is airway obstruction, as well as in paediatric patients.

**LASER AND OTHER THERMAL ABLATION TECHNIQUES.** Laser technology was first applied in the treatment of airway conditions in the 1970s when advances in fibre optic technology allowed laser beams to be passed through flexible fibres, and thus combined with endoscopic procedures. Its use in the tracheobronchial tree was first reported by Toty in 1979. The term laser is an acronym for “Light Amplification of Stimulated Emission of Radiation”, and is characterized by electromagnetic energy that is collated and delivered as parallel, synchronous rays of light of the same wavelength. The most commonly used lasers for bronchoscopic purposes have been the carbon dioxide (CO2) laser with a wavelength of 10,600 nm, the Neodynium:Yttrium-Aluminium-Garnet (Nd:YAG) laser with a wavelength of 1064 nm, and the potassium-titanyl-phosphate (KTP) laser with a wavelength of 532 nm.

The Nd:YAG laser is the one most commonly used in pulmonary medicine and is the one addressed here. It can be delivered via a flexible fibre that can be passed down a rigid or flexible bronchoscope. It has a power output of between 5 W and 100 W so that photocoagulation is the predominant effect at low settings and vaporization at high settings, with a tissue penetration of 5–10 mm. Although laser therapy can be delivered exclusively with flexible bronchoscopy, most operators favour use in conjunction with rigid bronchoscopy under general anaesthesia, as this allows better control of haemorrhage and hypoxaemia, and also facilitates removal of tumour and debris using the chisel action of the rigid bronchoscope, as well as large forceps and suction tubes.

**STENTS.** Endobronchial stents are devices made of silicon, metal or hybrid material used primarily to palliate dyspnoea in patients who have major airway obstruction due to extrinsic compression or mixed compression and vegetation lesion. A fundamental part of training is learning to distinguish those cases that are symptomatic enough to actually need any intervention at all, and to understand the urgency with which intervention may or may not be required, as well as becoming familiar with simple alternative non-interventional techniques to improve a patient’s quality of life, particularly where life expectancy is short. Whereas in malignant conditions either silicone or metallic stents can be used, in benign conditions non-metallic stents are generally preferred.
These are highly complex procedures: a specific knowledge of how to manage tracheobronchial stenosis (see section on “Malignant and non-malignant central airway disorders”) and knowledge of further indications for the procedure (see section on “Emergency in IP” for the removal of foreign bodies, and massive haemoptysis) is a pre-requisite for admission to training. Trainees must also have experience in flexible bronchoscopy (see section on “Flexible bronchoscopy and basic sample technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”). Trainees must also possess in-depth knowledge of treatment devices and strategies. Practical training can be performed on animal, cadaver or plastic models.

<table>
<thead>
<tr>
<th>Indications for the Procedure</th>
<th>RIGID BRONCHOSCOPY:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control and management of massive haemoptysis</td>
</tr>
<tr>
<td></td>
<td>Removal of foreign bodies from the tracheobronchial tree</td>
</tr>
<tr>
<td></td>
<td>Treatment of airway stenosis by dilatation</td>
</tr>
<tr>
<td></td>
<td>Removal of neoplastic obstruction</td>
</tr>
<tr>
<td></td>
<td>Placement of tracheal or bronchial stents</td>
</tr>
<tr>
<td></td>
<td>Laser bronchoscopy</td>
</tr>
</tbody>
</table>

**LASER AND OTHER THERMAL ABLATION TECHNIQUES:**
- Malignant intraluminal obstruction of the proximal tracheobronchial tree in order to re-establish ventilation, eliminating secretions accumulated behind obstructions, and relieving symptoms such as haemoptysis, dyspnoea and cough
- Benign obstruction due to fibromas, hamartomas, papillomas, inflammatory granulomas, tracheobronchial stenoses, etc.

**STENT:**
- Extrinsic stenosis of central airways with or without intraluminal components due to malignant or benign disorders
- Complex, inoperable tracheobronchial strictures
- Tracheobronchial malacia
- Palliation of recurrent intraluminal tumour growth
- Central airway fistulae (oesophagus, mediastinum, pleura)

<table>
<thead>
<tr>
<th>Knowledge &amp; Skills</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Experience Requirements</td>
</tr>
<tr>
<td>- Rigid bronchoscopy: Trainee must have completed training described in sections on “Lung cancer” and “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”</td>
</tr>
<tr>
<td>- Laser: Trainee must have achieved competency in rigid bronchoscopy, possess a thorough knowledge of tracheobronchial anatomy and adjacent structures, and have completed a laser safety course.</td>
</tr>
<tr>
<td>- Stents: Trainees must have expertise with flexible and rigid bronchoscopy (Note: experience with rigid bronchoscopy is not essential for the insertion of all stent types, such as those inserted over a guidewire; however, occasionally even with these stents rigid bronchoscopy may be needed. Other stents, such as the Dumon stent, require rigid bronchoscopy for insertion. Sometimes, these stents are inserted after a rigid bronchoscopy procedure to debulk an obstructing endobronchial lesion)</td>
</tr>
</tbody>
</table>

- Operative protocols relating to malignant central airway disorders and to non-malignant central airway obstruction due to tracheobronchial obstruction secondary to, for example, granulomatosis with polyangiitis, post-intubation/tracheostomy, tuberculosis, sarcoidosis, amyloidosis, recurrent respiratory papillomatosis, broncholithiasis, tracheobronchial malacia or excessive dynamic airway collapse secondary to relapsing polychondritis, Mounier-Kuhn syndrome, COPD, foreign bodies, vocal cord disorders, pseudomembranes
<table>
<thead>
<tr>
<th>Knowledge</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>• Techniques of general anaesthesia and oxygenation, and management of related complications (See section “Sedation in IP”)</td>
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</tr>
<tr>
<td>• Full working knowledge of all the equipment involved, and organization of the endoscopy room (structural, technological and organizational requirements)</td>
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</tr>
<tr>
<td>• Indications, contraindications and management of complications related to rigid bronchoscopy, stent and ablation techniques</td>
<td></td>
</tr>
<tr>
<td>• Physics and clinical characteristics of the different types of laser and other ablation techniques, and indications for their use and their effect on tissues, as well as issues relating to operator protection</td>
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<tr>
<td>• Characteristics, methods of positioning, advantages and disadvantages, complications, monitoring and timing of different stent types (metal, silicon, hybrid, partially and totally covered stents).</td>
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<tr>
<td>• Complications related to the different techniques and how to manage them.</td>
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<table>
<thead>
<tr>
<th>Core Basic Skills</th>
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<tbody>
<tr>
<td>• Interpretation of endoscopic images of lesions (intraluminal, extraluminal, mixed) and evaluation of the lumen’s residual patency as well as extent of stenosis.</td>
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</tr>
<tr>
<td>• Selection of the appropriate approach depending on: acuteness of presentation, underlying cause and type of lesion, patient stability, the patient’s general, cardiac, and pulmonary status, quality of life, overall prognosis, physician’s expertise, and the technology available</td>
<td></td>
</tr>
<tr>
<td>• Decision regarding endoscopic or surgical approach</td>
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<tr>
<td>• Skills on interventional procedures with rigid bronchoscopy (introduction and correct use) and thermal techniques (laser, electrosurgery, Argon Plasma Coagulation – APC, cryotherapy) and non-thermal endoscopic airway procedures (brachytherapy, photodynamic treatment, microdebrider, airway dilatation, stenting)</td>
<td></td>
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<tr>
<td>• Patient management during the procedure (collaboration among bronchoscopist, nurses, anaesthetist) and management of possible complications</td>
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<tr>
<td>• Certified competence in laser usage</td>
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<tr>
<td>• Competence in different kinds of dilative and ablative techniques: rigid core debulking, laser, electrosurgery, Argon Plasma Coagulation – APC, cryotherapy and stents (both insertion and removal)</td>
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</tr>
<tr>
<td>• Control and management of massive haemoptysis, both with drug administration (adrenaline, ornipressin, tranexamic acid) and by mechanical tamponade</td>
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<tr>
<td>• Patient follow-up</td>
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<table>
<thead>
<tr>
<th>Procedural Steps for Practical Training (Check list)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prepare all equipment and devices needed for the procedure, and check that equipment is functioning correctly, before beginning: Rigid tracheobronchoscope Flexible bronchoscope Ablation and dilatation devices, stents</td>
<td></td>
</tr>
<tr>
<td>• Perform the following procedural steps:</td>
<td></td>
</tr>
<tr>
<td>1. The patient should be placed in the supine position, with the patient’s head at the edge of the bed, in the “sniffing” position for intubation. The “sniffing” position optimally aligns the pharynx, larynx, and trachea. There should be a pillow underneath the head and a roll under patient’s shoulder.</td>
<td></td>
</tr>
<tr>
<td>2. The patient’s lips and teeth should be protected. This is done directly with either a tooth guard or a saline-soaked sponge. Importantly, the surgeon’s thumb protects the teeth and s/he makes certain that tongue is not placed on the teeth when moving the rigid scope.</td>
<td></td>
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<tr>
<td>3. A right-handed surgeon protects the patient’s teeth with her/his left thumb and inserts the scope into the right side of the mouth, advancing to the base of the tongue at the posterior median groove. This is achieved by directing the scope directly down. The</td>
<td></td>
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</tbody>
</table>
The proximal end is then slowly brought downward into a more horizontal fashion while carefully protecting the patient’s teeth. Elevating the tongue and advancing slowly will bring the epiglottis into view. If the epiglottis is not visualized, then the scope should be brought back and advanced slowly again. Proper observation of the epiglottis is the crucial step in proceeding to intubate the cords. Once the epiglottis is visualized, the scope is advanced posteriorly and is used to lift the epiglottis gently, exposing the glottis. As the cords are approached, the bronchoscope should be rotated 90 degrees so that it traverses the cords with the minimum diameter. In general, when choosing the size of the scope, the largest scope that can traverse the stenosis (if one is present) should be used, without damaging the cords. Generally a 12 mm scope is used. Once the tip of the scope has passed the glottic aperture, the bronchoscope should be rotated back to its usual orientation with the ventilating side port pointing toward the ceiling. After intubation of the cords, the pillow may be removed and the head extended further. To assess the right or left bronchi, the patient’s head is turned to the opposite side.

4. Evaluation of the stenosis or lesion to be treated
5. When considering tracheal resection for benign and malignant pathology, precise measurements of normal and abnormal airway must be taken
6. Execution of the procedures of dilatation, or of mechanical or physical ablation. Tumours can always be bypassed on the contralateral side to the tumour. Circumferential tumours can be passed through the middle. The dilatation of a fibrous stenotic lesion is approached and traversed with the tip of the rigid bronchoscope without undue pressure and with a gentle corkscrew motion, to advance the scope beyond the lesion
7. Choice and positioning of the stent, if needed, using different techniques according to the stent chosen (metal, silicon or hybrid)
8. Management of complications

Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”

<table>
<thead>
<tr>
<th>Hands-on Practice TRAINING</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES:</td>
</tr>
<tr>
<td>SPECIFICALLY, FOR OPERATIVE BRONCHOSCOPY PROCEDURES:</td>
</tr>
<tr>
<td>• Live sessions and clinical case discussions, with emphasis on the strategy to be applied in different situations</td>
</tr>
<tr>
<td>• Task trainer simulation with plastic model for intubation, stent implantation, stent removal</td>
</tr>
<tr>
<td>• Non-technical skill simulation as training on how to manage the complications within the multidisciplinary team, with anaesthetist and nurses</td>
</tr>
<tr>
<td>• Training on animal models and cadaver</td>
</tr>
<tr>
<td>• Training on patient under supervision (in cases where it is allowed by law)</td>
</tr>
</tbody>
</table>

| QUANTITATIVE ASSESSMENT WITH LOGBOOK |
| (MINIMUM VOLUME) |
| No. OF PROCEDURES: |
| **ATS/ERS** | **ACCP** |
| RIGID BRONCHOSCOPY | 20 | 20 |
| LASER | 20 | 15 |
| ELECTRO/APC | 10 | 15 |
| CRYO | 10 | 10 |
STENT | 10 | 20

### QUALITATIVE ASSESSMENT
- MCQ
- Case-based questionnaires

### OUTCOME ASSESSMENT

#### For Rigid bronchoscopy:
- Ability to pass instrument into the trachea on first attempt in > 90% of cases without significant hypoxic periods
- Injury to teeth, gums or larynx on < 2% of cases
- Therapeutic results (% of disobstruction, symptom improvement, quality of life)

#### For Laser:
- Relief of symptoms in > 85% of cases
- Complication rate (haemorrhage, hypoxaemia, perforation, cardiac events): <5%

#### For Stents:
- A significant improvement in the score of breathlessness (as measured by an appropriate instrument) should be demonstrated in at least 80% of cases
- Patency achieved demonstrated by a picture of pre- and post-procedure endobronchial appearance and chest X-ray in all cases
- Typical procedure time (not including laser or other ablation technique) for stent: 20–30 min
- For fistulae, there should be reduction in fistula sequelae in 80% of cases
- Complications should occur in <20% of cases. These include stent displacement, cough, mucus impaction, granulation tissue at stent ends, infection and perforation of airway walls.

### Competence Maintenance (by LOGBOOK)

<table>
<thead>
<tr>
<th>No. OF PROCEDURES /YEAR:</th>
<th>ATS/ERS</th>
<th>ACCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIGID BRONCHOSCOPY</td>
<td>10-15</td>
<td>10</td>
</tr>
<tr>
<td>LASER</td>
<td>10-15</td>
<td>10</td>
</tr>
<tr>
<td>ELECTRO/APC</td>
<td>5-10</td>
<td>10</td>
</tr>
<tr>
<td>CRYO</td>
<td>5-10</td>
<td>5</td>
</tr>
<tr>
<td>STENTS</td>
<td>5-10</td>
<td>10</td>
</tr>
</tbody>
</table>

### Recommended Literature


22. Grosu HB, Eapen GA, Morice RC, Jimenez CA, Casal RF, Almeida FA, Sarkiss MG, Ost DE. Stents are associated with increased risk of respiratory infections in patients undergoing
5.2.2 Bronchoscopic treatment of emphysema
Endoscopic Lung Volume Reduction Treatment (ELVR)

Introduction
Endoscopic LVR was conceived and developed in order to benefit from the results offered by the surgical procedure without the disadvantages of its high rate of peri-procedural and post-procedural surgical and anaesthetic complications. Several different technologies have been developed. The most advanced technique is based on one-way valves that facilitate airflow and drainage of secretions from a lung affected by emphysema, while preventing airflow into these areas. Valves are even proposed for other indications such as pleural air leaks and collapse therapy for TB cavities. Valves are also Other technologies currently being developed are designed to function independently from collateral ventilation. The insertion of nitinol wire coils into an emphysematous lung during bronchoscopy is one such approach. Once the wire is inserted, it returns to its pre-formed state, resembling a coil that retracts and compresses lung parenchyma. Another interesting new technique is emphysematous lung sealant, a synthetic polymer that achieves LVR by occluding airways and collateral ventilation pathways, thereby sealing the collapsed region. Bronchoscopic thermal vapour ablation uses heated water vapour to create a thermal reaction in emphysematous lung, leading to local inflammation and, ultimately, to permanent fibrosis and atelectasis of the targeted region.

This is a highly complex procedure: a first-level competence is a pre-requisite for admission to training.
Trainees must possess in-depth knowledge of anatomy and be capable of interpreting imaging findings, especially in terms of evaluating fissures and pulmonary density by means of HRCT; the practical training must be based on discussion of clinical cases and the insertion techniques of the different devices on plastic or animal models, or on cadavers. A specific course, offering final certification, has been developed on the use of Zephyr valves.

<table>
<thead>
<tr>
<th>Indications for the Procedure</th>
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<tbody>
<tr>
<td><strong>One-way valve</strong></td>
</tr>
<tr>
<td>• Patients with heterogeneous or homogeneous emphysema, without collateral ventilation</td>
</tr>
<tr>
<td>Inclusion criteria: COPD, non-smoker, post-pulmonary rehabilitation, pulmonary function:</td>
</tr>
<tr>
<td>• FEV1 &lt; 45% predicted</td>
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<tr>
<td>• RV &gt; 180% predicted</td>
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<tr>
<td>• RV/TLC &gt; 55% predicted</td>
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<td>• Prolonged air leaks</td>
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| Coils |
| • Patients with heterogeneous or homogeneous emphysema, with or without collateral ventilation |

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<thead>
<tr>
<th>Knowledge &amp; Skills</th>
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<tr>
<th>Prior Experience Requirements</th>
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<tr>
<td>• Trainee must have completed training described in sections on “COPD and Asthma” and “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”</td>
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<table>
<thead>
<tr>
<th>Knowledge</th>
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</thead>
<tbody>
<tr>
<td>• Pathophysiology, classification, and pharmacological and non-pharmacological treatment of severe COPD</td>
</tr>
<tr>
<td>• Pulmonary function testing</td>
</tr>
</tbody>
</table>
• Imaging of emphysema with Quantitative CT and Fissure integrity, 3D systems (i.e. Strat-X, VIDA), Perfusional scintigraphy
• Indications and contraindications for endoscopic treatment of emphysema
• Bronchial anatomy
• Knowledge of tools and procedures used in endoscopic lung volume reduction treatment (one-way valves, coils, thermal vapour, sealants, Chartis system)
• Possible complications, team management and follow up
• Surgical treatment of emphysema

**Core Basic Skills**

- Competency in flexible and – optional – rigid bronchoscopy (see section on “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” and “Rigid bronchoscopy”)
- Active participation within the multidisciplinary team, with radiologists, pathologists, thoracic surgeons
- Sedation and oxygenation techniques, and management of related complications (see section: “Sedation in IP”)
- Clinical and radiographic (CT Scan and PET) evaluation of the patient, his/her comorbidities, risks and management of difficulties and complications
- Radiographic/endoscopic correlations
- Technique of preparation, loading and delivery of the different devices
- Technique for the removal of the various devices
- Prevention and management of possible complications (pneumothorax, respiratory failure, pneumonia, bleeding, exacerbation of COPD)
- Management of the patient’s follow-up

**Procedural Steps for Practical Training (Check list)**

**Procedural steps for the implant of valves EBV/IBV**

- The procedure may be performed under conscious sedation or general anaesthesia
- In case of general anaesthesia, the patient is intubated with endotracheal tube or rigid bronchoscope.
- Evaluate the integrity of fissure with Chartis system (see below)
- The valve is deployed by means of flexible bronchoscopy with a catheter-load system that compresses the valve into a 2.2-mm flexible delivery catheter, with an integral deployment rod. The catheter is then placed through the working channel (>2.6 mm) of the flexible bronchoscope and directed into the targeted airway.
- Under direct vision the size of the target airway is estimated. For the Zephyr valve, an appropriately-sized device on its catheter is inserted through the instrument channel of the bronchoscope and the valve is partly deployed.
- The positioning catheter is inserted through the operative bronchoscope channel, in front of the segment or subsegment of the selected bronchial lobe
- Push the catheter slowly out of the operative channel until it enters into the bronchial branch, with its depth benchmark just distal to the ostium
- The valve is then wedged onto a carina in the target area to prevent distal or incorrect placement. Once appropriately positioned, the valve is fully deployed.
- Further valves are placed in order to achieve complete occlusion of the target lobe.
- Placement of the IBV requires accurate airway sizing with a calibrated balloon catheter. Airways are sequentially sized with a calibrated balloon to determine valve size. Available valve diameter sizes are 4, 5, 6, and 7 mm. For segments with a diameter greater than 7 mm, sub segmental orifices are measured to define sub segmental valve size. The valve is visualized through the clear sheath of the delivery catheter and positioned so that the top of the valve membrane and struts is at the level of the desired position in the airway. The valve is then deployed, the position is assessed, and adjustments are made as necessary.
**Procedural steps for Chartis:**
- Procedure performed with a flexible bronchoscope
- The patient is under conscious sedation or general anaesthesia
- The target lobar airway is temporarily occluded by means of a balloon catheter, which blocks inspiratory flow but allows expiratory flow
- A continuous expiratory flow through the catheter indicates collateral ventilation, and a flow gradually declining to zero indicates no collateral ventilation

**Procedural steps for the implant of LVR- Coils:**
- A prophylactic regimen of antibiotics should be taken on the day of the procedure and for at least seven (7) days after the procedure. It is recommended that steroids be taken two (2) days before and at least seven (7) days after the procedure.
- Perform radiographic procedures and prepare subject for bronchoscopy as per standard hospital practice. After the procedure, allow the patient to recover from anaesthesia and monitor as per standard hospital practice.
- A chest X-ray should be taken post-procedure to verify Coil placement and to ensure no pneumothorax is present. A second chest X-ray should be taken at least 4 hours following the first chest X-ray.

**PREPARE DEVICES FOR USE**
1. Remove the Guidewire and Catheter together from the packaging hoop.
2. Remove the Forceps and the Cartridge from the packaging.
3. Flush the Cartridge with sterile saline (prior to first Coil deployment only).

**POSITION DELIVERY SYSTEM**
4. Identify the airways leading to the diseased parenchyma.
   a. Treatment should target the most damaged lobe (upper or lower) in each lung, identified through pre-procedure assessment method.
   b. Start deploying Coils in the segment which presents the most difficult access first and progress to less difficult segments.
   c. The recommended treatment strategy is to deploy **10-12 Coils in upper lobes** or **10-14 Coils in lower lobes**. When approaching the upper limit, discontinue deploying additional Coils if increased resistance is felt while advancing the proximal end of the Coil into the lung.
   d. To achieve optimal Coil placement, position Coils in the area between the hilum and the pleura, leaving a “Coil-free zone” approximately 4cm adjacent to the pleura. This placement will result in a “fan-like” distribution of Coils in the subsegmental airways throughout the treated lobe.
5. Navigate and wedge the bronchoscope into the selected airway (at the ostium leading to sub-segmental airways).
6. Align the tip of the Guidewire and the Catheter.
7. Insert the Catheter and Guidewire into the working channel of the bronchoscope.
8. Advance the Catheter and Guidewire to the tip of the bronchoscope.
9. Advance the Guidewire to the end of the targeted airway.
   Caution: Use fluoroscopy to visualize the Guidewire when it is beyond the visual range of the bronchoscope. Turn on fluoroscopy when the Guidewire fluoroscopy marker band enters the Catheter hub.
   a. Gently navigate the Guidewire into the distal airways under fluoroscopic guidance until the tip reaches the pleura or suddenly curves from a straight
path.

Caution: Do not advance the Guidewire against resistance. Caution: Forcing the
Guidewire past a sudden curve in a distal airway could cause tissue to become
pinched within the curved portion of the Guidewire.

10. Retract the Guidewire tip by grasping the proximal end of the Guidewire, adjacent to
the Catheter hub, and withdrawing 4-5cm (using predetermined measurement reference)
from the hub.

11. While holding the Guidewire position fixed relative to the bronchoscope, advance the
Catheter distally until it is even with the tip of the Guidewire.

Caution: Fluoroscopy should remain on to make sure the Guidewire does not move
during Catheter advancement.

Caution: Do not force the Catheter around a sharp bend on the Guidewire.

Caution: If unable to advance the Catheter to the distal end of the Guidewire, pull
the Guidewire back to be aligned with the tip of the Catheter. Do not force the
Catheter.

- SELECT COIL

12. Select the appropriate Coil size by counting the number of radiopaque markers on the
Guidewire visible outside the bronchoscope

  a. The markers indicate the minimum recommended Coil size to be used.
  b. Do not count the Guidewire tip as a marker for Coil selection.

13. Remove the Guidewire from the Catheter while maintaining the Catheter position and
turn fluoroscopy off.

- LOAD COIL

14. Remove the plastic shell containing the selected Coil from the carton and pouch.

15. Insert the Forceps into and through the Cartridge, making certain that the Forceps exits
the Luer lock end of the Cartridge.

16. Unlock the Forceps by closing the jaws with force and lifting the Lock up (close by
squeezing the Finger Handle and Thumb Ring closer together).

17. Open the Forceps jaws by increasing the distance between the Finger Handle and
Thumb Ring.

18. Grasp the Coil by closing the Forceps jaws around the proximal ball.

19. Close and lock the Forceps jaws closed (press the blue locking tab to the handle until an
audible clicking sound is heard) to prevent releasing the Coil.

20. Seat the Cartridge into the opening of the plastic protective shell

21. Slowly pull the Forceps until the Coil is removed from the plastic protective shell and
completely inside the Cartridge.

Caution: Do not pull the Forceps jaws or the Coil out of the proximal end of the
Cartridge while loading a Coil. Pushing the Coil back into the Cartridge may cause
damage to the Coil. If this happens, do not use the Coil.

Caution: Do not use the Coil if the Coil is dropped or outside of the packaging shell
for any reason.

22. Connect and lock the Cartridge to the Luer lock hub of the Catheter.

23. Deliver the Coil into the Catheter by advancing the Forceps and Coil.

Caution: Grip the Forceps no more than 5cm from the proximal end of the Cartridge
to prevent kinking while advancing.

24. Turn on fluoroscopy when the fluoroscopy marker band (on Forceps shaft) enters the
Cartridge.

25. Advance the Coil distal ball to the distal end of the Catheter and verify the position of
the Coil via fluoroscopy.

26. Have the assistant hold the bronchoscope fixed relative to the patient.

Caution: Do not move the bronchoscope position during the deployment
procedure.
- **DEPLOY COIL**
  27. Deploy the Coil by distally advancing the Forceps. Advance the Coil out of the distal end of the Catheter until the first half-loop is positioned in the target airway. Note: If the view of the Coil is obstructed, adjust the fluoroscope to allow adequate visualization.
  28. Retract the Catheter while maintaining a slight constant pressure to advance the Forceps forward until the Forceps jaws are visible approximately 2cm distal to the end of the bronchoscope. Maintain Forceps position and continue to retract the Catheter into the bronchoscope.
  29. Verify the position of the Coil prior to unlocking the Forceps and releasing the Coil.
    a. Ideally the proximal end of the Coil is in the segmental airway or more distal.
    b. If Coil position is not ideal,
- **DETACH AND REMOVE DELIVERY SYSTEM**
  30. Gently retract the Forceps approximately 1cm to create slight tension between the Forceps and the Coil. Maintain the tension.
  31. Unlock and open the Forceps jaws.
    Caution: The Forceps jaws cannot open if they are within the Catheter. The Forceps jaws must extend at least 1cm beyond the distal end of the Catheter and the bronchoscope to release the Coil.
  32. Close and lock the Forceps jaws.
  33. Confirm that the proximal ball has been released before turning the fluoroscopy off.
  34. Unlock the Cartridge from the Catheter (Luer lock), and remove the Cartridge and Forceps from the Catheter together as a unit.
  35. Withdraw the distal tip of the Catheter into the bronchoscope.
- **Note:** The Catheter may remain in the bronchoscope during positioning to the next treatment airway. Repeat Steps 7 to 35 to deploy additional Coils.

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**Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”**

<table>
<thead>
<tr>
<th>Hands-on Practical TRAINING</th>
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<tbody>
<tr>
<td>GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES: see page</td>
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<tr>
<td>SPECIFICALLY FOR ENDOSCOPIC LUNG VOLUME REDUCTION TREATMENT:</td>
</tr>
<tr>
<td>• Live session and clinical case discussion with emphasis on the strategy to follow in different situations</td>
</tr>
<tr>
<td>• Online training (<a href="https://pulmonx.com/ous/professionals/education/">https://pulmonx.com/ous/professionals/education/</a>)</td>
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<tr>
<td>• Task trainer simulation with plastic model</td>
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<tr>
<td>• Non-technical skill simulation for the training on how to manage complications within a multidisciplinary team with anaesthetist and nurses</td>
</tr>
<tr>
<td>• Training on animal models and cadaver</td>
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<td>• Training on patient under supervision</td>
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<tr>
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<tr>
<th>QUALITATIVE ASSESSMENT</th>
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<tbody>
<tr>
<td>• MCQ</td>
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<tr>
<td>• Case-based questionnaires</td>
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<tr>
<td>• DOPS</td>
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</tbody>
</table>
| OUTCOME ASSESSMENT                                                                 | • Assessment of outcomes (mortality, survival, complications, pulmonary function, quality of life, dyspnoea scores)  
|                                                                                 | • National and international registers (e.g. coils) |
| Competence maintenance (by LOGBOOK)                                          | No. OF PROCEDURES /YEAR:  
<p>|                                                                                 | • Unknown |</p>
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**COILS**

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**Multimedia resources**

5.2.3 Thermoplasty

| Introduction | Bronchial thermoplasty (BT) is an innovative bronchoscopic treatment for patients with severe persistent asthma who are already being treated with the maximum doses of inhaled corticosteroids and long-acting beta-agonists, yet continue to suffer from asthma symptoms. BT aims to reduce smooth-muscle mass in the airways by delivering heat energy to the bronchial wall. The treatment targets lobar and segmental bronchi and is divided into three sessions, each 2 to 3 weeks apart. BT is performed using a radiofrequency electrical generator and a disposable catheter that passes through the working channel of a flexible bronchoscope and delivers heat at four contact points on its expandable distal basket. This is a highly complex procedure: first-level competence is a pre-requisite for admission to training. Trainees must possess in-depth knowledge of bronchial anatomy and of bronchial abnormalities; practical training shall be performed on plastic and animal models, and on cadavers. |
| Indications for the procedure | Bronchial thermoplasty is indicated for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta-agonists. |

### Knowledge & Skills

**Prior Experience Requirements**
- Trainee must have completed training described in sections on “COPD and Asthma” and “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”

**Knowledge**
- Pathophysiology, guidelines for the diagnosis and treatment of severe asthma (see section on “COPD and Asthma”)
- Differential diagnosis of severe asthma (COPD, foreign bodies, other bronchial obstructions)
- Pulmonary function testing
- Indications, contraindications and complications of asthma treatment with thermoplasty
- Bronchial anatomy
- Physics and technological principles of thermoplasty
- Knowledge of the equipment and methodology of thermoplasty and related protocols (bronchial mapping, hospital setting)
- Management of severe asthma exacerbations

**Core Basic Skills**
- Competency in flexible and – optional – rigid bronchoscopy (see section “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” and “Rigid bronchoscopy”)
- Sedation and oxygenation techniques and management of related complications (see section: “Sedation in IP”)
- Ability to use the thermoplasty equipment
- Management of short and long term complications

**Procedural Steps for**
- Flexible bronchoscopy for the preliminary evaluation of bronchial anatomy
- The procedure may be performed under conscious sedation or general anaesthesia
- In case of general anaesthesia, the patient is intubated with endotracheal tube or rigid
bronchoscope.

- BT is performed in three separate sessions to attenuate the clinical consequences of irritating large surface areas in the asthmatic airways. The first two sessions target each lower lobe separately and the third session targets both upper lobes. The right middle lobe is not treated.
- A 5-day course of oral prednisone (50 mg/d) is started 2 to 3 days before the procedure and continued afterward to reduce airway inflammation.
- The bronchoscope is advanced to the segmental bronchi of the target lobe and the catheter is advanced via the working channel into airway branches.
- The distal basket must be visible when delivering energy; therefore, usually only third to sixth generation airways are treated.
- The basket is expanded via a proximal handle to ensure contact of its wires with the airway wall.
- The energy is delivered by activating a foot switch: each application lasts approximately 10 s.
- Once an application is complete, the basket is collapsed and retracted 5 mm to start the next application.
- Repeated applications are carried out from distal to proximal branches at 5-mm intervals to achieve contiguous, non-overlapping treatment of the entire targeted airway.
- All the application sites are recorded on an airways map.
- Post-procedure, patients are monitored in the recovery area and are discharged when stable, and when their post-procedure FEV1 is 80% of pre-procedure measurement.

### Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”

#### GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES: vedi a pag. 30

**SPECIFICALLY, FOR THERMOPLASTY:**

- Live sessions and clinical case problem discussion, with emphasis on the strategy to be followed in different situations
- Task trainer simulation with plastic model
- Non-technical skill simulation for the training on how to manage complications within the multidisciplinary team, with anaesthetist and nurses
- Training on animal models, such as for example porcine lung, fresh, frozen or preserved under plastic lamination, and on cadaver
- Training on patient under supervision
- BT certification

#### QUANTITATIVE ASSESSMENT WITH LOGBOOK (MINIMUM VOLUME)

**No. OF PROCEDURES:**

- At least 3 procedure under supervision

#### QUALITATIVE ASSESSMENT

- MCQ
- Case-based questionnaires
- DOPS
<table>
<thead>
<tr>
<th>OUTCOME ASSESSMENT</th>
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</table>
| - Assessment of outcomes (mortality, survival, complications, pulmonary function, quality of life, dyspnoea scores)  
- National and international Registers  
- Average duration of procedure: 30 – 45 minutes per session  |

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<tr>
<th>Recommended Literature</th>
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</table>
4. GINA guidelines available at www.ginasthma.org  
5. Linee guida GINA (traduzione italiana) available at www.ginasma.it  
13. A. Shifren, P. Chenna, A. Chen, M. Castro Bronchial Thermoplasty; from J P Diaz-jemenez, A.N. Rodriguez Interventions in Pulmonary Medicine, 405-417 Springer 2013  
14. S. Khatri, T Gildea Bronchial Thermoplasty for severe asthma; from A. Mehta, P. Jain Interventional Bronchoscopy,189-200 Springer 2013  
15. Wechsler M, et al., Benefits of Bronchial Thermoplasty Persist Out to 5 Years in Patients with Severe Asthma, Journal of Asthma and Clinical Immunology, August 2013  
5.3 Sedation in IP

Sedation in IP

Introduction
Sedation for bronchoscopy procedures is usually the responsibility of bronchoscopists, although for some procedures anaesthetist-delivered sedation is preferred. When the bronchoscopist administers the sedation it should be carefully titrated, using small incremental doses to avoid oversedation, particularly given the significant variability in patient response to sedatives.

Training for this procedure must be compulsory for all levels. Trainees are required to possess an in-depth knowledge of the pharmacology of the sedatives that specialized pulmonologists may use (benzodiazepines and opioids) as well as of local anaesthetics. Trainees must also be competent in managing complications related to these drugs. The most suitable training method is the high-fidelity simulation for non-technical skills. Deep sedation and general anaesthesia must be administered by the anaesthetist.

Indications for the Procedure
- Flexible bronchoscopy
- Rigid bronchoscopy
- Thoracoscopy (biopsies and talc poudrage)

KNOWLEDGE & SKILLS

Knowledge
- Tools, including the Ramsay Scale and the Modified Observer’s Assessment of Alertness/Sedation score (These tools are especially useful in documenting the patient’s sedation level as part of the bronchoscopy record)
- Drugs used as sedatives for bronchoscopy such as benzodiazepines (e.g. midazolam), propofol, ketamine and opioids (e.g. fentanyl, alfentanyl), Dexmedetomidin; indications and contraindications
- Techniques and drugs used for anaesthesia: indications and contraindications
- Pre-anaesthesia evaluation (i.e. Mallampati, etc.)
- Equipment and procedures inherent to anaesthesia
- Devices for ventilation:
  - Facial Mask, simple and with hole for endoscopy
  - Laryngeal Mask
  - Helmet for NIV
  - Endotracheal fireproof tubes and cannulae
  - Endotracheal double-lumen tube and double-lumen endobronchial tube – DLT (Carlens, Robertshow, Univent, combitube) and tube exchangers
  - Airtrack
- Ventilators and ventilation modalities:
  - Spontaneous respiration in the patient in deep sedation
  - Negative Intermittent Pressure Ventilation (NIPV)
  - Positive Intermittent Ventilation
  - HF Jet-ventilation
- Risk/benefit, limits and complications of different types of sedation
- Management of complications related to anaesthesia in operative bronchoscopy:
  - Patient-related: airway obstruction due to the presence of vegetation, extrinsic obstruction and infiltration, comorbidities, respiratory failure, V/Q abnormality
  - Procedure-related: peri-operative bleeding, artificial obstruction of the airways caused by stent, balloons, dilatators, laser-related burn, risk of over-sedation and respiratory depression,
### Core Basic Skills

- Pre-operative assessment of the patient: use checklist to identify any sedation risk factors prior to procedure. Instructions on activities subsequent to procedure provided.
- Pre-operative discussion with doctors and nurses on the goals of the operation, times and possible complications.
- Insertion of secure venous access.
- Anaesthesiology drugs management and delivery, based on the specific competence of pulmonologists and anaesthetists.
- Specific antagonist drugs should be immediately available, if needed.
- Pre-medication with lidocaine.
- Monitoring of heart rate, blood pressure and oxygen saturation before, during and after the procedure; during operative procedures include ECG and transcutaneous CO2.
- Ability to ventilate in case of respiratory failure (with mask or via endotracheal tube): patient trolley should be capable of being tipped head down. Suction, airway management equipment, reversal agents for opioids or benzodiazepines (e.g. naloxone, flumazenil), resuscitation medications and equipment should be immediately available.

### Procedural Steps for Practical Training (Check list)

- Insertion of secure venous access.
- Intravenous midazolam is the preferred drug for sedation, having a rapid onset of action, being titratable to provide the required depth of sedation and being reversible. No more than 5 mg midazolam should be initially drawn up into any syringe prior to bronchoscopy for patients under the age of 70 (2 mg midazolam for patients over 70) to prevent potential inadvertent over-sedation.
- Combination opioid and midazolam sedation should be considered in patients to improve bronchoscopic tolerance.
- While propofol has similar efficacy to midazolam, it should only be used when administered by practitioners formally trained in its administration (e.g. anaesthetists) since it has a narrow therapeutic window beyond which general anaesthesia is achieved.
- When opioids are used, short-acting agents (such as fentanyl or alfentanil) should be used to minimise post-procedural sedation.
- Apply technique and equipment for oxygenation and ventilation.
- Administration of specific antagonist drugs and drugs for the management of complications.

### Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”

**Hands-on Practice TRAINING**

**GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES:** vedi a pag. 30

**SPECIFICALLY FOR SEDATION ON IP:**

- Theoretical lectures on indications, contraindications, range of tools and devices, organization of the endoscopy room, description of the procedure.
- Manikin and plastic model for simulation of the procedures and management of complications.
- Non-technical skills simulation in operative room scenario for the training on how to manage complications, within the multidisciplinary team with anaesthetist and nurses.
- Training on patient under supervision, until trainee has achieved quantitative and qualitative competency.
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<th>Recommended Literature</th>
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**Multimedia resources**

## 5.4 Pleural procedures

### 5.4.1 Thoracic ultrasound

**Introduction**

Ultrasonography is extremely useful in the diagnosis and treatment of pleural and pulmonary diseases. It is a valuable and easily accessible tool for pulmonology specialists and intensive care physicians.

An important application is the use of ultrasound to guide thoracentesis and the insertion of a pleural device in critically ill patients. The skills required in performing this procedure include the ability to competently identify the site, the angle and the depth for safe needle introduction. In cases of post-procedure pneumothorax, the specialist must be capable of assessing lung sliding, of establishing a semi-quantitative assessment of the remaining fluid and identifying the correct position for an intrapleural device. A good knowledge of pleural diseases is a requirement, as well having completed a dedicated thoracentesis and chest tube drain practical training course, to ensure that trainee has developed and practiced the skills necessary to gain proficiency in using ultrasound to identify and guide needle and catheter insertions in the patient with pleural effusions.

**Indications for the procedure**

- Bedside clinical examination
- Bedside detection of pleural fluid
- Bedside detection of pneumothorax
- Guidance for diagnostic and therapeutic thoracentesis
- Guidance for placement of thoracostomy tubes

### Knowledge & Skills

**Prior Experience Requirements**

Knowledge of:

- Physics of ultrasound
- Generation of sonographic images
- Generation of artifacts
- Available technologies and related accessories (ultrasound scanners, probes, applications)
- Normal ultrasonographic patterns
- Disorders of the pleura
- Sensitivity, specificity, and diagnostic accuracy and limits of ultrasound examination

**Knowledge**

- Knowledge of basic concepts of physics of ultrasound. Ultrasonographic images are generated by the interaction of ultrasound signals with tissue. An understanding of the fundamental principles of ultrasound physics is required to obtain high quality images and to understand and recognise artifacts of ultrasound imaging.
- Knowledge of machine controls and transducer manipulation. The clinician must be able to acquire the ultrasound images personally at the bedside with the use of convex and linear probes.
- Knowledge of normal and abnormal ultrasonographic patterns and the pathophysiological consequences of ultrasonographic images.
- Knowledge of image interpretation, clinical applications, and the specific limitations of ultrasonography.
Performance of examination. Procedural steps:
1. Correct positioning of patient: supine or sitting, depending on clinical conditions
2. The clinician determines the thoracic surfaces to be explored and the clinical objectives
3. Choice of probe, site of examination, adjustment of machine
4. Systematic approach to patient examination:
   a. General exploration with longitudinal and transversal scans in succession on each hemithorax, along usual anatomical vertical lines
   b. Recognition of pathological elements and evaluation of abnormalities through systematic and continuous changes/adaptations of machine/probe settings, in order to obtain high quality images:
   c. Technical (Image Acquisition) and Cognitive (Image Interpretation) Elements Required for Competence in Pleural Ultrasonography (Chest. 2009 Apr;135(4):1050-60):
      i. Identification of a relatively hypoechoic or echo-free space surrounded by typical anatomic boundaries: diaphragm, chest wall, ribs, visceral pleura, normal/consolidated/atelectatic lung
      ii. Identification of liver and ascites, spleen, kidney, heart, pericardium and pericardial effusion, aorta, inferior vena cava
      iii. Identification of characteristic dynamic findings of pleural fluid, such as diaphragmatic motion, floating lung, dynamic fluid motion, respirophasic shape change
      iv. Characterization of fluid: anechoic; echogenicity (using liver/spleen as reference); homogeneous or heterogeneous; presence of strands/debris/septations
      v. Identification of miscellaneous findings, such as pleural-based masses or thickening
      vi. Performance of semi-quantitative assessment of fluid volume
   d. Technical (Image Acquisition) and Cognitive (Image Interpretation) Elements Required for Competence in Lung Ultrasonography (Chest. 2009 Apr;135(4):1050-60):
      a. Knowledge of the basic semiology of lung ultrasound: normal pattern, reverberation artifacts (A-lines), vertical artifacts (B-lines), sliding sign, curtain sign, pre-consolidated patterns (i.e. sonographic interstitial syndromes), consolidated patterns (i.e. lung consolidation, atelectasis), lung point, lung pulse.
      b. Identification and characterization of consolidated lung: identification of tissue density lung, with or without air bronchograms
      c. Identification and characterization of air artifacts suggestive of the normal aeration pattern: A-lines with sliding lung
      d. Identification and characterization of air artifacts suggestive of alveolar interstitial pattern: number and location of B lines
      e. Knowledge of the limitations of not visualizing lung sliding/B lines
      f. Identification and characterization of air artifacts to rule out pneumothorax: presence of sliding lung, presence of B-lines
      g. Identification and characterization of findings that null’ in pneumothorax: presence of lung point (both by 2D imaging and M-mode)
5. Integration of ultrasonographic findings with clinical signs and symptoms
6. Elaboration of clinical suspicion
7. Indication/planning of interventional procedures  
8. Draft clinical report specifying:  
9. Clinical context  
10. Machine  
11. Patient’s position  
12. Type of breathing / oxygen therapy  
13. Normal / abnormal patterns

**Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”**

**TRAINING TEORICO/PRÁCTICO**

**Hands-on Practical TRAINING**

**DELLÉ “CORE COMPETENCES”**

**GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES:** see page ........

**SPECIFIC ASPECTS FOR CHEST ULTRASONOGRAPHY:**
- Theoretical and practical training course on ultrasound in general
- Intensive theoretical and practical on thoracic ultrasound (2-3 days)
- Practical training in healthy subjects and on simulators (1 tutor and 1 ultrasound machine or simulator every 5 participants) in order to develop skills in:
  1. probe orientation, settings adjustment, and the correct acquisition of images  
  2. identifying normal/abnormal patterns  
  3. interpreting images  
  4. integrating ultrasonographic findings with clinical signs  
- Practical training on patient  
- Plastic models and simulators for the simulation of procedures under ultrasound guidance  
- Simulation on animals or animal organs  
- Hands-on training on patient under clinical supervision, in order to achieve appropriate competence and expertise  
- Assistance in procedures performed in specialized high volume centres

**QUANTITATIVE ASSESSMENT WITH LOGBOOK (MINIMUM VOLUME)**

**No. of procedures**
- 100 clinical examinations with chest ultrasound  
- 10 echo-guided thoracentesis  
- 5 echo-guided insertions of chest tube

**QUALITATIVE ASSESSMENT**

- Questionnaires MCQ  
- Case-based questionnaires, with decision-making process  
  1. Assessment tools: UGSTAT (the Ultrasound-Guided Thoracentesis Skills and Tasks Assessment Test: an 11-domain, 100-point assessment sheet in line with British Thoracic Society guidelines).

**Competence maintenance (by LOGBOOK)**

**No. of procedures**
- 10 clinical examinations with chest ultrasound  
- 5 echo-guided thoracentesis  
- 1 echo-guided insertion of chest tube

**Recommended Literature**


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<th>Dec;35(6):693-705.</th>
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### 5.4.2 Pleural drainage

#### Introduction

Pleural drainage is a diagnostic and therapeutic procedure used in the treatment of pneumothorax, pleural infections and in neoplastic pleural effusions. In neoplastic pleural effusions indications for pleurodesis drainage are: effusion-induced symptoms (dyspnoea) which regress after thoracentesis; recurrent effusion; a reasonably good life expectancy; re-expandable lung.

The following complications may occur in relation to this procedure:

1. Faulty insertion of the chest drain
2. Infections (empyema, pneumonia)
3. Pulmonary oedema
4. Trauma affecting other organs (lung, heart, liver, spleen, stomach, colon, diaphragm).

Trainees must possess a perfect knowledge of thoracic ultrasonography. Practical training to be performed with low fidelity simulation.

#### Indications for the Procedure

**INDICATIONS FOR THE CORRECT INSERTION OF A CHEST DRAIN:**

1. Pneumothorax
2. Malignant pleural effusion
3. Empyema
4. Parapneumonic pleural effusion with complications
5. Haemopneumothorax with complications
6. Post-surgery

Indications for pleural drainage in patients with pleural infections:

1. Frankly purulent or dark pleural fluid
2. Presence of microorganisms identified by Gram staining or by culture in non-purulent pleural fluid
3. pH < 7.2
4. Slow clinical progression, despite antibiotic therapy
5. Major non-purulent pleural effusions

#### KNOWLEDGE & SKILLS

**Prior Experience Requirements**

Trainees must have completed the training as described in the sections on “Pleural disease” and “Thoracic ultrasound”.

**Knowledge**

In-depth knowledge of:

- Pleural diseases (see section..)
- Thorax ultrasound (see section on Thoracic ultrasound)
- Existing types of chest drains and related accessories and devices
- Appropriate healthcare setting
- Indications and contraindications for the insertion of a chest drain:
  1. Lung adhering densely to chest wall throughout the hemithorax
  2. Transudate pleural effusions caused by liver failure
- Sensitivity, specificity, diagnostic accuracy in all pathologies and limitations of the technique
- Techniques required to establish a surgical sterile field
- Prevention and management of clinical risk, informed consent and medical-legal aspects
- Information to patient and obtaining specific consent for the procedure; information to
### Core Basic Skills

- Pre-procedure clinical and radiographic evaluation:
  1. Choosing the safest and most reliable diagnostic technique
  2. Co-morbidities
  3. Interpretation of thoracic imaging

- Performance of thoracic ultrasound (see section on “Thoracic ultrasound”)
- Insertion of chest drain using Seldinger’s method, percutaneous drainage set UNICO™ or standard method using a trocar
- Patient monitoring and management after insertion of chest drain and after its removal

### Procedural Steps for Practical Training (Check list)

Performing the procedure: (see: DBH-NHS Guidelines for the Insertion and Management of Chest Drains)

- Preparation of patient: positioning, pre-medication and local anaesthesia
- Choosing the appropriate drain:
  1. Small drain: to be used as a first choice in treatment of pneumothorax and exudate effusions
  2. Large drains: to be used in acute haemothorax, to monitor blood loss
    - Small tube (6-14 Fr)
    - Medium tube (16-24 Fr)
    - Large tube (>24 Fr)
    - 1 French = 3 mm
- Chest drain insertion methods (those most commonly used):
  1. Standard method, using a trocar and blind dissection of chest planes with blunt-tip scissors
  2. Seldinger method, using a serial dilatation along a guidewire
  3. Percutaneous drainage set UNICO™
- Selecting the site for insertion and correct positioning of drain tube
- Drain management
- Management and treatment of any complication that may arise
- Removal of drain tube

### Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”

**Hands-on Practical TRAINING**

**GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES:** see page

**SPECIFICALLY FOR PLEURAL DRAINAGE:**

- Online questionnaire in the insertion of a chest tube (TZANS, “Insertion of chest tubes and management of chest drains in adults”)
- Manikin, plastic models and simulators, in order to learn the procedure and to improve trainee’s skills
- Simulation on animal models or on animal organs (low cost)
- Training on patient under supervision until trainee has achieved competence
- Attend courses in specialized high volume centres

**QUANTITATIVE ASSESSMENT WITH LOGBOOK**

**No. OF PROCEDURES:**

- 5 – 7 drainages under supervision
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<th>QUALITATIVE ASSESSMENT</th>
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<tr>
<td>MCQ</td>
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<tr>
<td>Case-based questionnaires, including evaluation of correct decision-making</td>
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<td>DOPS (e.g. UGSTAT and EUTAT, TUBE-iCOMPT (the Chest Tube Insertion Competency Test: a 5-domain 100-point assessment tool in line with British Thoracic Society guidelines and international consensus))</td>
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<tr>
<th>OUTCOME ASSESSMENT</th>
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<tr>
<td>Outcome monitoring</td>
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<tr>
<td>National and international Registers of:</td>
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<tr>
<td>volume of exams performed</td>
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<tr>
<td>diagnostic yield</td>
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<td>% of complications</td>
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<tr>
<td>Assessment of outcomes and complications</td>
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<tr>
<td>Patient comfort</td>
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<td>Percentage of complications as ratio of total number of procedures performed</td>
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<td>Management of complications</td>
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<th>Competence maintenance (by LOGBOOK)</th>
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<tr>
<td>No. of PROCEDURES / YEAR:</td>
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<td>3 / year</td>
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<tr>
<th>Recommended Literature</th>
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<tbody>
<tr>
<td>7. Peter Doelken. Placement and management of thoracostomy tube UpToDate - September 2011</td>
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5.4.3 Thoracoscopy and talc poudrage

**Introduction**

Medical thoracoscopy is a minimally invasive procedure aimed to inspect the pleural space. Diagnostic and therapeutic procedures can be performed during a single exam. After pleural fluid aspiration, biopsy samples can be collected from the parietal, diaphragmatic and visceral pleura in selected patients. In the presence of fibrinous adhesions causing a loculated effusion, the procedure can be useful to resolve them all/completely. Talc insufflation is recommended at the end of the procedure, in case of pleural effusion recurrence.

Diagnostic yield is 95% in patients with pleural malignancies and higher in pleural tuberculosis. In parapneumonic complex effusion medical thoracoscopy allows to avoid surgery in most cases.

Thoracoscopy training should be considered as important as bronchoscopy training for Pulmonology fellows, given the prior acquisition of ultrasonography and chest tube insertion skills.

Thoracoscopy is an easy-to-learn and safe procedure but it could be complex in some circumstances, thus two levels of training are identified: a primary level focused on the management of indeterminate pleural effusion, malignancy and pneumothorax, and an advance level targeted on performing the procedure in parapneumonic complex pleural effusions and empyema.

**Indications for the Procedure**

- In pleural effusions: for diagnostic purposes (with biopsy) and for treatment purposes
- Pneumothorax

**KNOWLEDGE & SKILLS**

**Prior Experience Requirements**

Trainees must have completed the training as described in the section on “Pleural disease” and “Thoracic ultrasound”.

**Knowledge**

In-depth knowledge of:

- Pleural diseases (see section)
- Role of thoracoscopy in the diagnosis and treatment algorithm
- Thoracoscopy techniques
- Indications, contraindications and risk/benefit analysis for thoracoscopy
- Sensitivity, specificity, diagnostic accuracy of the various pathologies and limitations of this procedure
- Indications, contraindications and risk/benefit analysis for chest drain (see section on “Pleural drainage”)
- Organization of the thoracoscopy room
- Techniques required to establish a surgical sterile field
- Prevention and management of clinical risk, informed consent and medical-legal aspects

**Core Basic Skills**

- Sterile field techniques (performing all manoeuvres to obtain highest level of sterility) and techniques aimed at identification-traceability (check list: site-side-procedure)
- Performance of thoracentesis in autonomy
- Insertion and use of thoracoscopy, including optical and biopsy collection accessories
- Insertion and management of a chest drain using surgical technique (see section on Pleural drainage)
- Prevention, monitoring and management of possible complications related to the procedure (acute onset, ...)
### Procedural Steps for Practical Training

*(Check list)*

**Performance of the procedure:**
- **Procedural steps:**
  1. Patient is placed in lateral decubitus position
  2. Preparation of patient, pre-medication and local anaesthesia
  3. Conscious or deep sedation (with assistance from anaesthetist, depending on patient’s conditions and on normal practice in the centre)
  4. Creating the thoracoscopy access port
  5. Introduction of trocar
    - Inspection of the pleural cavity
    - Aspiration of pleural fluid
    - Biopsy of pleural wall and, in select cases, of visceral pleura; haemostasis control
    - Choosing and correctly inserting the chest drain; monitoring its correct functioning
    - Suturing the access port and ensuring correct drainage

### Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”

**Hands-on Practical TRAINING**

- **GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES:** see page 30

**SPECIFICALLY FOR THORACOSCOPY:**

**N.B.** In order to be accepted as trainees on the medical thoracoscopy course, candidates must be competent in thoracentesis and know how to insert and manage chest drains.

- Theoretical and practical lessons in medical thoracoscopy and pleural procedures, and ERS Course (see section on Multimedia resources)
- Complete the online questionnaire in the insertion of a chest tube (TZANS, “Insertion of chest tubes and management of chest drains in adults” is recommended)
- Live sessions: practical sessions and simulated clinical cases.
- Manikin and plastic models that can be perforated, with simulation practice in order to learn the procedure and improve coordination among team members in managing complications
- Virtual reality simulation to develop the manual dexterity and skills needed for the procedures
- Simulation on animal models in vivo or on individual organs (low cost)
- Training on patient under supervision until trainee has achieved sufficient quantitative and qualitative levels of competence
- Attending courses in specialized high volume centres
- Recording procedures performed as lead operator in trainee’s own centre so that they can be viewed again later, as part of the learning process

<table>
<thead>
<tr>
<th>QUANTITATIVE ASSESSMENT WITH LOGBOOK (MINIMUM VOLUME)</th>
<th>No. OF PROCEDURES:</th>
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<tbody>
<tr>
<td><strong>MCQ</strong></td>
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<th>QUALITATIVE ASSESSMENT</th>
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<td><strong>MCQ</strong></td>
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<td>Case-based questionnaires, on appropriate decision-making</td>
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<td><strong>DOPS</strong></td>
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### OUTCOME ASSESSMENT

Assessment of outcomes – Registers of:

- Volume of exams performed
- Diagnostic yield
- % of complications

### Competence maintenance (by LOGBOOK)

**No. OF PROCEDURES / YEAR:**
- 10 / year

### Recommended Literature

## 5.5 Paediatric bronchoscopy

### Introduction
Flexible endoscopy of paediatric airways (FAE) includes examination of the nose, pharynx, larynx and tracheobronchial tree. Small models of paediatric flexible bronchoscopes have become available, creating opportunities for applications that had hitherto been unthinkable. Modern anaesthetic techniques have also rendered the examination of small and very sick infants much safer than before.

This is a highly complex procedure: first-level competence must be a requirement for admission to training. Trainees must possess a perfect knowledge of paediatric pathologies causing airway obstruction and are required to complete a training course on manikin that includes anaesthesiology, since anaesthesia is compulsory in paediatric patients. Non-technical skills teamwork simulation sessions are also very useful, including procedure room scenarios. Training on diagnostic procedures is addressed separately from training on operative procedures.

### Indications for the Procedure
- **Airway obstruction**
  - Stridor/noisy breathing
  - Persistent/recurrent wheezing
- **Radiographic abnormalities**
  - Atelectasis
  - Recurrent/persistent consolidations
  - Atypical and unknown infiltrates
  - Localised hyperinflation
- **Chronic cough**
  - Suspected foreign body aspiration
  - Haemoptysis
  - Evaluation of the artificial airway
- **Therapeutic bronchoscopy**
  - Restoration of airway patency
  - Mucus plugs or blood clots
  - Alveolar filling disorders (alveolar proteinosis, lipid pneumonia)
- **Special procedures**
  - Bronchoalveolar lavage
  - Brushing or biopsy of the bronchial mucosa
  - Biopsy of endobronchial lesions
  - Transbronchial Needle Aspirations
  - Transbronchial biopsy
  - Administration of drugs
  - Endoscopic intubation

### KNOWLEDGE & SKILLS

<table>
<thead>
<tr>
<th>KNOWLEDGE &amp; SKILLS</th>
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## Prior Experience Requirements

- Trainee must have completed training described in sections “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”

## Knowledge

- Anatomy and foundations of embryology (development of airways and digestive tract)
- Basic knowledge of paediatric chest radiology
- Basic knowledge of paediatric pulmonology
- Anaesthesiology and sedation procedure in children
- Monitoring system, ventilation and oxygen support in children
- Thoracic paediatric diseases
  1. obstructive
  2. infective
  3. interstitial
  4. laryngeal
  5. congenital and vascular malformation
- Rigid and flexible paediatric equipment: see sections on “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” and “Rigid bronchoscopy, laser and stent”
- Indications, contraindications and risk/benefit analysis of paediatric bronchoscopy
- Possible complications, team management and follow-up

## Core Basic Skills

- Understanding indications and contraindications
- Pre-bronchoscopy clinical and radiographic evaluation:
  1. Potential difficulties in intubating the patient
  2. Choosing the appropriate procedure for the patient - Choosing the correct instrument (Flexible bronchoscope vs Rigid bronchoscope)
- Obtaining appropriate informed consent and evaluation of possible alternative procedures
- Patient safety. Correct monitoring and ability to respond to abnormalities and achieve infection control
- Ability to perform Flexible bronchoscopy through the nasopharynx, mouth, mask, laryngeal mask airway (LMA) and endotracheal tube
- Ability to identify normal anatomy and variants
  - Ability to identify normal upper airway anatomy and function
  - Ability to identify normal lower airway anatomy and function
  - Identify and enter segmental bronchi
  - Ability to keep the flexible bronchoscope centred and avoid excessive airway wall trauma
- Ability to recognize pathological abnormalities:
  - Secretions (i.e., clear, frothy, mucoid, purulent, bloody)
  - Upper airways: nasal polyps, laryngomalacia, laryngeal clefts, adenoid and/or tonsillar hypertrophy, pharyngeal collapse, tongue-base obstruction
  - Larynx and upper airways: Vocal cord paralysis/paresis, subglottic stenosis, subglottic oedema, subglottic or supraglottic haemangioma, laryngeal or tracheal web, laryngeal papilloma, laryngeal cyst, tracheal stenosis, tracheal rings, tracheomalacia, bronchomalacia, bronchial stenosis, airway compression, mass lesion, foreign body, mucus plug, airway granuloma, trachea-oesophageal fistula, tracheal bronchus
- Management of anaesthesia and sedation procedure in children
- Ability to use of the basic supplies for paediatric bronchoscopy: slip-tip syringes, specimen
traps, gauze sponges, bite blocks, appropriately sized flexible bronchoscopes, transbronchial aspiration needles, biopsy forceps, grasping forceps, retrieval baskets, cytology brushes.

- Main tissue sampling procedures (e.g. bronchoalveolar lavage - BAL; biopsy brushing, TBNA)
- Knowledge of complications and their management
- Basic knowledge of instruments cleaning and disinfection

2nd level competencies:
- Percutaneous tracheostomy: (see section on “Bronchoscopy and anaesthesiology in ICU”)
- Management of tracheostomy cannulae (see section on “Bronchoscopy and anaesthesiology in ICU”)
- Ability to introduce and use a rigid bronchoscope and related procedures (foreign body removal, stent, laser, etc.)

Procedural Steps for Practical Training (Check list)

Performance and technique of the procedure:
- Flexible bronchoscopy: choice of the proper anaesthesia, technique for ventilation and oxygenation support, introduction of the bronchoscope, BAL, bronchial and transbronchial biopsy, bronchoscopy intubation in difficult pediatric airway, transbronchial needle aspiration
- Rigid bronchoscopy (2nd level): choice of the proper anaesthesia, technique for ventilation and oxygenation support, introduction of the bronchoscope, foreign body removal with rigid bronchoscope, use of laser to remove granulation tissue (e.g., at the site of a tracheostomy before decannulation), infectious tumours (e.g., non-tuberculous mycobacterial granulomas), cicatricial obstructing lesions in the trachea, incision of bronchogenic cysts

Theoretical and Practical TRAINING: Resources and Assessment Tools for "CORE COMPETENCES"

GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES: see page 30

SPECIFICALLY FOR PAEDIATRIC BRONCHOSCOPY:
- Training in adult IP
- Video libraries
- Training on plastic manikins of infants and children
- Simulation on self-made phantoms, on animal models such as pig lung, either frozen or preserved under plastic lamination
- Virtual simulation trainers used for adult bronchoscopy, which can be adapted to training for paediatric age patients.
- Theoretical and practical courses: i.e. ERS Skills Based Course (25% of the course should address theoretical aspects of flexible bronchoscopy in children; 25% should be taken up by discussion of clinical cases; 50% of course should be practical). Sessions should last about 90 minutes and focus on: introduction of bronchoscope, BAL, bronchial and transbronchial biopsy, intubation through flexible bronchoscope.
- Training on patient under supervision until trainee has achieved quantitative and qualitative competence
- Attend procedures in endoscopy room at high volume centres of excellence

QUANTITATIVE ASSESSMENT WITH LOGBOOK
- No. of PROCEDURES: 50 (once trainee has achieved competency in adults)
### (MINIMUM VOLUME)

#### QUALITATIVE ASSESSMENT
- MCQ
- Case-based questionnaires, on appropriate decisions
- DOPS with flexible and rigid bronchoscope on manikin and patient

#### OUTCOME ASSESSMENT
- Indication, diagnostic yield, complications, quality of documentation, and overall cost-effectiveness

### Competence maintenance (by LOGBOOK)

**No. OF PROCEDURES /YEAR:**
- Unknown

### Recommended Literature

7. Leonardo L. Donato Pediatric Interventional Bronchoscopy Clinics in Chest Medicine 2013, 34; 569-582
8. Nicolai T Pediatric Bronchoscopy Pediatric Pulmon. 2001 31; 150-164
5.6 Bronchoscopy in anaesthesiology and Intensive Care Unit (ICU)

### Introduction

Bronchoscopy has become an indispensable tool not only for pulmonologists, but also for anaesthetists, as a guide in airway control. The ability to address difficulties in airway control is fundamental in anaesthesia and resuscitation, and bronchoscopy is an indispensable tool to achieve correct intubation and to improve patient ventilation and oxygenation in any medical setting. Bronchoscopy in the ICU commonly involves intubated patients supported by mechanical ventilation, with significant other illnesses and comorbidities. Bronchoscopy therefore requires careful consideration in this patient population. The specifications of a bronchoscope suitable for use in the ICU call for a degree of compromise. The internal diameter of the ET may restrict the size of the bronchoscope, while efficient suctioning requires a larger bronchoscope with a wide suction channel. Fibre-optic intubation (FOI) is an effective technique for accessing airways in the management of anaesthesia when treating patients in whom airway difficulties are anticipated; but it is also effective in patients in whom such difficulties are not anticipated. FOI remains the accepted standard in elective airway management of the conscious and spontaneously breathing patient with an anticipated difficult airway.

This section addresses the knowledge and skills that must be mastered by both pulmonologists and anaesthetists. It is therefore essential that training sessions should be organized jointly, with an exchange of experiences. The tools useful in the practical training include low and high fidelity simulators, but non-technical skills and teamwork simulation are also highly recommended.

### Indications for the Procedure

- Treatment of lobar and lung collapse due to retained bronchial secretions which may obstruct major airways; local directed suction using a wide channel bronchoscope combined with saline instillation has been used to treat this condition
- Diagnosis and management of haemoptysis/haemorrhage
- Diagnosis of infection in ICU/ventilated patients (VAP: Ventilatory Acquired Pneumonia)
- Transbronchial biopsies and needle aspiration in the ICU/ventilated patients
- Diagnosis of acute respiratory distress syndrome
- Known difficult intubation and suspected difficult intubation by direct laryngoscopy (e.g. history of difficult intubation, limited mouth opening, decreased thyromental distance), unstable cervical spine, abnormal anatomy, congenital airway deformities (e.g. Pierre Robin syndrome), head and neck cancers (e.g. supraglottic tumours), trauma of face/neck or upper airway
- Management of tracheostomy cannulae, laryngeal mask and endotracheal tubes
- Performance of dilatational tracheostomy
- Suspected tracheal lesions

### Prior Experience Requirements

- Trainee must have completed training described in sections on “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”
### Knowledge & Skills

#### Knowledge

See: Knowledge in the section “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBJA, ROSE, BAL, brushing”

- Normal, variant and abnormal bronchial anatomy, and relationships of bronchial tree to other important intra-thoracic structures (mediastinum, and other intrathoracic structures)
- Thoracic imaging (CT scan, PET)
- Full working knowledge of all the equipment involved (bronchoscopes, forceps, BAL, brushing) including disposable bronchoscopes
- Anaesthesia and sedation technique and complications (see section “Sedation in IP”)
- Prevention and management of possible complications
- Predictors of difficult/impossible mask ventilation and difficult intubation: limited mandibular protrusion, abnormal neck anatomy, sleep apnoea or snoring, and obesity with a body mass index of 30 kg/m² or greater, congenital airway deformities (e.g. Pierre Robin syndrome), head and neck cancers (e.g. supraglottic tumours), trauma of face/neck or upper airway
- Prediction tests for difficult intubation conditions:
  - Mallampati test
  - Mc Cormack-Leane test
- Indications for bronchoscopy in ICU
- Emergency bronchoscopy
- Thoracic ultrasound in emergency (see section...)
- Paediatric bronchoscopy (see section “Paediatric bronchoscopy”)
- Devices for bronchoscopy with ventilation:
  - Non-invasive ventilation and facial mask, both simple and with hole for endoscopy
  - Laryngeal mask
  - Endotracheal tubes and cannulae
  - Endotracheal double-lumen tube and double-lumen endobronchial tube – DLT (Carlens, Robertshow, Univent, combitube) and tube exchangers
- Risk management and prevention
- Difficult intubation
- Percutaneous dilatational tracheostomy and role of bronchoscopy: indications, contraindications and complications

#### Core Basic Skills

See section on “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBJA, ROSE, BAL, brushing” on patient assessment and monitoring, and on skills required in flexible bronchoscopy and basic sampling procedures.

**Specific skills for the ICU:**

- Safe administration of intravenous sedation and how to reverse excessive sedation (competence)
- Safe administration of local anaesthetic including appreciation of potential toxicity (competence)
- Prevention and management, within the multidisciplinary team, of any complications arising during the procedure (bleeding, pneumothorax, cardiac and respiratory complications)
- Choice of the size of bronchoscope, devices for ventilation and modality of ventilation and oxygenation
- Replacing tracheostomy cannulae and bronchoscopy evaluation in case of weaning and decannulation
- Performance of percutaneous tracheostomy with bronchoscopy guide
- Assessment of tracheal lesion:
  - Perforation
  - Ring fracture
  - Granulomas
  - Cicatricial stenosis
- Percutaneous tracheostomy (optional)
- Prevention and management, within the multidisciplinary team, of any complications arising during the procedure (bleeding, pneumothorax, cardiac and respiratory complications)

Procedural Steps for Practical Training (Check list)

See section on “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” on patient assessment and monitoring, and on skills required for flexible bronchoscopy and basic tissue sampling procedures.
- Difficult intubation:
  - Choice of the proper endotracheal tube (ETT); loading the ETT and passing the bronchoscope through the ETT
  - Introduction of the bronchoscope (FOI) can be performed nasally or orally with an oral bite block in conscious patients with topical anaesthesia alone, or in sedated or anaesthetized patients. In circumstances in which mask ventilation may be difficult and risk of airway loss is high, a conscious technique is preferred. A nasal approach is particularly useful in patients with a large tongue, limited mouth opening, receding lower jaw, or tracheal deviation, or in cases in which an unobstructed surgical field is beneficial (e.g. dental surgery).
  - Techniques to facilitate FOI include the jaw thrust, tongue protrusion, positioning the scope in the midline of the pharynx during advancement, and rotating the ETT 90° counter-clockwise, if resistance is encountered during advancement, to facilitate passage through the vocal cords.
  - A laryngoscope blade can be used as an adjuvant to displace the tongue in order to promote bronchoscope and ETT passage
  - Once the scope enters the trachea, it is advanced to the level of the mid-trachea, where a previously loaded ETT is then guided into the trachea
  - The ETT should be turned gently counter-clockwise with retraction and then re-advanced if resistance is encountered during placement.
  - Once the ETT is passed, a bronchoscopic view can verify placement, with optimal tube positioning 2–3 cm above the carina in an adult patient. The scope is then withdrawn as the tube is held in place by hand
  - Finally, tube placement is checked by end-tidal carbon dioxide and auscultation and subsequently secured and connected to a circuit for ventilation.
  - Deep sedation only after sure passage of the ETT beyond the vocal cords

Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”

Hands-on Practical TRAINING

GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES: see page ............

SPECIFICALLY FOR TRACHEOSTOMY:
- Printed and multimedia resources concerning difficulties in airway management
- Skill simulation and task training on plastic simulators, e.g. AirSim Advance Combo bronchi
- Non-technical skill and teamwork simulation: the simulation and practice of crisis management may be as important as technical skill learning with any particular airway technique. Algorithms developed for difficult airway management as well as pre-planned strategies may be most useful during such clinical scenarios
- Simulation with virtual simulators, e.g. BRONCH Mentor – AccuTouch Virtual Reality Bronchoscopy Simulator
- Training on animal model and cadaver
- Training on the patient with a tutor and then under supervision: a video monitor for larger image display may be most effective for the novice or trainee
- A course on bronchoscopy in Anaesthesiology and ICU must include an introductory session, ending in a quantitative and qualitative competence assessment on “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” (see section..) and then a specific session on the topic.

<table>
<thead>
<tr>
<th>QUANTITATIVE ASSESSMENT WITH LOGBOOK (MINIMUM VOLUME)</th>
<th>No. OF PROCEDURES:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td></td>
<td>Bronchoscopy via nasal and oral route and via tracheostomy and ETT: 100</td>
</tr>
<tr>
<td></td>
<td>Difficult intubation: unknown (Some have suggested that FOI is best accomplished by those clinicians who use a bronchoscope in their daily practice)</td>
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<tr>
<td></td>
<td>Tracheostomy: 3 procedures for every type of percutaneous tracheostomy performed</td>
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<thead>
<tr>
<th>QUALITATIVE ASSESSMENT</th>
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<tr>
<td></td>
<td>MCQ</td>
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<td></td>
<td>Case-Based Questionnaire</td>
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<tr>
<td></td>
<td>Simulated assessment</td>
</tr>
<tr>
<td></td>
<td>DOPS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OUTCOME ASSESSMENT</th>
<th></th>
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<tbody>
<tr>
<td>Percentage of complications from the Operative room register</td>
<td></td>
</tr>
<tr>
<td>Ability to introduce the bronchoscope: &gt;90%</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Competence maintenance (by LOGBOOK)</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>No. OF PROCEDURES/YEAR:</td>
<td></td>
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<tr>
<td>Bronchoscopy via nasal and oral route and via tracheostomy and ETT: 50/year</td>
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<tr>
<td></td>
<td>5. Facciolongo N. La broncoscopia in unità di terapia intensiva Rassegna di Patologia</td>
</tr>
</tbody>
</table>
dell’Apparato Respiratorio 2009; 24: 212-219


16. Ciaglia P. Video-assisted endoscopy, not just endoscopy, for PDT. Chest 1999; 115:915-916


Multimedia resources
# 5.7 Bronchoscopy in thoracic surgery: Syllabus for Interventional Pulmonologists and Thoracic Surgeons

## 5.7 Bronchoscopy in thoracic surgery

### Introduction

The American Board of Thoracic Surgery (ABTS) requires resident-trainees in the general thoracic surgery track to perform 40 bronchoscopic procedures. Of those, 30 can be simple diagnostic procedures, including airway inspection, BAL and endobronchial or transbronchial biopsy. An additional 10 must be therapeutic procedures, including “core out” of tumour, laser, dilatation of strictures, stent placement, and photodynamic therapy, or other interventions such as cryotherapy, electrocautery, or argon plasma coagulation. A thorough understanding of the role of bronchoscopy is necessary in the diagnostic evaluation and management of patients with benign and malignant disorders of the chest. Pulmonary and thoracic surgery trainees have a different bronchoscopic approach. Pulmonary fellows may be more focused on the diagnostic and palliative management of a particular chest disorder; thoracic surgery trainees focus on the information that endoscopic findings can give them regarding surgical treatment. At the moment there are no reports in the literature evaluating the level of proficiency of recently graduated thoracic surgery trainees, but it is highly unlikely that most are fully competent in advanced therapeutic bronchoscopy at the completion of their residency.

This section describes the knowledge and skills that both pulmonologists and thoracic surgeon fellows must master. Some procedures are prevalently related to pulmonology (e.g. EBUS/EUS), but they must become part of the knowledge of a thoracic surgeon as well; while the interventional pulmonology fellow must become acquainted with others, although they are prevalently surgical in nature. It is therefore fundamental that training sessions be organized jointly, with an exchange of experiences between the two. The tools for the practical training include low and high fidelity simulators, although non-technical skills and teamwork simulation are recommended.

### Indications for the Procedure

- Pre-operative bronchoscopy: Information regarding surgical treatment of pulmonary resection
- Post-operative bronchoscopy:
- Haemorrhagic complications
- Hypersecretion and bronchial mucus plugs
- Suture-related complications
- Broncho-pleural fistulae
- Tracheobronchial stenosis
- Pleural infections
- Pulmonary infections (empyema, abscess, etc.)
- Pleural effusion

### Knowledge & Skills

- Trainee must have completed training described in sections on “Lung cancer”, “Malignant and non-malignant central airway disorders”, “COPD and Asthma”, “Pleural disease”, “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”, “Pleural procedures”, “Operative bronchoscopy procedures”
Knowledge

- Knowledge described in sections on “Lung cancer”, “Malignant and non-malignant central airway disorders”, “COPD and Asthma”, “Pleural disease”, and in particular on:
  1. Lung cancer and mesothelioma: radiographic and ultrasound chest imaging, diagnosis and staging
  2. Pneumothorax and pleural effusion
  3. Emphysema and Lung volume reduction surgery (LVRS)
  4. Lung transplantation
  5. Tracheal stenosis

- Thorough understanding of airway anatomy and its anatomical variants
- Familiarity with surgical techniques (which thoracic surgeons already possess, but is knowledge that pulmonologists are required to master), and ability to select the most appropriate treatment option
- Peri-operative and post-operative complications (diagnosis and treatment): see above
- Technical knowledge of flexible and operative bronchoscopy, interventional endosonography, pleural procedures, endoscopic and surgical emphysema treatment (see sections “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing,” “Operative bronchoscopy procedures, “EBUS-TBNA”, “EUS-FNA - EUS-B-FNA” and “Radial EBUS ”) and in particular:
  - Insertion and management of chest drainage
  - Rigid bronchoscopy and positioning of stent, valves and coils
  - Glues and resorbable materials
  - Thoracoscopy and Video-assisted thoracoscopy (VATS)
  - Mediastinoscopy
  - Laryngoscopy

Core Basic Skills

- Expertise in the clinical evaluation and management of the main respiratory diseases; active participation in the multidisciplinary team – including pulmonologist, radiologist, oncologist, thoracic surgeons, etc. – in making the best diagnostic and staging evaluation and final decision
- Competency in flexible and, optionally, rigid bronchoscopy (see section “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, trans-bronchial biopsy, TBNA, ROSE, BAL, brushing” and “Rigid bronchoscopy”)
- Pre-operative assessment in lung cancer: inspection bronchoscopy, including with Narrow Band Imaging (NBI) and EBUS, in order to select the most appropriate treatment option; histology diagnosis of the lesion and assessment of the planned resection margins, including evaluation with multiple biopsies of submucosal infiltration; evaluation of lung sparing surgery; evaluation of the bronchial calibre for possible discrepancies
- Diagnosis, evaluation and treatment of tracheal stenosis: when considering tracheal resection for benign and malignant pathology; accurate measurements of normal and abnormal airway must be taken with rigid bronchoscope
- Diagnosis and treatment of surgical complications (see above) with flexible and rigid bronchoscopy, thoracic ultrasound and pleural procedures

Procedural Steps for

- See section: “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”, “Pleural procedures”, “Operative bronchoscopy procedures”
- Steps involved in the measurement of tracheal stenosis for resection: the rigid
bronchoscope, with telescope inserted almost to the end, is used to measure the distance from the carina to the inferior margin, superior margin, and inferior border of the cricoid. This is done by starting distally and moving proximally. A ruler measures a proximal fixed point from the bronchoscope to the incisors. This allows the surgeon to make a schematic drawing showing relative distances between the carina and the distal margin of the lesion, the length of the lesion, and between the proximal margin of the lesion and the cricoid cartilage.

<table>
<thead>
<tr>
<th>Practical Training (Check list)</th>
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<tbody>
<tr>
<td><strong>Hands-on Practical Training</strong></td>
<td><strong>GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES:</strong> vedi a pag. 30</td>
</tr>
<tr>
<td></td>
<td><strong>Specifically for bronchoscopy in thoracic surgery:</strong></td>
</tr>
<tr>
<td></td>
<td>1. Pre-operative bronchoscopy</td>
</tr>
<tr>
<td></td>
<td>- See section: “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” (an established practice in most thoracic surgery programmes is to perform intra-operative bronchoscopy in almost all patients undergoing thoracic surgical procedures) and “Interventional Endosonography”</td>
</tr>
<tr>
<td></td>
<td>- Course in Thoracic Surgery Operating Room to include of at least 25 lobectomies and sleeve lobectomies (for Interventional Pulmonologists as observer)</td>
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<td></td>
<td>- Case-based discussions of patients eligible for procedure</td>
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<td></td>
<td>- Participation at Tumour Board meetings</td>
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<td></td>
<td>2. For diagnosis and treatment of surgical complications:</td>
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<tr>
<td></td>
<td>- Observer at a Course in a Thoracic Surgery Unit where at least 100 procedures/year are performed, being present in the operating room twice a week for 4 weeks, to observe the surgical procedures and to position chest drainage under supervision</td>
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<td>- Videoforum on emergency and elective surgery cases</td>
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<td>- Use of video systems for tutoring, as well as the most recent disposable bronchoscopes</td>
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<td>- Skill simulation or task training and non-technical skill team simulation</td>
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<td></td>
<td>3. Tracheal stenosis and LVRS: see section “Malignant and non-malignant central airway disorders”, “COPD and Asthma”, “Operative bronchoscopy procedures”</td>
</tr>
<tr>
<td></td>
<td>4. Non technical skill OR scenarios</td>
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<tr>
<td><strong>QUANTITATIVE ASSESSMENT WITH LOGBOOK (MINIMUM VOLUME)</strong></td>
<td><strong>No. OF PROCEDURES:</strong></td>
</tr>
<tr>
<td></td>
<td>For Interventional Pulmonologists: See section “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” (an established practice in most thoracic surgery programmes is to perform intraoperative bronchoscopy in almost all patients undergoing thoracic surgical procedures),“Interventional Endosonography” and “Operative bronchoscopy procedures”</td>
</tr>
<tr>
<td></td>
<td>For Thoracic Surgeons: the American Board of Thoracic Surgery (ABTS) requires resident-trainees in the general thoracic surgery track to perform 40 bronchoscopic procedures: 30 simple diagnostic procedures, including airway inspection, BAL, and endobronchial or transbronchial biopsy, and 10 therapeutic procedures.</td>
</tr>
<tr>
<td><strong>QUALITATIVE ASSESSMENT</strong></td>
<td>- MCQ</td>
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<tr>
<td></td>
<td>- Case-based questionnaires</td>
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<tr>
<td></td>
<td>- DOPS for flexible and rigid bronchoscopy</td>
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</tbody>
</table>
| OUTCOME ASSESSMENT | See flexible and rigid bronchoscopy  
• Assessment of outcomes and complications  
• Infiltration of the margins of surgical pulmonary resection  
• % of “lung sparing” surgical procedures in comparison with preliminary evaluation |
| Competence maintenance (by LOGBOOK) | **No. OF PROCEDURES / YEAR:**  
• See section: “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBN, ROSE, BAL, brushing” (an established practice in most thoracic surgery programs is to perform intraoperative bronchoscopy in almost all patients undergoing thoracic surgical procedures), “Interventional Endosonography” and “Operative bronchoscopy procedures” |

**Multimedia resources:**
5.7.1. Bronchoscopy in lung transplantation

Introduction

When candidates and donors are carefully selected, lung transplantation offers patients with end-stage lung disease the potential of increased survival and improved quality of life. Success of transplantation is dependent on careful screening of the donor. The standard lung donor criteria are as follows: age less than 55; ABO compatibility; clear chest radiograph; absence of chest trauma or surgery; absence of potentially pathological organisms on sputum Gram stain or of purulent secretions at bronchoscopy; PaO2/FIO2 (fraction of inspired oxygen) ratio greater than 300 on positive end-expiratory pressure of 5 cm H2O and FIO2 100%; smoking history of less than 20 pack-years; and no evidence of sepsis. Post-transplantation complications can be graft-related, such as primary graft dysfunction, acute and chronic rejection (also called bronchiolitis obliterans and restrictive allograft syndrome), or anastomotic complications.

In lung transplantation bronchoscopy procedures play a central role in selecting the patient and in the post-operative management, especially in diagnosis and treatment of post-transplantation complications: airway stenosis, fistulas, infections, acute and chronic rejection. Traditional diagnostic bronchoscopy can be used as a regular monitoring tool (for follow-up at specific intervals, or for the early diagnosis of complications) or “as needed”, based on clinical requirements. Overall, both subclinical early diagnosis of rejection or infections, especially viral ones, and evaluation of the balance between infection and immunity, lead to changes in treatment plans in 60% of protocol diagnostics. Bronchial and transbronchial biopsies are crucial in the diagnosis of lymphocyte bronchitis-bronchiolitis and acute or chronic rejection. The management of surgical complications calls for considerable experience with rigid bronchoscopy.

Indications for the Procedure

- Chronic obstructive pulmonary disease (COPD) BODE index 7-10, FEV1<20%, DLCO<20%, Pulmonary Hypertension, Frequent Exacerbations.
- Cystic fibrosis: FEV1 less than 30%, FEV1 30% or greater with associated hypercapnia, rapid decline in FEV1
- Idiopathic pulmonary fibrosis: decrease in FVC greater than 10% or in DLCO greater than 15%, or an increase in level of dyspnoea or fibrosis.
- Pulmonary arterial hypertension, progressive dyspnoea, right heart failure, or a decline in 6-minute walking distance to less than 350 m, despite maximal therapy

Absolute contraindications: recent malignancy, a history of non-compliance, certain chronic infections, substance abuse in the past 6 months, morbid obesity, or untreatable psychiatric disorder.

Relative contraindications: obesity, age greater than 65 years, malnutrition, colonization with virulent organisms, poor functional status, and severe osteoporosis

Knowledge & Skills

Prior Experience Requirements

- Trainee must have completed training described in sections on “Bronchoscopy in thoracic surgery”

- Knowledge described in sections “Malignant and non-malignant central airway disorders,” “COPD and Asthma and COPD”, “Interstitial lung diseases”,
- Knowledge of cystic fibrosis, pulmonary hypertension, respiratory infections and indications for transplantation
- Thorough understanding of airway anatomy and its anatomic variants
### Knowledge
- Imaging interpretation
- Familiarity with surgical techniques of lung transplantation
- Peri-operative and post-operative complications of lung transplantation (diagnosis and treatment): see above
- Technical knowledge of flexible and operative bronchoscopy, endoscopic and surgical emphysema treatment (see sections “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”, “Operative bronchoscopy procedures”)
- Clinical knowledge on transplantation
  - Onset times of complications from re-perfusion after lung transplantation
  - Primary graft dysfunction, acute and chronic rejection (Chronic Lung Allograft Disfunction - CLAD - also called bronchiolitis obliterans Syndrome - BOS - and restrictive allograft syndrome - RAS -)
  - Anastomotic complications (suture complications)
  - Bacterial, viral, mycotic and parasitic infections
- Interpretation of BAL, EBB and TBB
- Local epidemiology of infections
- Procedures of removal and transplantation
- Surgical technique and end-to-end anastomosis
- Immunosuppressive regimens of induction and maintenance employed to reduce the rate of rejection and infection-related complications
- Interpretation of the microbiology and immunology (eosinophils, neutrophils, lymphocytic alveolitis) reports
- Management of the waiting list ranked by lung allocation score (LAS)

### Core Basic Skills
- Expertise in the clinical evaluation and management of respiratory diseases; active participation in the transplantation multidisciplinary team – including pulmonologist, radiologist, oncologist, thoracic surgeons, etc. – in the selection of candidates
- Competency in flexible and rigid bronchoscopy [see section “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” and “Rigid bronchoscopy”] with particular competence in bronchial and transbronchial biopsies, mechanical dilatation, stent choice and positioning (optional and under evaluation: transbronchial cryobiopsies)
- Competency in endoscopic lung volume reduction procedures for the management of native lung hyperinflation in single lung transplantation for COPD and of prolonged post-surgical air leaks
- Specific competency in the management of post-transplantation complications (see above) with flexible and rigid bronchoscopy.

### Procedural Steps for Practical Training (Check list)
- Pre-operative evaluation:
  - Exclusion of bronchial lesion and full evaluation of microbiology and cytology of recipients of organs, to be done during the initial selection stages
  - Exclusion of purulent secretion in the donor
- Performance of flexible bronchoscopy in acute and chronic rejection: See section: “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”
- Performance of rigid bronchoscopy and stent positioning: See section “Operative bronchoscopy procedures” with specific skills for the different anatomical variants
- Management of the post-procedural phase and patient follow-up

### Theoretical and Practical Training: Resources and Assessment Tools for “Core Competences”

<table>
<thead>
<tr>
<th>Hands-on Practical Training</th>
<th>General Theoretical and Practical Training Common to all Procedures: Specifically for Bronchoscopy in Lung Transplantation:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>For flexible bronchoscopy and relative procedures see section: “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” (optional section “cryobiopsy”)</td>
</tr>
<tr>
<td></td>
<td>Course in Lung Transplantation Unit where at least 20 transplantations/year are performed, participating in pre- and post-transplantation bronchoscopy procedures in the operating room, in the ICU for microbiology and anastomosis monitoring procedures, in resuscitation-related procedures, in the pulmonology ward for follow-up procedures</td>
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<tr>
<td></td>
<td>Case-based discussions on patients eligible for operation</td>
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<td></td>
<td>Participation at Tumour Board meetings discussing lung transplantation</td>
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<tr>
<td></td>
<td>For anastomotic complications see section “Malignant and non-malignant central airway disorders” and “Operative bronchoscopy”</td>
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<tr>
<td></td>
<td>Non-technical skills scenarios</td>
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</tbody>
</table>

### Quantitative Assessment with Logbook (Minimum Volume)

**No. of Procedures:**
See section: “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” and “Operative bronchoscopy procedures”
To reach the specific competence for lung transplantation the learning curve is longer (20% more).

### Qualitative Assessment

- MCQ
- Case-based questionnaires
- DOPS for flexible and rigid bronchoscopy

### Outcome Assessment

- Assessment of outcomes and complications

### Competence Maintenance (by Logbook)

**No. of Procedures / Year:**
- See section: “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing” and “Operative bronchoscopy procedures”

### Recommended Literature


### 5.8 Emergency in IP

#### Introduction
The main indications are tracheobronchial obstructions and haemoptysis. Obstructions are described in sections 4.1 through 5.1. Bronchoscopy can be used to investigate haemoptysis. CT scans have changed diagnostic procedure protocols and should always be considered prior to bronchoscopy. Consider bronchoscopy after a normal CT if the patient is high risk for lung carcinoma or if the haemoptysis continues.

Training should therefore be focussed on the management of bleeding and tracheobronchial stenoses.

The tools for practical training include low and high fidelity simulation, although non-technical skills and team simulation are especially recommended.

#### Indications for the Procedure
- Haemoptysis
- Tracheobronchial stenosis
- Foreign bodies

#### KNOWLEDGE & SKILLS

<table>
<thead>
<tr>
<th>Prior Experience Requirements</th>
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<tbody>
<tr>
<td>Trainee must have completed training described in sections on “Malignant and non-malignant central airway disorders”, “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”, “Operative bronchoscopy procedures” and “Paediatric bronchoscopy”</td>
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<table>
<thead>
<tr>
<th>Knowledge</th>
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<tbody>
<tr>
<td>Specific knowledge: Knowledge on techniques for airway control and oxygenation/ventilation Equipment for bronchoscopy in emergency</td>
</tr>
<tr>
<td>Haemoptysis:</td>
</tr>
<tr>
<td>- Causes of haemoptysis</td>
</tr>
<tr>
<td>- Treatment flowchart for massive haemoptysis</td>
</tr>
<tr>
<td>- Indications and contraindications for bronchoscopy</td>
</tr>
<tr>
<td>- Techniques of interventional radiology for angiography and embolization</td>
</tr>
<tr>
<td>Foreign bodies removal:</td>
</tr>
<tr>
<td>- Causes in different ages</td>
</tr>
<tr>
<td>- Clinical history and physical exam elements</td>
</tr>
<tr>
<td>- Radiographic interpretation</td>
</tr>
<tr>
<td>- Indication for bronchoscopy removal and proper technique</td>
</tr>
<tr>
<td>Tracheobronchial stenosis Causes</td>
</tr>
<tr>
<td>- Indications for rigid bronchoscopy and ablation technique and stent</td>
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<tr>
<td>- Indications for surgical correction and tracheostomy</td>
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<tr>
<td>Knowledge of medical legal issues</td>
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<thead>
<tr>
<th>Core Basic Skills</th>
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<tbody>
<tr>
<td>- Haemoptysis:</td>
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<tr>
<td>- Selection and interpretation of appropriate imaging to assist in the diagnosis of haemoptysis</td>
</tr>
<tr>
<td>- Ability to use the technique for airway control and oxygenation/ventilation</td>
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<tr>
<td>- Ability to selectively intubate the patient with flexible bronchoscopy</td>
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<tr>
<td>- Ability to perform a cardiopulmonary resuscitation</td>
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<tr>
<td>- Ability to administer correctly drugs such as adrenaline, ornipressin and tranexamic acid</td>
</tr>
<tr>
<td>- Ability to perform a mechanical tamponade with balloon, blocker tubes and rigid bronchoscope</td>
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</tbody>
</table>
- Foreign bodies:
  - selection and interpretation of appropriate imaging to aid in the diagnosis of paediatric airway foreign body.
  - selection and assembly of appropriate instrumentation for bronchoscopic foreign body removal.
  - master the technical skills of direct laryngoscopy and bronchoscopy with removal of a main stem foreign body.
  - recognise and respond to a range of possible complications during bronchoscopy, including laryngospasm and desaturation.
  - ability to assist with anaesthesia and cooperate with operating room staff during preparation for and removal of an airway foreign body.

For tracheobronchial stenosis: see sections on the subject

<table>
<thead>
<tr>
<th>Procedural Steps for Practical Training (Check list)</th>
</tr>
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<tbody>
<tr>
<td><strong>Bleeding after biopsy (CHEST live learning):</strong></td>
</tr>
<tr>
<td>- <strong>Step 1:</strong> wedge the bronchoscope</td>
</tr>
<tr>
<td>o Maintain wedge position after biopsy (1-2 minutes)</td>
</tr>
<tr>
<td>o Avoid suctioning after biopsy</td>
</tr>
<tr>
<td>- <strong>Step 2:</strong> safety position (lateral decubitus)</td>
</tr>
<tr>
<td>o Turn the patient onto a safety position (bleeding side down) to protect the contralateral airway</td>
</tr>
<tr>
<td>o Allow face to face contact with patient if operator working from the front or side of the patient</td>
</tr>
<tr>
<td>o Allow blood and secretions to flow from the larynx and out of the corner of the mouth</td>
</tr>
<tr>
<td>o Avoid collapse of the larynx and laryngeal obstruction by tongue or oedematous upper airway</td>
</tr>
<tr>
<td>o Oral pharynx easily suctioned</td>
</tr>
<tr>
<td>- <strong>Step 3:</strong> saline lavage</td>
</tr>
<tr>
<td>o Immediate administration of large aliquots of iced saline using a wedged or partially wedged bronchoscope and continuous or intermittent suction and gravity dependent clot formation, which will stop most bleeding</td>
</tr>
<tr>
<td>- <strong>Step 4:</strong> intubation with cuffed endotracheal tube</td>
</tr>
<tr>
<td>o If bleeding persists and airway is compromised, intubate the patient</td>
</tr>
<tr>
<td>o Selective main stem intubation may be necessary</td>
</tr>
<tr>
<td>- <strong>Step 5:</strong> insert bronchial blockers (the bronchial blocker can be inserted inside or outside endotracheal tube)</td>
</tr>
<tr>
<td>o Bronchial blockers placement into bleeding site may be considered</td>
</tr>
</tbody>
</table>

In the event of significant unexpected bleeding (*Thorax*, 2013 Aug;68 Suppl 1:i1-i44):

- Ensure adequate oxygenation and IV access for fluid resuscitation. Vital signs should be monitored regularly.
- Retract the bronchoscope proximally to maintain vision; apply suction to remove free blood so as to preserve airway patency. Consider lying patient onto the side of the bleeding. Do not suction to remove clot.
- Consider the application of local vasoconstrictor therapy. Agents include 5-10ml 1:10000 epinephrine or 5-10ml 4°C saline. Saline has the advantage that it may be administered repeatedly.
- If bleeding continues, the bronchoscope should be wedged into the bleeding segmental bronchus, if possible, and held in place for 10-15 minutes.
- If this does not control the bleeding, a balloon catheter can be used to apply pressure and isolate the segment.
- Check platelet count, PT and PTT, and recheck drug history.
- Seek senior/expert assistance, and consider referral to critical care

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<th>Theoretical and Practical TRAINING: Resources and Assessment Tools for “CORE COMPETENCES”</th>
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**GENERAL THEORETICAL AND PRACTICAL TRAINING COMMON TO ALL PROCEDURES**

For Flexible bronchoscopy and related procedures, see section: “Flexible bronchoscopy and basic biopsy technique: endobronchial biopsy, transbronchial biopsy, TBNA, ROSE, BAL, brushing”

For Rigid bronchoscopy training, see section: “Operative bronchoscopy procedures”

**Specifically for bronchoscopy:**
- Case-based discussions
- Low and high fidelity simulation. BRONCH Mentor has a specific module for haemoptysis
- Non-technical skill scenarios

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<td>• DOPS for flexible and rigid bronchoscopy</td>
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5. Griffin GR, Thorne MC. Validity and Efficacy of a Pediatric Airway Foreign Body Training Course in Resident Education. American Society of Pediatric Otolaryngology/COSM, Chicago, IL. May 2011