

Developing a simulation-based training curriculum in transesophageal ultrasound with the use of the endobronchial ultrasound-endoscope

Leizl Joy Nayahangan¹, Paul Frost Clementsen¹, Alison Doubleday², Janet Riddle², Jouke T. Annema³, Lars Konge^{1,4}

¹Copenhagen Academy for Medical Education and Simulation, Centre for Human Resources and Education, The Capital region of Denmark, Copenhagen, Denmark; ²Department of Medical Education, University of Illinois at Chicago, Illinois, USA; ³Department of Respiratory Medicine, Amsterdam UMC, University of Amsterdam, Amsterdam, Netherlands; ⁴Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark

ABSTRACT

There is an increasing need to focus on how best to train respiratory physicians to perform EUS with bronchoscope-guided fine-needle aspiration biopsy (EUS-B-FNA). At current, training is mostly performed in the clinical environment under expert supervision; however, the advent of simulation-based education now provides a low-risk setting for novice trainees to learn and practice basic endosonography skills from identifying and understanding normal anatomy as well as pathology, maneuvering of endoscope, interpretation of images, and mastering of sampling techniques. In this descriptive educational paper, we used a six-step approach as a framework to describe the development of a structured training program combining EUS-B-FNA with the already well-established certification training program in endobronchial ultrasound transbronchial needle aspiration. This comprehensive training curriculum includes a theoretical course to achieve foundational knowledge, followed by simulation-based training until mastery standards are met, and supervised clinical apprenticeship. All steps should end with an objective assessment to achieve certification. This systematic development will hopefully encourage endosonography leaders and educators to collaborate and implement an evidence-based comprehensive endosonography curriculum that aims to provide the trainee with the essential EUS-B competencies to ensure that lung cancer patients are diagnosed and staged correctly.

Key words: endobronchial ultrasound, endosonography, EUS with bronchoscope-guided fine-needle aspiration, simulation, training

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Address for correspondence

Dr. Leizl Joy Nayahangan, Copenhagen Academy for Medical Education and Simulation, Ryegade 53, Copenhagen, Denmark.
 E-mail: leizl.joy.nayahangan@regionh.dk

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INTRODUCTION

EUS with bronchoscope-guided fine-needle aspiration biopsy (EUS-B-FNA) is gaining ground in pulmonary medicine and is recommended as a safe and effective approach in the diagnosis and staging of lung cancer in addition to endobronchial ultrasound transbronchial needle aspiration (EBUS-TBNA).^[1,2] Other diagnostic indications include mediastinal cyst, suspected sarcoidosis mediastinal metastases of esophageal and extrathoracic malignancies.^[3] EUS can be performed either with a conventional curvilinear gastrointestinal echoendoscope (EUS) or using the EBUS-scope in the esophagus (EUS-B).^[2] The esophageal approach gives access to paraesophageal lymph nodes and lung tumors and also structures under the diaphragm such as the left adrenal gland,^[4,5] retroperitoneal lymph nodes, and the liver,^[6] while the endobronchial approach provides access to structures close to the large airways.^[2] The two procedures are complementary in their diagnostic reach, and the combination is preferred for mediastinal nodal staging in patients with suspected or proven non-small-cell lung cancer. Several studies have shown positive effects when performing EBUS-TBNA combined with EUS-B-FNA.^[1,3,7,8] One study found that the combination of these two provided additional clinically relevant staging information in 10% of patients.^[8] Furthermore, an EUS-B approach to lymph nodes paratracheal to the left and in the lower mediastinum is often easier compared to a transbronchial approach because the cough reflex and cartilage rings are absent.

There has been a debate whether gastroenterologists or respiratory physicians should perform EUS-B.^[9,10] Respiratory physicians are directly responsible for the complete diagnostic workup of the lung cancer patient including the performance of bronchoscopy.^[11,12] A diagnostic strategy in which a patient undergoes a bronchoscopy combined with EBUS and EUS-B in a single session following positron emission tomography-computed tomography is preferred.^[2] Therefore, respiratory physicians should be trained not only in EBUS but also in EUS-B-FNA.^[11-14] We must now focus on how best to train respiratory physicians to perform EUS-B-FNA without compromising diagnostic yield and patient safety.^[11,13] The current guidelines by the European Society of Gastrointestinal Endoscopy in cooperation with the European Respiratory Society (ERS) underline the need for training in EUS-B-FNA^[2] and the importance

of developing optimal and efficient educational interventions to ensure that basic competencies are acquired before performing supervised procedures in patients.

Training of this procedure is mostly performed on patients under the tutelage of a skilled supervisor. Trainee participation in advanced interventional pulmonology cases increases procedure time and amount of sedation used and may increase complications.^[15] Furthermore, it can be a challenge for trainees to receive ample exposure to learning procedures in the clinical environment. Simulation-based training is a transformative addition to procedural training in response to urgent calls to mitigate medical and surgical errors to promote patient safety.^[16] It provides a low-risk setting that allows a learner-centered experience where novice operators are able to learn and practice procedural skills such as basic endosonography skills-from identifying and understanding normal anatomy as well as pathology, maneuvering of endoscope, interpretation of images, and mastering of sampling techniques. While there are evidence-based simulation-based training programs for EBUS-TBNA,^[17] there is no standardized training for EUS-B-FNA.

In this narrative, educational paper, we propose the development of a training curriculum in EUS-B-FNA as an addition to the already existing EBUS-TBNA structured training program. The goal would be a comprehensive endosonography curriculum that combines EBUS-TBNA and EUS-B-FNA. We will use the six-step approach to curriculum development as a foundational framework [Figure 1]:^[18]

1. Problem identification and general needs assessment;
2. Targeted needs assessment;
3. Goals and objectives;
4. Educational strategies;
5. Implementation;
6. Evaluation.

STEP 1. PROBLEM IDENTIFICATION AND GENERAL NEEDS ASSESSMENT: ESTABLISHING THE NEEDS FOR CHANGE

At present, the selection of what to develop as a training program in a simulated setting is mostly based on commercially available simulation equipment or local management decisions. The increasing availability of innovative, state of the art simulation equipment is often

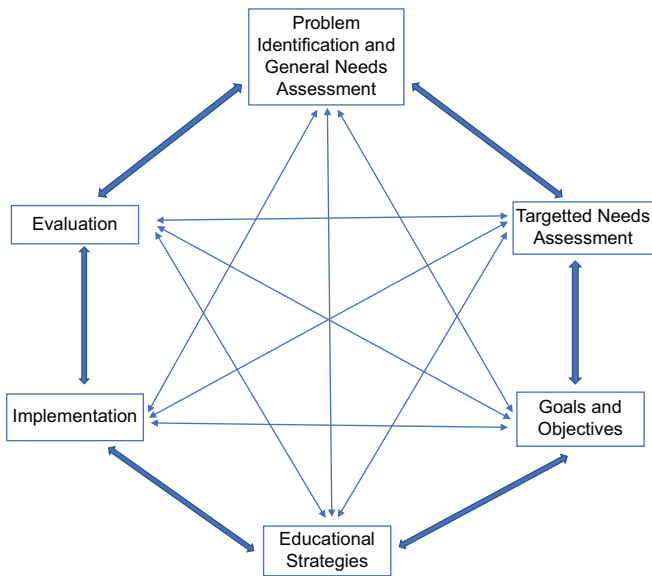


Figure 1. The six-step approach to curriculum development, Adapted from Thomas PA, Kern DE, Hughes MT, *et al.* Curriculum Development for Medical Education: A Six-Step Approach. John Hopkins University Press; Baltimore, Maryland, USA; 2016.

a tempting impulse for educators to take advantage of however this runs the risk of equipment not being utilized properly because there is simply not enough need nor demand. These expensive simulators risk ending up in the corner of a department gathering dust. Identifying the problem and performing a needs assessment is an important step to ensure that the development of training programs is grounded in current trainee needs. This can be performed by involving experts in the field who are able to provide relevant and valuable information regarding the topic and who are nationally and internationally dispersed to ensure generalizability.^[19,20] In 2016, key opinion leaders in pulmonary medicine were involved in a three-round iterative survey process and have achieved consensus on 11 technical procedures that should be developed as simulation-based training programs, of which EUS-B-FNA ranked fourth, further underlining the need for training in this procedure.^[21] Additionally, the need to provide training in EUS-B-FNA has been recognized and specified in previous guidelines.^[2,22-24]

STEP 2. TARGETED NEEDS ASSESSMENT: DEFINING YOUR LOCAL CONTEXT AND SETTING

Recognizing differences among trainees and in training requirements in different countries, it is important to examine the need for training EUS-B-FNA in the local setting. A targeted need assessment explores (1) the learning needs of trainees who will participate in the simulation training (the gap between their current

and intended levels of competence) and (2) the local patient care context.^[18,19] The primary stakeholders in this training program are the trainees who will benefit from the training and whose learning outcomes will be measured. Simulation-based training has been shown to benefit novices and intermediate trainees with limited clinical experience; however, it also provides an opportunity for experienced doctors to learn new procedures.^[25,26] Additionally, it could also pave the way for certification and recertification for expert EUS-B-FNA operators.^[2]

When investigating the local context, it is important to involve not only the targeted learners but also other stakeholder groups such as the management (*e.g.*, heads of department) and the faculty (*e.g.*, respiratory consultants as instructors). Questions or concerns of the different stakeholders about the educational problem should be explored, as well as the outcomes of the training program that are of greatest interest for the groups. This will define the content and scope of the EUS-B-FNA training program depending on the local context and setting as well as inform the succeeding steps in developing the curriculum.

STEP 3. GOALS AND OBJECTIVES: DEFINITION OF LEARNING OUTCOMES

After performing a needs assessment to understand the learners and the training environment, the next step is to define the goals and objectives. The learning objectives of a simulation-based training curriculum of EUS-B-FNA could include:

1. To describe the anatomy, theoretical approach, indications and contraindications of EUS-B-FNA.
2. To demonstrate correct insertion and navigation of the endoscope as well as produce endosonographic pictures
3. To recognize and demonstrate the different anatomic landmarks
4. To demonstrate correct biopsy technique using sheet and needle.

Learning objectives drive the development of learner assessment. The Miller's pyramid provides a framework for designing and matching learning outcomes and assessment of competence [Figure 2]. The four levels include knowledge (knows), how knowledge is employed (knows how), competence or the demonstration of performance (shows how), and action such as independent clinical practice (does).^[27] The assessment provides an insight into the actual

performance and should be measured using assessment instruments with validity evidence and set standards or benchmark measures to ensure competence.^[28,29] This is in contrast to conventional practices in which procedural numbers are used to define when a trainee reaches competency. Studies reported that the performance of 50 EBUS-TBNA procedures^[30,31] or 20 EUS-FNA procedures^[32] does not ensure competency. Simulation plays a vital role in assessment and allows conditions for testing to be standardized across learners, cases, scenarios, and other critical tasks. Training and assessment can be tailored to provide feedback (formative assessment) or for testing and certification (summative assessment). A valid tool to assess EBUS performance in simulation and in the clinical environment is the EBUS Assessment Tool (EBUSAT).^[17] To assess trainee competence in EUS specifically for the mediastinal staging of non-small cell lung cancer, the EUS Assessment

Tool (EUSAT) has been developed and evidence of validity was established.^[33] EUSAT evaluates anatomical knowledge and technical skills when performing EUS-FNA starting with insertion of the scope followed by a systematic approach to identify the six anatomical landmarks [Figure 3]. It can be used as a formative tool by providing systematic feedback during training or as a summative tool to assess trainee competency.

STEP 4. EDUCATIONAL STRATEGIES: ESTABLISHING A COMPREHENSIVE COMPETENCY-BASED ENDOSONOGRAPHY TRAINING PROGRAM

Central to this descriptive paper is the choice of educational strategies that will yield the optimal results for trainees to learn endosonography. Ideally, a comprehensive competency-based training program in endosonography should incorporate all levels of

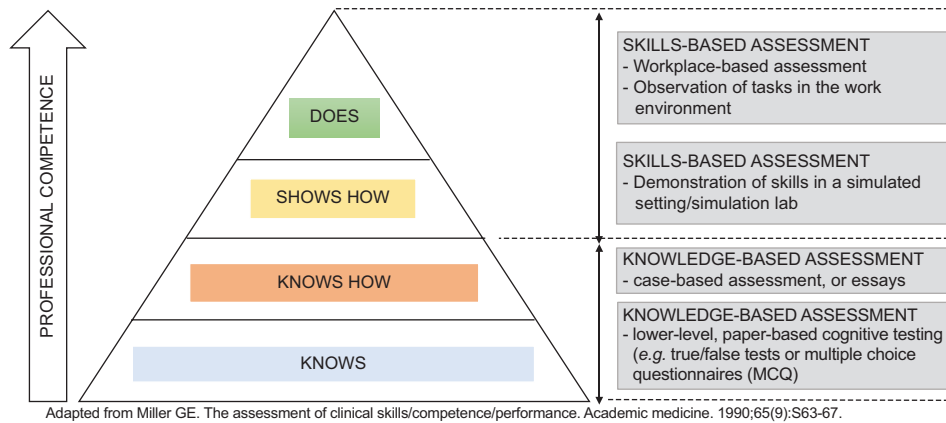


Figure 2. Miller’s pyramid of professional competence

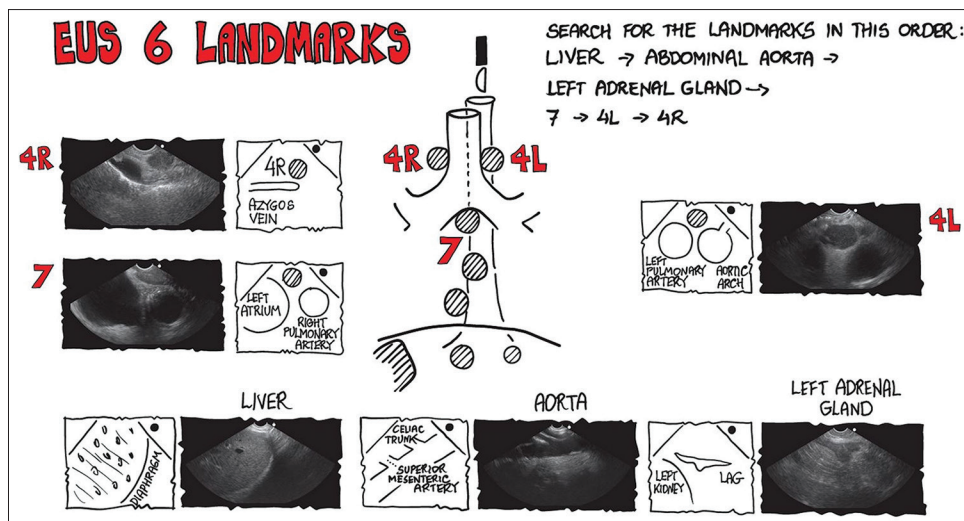


Figure 3. The six EUS-B anatomical landmarks, Owner of image copyright, Paul Frost Clementsen

Miller's pyramid including foundational knowledge in different topics as well as procedural skills.^[14,34,35] The Europe-wide EBUS training program implemented by the ERS follows this approach divided in three parts:^[36] Part 1-online self-directed modules; Part 2-intensive simulation-based training complemented with active clinical observation; Part 3-supervised training in the clinical environment. All three parts conclude with an assessment that needs to be successfully completed to be certified. This structured training program can be expanded to include EUS-B-FNA with focus on three main topics:^[37] (1) Pattern recognition-this includes learning and mastering the six anatomical landmarks for basic pattern recognition in EUS, as well as the six landmarks for EBUS-TBNA. (2) Handling of the endoscope-both the EBUS-TBNA and EUS-B-FNA procedures use the same endoscope, which provides efficient opportunity to train proper maneuvering and navigation of the endoscope, as well as taking images. (3) Sampling technique which includes positioning the transducer correctly and using the sheath and the needle for sampling. These can be initially trained in a simulated setting using table-top trainers such as manikins or phantoms, animal organs, live anaesthetized animals, or virtual reality simulators. Training is tailored according to individual needs, capabilities, and learning progress.^[38] This mastery learning approach

include rigorous deliberate practice involving focused, repeated practice of tasks with provision of immediate feedback.^[38-40] A four-step simulation-based training approach is proposed^[41] [Figure 4]:

1. *Theoretical preparation (Foundational knowledge)* consisting of reading materials such as practical handbooks and scientific papers; and e-learning (*i.e.*, instructional videos)
2. *Introduction by a specialist* in respiratory medicine provides the introduction to the procedure, learning goals and objectives, and the simulation equipment
3. *Self-training following* directed self-regulated learning where a trainee practices in a structured environment with an instructor or training assistant^[42]
4. *Assessment.* The practical, summative assessment of competencies using the EUSAT is performed individually and by the same specialist who delivered the introduction.

STEP 5. IMPLEMENTATION. WIDE IMPLEMENTATION OF THE SIMULATION-BASED TRAINING IN ENDOSONOGRAPHY

Well-planned implementation of the training program will increase the likelihood of achieving the desired outcome^[43]-that is, a comprehensive competency-based

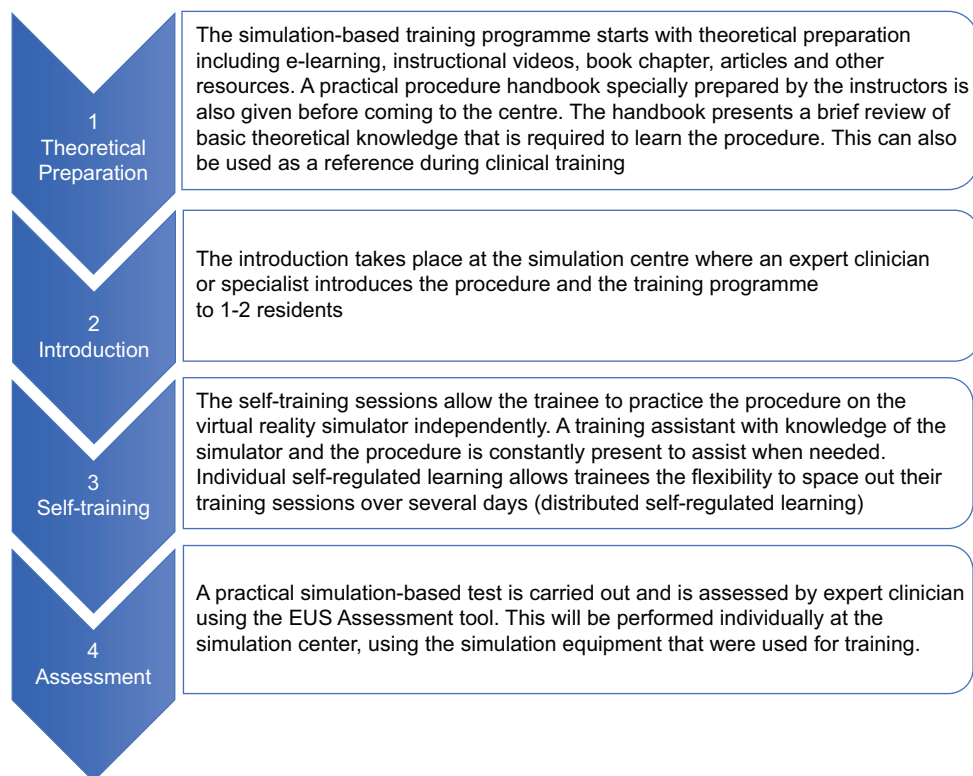


Figure 4. The 4-step approach for simulation-based training

endosonography training program that is implemented across different geographical locations with a high rate of participation. Involving of key stakeholder groups in the beginning phase (*i.e.*, general needs assessment) will obtain explicit buy-in and support for the program. The already established ERS-EBUS certification program could facilitate the implementation of an extended curriculum to include EUS-B-FNA. At current, trainees in Europe attend and complete the training program at three dedicated centers in Copenhagen, Heidelberg, and Amsterdam.^[44] The goal is to expand the training centers to other countries (*i.e.*, Greece, Italy) to cater for the increasing number of respiratory physicians wanting to learn the procedure. Implementation is a complex process that entails different contributing factors. Some of the important considerations are discussed below:

Personnel

A simulation training program director (*e.g.*, an expert respiratory physician with extensive experience in endosonography and simulation) should lead the training program—from ensuring relevant content to teaching as well as collaborating with other stakeholders to promote acceptability and attendance. Dedicated and trained administrative staff, as well as training assistants should be available. These could be medical students trained to assist the trainees when needed, allowing self-regulated learning.^[45]

Time

Time (especially protected time) is one of the main barriers to implementation of simulation-based training.^[46,47] The concept of directed self-regulated learning is ideal as trainees tailor their training time accordingly.^[42] Additionally, this approach to learning also addresses one of the challenges in simulation that is the need for substantial faculty staff time.^[42]

Facilities and equipment

Training centers should be accessible to trainees, equipped with a variety of simulation equipment. One of the main challenges however is the shortfall of EUS-B-FNA simulation-based equipment.^[21,48] With the advent of new technological advances as well as growing evidence for its use and the need for training, we hope that this will inspire a supportive collaboration among experts in the field, the societies, and simulator companies to develop and produce practical simulators for training.

STEP 6. EVALUATION AND FEEDBACK END OF COURSE EVALUATION

The evaluation at the end of the training program provides information on whether the goals and objectives are met and if improvements of the curriculum are needed. Therefore, careful design of evaluation questions should be maintained and should be in congruence with the course objectives and the defined learning outcomes. One of the widely used frameworks to guide the development of evaluation plans is the Kirkpatrick's levels of evaluation *where* level 1 explores the learners' satisfaction of the training program; level 2 evaluates if there is an improvement in knowledge, skills and attitude following training; level 3 evaluates behavioral change or if there is transfer of learning from the simulated setting to the work environment; and finally level 4 measures how training benefits organizational practice and most importantly patient outcomes.^[49] The evaluation plan for this comprehensive training program will extend beyond merely measuring learner satisfaction and instead explore to what extent have the trainees acquire the intended knowledge, skills, and attitudes as a result of participating in training program (Level 2). A strength of the assessment instruments (EBUSAT and EUSAT) discussed above is the objective evaluation of knowledge and skills which correspond to levels 2 and 3 of the Kirkpatrick model. Following the assessment of competencies after simulation-based training, the next step should include the evaluation of transfer from the training center to the clinical environment (level 3) and ultimately how training impacts patient outcomes (level 4).

CONCLUSION

There is a huge need for training of EUS-B-FNA for the diagnosis and staging of patients suspected of lung cancer among respiratory physicians. A structured training program combining EUS-B-FNA with the already well-established certification training program in EBUS-TBNA can be designed and implemented. This includes a three-step approach starting with a theoretical course for foundational knowledge, followed by simulation-based training and supervised clinical apprenticeship. Objective assessment of all these steps should be mandated towards certification. We hope that this systematic development presented with conceptual definitions will inspire endosonography leaders, educators, and companies to join forces, establish

and implement an evidence-based comprehensive endosonography curriculum. The overall purpose of this training curriculum is to ensure that lung cancer patients are diagnosed and staged correctly in order to be able to offer the treatment that leads to the greatest likelihood of improving the patients' prognosis.

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Conflicts of interest

Lars Konge is an Editorial Board Member of the journal. The article was subject to the journal's standard procedures, with peer review handled independently of this editor and his research group.

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