

## Establishing a quality indicator format for endoscopic ultrasound

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### Abstract

**AIM:** To perform a quality control (QC) review of endoscopic ultrasound (EUS) with emphasis on current consensus established quality indicators.

**METHODS:** A national quality control study of EUS was performed with expanded international comparison. Ten different healthcare institutions in Israel participated in coordination with University of Chicago Medical Center. Each Israeli center provided ten patient reports, compared with twenty reports from University of Chicago Medical Center. Quality indicator forms were prepared with sections to be completed before, during, and after EUS. Physician compliance to all listed indicators was

evaluated. Quality indicators were evaluated prior to, during, and after performing EUS.

**RESULTS:** One hundred different EUS procedural reports were analyzed. The mean patient age was 59 years old. Indications for referral were mostly for pancreatic or biliary reasons. QC showed several strongly reported areas, including indications for EUS (97%), anesthesia given (94%), periprocedural pancreatic evaluation (87%), and an overall summary of the EUS examination (82%). Intermediately reported areas included patients' pertinent past medical history (71.7%), evaluation of the biliary tree (63%), and providing medical guidance about potential procedural adverse events, including pancreatitis and bleeding (52%). Half of the reports (50%) did not include a systemic organ evaluation. Other areas, including systematic reporting of screened organs (36%), description of fine needle aspiration (15%), tumor description *via* tumor-node-metastasis (5%), and listing of adverse events (0%) were largely lacking from procedural documentation.

**CONCLUSION:** Documenting specific EUS quality indicators including listing post-procedural recommendations may improve the quality and efficiency of future EUS examinations and subsequent patient follow-up.

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**Key words:** Endoscopic ultrasound; Quality indicators; Quality control; Fine needle aspiration; Malignancy

**Core tip:** Certain key points of quality control have been delineated as quality indicators by American and European Gastrointestinal Societies, which serve to establish and maintain high-quality gastrointestinal minimally invasive procedures and reports, minimize potential adverse events, and to optimize costs, resulting in savings for both hospitals and patients while optimizing patient care in the process. This national quality control study of endoscopic ultrasound (EUS) with expanded international comparison emphasized developing a

standardized quality indicator table for EUS and subsequently evaluating physician adherence.

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## INTRODUCTION

The advent of computerized documentation and electronic medical records (EMR) allows organized and effective quality control (QC) analysis of gastrointestinal procedures<sup>[1]</sup>. The burgeoning costs of medicine have led to pushback efforts, including ensuring that value for cost is being delivered by high-quality examinations<sup>[2]</sup>. Several studies have been undertaken by endoscopists have demonstrated the importance of QC in achieving these goals. One example of this effect was demonstrated for colonoscopy. A retrospective study by Imperiali *et al*<sup>[3]</sup> in Northern Italy found wide variation in polyp detection rates and in the percent of procedural completion, both of which were significantly increased after offering more colonoscopy training sessions to less experienced endoscopists. As continuous quality control studies have shown to be useful in improving the effectiveness of colonoscopy, one can infer that other endoscopic procedures may be improved in a similar manner. QC analysis for endoscopic ultrasound (EUS)-guided fine needle aspiration (FNA) has also demonstrated several methods of improving the yield of tissue sample aspirates. Among these are simplified recommendations to take more passes from suspected lesions and to use newer flexible 25 gauge needles when attempting to biopsy masses that are very hard in consistency due to desmoplasia. Recent QC of EUS-FNA cytology has determined procedural FNAs to have 94% accuracy in diagnosing malignancy of the upper gastrointestinal tract and surrounding areas, further promoting its worth in medicine's evolving minimally invasive procedures<sup>[4,5]</sup>. QC may identify remediable areas of practice for which low-cost solutions might be implementable to increase procedural efficiency.

One way to bolster QC of endoscopic procedures is by establishing quality indicators. Quality indicators are established by expert physicians possessing years of experience operating gastrointestinal endoscopy on a more or less daily basis while taking into account new emerging technology being integrated into gastroenterology. These quality indicators are a compilation of guidelines and/or instructions designed for optimal procedural performance and safety. One procedure in particular studied was colonoscopy, where the investigators emphasized the importance of performing a complete examination including a thorough evaluation of any discovered polyps and adenomas<sup>[6]</sup>. In 2000, the American Society for

Gastrointestinal Endoscopy (ASGE) published the first listing of quality indicators for common gastrointestinal procedures, including upper endoscopy and colonoscopy<sup>[7,8]</sup>, which have also been set forth by the American College of Gastroenterology (ACG). These indicators also served to demonstrate to physicians areas of potential improvement and encourage periodic self-assessment. Therefore, this may lead to improved overall gastrointestinal (GI) procedural quality and efficiency.

Similar to quality improvement in EGD and colonoscopy, QIs also play a valuable role in endoscopic ultrasound. Perhaps as important as measuring the quality of EUS will be the measures found to be useful in raising the quality of less than optimal endoscopy. Although quality measures have been set by multiple well-known organizations including ACG, European Society of Gastrointestinal Endoscopy (ESGE)<sup>[9]</sup>, and ASGE quality indicator guidelines<sup>[10]</sup>, few healthcare centers have rigorously applied these guidelines and reported their results. Such an attempt was undertaken by Coe *et al*<sup>[11]</sup>, who studied adherence of physicians to EUS quality indicators over an eight year period and subsequent improvements in areas of poorer quality. The study's outcome resulted in statistically significant improvement in those areas of EUS found to be weakest by QC. This study aimed to investigate adherence to the aforementioned EUS QI guidelines across various medical centers in Israel along with a cross-sectional international comparison with the University of Chicago. The assessed quality indicators were studied based upon the aforementioned EUS quality indicator table, which allows identification of quantitatively weaker areas that may be remedied in a cost-effective manner to improve EUS performance and documentation. In doing so, this may increase the overall effectiveness of EUS, optimize treatment, and encourage patient follow-up.

## MATERIALS AND METHODS

### Data evaluation

A quality indicator table was assembled that emphasized important factors compiled after thorough literature review. The table was modeled after quality indicators presented by the various relevant societies including ASGE, ACG, ESGE quality indicators for EUS.

### Population

Fifteen different healthcare centers in Israel that perform routine EUS examinations were asked to participate in this study. Each center was requested to send ten randomized consecutive EUS reports which would be evaluated for purposes of this research. Ten of these healthcare centers agreed to participate in this study which accumulated one hundred total reports. Twenty additional reports were sent in cooperation of the University of Chicago gastrointestinal department. Thus, this study represents a national cross-sectional assessment of EUS QIs with expanded international comparison.

**Table 1 Endoscopic ultrasound quality indicators**

Pre-EUS indicators
Indications for procedure
Detailed description of the patient by the referring physician
Patient completed procedural preparation of minimum 6 h NPO
Antibiotics per protocol were given in the need to perform FNA of pancreatic cysts
Listing of sedatives administered prior to and during EUS
Patient signed agreement of informed consent for EUS and/or if consented for research study
Intra-procedural indicators
A detailed description of the methods used to visualize routinely evaluated EUS organs. If there is any suspicion of organ pathology, the respective organ parenchyma should be described:
Suspected pancreatic lesions should include a parenchymal description including the body, head, tail, and duct
Common bile ducts and gallbladder contents should be detailed and a description of the biliary tree for sludge, stones, or other findings
If found, prominent lymph nodes should be described in detail as well as the kidneys and left liver lobe for the presence or absence of lesions
The celiac axis should be described for general arterial structure along with the aorta and superior mesenteric artery as well as the presence or absence of identifiable lymph nodes
Description of abnormal/pathological results:
Description of any tumor by the tumor, node, and metastasis system
Accurate detailing of the lesions and its surroundings in accordance with layers visualized by EUS
Degree of tumor penetration into organ mucosa and surrounding structures
Detailing the presence of lymph nodes when suspicious for malignancy and when performing FNA
Intra-procedural issues
Presence or absence of any mechanical problems or difficulties including past abdominal surgeries or ascites
Patient awakened/uncooperative during the procedure
Details of the number of FNAs performed with respective number of passes into each suspected lesion including:
Number of passes
Needle size
Number of needles
Impressions of aspirate (bloody, mucinous, color, <i>etc.</i> )
Cytology and/or histological examination
In-room tentative diagnosis
Post-procedural indicators
Summary of medical diagnoses
Examination findings, even if not relevant to the reason for EUS referral, should be listed
Physician recommendations shall be listed with respect to examination findings including instructions for the patient
Instructions for how patients will receive the results and for referring physician
After EUS, the incidence of adverse events should be listed, including pancreatitis, bleeding, and/or infections and the need for hospitalization

The above table is the standardized table of endoscopic ultrasound (EUS) quality indicators. This includes an itemized list for documentation prior to, during, and after performing EUS. FNA: Fine needle aspiration.

## Research methods

Each EUS report was evaluated by the quality indicator table. QIs were evaluated prior to, during, and after performing EUS. Subsequent statistical analyses were then performed for the frequency of each indicator if listed or not listed in the various EUS reports. Reporting frequencies of each QI were calculated as percentages from which conclusions could be drawn. Each of the ten participating healthcare centers were provided with the results of this study so that they may be able to practically implement changes on their own respective terms that may improve the overall effectiveness of EUS as a whole. From the QI table, a sample EUS reporting document was proposed to be used by physicians performing EUS. Institutional Review Board approval was obtained prior to initiation of this study ensuring the privacy of all physicians, patients, and personal records. No direct patient contact took place nor were any patients harmed as a result of this research.

## RESULTS

One hundred different EUS procedural reports were

collected from ten different healthcare centers of which each center contributed ten reports. These reports were evaluated for adherence to the quality indicator table developed, based upon the indicators presented by ACG<sup>[9]</sup> (Table 1). The mean patient age was 59 years old, 52.8% of patients were female. The primary reasons for referral to EUS included suspected choledocholithiasis, suspicion of pancreatic tumor, suspicious lesions seen on imaging including ultrasound and computed tomography (Table 2).

Of the pre-procedural QIs, 71.7% of reports indicated patients' pertinent past medical history including cardiovascular disease, diabetes mellitus, gallstones, IBD, rheumatologic conditions, past surgeries, and malignancy among others. This is also to state that 29.3% of reports failed to mention the presence or absence of such conditions. Nearly of all the reports (97%) included indications for performing EUS, 82% included a detailed patient description, 61% of reports included that patients had signed a document evidencing informed consent, and 8% of reports mentioned the pre-procedural preparation. Ninety-four percent of patients received anesthesia with fentanyl combined with one or more sedatives includ-

**Table 2** Indications for endoscopic ultrasound referral

Reason for EUS referral	Percent of cases
Suspected choledocholithiasis	31%
Pancreatic tumor suspicion	17%
Pathologic finding of imaging	16%
Suspicion of esophageal of stomach Tumor	12%
Pancreatic cyst	8%
Pancreatitis	3%
Obstructive Jaundice	3%
Other	19%

The above table displays the various main reasons for endoscopic ultrasound (EUS) referral. Although most commonly due to gallstone of pancreatic pathology, one can observe that EUS may be used to diagnose and to stage other areas in the gastrointestinal tract and surrounding areas.

ing propofol and midazolam. Three patients received ketamine and three patients received flumazenil (anexate) during the procedure. These agents were generally administered in the minimum accepted therapeutic intervals. For 6% of patients it was unknown which type of anesthesia, if any, which was administered (Table 3).

The most frequently documented intra-procedural QIs were pancreatic and bile duct pathology as these were the main reasons for referral. Thirty-six percentage of reports described the systematic evaluation of organs during EUS while half of the reports (50%) did not follow this systematic method. Therefore, 87% of reports included a thorough description of the pancreas including parenchyma and its different segments while 63% of reports included a description of the biliary tree. Thirty-four percent of reports outlined the evaluation of the celiac axis, and none of the reports mentioned the adrenal glands. Six percent of procedures documented intra-procedural problems which included insufficient anesthesia (2%), anesthesia-related complications (2%), ascites, and past abdominal surgeries. In cases where FNA was performed, 15% of reports documented the number of passes, needle size, and results of immediate cytological examination. Most reports simply stated that FNA was performed. Because of the high suspicion for tumors in nearly half of the reports, great care was placed on assessing the tumor-associated quality indicators (Table 3).

Post-Procedural QIs also primarily focused on the reason for referral. Although 81.9% of reports contained a clear summary of EUS findings, 37.2% of examinations contained findings unassociated with the original reason for referral, such as liver, stomach, or pancreatic pathology that were subsequently not documented. 79.8% of reports listed treatment recommendations, and 52.1% listed medical guidance about potential procedural adverse events, including pancreatitis and bleeding, of which none of the reports indicated if such adverse events occurred (Table 3). The post-procedural quality indicators are most vital as they allow physicians to summarize diagnostic findings, detail any EUS adverse effects, and outline treatment with proper follow-up and patient education. Upon expansion of this research to include twenty additional EUS reports in collaboration

**Table 3** Endoscopic ultrasound pre-procedural, tumor-associated, post-endoscopic ultrasound quality indicators

Quality indicators	Percent documented
<b>EUS pre-procedural<sup>1</sup></b>	
Listed indications for procedure	97%
Detailed patient description from the referring physician	82%
Received minimum six hour fast	8%
Given antibiotics per protocol prior to FNA of pancreatic cyst	40%
Listing of anesthesia administered prior to starting EUS	94%
Patient signed agreement of informed consent	61%
<b>EUS findings consistent with or highly suspicious for tumor<sup>2</sup></b>	
Description by the TNM system	5%
Tumor description (or suspected)	78%
Description of degree of tissue invasion	65%
Presence or absence of lymph nodes	46%
Reports malignant or suspicious lesions	48.50%
<b>Post-EUS<sup>3</sup></b>	
Summary of medical diagnoses	81.90%
Examination findings, even if not relevant to the reason for EUS referral, should be listed	37.20%
Treatment recommendations with respect to examination findings	79.80%
Advice given to patients after performing EUS	52.10%
Incidence of adverse events, including pancreatitis, bleeding, and/or infections and the need for hospitalization	0%

<sup>1</sup>The above chart lists the percent of endoscopic ultrasound (EUS) reports in which pre-procedural quality indicators were documented. Indications and anesthesia were most frequently listed, while pre-procedural preparation, administration of antibiotics prior to fine needle aspiration of pancreatic cysts, and signing informed consent were less often listed in reports; <sup>2</sup>This chart demonstrates the adherence to EUS quality indicators for lesions consistent with or suspected to be of malignant etiologies. Although tumors and depth of invasion were commonly described, the tumor, node, and metastasis system was seldom used; <sup>3</sup>This table lists the physician adherence to post-procedural EUS quality indicators. Diagnoses, procedural findings relevant to reason for referral and treatment recommendations were most often documented whereas findings inconsistent with the reason for referral, post-procedural patient advice, and listing adverse events were far less often emphasized. FNA: Fine needle aspiration; TNM: Tumor, node, and metastasis.

with two expert US endosonographers, it was found that significantly greater adherence to quality indicators was observed.

## DISCUSSION

Statistical analysis allowed the formation a quality indicator table composed of indicators prior to, during, and after EUS as proposed earlier in accordance with ACG guidelines<sup>[9]</sup>. QI emphasized many factors including past medical conditions, current medications, comprehensive intra-procedural documentation, and implications of the procedure including treatment and potential adverse events that were not always documented. High-quality EUS examinations in particular include documenting a thorough exam, medical equipment used, nursing data, patient status, and discharge notes, among others. Physician adherence to QIs may produce a clear concise report that not only ensures a comprehensive examination, but

also that future medical providers can quickly reference a patient's past EUS<sup>[12]</sup>. Analysis of EUS reports sent from the University of Chicago showed significantly greater adherence to the documentation of quality indicators, thus producing a higher quality report.

In regards to pre-procedural indicators, most reports were thorough in listing the indications for EUS. Frequently detailed also were the anesthesia and respective dosage of each sedative administered, although a small but significant percentage of reports failed to document this (Table 3). It is very important to describe the type and dose of sedative administered as well as any medication-related adverse effects. There was no mention of which patients were evaluated by the operating endoscopist prior to EUS. Open access is frequently used for EUS patients, and reports that lack such a description make it difficult for the echo-endoscopist to perform a thorough yet focused examination thus resulting in increasing amounts of EUS procedures in which smaller pathologic conditions may be missed that would have otherwise been detected had the patient had prior appropriate documentation. The risk of missing important findings may be even greater if the operating echo-endoscopist is unfamiliar with the patient undergoing EUS. Furthermore, 61% of reports mentioned that patients had signed forms of informed consent, which is a glaring number when one considers the ethical and legal concerns. Although it is likely that every patient had given informed consent, documentation should nevertheless report this. Forty percent of reports listed antibiotic prophylaxis when FNA was performed on pancreatic cysts. Although it is not evidence-based, expert opinion suggests benefits of prophylactic antibiotics on decreasing the infection rate after FNA of pancreatic cysts<sup>[13]</sup>. Lastly, pre-EUS preparation consisting of a minimum of 6 h fasting was very seldom documented (8%). This indicator bears great importance because poorly prepared procedures will be of diminished quality due to impaired operator visibility and greater risk of aspiration that may increase the likelihood of missed findings and adverse events occurring during EUS.

As EUS is capable of diagnosing a wide range of pathologies in multiple organ systems, intra-procedural indicators were developed to optimize procedural effectiveness. After review of the various reports, it was discovered that they often lacked a comprehensive system for assessing and documenting organ systems, especially those not directly related to the reason for admission. For example, the adrenal glands were not listed in any of the EUS reports, although any discovered lesions may significantly impact patients' health. For this reason and others, it is important that a standardized table of quality indicators be used for documentation. The advantage of a standardized QI table is that it includes a list of all organs examined during EUS as well as a description of their structure to describe potential lesions, those that have suspicious characteristics, and also as a method to exclude regions as a cause for a patient's chief complaint

(Table 1).

Approximately half of the total reasons for EUS referral were for suspicion of malignancy. This is due to EUS being a highly sensitive and specific procedure for tumors in the GI tract and surrounding areas and thus may optimize subsequent treatment<sup>[14]</sup>. Therefore, all suspected tumors should be staged according to the tumor, node, and metastasis system, based characteristics including tumor size, depth of invasion, and surrounding vascular involvement (Table 3). The diagnostic ability of EUS is further augmented by taking fine needle aspirations of such lesions. Although one third of the EUS reports involved FNAs, few reports documented the number of passes, the size of the needle, or if immediate cytological examination of the aspirated contents was performed. These details are necessary in evaluating the EUS procedural standards, which may be remedied by quality control to optimize FNA effectiveness<sup>[3]</sup>. Therefore, proper diagnoses and thorough documentation based upon each of the described lesion characteristics described during EUS may further guide the decision for optimal treatment for the diverse benign and malignant conditions affecting the GI tract.

A number of interventions may lead to improved EUS quality. Granting quality recognition awards for those who have been consistently able to produce high-quality EUS reports is one such widely-implemented method<sup>[2]</sup>. Especially in the era of quality driven markets, delivering high-quality endoscopic reports may lead to increased healthcare recognition and funding. Weak areas may be remedied *via* continuous quality control monitoring of reports listed on EMR. However, despite these efforts, the brunt of quality improvement relies on the individual physician to perform his or her duty of delivering the best medical care possible while ensuring minimal harm coming to patients. High-quality reports, as seen by evaluation of the twenty reports from the United States, also help protect and reduce the costs of litigation as proper documentation may lead to fewer malpractice lawsuits.

It must be acknowledged that EUS gives rise to infrequent but important adverse events. It was noted that while analyzing the 100 EUS reports from Israeli centers, there was no mention of adverse events that arose during EUS. Although there are always those present in healthcare systems who fail to comply with procedures and documentation policies, procedural complications should always be recorded. Such adverse events may include bleeding, infection, pancreatitis, intestinal perforation, and others should be listed<sup>[15]</sup> as it is important for quality control purposes to identify and promptly remedy possible causes of such adverse events. Follow-up protocols should be included and clearly detailed according to EUS findings and diagnoses. The key advantage of post-procedural quality indicators is to have an area for summary of findings, diagnoses, and for medical recommendations with follow-up instructions (Table 3). It is important to note that by alone ensuring thorough EUS performance

and subsequent documentation does not cover all aspects of EUS quality control. There are many aspects of quality control that can and should be investigated in order to further augment the quality of EUS.

Summarizing important procedural findings for tailoring optimized treatment and to encourage patient follow-up is key to the long-term success of EUS and for patient care in general. Patient diagnoses must be summarized based on findings or lack thereof during EUS. As evidenced by this study, there is very little standardization was found among Israeli gastroenterologists; EUS findings need to be properly detailed with appropriate clinical correlation (Table 3). It is important as well to include incidentally discovered findings that are not connected to patients' primary complaints as these discovered lesions may significantly impact patients' future well-being and may be treated at an early stage. In adhering to a standardized QI table specific for EUS, doctors and patients alike may benefit from higher quality and more fruitful procedures while identifying cost-effective ways to remedy weak areas in its performance.

This study involved a multitude of diverse healthcare centers in Israel, each with its individual unique staff that causes variability in performing and documenting of EUS, which may or may not reflect the healthcare setting in other countries. Reports were evaluated multitude of diverse healthcare centers in Israel, causing variability in EUS performance and documentation of EUS, which may or may not reflect the healthcare setting in other countries.

In conclusion, having a standardized table including relevant quality indicators for EUS may increase the overall effectiveness and quality of EUS by ensuring comprehensive procedural documentation while simultaneously limiting error and strengthening patient education of potential findings during EUS.

## COMMENTS

### Background

Quality control in gastroenterology has focused on the implementation of quality indicators (QIs). Such QIs are established pre, peri, and post procedural features that various gastrointestinal societies have deemed necessary for documentation to achieve and maintain high quality in procedures and subsequent reports. Maintaining high-quality gastrointestinal procedures and reports *via* physician adherence to QIs may also minimize potential adverse events, and to optimize costs, thus saving hospitals and patients alike while improving patient care in the process.

### Research frontiers

While quality indicators have been established for procedures such as colonoscopy, their effectiveness has not been well studied in regards to endoscopic ultrasound (EUS). This study assesses physician adherence to American Society for Gastrointestinal Endoscopy (ASGE) and European Society of Gastrointestinal Endoscopy (ESGE)-established quality indicators for EUS and offers a sample table intended for ease of implementing such QIs.

### Innovations and breakthroughs

This study demonstrates that EUS reports compiled from Israeli centers most often adhered to indicators closely linked with the presenting pathology and infrequently documented a fully-detailed comprehensive report. In contrast to EUS reports evaluated from the University of Chicago, such reports were consistently found to adhere to EUS QIs. Therefore, the authors have prepared a table based on established QIs for ease of documenting a high-quality EUS report.

### Applications

In using the proposed standardized table, physicians may find it easier to document high quality reports which may optimize costs, limit error, and ensure proper patient follow-up.

### Terminology

Endoscopic ultrasound is a method of upper endoscopy that allows the operator to utilize ultrasound to accurately visualize deeper areas of the GI tract and to identify and biopsy suspicious lesions. Although it has been proven to be a highly accurate diagnostic method for malignancies in multiple regions of the GI tract, its effectiveness is operator dependent. Therefore, physician adherence to quality indicators *via* the proposed QI table is a low cost option that may augment the effectiveness of EUS that may benefit patients and healthcare providers alike.

### Peer review

This study assesses physician adherence to ASGE and ESGE-established quality indicators for EUS and presents a table based on established QIs for ease of documenting a high-quality EUS report. The novelty and innovation of the research is high. The presentation and readability of the manuscript is good.

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