

Evidence-based recommendations for establishing and implementing an EUS program: Recommendations for sustainable success and improved clinical outcomes across the continuum of care

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BACKGROUND

“Since its introduction, in the 1980s, endoscopic ultrasonography has been shown to be a safe and effective diagnostic and therapeutic tool for the evaluation of hepatobiliary and gastrointestinal conditions.”^[1] Interventional endoscopy, which includes ERCP and EUS, can provide both diagnostic and therapeutic benefits to many types of patients. EUS has been adopted into numerous interventional techniques and strategies that promise to improve diagnosis and management of gastrointestinal (GI) cancers. EUS has matured beyond its conventional role in locoregional staging of GI cancers and should be a standard of care recognized as a well-established procedure. EUS can assist gastroenterology providers with the detection of intraductal extension of adenomas and the detection and staging of pancreatic cancer and can serve as an adjunct to traditional imaging studies, such as computed tomography (CT) and magnetic resonance imaging (MRI). EUS has been proven to be clinically

superior to CT, MRI, and transabdominal ultrasound for tumor staging in multiple clinical studies. It is also a tremendous clinical asset for staging GI cancers such as gastric, ampullary, rectal, cholangiocarcinoma, and esophageal and other cancers such as lung cancer. EUS is well documented in assessing for chronic pancreatitis and evaluating thick gastric folds and pancreatic lesions, masses, stones, and strictures. The addition of an EUS program to an existing core and/or interventional gastroenterology program can be advantageous for healthcare facilities, interventional endoscopists, patients, and communities. In an effort to drive quality and value in endoscopy, PENTAX Medical (Canada) held an advisory board in September 2018 during the Forum for Canadian endoscopic UltraSound (FOCUS) in Montreal, Canada. The goal of this panel discussion was to develop a framework to assist physicians in establishing an EUS program in

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their hospital. In attendance were physicians with a wide range of experience, who either had well-established programs with high patient volumes or were aiming to implement a new program at their facility. The considerations for discussion were personal experiences and challenges with EUS programs, considerations before starting new EUS programs, building a business case to start new EUS programs, and EUS training program requirements.

STAGES OF PROGRAM IMPLEMENTATION

Introductory discussions and exploration

Dynamic discussions were conducted around the consideration for starting a new EUS program as well as the challenges related to funding in Canada. Many physicians indicated that their programs were made possible by generous donations from their hospital foundations and that one of the obstacles they faced in starting a new program was the tight operating budgets of their respective endoscopy units. After much deliberation, it was concluded that for an EUS program to be sustainable and cost-effective, an internal evaluation team should be formed. This team would be responsible for assessing the program objectives, conducting a formal needs analysis, and establishing metrics for successful implementation. The team should ideally be composed of gastroenterology department leadership, nursing leadership, EUS providers, materials management personnel, pathology department leadership, radiology department leadership, surgical department leadership, and procurement and medical device reprocessing department leadership. A project plan should be created that includes the goals of the program, target patient populations, physician oversight of the program, training needs and costs, equipment acquisition costs, reprocessing needs, physical footprint (such as space and power supply), and marketing of the program to referring physicians, regional cancer centers, and other healthcare facilities. Most EUS endoscope manufacturers have project planning templates and support resources to assist with planning and implementation of such programs.

Implementation planning and strategy

During the initial implementation phases, the healthcare facility and gastroenterology leadership should establish a method to assess EUS provider competency within the scope of the procedures they will be performing.^[2]

Establishing goals and objectives early in the process ensures that success can be achieved and measured and highly reliable patient care can be provided. In addition, training would be required for physicians, nurses, and reprocessing personnel before implementation of the program.

The American Society for Gastrointestinal Endoscopy (ASGE) formally recommends that EUS programs use The EUS and ERCP Skills Assessment Tool (TEESAT), which is a competency-driven assessment tool for both EUS and ERCP. This well-researched tool evaluates both cognitive and psychomotor skills and ensures that EUS provider competency can be objectively assessed using a standardized instrument. This tool can also be used as a formal professional development tool to develop EUS providers who are at more mature career stages through fellowships.^[3-5]

In 2016, Drs. N. Arya., A. V. Sahai, and S. C. Paquin published an article reviewing the current practices for EUS credentialing in Canada and proposed new guidelines that were discussed at the FOCUS. They proposed guidelines to help institutions assess the training and competency of endosonographers for credentialing purposes.^[6] The principles of competency validation should extend to healthcare support staff to include clinical nursing and reprocessing personnel. These healthcare professionals, while part of the procedural support team, play an instrumental role in assisting the physician during the procedure and are equally important in maintaining the EUS endoscope safely and in accordance with the manufacturer's instructions for use. Damage to EUS endoscopes can be costly, increase risk of nosocomial infections, and create delays in care to patients. Therefore, extensive training on the handling, reprocessing, and storage of these devices is an essential component of a well-defined EUS program strategy.

EUS platform implementation

An EUS program can add new clinical services to an existing core and interventional gastroenterology program. When adding EUS services, a healthcare facility must also ensure that adequate support is available from other internal departments, such as radiology, oncology, general surgery, and pathology. During discussions regarding communication with other hospital programs, Drs. James, Wyse, and Levy all spoke about the success they have had in collaborating with

the surgical and oncology groups at their respective facilities and the benefits this collaboration has brought to the patients as well as the institutions. An estimated clinical volume of procedures should be shared with these support functions before program implementation to ensure that the clinical needs of EUS procedures can be met within specific timeframes. Utilizing these estimates will help ensure that there are no delays to patient care and diagnosis and may reduce costs in the delivery of the EUS program.

Healthcare facilities should work collaboratively with the EUS endoscope manufacturer to create a plan for equipment delivery, installation, and troubleshooting before commencing the program. Creating a test room where interoperability can be tested is extremely beneficial and will reduce the possibility of systems issues once the EUS program is officially launched. The device manufacturer serves as the facility's best resource for device information, informatics, clinical and reprocessing training, troubleshooting, servicing, and instructions for use.

Onsite clinical support

It is prudent to work collaboratively with the EUS technology's original equipment manufacturer to conduct on-site product support through the availability of clinical specialists and product experts. These experts should be available for the initial implementation to provide case support and serve as experts for the EUS providers and associated healthcare support staff. The learning curve for EUS procedures is steep, but the process can be expedited when proper clinical support infrastructure is in place at the healthcare facility level. Clinical nursing personnel and clinical administration leaders are critical components of the equation for successful program implementation. Training for clinical nursing personnel is available from multiple sources and professional societies. For healthcare facilities with limited experience to EUS procedures, it may also be beneficial for both clinical nursing personnel and EUS physicians to visit other healthcare facilities with more mature EUS programs to conduct on-site observations and learn about strategies for successful long-term success of community EUS programs. This on-site experience offers an opportunity for both disciplines to gain valuable insights and expertise in how to handle patient needs, the EUS scopes, reprocessing challenges, and the potential need for additional training on

third-party devices that might be passed through the endoscope during the EUS clinical procedure.^[7]

Finally, the EUS program must consider additional clinical stakeholders such as anesthesia providers and reprocessing professionals. The EUS providers, clinical nurses, reprocessing professionals, and anesthesia providers must establish a clinical flow plan that will meet the needs of the EUS providers, provide for a safe and comfortable patient care experience, and ensure containment of healthcare delivery costs. Due to the high costs of EUS endoscopes, reprocessing personnel should receive comprehensive training from the device manufacturer on the official reprocessing instructions for use to include all relevant steps of scope handling, from the withdrawal of the scope to the storage of the device postprocedure.

Program evaluation

Once an EUS program is implemented, it is critical to conduct ongoing evaluation of the program's effectiveness from a medical perspective, access to care, and financial standpoint. The Institute for Healthcare Improvement Triple Aim initiative is a good frame of reference for program evaluation. The EUS program should positively contribute to effective population health management, improve the clinical experience of care for the patient, and reduce the per capita costs of healthcare delivery. In the province of Ontario, it has been estimated that there exist significant differences in the access to EUS care based on a patient's geographical location.^[1] Based on the patient care needs of a given geographical area, a healthcare facility that establishes a comprehensive EUS program can provide patients in the local community access to interventional endoscopy and improve overall clinical outcomes and access to care.

EUS program leaders and healthcare administrators must work collaboratively to measure preestablished metrics of success, operationalize identified opportunities for improvement, and regularly evaluate the overall clinical care system. Findings should be shared and interprofessional teams can work collaboratively to address any potential challenges. Equipment should also be carefully maintained according to the manufacturer's recommended maintenance schedule, and service should be conducted only by specially trained manufacturer's service professionals.

RECOMMENDATIONS FOR CREDENTIALING AND GRANTING PRIVILEGES FOR EUS

The ASGE has published extensive guidelines for credentialing and granting EUS privileges. These evidence-based guidelines are critical for healthcare facilities and providers to closely follow to ensure the safety and efficacy of an EUS program across the healthcare continuum of care. A few of the core recommendations from this guideline are summarized below:^[8]

1. Credentialing for EUS procedures should be handled completely independently from any other privileging processes, such as core or interventional gastroenterology procedures;
2. Competency of an EUS provider must be assessed through academic and clinical training as well as cognitive competency;
3. The EUS provider should have successfully completed a formal training program in the form of a Fellowship or Residency;
4. The EUS provider should demonstrate ongoing competency in the form of continuing education for EUS privileges to be maintained;
5. EUS providers must have a comprehensive knowledge of the indications, contraindications, benefits, and risks of the procedures and can communicate these effectively to the patient;
6. EUS providers must follow all facility rules and local regulations regarding the informed consent process;
7. EUS providers must demonstrate the ability to readily and correctly interpret EUS images and make appropriate patient diagnoses.

Furthermore, ASGE has established recommended minimum numbers of EUS procedures for EUS providers that must be performed before proper competency can be assessed. The guidelines recommend a minimum of 125 supervised cases for both mucosal and submucosal clinical abnormalities and 150 supervised cases for comprehensive competency. In Canada, the FOCUS group proposed that “trainees undergo ‘hands-on’ training in at least 250 supervised cases,” including the provision that “trainees should perform at least 50 fine needle aspirations independently, and work on 100 pancreatic cases, 25 rectal cases, and at least 10 celiac plexus blocks/neurolysis. Other therapeutic cases, such as pseudocyst drainage, should be dependent on the training center availability and expertise.”^[6]

There does, however, remain conflicting information in the clinical literature regarding the recommended cases required to demonstrate competency. Therefore, healthcare facilities should carefully evaluate all available recommendations and then establish their preferred recommendations for EUS provider competency assessment and ongoing education requirements.

SUMMARY

EUS programs can be important tools of improvement in patient care of healthcare facilities and interventional endoscopists. These programs require a comprehensive and interprofessional approach to strategic planning, goal setting, implementation, training, and program maintenance. The healthcare facility should closely monitor the quality indicators and clinical outcomes of its EUS program and report these findings to all EUS program stakeholders. There are significant clinical benefits in making EUS available to patients, and with proper training, implementation, and ongoing monitoring, as described in this whitepaper, a comprehensive EUS program can transform a healthcare facility into a regional or national Center of Excellence. EUS providers and their teams should commit to ongoing learning, professional development, and adherence to established evidence-based clinical recommendations to deliver the highest level of clinical care to patients served by this interventional technique.

Conflicts of interest

Disclaimer: This educational whitepaper was produced in collaboration with the PENTAX Medical Clinical Affairs team and is based on the current evidence-based recommendations from professional clinical societies, the findings in the peer-reviewed literature, and in no way constitutes a medical recommendation. Healthcare facilities and EUS providers should comply with all local rules, regulations, and laws regarding the delivery of clinical care.

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