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Stricter national standards are required for credentialing of endoscopic-retrograde-cholangiopancreatography in the United States

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Abstract

Endoscopic-retrograde-cholangiopancreatography (ERCP) is now a vital modality with primarily therapeutic and occasionally solely diagnostic utility for numerous biliary/pancreatic disorders. It has a significantly steeper learning curve than that for other standard gastrointestinal (GI) endoscopies, such as esophagogastroduodenoscopy or colonoscopy, due to greater technical difficulty and higher risk of complications. Yet, GI fellows have limited exposure to ERCP during standard three-year-GI-fellowships because ERCP is much less frequently performed than esophagogastroduodenoscopy/colonoscopy. This led to adding an optional year of training in therapeutic endoscopy. Yet many graduates from standard three-year-fellowships without advanced training intensely pursue independent/unsupervised ERCP privileges despite inadequate numbers of performed ERCPs and unacceptably low rates of successful selective cannulation of desired (biliary or pancreatic) duct. Hospital credentialing committees have traditionally performed ERCP credentialing, but this practice has led to widespread flouting of recommended guidelines (e.g., planned privileging of applicant with 20% successful cannulation rate, or after performing only 7 ERCPs); and intense politicking of committee members by applicants, their practice groups, and potential competitors. Consequently, some gastroenterologists upon completing standard fellowships train and learn ERCP "on the job" during independent/unsupervised practice, which can result in bad outcomes: high rates of failed bile duct cannulation. This severe clinical problem is indicated by publication of ≥ 12 ERCP competency studies/guidelines during

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last 5 years. However, lack of mandatory, quantitative, ERCP credentialing criteria has permitted neglect of recommended guidelines. This work comprehensively reviews literature on ERCP credentialing; reviews rationales for proposed guidelines; reports problems with current system; and proposes novel criteria for competency. This work advocates for mandatory, national, written, minimum, quantitative, standards, including cognitive skills (possibly assessed by a nationwide examination), and technical skills, assessed by number performed (≥ 200 -250 ERCPs), types of ERCPs, success rate (approximately $\geq 90\%$ cannulation of desired duct), and letters of recommendation by program director/ERCP mentor. Mandatory criteria should ideally not be monitored by a hospital committee subjected to intense politicking by applicants, their employers, and sometimes even competitors, but an independent national entity, like the National Board of Medical Examiners/American Board of Internal Medicine.

Key words: Endoscopic retrograde cholangiopancreatography; Privileges; Credentialing; Gastroenterology fellowship training; Advanced gastrointestinal endoscopy training; Certification; Standards

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Core tip: An additional, optional year of endoscopic-retrograde-cholangiopancreatography (ERCP) training was added because of limited ERCP exposure during standard-three-year-gastrointestinal-fellowships and its greater endoscopic technical difficulty. Yet, many graduates from standard-three-year-fellowships intensely pursue ERCP privileges despite inadequate numbers of ERCPs, or low successful duct cannulation rates. Hospital credentialing committees have sometimes disregarded recommended ERCP credentialing guidelines. Consequently, some gastroenterologists learn ERCP “on the job”, after completing standard GI fellowships, during unsupervised practice. National, *mandatory*, standards for ERCP are advocated, including number (≥ 200 -250) of performed ERCPs, and $\geq 85\%$ -90% successful cannulation rate. An independent entity should oversee ERCP credentialing to prevent politicking within hospital committees.

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) compared to the other standard gastrointestinal (GI) procedures of esophagogastroduodenoscopy (EGD) and colonoscopy is technically far more difficult, requires greater skill, and entails a higher rate of clinically significant complications. Yet GI fellows have limited exposure to ERCP during a standard three years GI fellowship because ERCP is much less frequently performed than EGD or colonoscopy. This combination of a steep learning curve and limited exposure motivated the institution of an optional extra year of advanced endoscopy training, primarily devoted to ERCP but also devoted to endoscopic ultrasound (EUS). Yet many graduates from standard three years fellowships without an extra year of advanced training intensely pursue independent (unsupervised) ERCP privileges^[1]. Sometimes these requests are reasonable, but they may be unjustified if the applicant did not perform an adequate number of ERCPs during standard fellowship training and has a low rate of successful selective cannulation of the desired (biliary or pancreatic) duct^[1-3]. At least 18 studies, recommended guidelines, and editorials on ERCP credentialing have been published in the last 30 years, including 12 published since 2015 (Table 1). However, lack of mandatory, quantitative, written, criteria for ERCP credentialing has permitted ambiguities and neglect of recommended guidelines. Consequently, some

gastroenterologists upon completing standard fellowship training learn ERCP “on the job” during independent unsupervised practice, which can result in bad ERCP outcomes: Extremely high rates of failed bile duct cannulation which necessitates that patients undergo repeat ERCP by another gastroenterologist at another time^[2].

Fifty years after the institution of ERCP in 1968, this opinion piece calls for establishment of mandatory, written, and quantitative national criteria to prevent ambiguities and disregard of recommended guidelines. The monitor of the mandatory criteria should not ideally be an in-hospital committee because this committee is subject to intense political pressure by the applicants themselves and their employers (personal unpublished data, Cappell as Chief of Gastroenterology and Hepatology for last 12 years), but a truly independent entity. This work suggests consideration of establishing an independent national board, similar to the National Board of Medical Examiners or American Board of Internal Medicine, to maintain uniform national standards divorced from political pressure by local applicants, their private practice groups, competing gastroenterology groups, or hospitals. This work reviews prior recommended criteria for ERCP credentialing and their rationale; the compelling need for quantitative, mandatory criteria; and provides an example of mandatory credentialing criteria, which are merely illustrative because criteria should be established by consensus of a committee of ERCP experts preferably assembled under the auspices of the American Society of Gastrointestinal Endoscopy (ASGE), or similar professional GI organization.

METHODS

Literature on ERCP credentialing and training was comprehensively searched by computer using PubMed and Ovid with the following medical subject headings/keywords: (“ERCP” OR “endoscopic retrograde cholangiopancreatography” OR “endoscopic retrograde cholangiography”) AND (“privileges” OR “privileging” OR “credentials” OR “credentialing” OR “guidelines” OR “position paper” OR “recommendation” OR “American Society for Gastrointestinal Endoscopy” OR “ASGE” OR “competence” OR “competency” OR “competent” OR “training” OR “trainee” OR “quality” OR “independent practice”). The two authors independently performed literature searches, and decided on which articles to incorporate into this review according to appropriateness of article content and article priority based on consensus. This review was rendered up-to-date by repeating a computerized literature search just before submitting this work for publication which identified one new article just e-published ahead of print one week before submission of this opinion piece^[4].

This work is restricted to privileging of adult gastroenterologists for ERCP in the United States because practice patterns, standards of care, and medical malpractice litigation patterns differ in the rest of the world; and excludes ERCP credentialing for pediatric gastroenterologists, or GI, hepatobiliary, and pancreatic surgeons because they have different practice patterns.

RESULTS

History and clinical significance of ERCP

ERCP is currently the procedure of choice for many biliary and pancreatic disorders. About 350000-500000 ERCP's are currently performed annually in the United States^[3,5]. Common indications include choledocholithiasis, obstructive jaundice, biliary pancreatitis, malignant biliary obstruction, and benign biliary strictures; while uncommon indications include recurrent pancreatitis of unknown etiology, biliary or pancreatic duct leaks, pancreatic stones, pancreatic strictures, chronic pancreatitis, and sphincter of Oddi dysfunction^[6,7].

After William McCune, an obstetrician, performed the first ERCP in 1968, Peter Cotton, a gastroenterologist, reported a clinical series of 60 diagnostic ERCPs in 1972^[8]. Critical developments in diagnostic ERCP technology included side-viewing endoscopes to view the mural papilla en face, cannulation catheters, endoscopic elevators to facilitate papillary cannulation, guide-wires, biopsy forceps, and brushes. Classen and Demling in Germany^[9], and Kawai and colleagues in Japan^[10], pioneered ERCP therapy using sphincterotomes to open the ampulla and endoscopic devices to extract choledocholithiasis. ERCP has become increasingly therapeutic because of critical advances in therapeutic technology, including sphincterotomes for sphincterotomy, inflatable balloons or stents to dilate strictures, electrocautery to stem hemobilia, and baskets or inflatable balloons to retrieve choledocholithiasis.

Table 1 Literature review of criteria for endoscopic retrograde cholangiopancreatography privileging and practice

First author, Journal, Year study published	Type of study	Proposed Minimum number of ERCPs or other criteria for determining competence	Quality indicator or comments
Wigton <i>et al</i> ^[37] , American College of Physicians, Ann Intern Med 1988	Position paper, American College of Physicians	35 supervised ERCPs. No quality indicators specified.	Document to include degree of success of ERCP. Types of ERCP not specified.
Watkins <i>et al</i> ^[38] , Gastrointest Endosc 1996	Original prospective report of point at which GI fellow achieves 85% rate of cannulation of both pancreatic and bile ducts	100 supervised ERCPs	Point at which GI fellow achieves 85% rate of cannulation of desired duct (either pancreatic duct or bile duct)
Jowell <i>et al</i> ^[40] , Ann Intern Med 1996	Prospective study involved grading of 1796 ERCPs among 17 GI fellows	180 supervised ERCPs	Number of ERCPs for individual skills: 160 for cholangiography, 160 for pancreatic duct cannulation, 120 for stone extraction, and 60 for stent insertion.
Eisen <i>et al</i> ^[41] , Gastrointest Endosc 2002	Position paper, American Society for Gastrointestinal Endoscopy	180 supervised ERCPs	80% ability to cannulate the duct of interest (either bile duct or pancreatic duct)
Garcia-Cano ^[39] , Surg Endosc 2007	Letter to editor based on personal experience as surgeon training in ERCP	200 ERCPs	Based on personal experience at point at which achieved 80% rate of cannulation of bile duct. Anecdotal evidence.
Verma <i>et al</i> ^[43] , Gastrointest Endosc 2007	Retrospective review of single operator ERCP learning curve	> 80% rate of successful deep cannulation of bile duct	Achieved at performing 350-400 ERCPs
Shahidi <i>et al</i> ^[42] , Gastrointest Endosc 2015	Systematic review encompassing 9 studies	Competency achieved after 79 to 300 ERCPs, depending upon learning curve of individual trainee	Competency for specific quality indicators: 70 to 160 ERCPs for pancreatic duct cannulation, and 160 to 400 ERCPs for deep bile duct cannulation
Cotton ^[26] , Gastrointest Endosc 2015	Editorial	Supports guidelines set by Australian Conjoint Committee of 200 ERCPs	To include a minimum of 80 sphincterotomies with intact papillary sphincters, and a minimum of 60 stents
Adler <i>et al</i> ^[44] , Gastrointest Endosc 2015	Position paper, American Society for Gastrointestinal Endoscopy Quality Assurance in Endoscopy Committee	> 90% rate of deep cannulation of duct of interest with native papilla, > 90% rate of extraction of common bile duct stone < 1 cm in patient with normal bile duct anatomy, > 90% successful stent placement in patient with normal anatomy	---
Ekkelenkamp <i>et al</i> ^[47] , Endoscopy 2015 ^[47]	Nationwide analysis of 8575 ERCPs by 171 endoscopists in Holland during 1 yr.	Overall rate of "successful" ERCPs was 83.4% for native papilla and 89.4% after sphincterotomy.	Provides a reasonable estimate of expected success rate for ERCP operators.
Wani <i>et al</i> ^[48] , Gastrointest Endosc 2016	Prospective multicenter trial conducted among 5 advanced GI endoscopy fellows at 5 medical centers	Number of ERCPs to achieve successful cannulation rate > 90% of biliary duct varied from 26 to 211 ERCPs.	Demonstrates variability in learning curves to achieve competence in ERCP as determined by > 90% rate of bile duct cannulation
Wani <i>et al</i> ^[49] , Clin Gastroenterol Hepatol 2017	Prospective multicenter study of 22 advanced GI endoscopy trainees at 20 medical centers	Demonstrated substantial variability in learning curves for cognitive and technical ability in ERCP. This suggests basing criteria for competence not on volume, but on achieving landmarks for quality indicators (<i>e.g.</i> , successful cannulation rate).	Variable learning curves for achieving cognitive and technical success in ERCPs upon completion of advanced endoscopy fellowship
Wani <i>et al</i> ^[45] , Gastrointest Endosc 2018	Gastrointestinal Endoscopy white paper	Developed comprehensive data collection and reporting tool for assessing ERCP performance	Demonstrated feasibility of using a central database to monitor GI fellow performance
Faulx <i>et al</i> ^[50] , Gastrointest Endosc 2017	American Society for Gastrointestinal Endoscopy Standards of Practice Committee Guideline	200 supervised ERCP procedures for assessing competency. Additionally, independently perform > 80 sphincterotomies and > 60 biliary stent placements	
Wani <i>et al</i> ^[53] , Gastroenterology 2018	Prospective multicenter clinical trial involving 22 advanced GI endoscopy fellows	After completing an advanced endoscopy fellowship, ERCP operators achieved an average successful cannulation rate of 94.9% in private practice.	This work shows that advanced endoscopy fellowship training leads to successful ERCP performance in private practice.

Cotton ^[60] , Gastrointest Endoscopy 2017	Survey of 1126 responding United States gastroenterologists	No written guidelines for initial ERCP credentialing-21%. No written guidelines for repeat credentialing process-54%.	Urgent need to improve credentialing process.
Cassani <i>et al</i> ^[63] , Gastrointest Endosc 2017	Editorial on sorry state of ERCP credentialing	"Despite repeated studies, editorials, gastroenterology society papers, credentialing committees have yet to take the initiative and require increased scrutiny for both hospital and (ERCP) procedural outcomes."	Frank discussion of current failures in credentialing process.
Wani <i>et al</i> ^[4] , Gastrointest Endoscopy 2019	Prospective multicenter study determining standards for competency for ERCP based on learning curves for 37 advanced endoscopy fellows in 32 programs.	Advanced endoscopy fellow required an average of 226 ERCPs to achieve competency in native papillary cannulation, and required an average of 120 sphincterotomies to achieve competency in biliary sphincterotomy.	Provides guidance on threshold number of ERCPs at which to assess competency.

ERCP: Endoscopic retrograde cholangiopancreatography; GI: Gastrointestinal.

Therapeutic ERCP often produces dramatic cures of life-threatening conditions, and is less invasive and safer than surgical options for various disorders, such as ascending cholangitis from choledocholithiasis^[11]. ERCP therapies have largely obviated surgery for choledocholithiasis and choledochal strictures, and can improve survival in patients with cholangiocarcinoma^[12,13]. The relatively recent change of ERCP to become a predominantly therapeutic modality has also been fostered by development of less invasive and safer pancreatobiliary diagnostic tests than ERCP, including EUS and magnetic resonance cholangiopancreatography (MRCP).

ERCP entails greater risks of clinically significant complications than other standard GI endoscopic procedures, such as EGD or colonoscopy^[14]. ERCP has a reported mortality ranging from 0.2%^[15] to 1%^[16], depending upon patient age, medical status, and planned therapeutic intervention. Kalaitzakis *et al*^[17] reported a dramatic 12% mortality at 3 mo from post-ERCP pancreatitis, though patient-related factors, including cancer diagnosis and advanced age were contributing factors. Moreover, ultimately fatal post-ERCP pancreatitis is probably under-reported^[18-20]. Life-threatening complications after ERCP and sphincterotomy include post-sphincterotomy bleeding, unremitting cholangitis, bile leak, and duodenal perforation. ERCP is a relatively common cause of medical malpractice litigation against gastroenterologists, and engenders a much higher rate of medical malpractice suits than other GI endoscopic procedures^[21].

ERCP is uncommonly performed relative to the other two standard GI endoscopic procedures of EGD and colonoscopy. For example, at William Beaumont Hospital in Royal Oak, one of the ten largest hospitals in the United States, ERCP represents only about 700 (3%) of a total of 24000 annual GI endoscopies. Moreover, this percentage probably overestimates its relative frequency in the United States because this tertiary hospital is a referral center for ERCPs. The technically demanding skills and relatively high risks of severe complications of ERCP vs. relatively infrequent exposure to ERCP during standard three years of GI fellowship prompted gastroenterologist-administrators to establish a year of advanced endoscopy fellowship training primarily devoted to ERCP. Advanced endoscopy programs also generally incorporate training in diagnostic and therapeutic EUS, and increasingly offer other relatively recently introduced advanced endoscopic procedures, including: Double balloon enteroscopy, ablation therapy for Barrett's mucosa, endoscopic mucosal resection, endoscopic submucosal dissection, peroral endoscopic myotomy, endoscopic clips to close GI perforations, endoscopic suturing, and peroral cholangiopancreatography. Advanced GI fellows also need to generate clinical income by performing routine EGDs and colonoscopies because their salaries are not funded by Medicare. Training in these other advanced techniques and performance of routine GI endoscopies can adulterate the advanced fellowship experience in ERCP. The core curriculum outlines ERCP trainee goals in terms of expectations and experiences^[22,23] (Table 2). In one survey, graduating advanced fellows were generally satisfied with their advanced endoscopy training, but some of them would have skipped the extra year of advanced training altogether if they had more exposure to ERCP and EUS during their standard GI fellowship^[24].

History and rationale of ERCP credentialing criteria

After the introduction of diagnostic ERCP in 1968 and therapeutic ERCP in 1974, clinical demand for ERCP burgeoned with scant regulation of ERCP privileges

Table 2 Core Curriculum for endoscopic-retrograde-cholangiopancreatography trainees

Cognitive
1 Obtain written, witnessed, and informed patient consent with discussion of the indication for the ERCP; potential complications including pancreatitis, hemorrhage, duct leak, perforation and infection; alternative tests or therapies; and adequately answer patient questions
2 Realize appropriate indications for ERCP and accessory interventions
3 Evaluate patient prior to procedure and optimize outcomes, in terms of potential bleeding (<i>i.e.</i> , hold antiplatelet and anticoagulants if possible), and administer antibiotics as necessary to prevent subsequent sepsis
4 Understand and practice prophylactic interventions, especially to prevent post-ERCP pancreatitis
5 Know “best practice” recommendations as to technical approaches during ERCP
6 Knowledge of optimal management of ERCP complications
7 Manage the patient after ERCP as in-patient or outpatient, as appropriate
8 Manage complications occurring during or after ERCP
9 Knowledgeably discuss findings and consult with allied specialists: hepatobiliary or pancreatic surgeons and interventional radiologists
Technical (not comprehensive)
1 Evaluate ampulla in a knowledgeable fashion
2 Access necessary ductal system via deep cannulation ≥ 90% attempts
3 Procure required fluoroscopic images of the biliary and pancreatic ductal systems
4 Working knowledge to interpret fluoroscopic images
5 Perform optimal biliary and/or pancreatic sphincterotomy as required
6 Extract biliary and pancreatic duct stones via basket or balloon.
7 Insert plastic and metal stents into pancreatic and biliary system as required
8 Perform intraductal endoscopy and associated diagnostic or therapeutic maneuvers, as required: EHL, laser, biopsies, and brushings

Adopted with major modifications from Jorgensen *et al*^[23]. ERCP: Endoscopic retrograde cholangiopancreatography; EHL: electrohydraulic lithotripsy.

because of a severe shortage of endoscopists trained and proficient in this novel procedure. Cappell vividly recalls how Jerry Siegel, a highly talented pioneer clinical ERCP practitioner, travelled to numerous major academic hospitals throughout New York City totting a briefcase containing his own ERCP endoscope and endoscopic accessories to perform ERCP on referred patients, after being granted temporary, emergency, ERCP privileges at these hospitals. This lightly regulated “Wild West” of “have ERCP scope will travel” was prevalent in the mid-to-late 1970s^[25]. Notable other ERCP pioneers included Peter Cotton at Duke University Hospital who has become the primary advocate of tighter regulation of ERCP privileges, Meinhard Classen in Germany, and Ito in Japan.

Now 50 years after its inauguration, mandatory, written, and strict regulations of training and credentialing of ERCP, based on national guidelines, should be adopted. Regulation is required because of: (1) High risks inherent to ERCP, especially of post-ERCP pancreatitis, bile leaks, and post-sphincterotomy bleeding; (2) Extremely high level of technical expertise and cognitive skills needed to master therapeutic ERCP, especially given the ever increasingly innovative and more sophisticated therapeutic technologies; and (3) Diverse ERCP training backgrounds of applicants for ERCP privileges. As GI Division Director, Dr. Cappell and the Credentials Committee members have “denied” five applicants’ applications for ERCP privileges because of insufficient documentation of ERCP training during their standard three year GI fellowship, low rate of bile duct cannulation, or request to perform ERCP at this tertiary university hospital while primarily based at a satellite hospital without arranging for emergency coverage to handle post ERCP emergencies on their patients at the academic teaching hospital. Indeed, one GI attending was denied ERCP privileges at a major academic hospital because of an extremely low volume of ERCP during a standard three year GI fellowship, and only a 20% rate of biliary cannulation afterwards in clinical practice^[2]. Cotton^[26] reported in 2015 that one GI fellow upon entering private GI practice was requested to join the ERCP rotation after having performed precisely 7 ERCPs during a standard three year GI fellowship. Contrariwise, applicants may be granted ERCP privileges despite inadequate training during a standard three years GI fellowship due to political pressure from a prominent GI group that the applicant is joining (Cappell, personal unpublished data). Such credentialing problems are exceedingly rare for other endoscopic procedures (Cappell, personal experience as Chief of Gastroenterology and Hepatology at an academic medical center during the last 12 years).

Concerns regarding ERCP training, competency, standard of practice, and

credentialing began to appear in the literature about 25 years after its introduction^[27,28]. At the time, few medical institutions offered one year advanced endoscopy training programs focused on diagnostic and therapeutic ERCP after standard GI fellowship. Graduating GI fellows who did not train via this extra year were still eligible to obtain ERCP privileges if they had adequate training and experience during the standard three years of GI fellowship, pursued extra training abroad, or simply were self-trained. The landscape began to change around the new millennium as advanced training programs became relatively common. About 66 advanced endoscopy training programs currently exist in the United States. Concurrently, administrators of advanced endoscopy fellowships formulated a core curriculum to help standardize ERCP training and practice^[22,29]. The ASGE has resolved that competency in ERCP is not required during standard GI fellowship training, and strongly recommended advanced endoscopy fellowship training to achieve clinical competence in ERCP^[22,30]. Despite these recommendations, a survey of GI fellows graduating from standard three year GI fellowships reported in 2003 that 91% of them intended to perform ERCP, even though only one-third had met ERCP volume thresholds for independent ERCP practice during fellowship training^[1]. This disparity between clinical practice and professional guidelines continues to some extent even today, despite criticism of “low-volume” operators and endorsement of quality metrics, including highly successful biliary cannulation rates and low ERCP complication rates^[3,31,32]. For example, a survey conducted in 2015 showed that 40% of graduating third year GI fellows believed that they would be able to perform ERCP independently upon graduation, even though only 19% of them had performed ≥ 200 ERCPs^[26].

Competency

ERCP competency is defined as thoroughly understanding the cognitive aspects of ERCP, and reliably achieving its technical goals^[33]. Patient outcome, patient satisfaction, and ERCP complication profile are also important. Criteria for competency, however, still remain controversial during the present era of numerous advanced GI fellowships (Table 3). One perspective suggested that biliary cannulation rate is a better parameter to assess competency than absolute ERCP numbers^[34]. ERCP practitioners and trainees should incorporate best practice guidelines and prevention strategies to minimize complications, especially to prevent post-ERCP pancreatitis^[35,36]. Overestimating ERCP skills or embellishing credentials can have dire clinical consequences^[2].

Competency in ERCP was initially determined by numbers performed during GI fellowship training. An early study recommended an extremely low threshold of 35 ERCPs to achieve competency^[37]. A prospective six-year study suggested a minimal threshold of 100 ERCPs to achieve competency, with a $> 85\%$ biliary cannulation rate^[38]. An important prospective study set 180-200 ERCPs as the threshold for competency, including 120 gallstone extractions, and 60 stent deployments^[39]. An anecdotal Spanish study similarly recommended 200 ERCPs as the threshold for competency for surgeons^[40], as was also recommended for gastroenterologists by the ASGE Standards of Practice Committee^[41]. A systematic review, published in 2015, reported that in five studies, the minimum threshold for competency, as determined by very high rate of successful selective, duct cannulation, ranged from 79 to 300 ERCPs^[42]. Cotton^[26] published an editorial applauding these findings, and reiterating that too many low-volume operators were performing ERCP.

Recent published recommendations have become stricter. The Mayo Clinic study^[43] recommended > 350 ERCPs performed on a native papilla as a threshold for competency. Other studies included ERCPs on patients with prior sphincterotomy that renders biliary cannulation much easier. Recent studies suggest a $\geq 90\%$ selective cannulation rate is an appropriate metric for a native ampulla^[44], but a “competent” ERCP operator should attain a $\geq 95\%$ rate in a papilla status post sphincterotomy or with precut maneuvers^[43].

Assessment of ERCP competency based solely on numbers is flawed because of wide variability in: training programs, individual experiences within given training programs, exposure to ERCP during standard three-year GI fellowships, innate endoscopic ability of individual trainees, and difficulty in translating training results during GI fellowship into clinical practice^[45]. For example, individual GI fellow experience at a given ERCP may vary from passive observation, attempting only one bile duct cannulation, performing the diagnostic ERCP, or performing the entire diagnostic and therapeutic ERCP. Also, individual learning curves for ERCP are non-linear. Relative difficulty of ERCP procedures can be graded according to patient characteristics (*e.g.*, stable patient *vs* acutely septic patient from ascending cholangitis), biliary anatomy (*e.g.*, status post Billroth II *vs* native anatomy), procedural indication (*e.g.*, obstructive jaundice *vs* recurrent idiopathic pancreatitis), and procedure intervention (*e.g.*, solely diagnostic *vs* sphincterotomy and stone

Table 3 Ongoing controversies in endoscopic-retrograde-cholangiopancreatography training and privileging

Ongoing controversies in endoscopic-retrograde-cholangiopancreatography training and privileging
1 What minimum number (if any) of ERCPs should be performed during a dedicated advanced training fellowship to justify credentialing?
2 What minimum number of ERCPs should be documented by a physician who seeks credentialing in ERCP after completing a standard 3 yr GI fellowship?
3 What should the profile of submitted ERCPs consist of in terms of therapeutic interventions?
4 Should all new physicians granted ERCP privileges have a probation period with monitoring by a proctor, and if so for how long?
5 What criteria, other than numbers, should be used to assess competency in ERCP?
Cannulation of desired duct(s)
Procedure outcome
Patient outcome
Complication rate
Monitoring of ERCPs during a probation period.
6 Should administrators of standard gastroenterology fellowship training programs that are 3 yr long be allowed to certify GI fellows in ERCP or should credentialing be restricted only to GI fellows who have completed an extra year of advanced endoscopy training?
7 Is post-training proctoring acceptable as a means to attain ERCP competency?
8 Should EUS training be mandatory for ERCP performance?
9 Should advanced GI fellowship training programs offer only a dedicated EUS or ERCP pathway but not both?
10 Should curriculum content for advanced therapeutic training be nationally standardized? Are there a sufficient number of advanced GI endoscopy program fellowships and are they of sufficient duration?
11 Should manpower concerns affect ERCP credentialing or should standards for competency be the only consideration?
12 Should individual hospital needs for ERCP operators affect credentialing?
13 Should all ERCP practitioners be compelled to participate in an on-call rotation for emergency ERCPs to be performed at night or on weekends?
14 Should all GI endoscopists with staff privileges for ERCP be compelled to join a rotation to perform ERCPs on public uninsured patients?
15 Should all ERCP practitioners be required to perform a minimum number of ERCPs per annum to maintain ERCP privileges (proficiency)? If so, what is the minimum number: 25 or 50 ERCPs per annum?
16 Should a national board exam, similar in concept to the examination in Gastroenterology by the American Board of Medicine be required for certification in ERCP to assess cognitive knowledge in ERCP and related clinical disciplines?

ERCP: Endoscopic retrograde cholangiopancreatography; GI: Gastrointestinal.

extraction for acute cholangitis). A reported grading system is useful to compare data on individual trainees or from different studies on ERCP competency^[46] (Table 4).

A recent trend is to emphasize learning curves rather than mere numbers. A Dutch study showed widely variable individual rates of acquisition of cognitive ability and technical skills, with a steeper learning curve for selective cannulation than for other technical skills, such as stent deployment^[47]. A sophisticated multi-center American study of > 1000 advanced endoscopy trainees reported a wide range of individual acquisition of cognitive ability and technical skills, which was only mildly-to-moderately correlated with ERCP volume^[48]. Another large American study found that only 60% of advanced endoscopy trainees attained technical ERCP competence, even though all trainees achieved cognitive competency^[49]. This study demonstrated the feasibility of a central database to determine individual learning curves for ERCP. The authors called their database tool TEESAT, an acronym for The EUS and ERCP Skills Assessment Tool. The 2017 ASGE Practice Guidelines^[50] recommended that ≥ 200 ERCP's should be performed before competency is assessed, and that this minimum threshold should include > 80 sphincterotomies, and > 60 biliary stent deployments. A national board examination may be required in the future to assess cognitive ERCP skills.

Training

Advanced endoscopy fellowship training will eventually become the predominant route for ERCP practice. Paradigm shifts regarding advanced endoscopy training during the last two decades include: (1) Not mandating ERCP training during standard GI fellowships; (2) Exponential increase in number of advanced endoscopic fellowship training programs^[51]; and (3) Recent transition from an "apprenticeship" to "milestones" model for medical education^[50,51,52]. In the apprenticeship model, trainees are evaluated in relation to their peers at the same year of fellowship training. In the milestone model, trainees are evaluated by reaching appropriate interim milestones until they are evaluated for the ultimate milestone at graduation of competence for "independent practice". The ASGE permits trainees to designate preference for

Table 4 Grading System for endoscopic-retrograde-cholangiopancreatography difficulty

Grading system for ERCP
Grade I Deep cannulation of CBD or main pancreatic duct Extraction of small-to-medium (≤ 10 mm) biliary stones Biliary stenting for leaks
Grade II Treatment of extra-hepatic benign or malignant ductal strictures Placement of prophylactic pancreatic stents Extraction of larger biliary stones
Grade III Pancreatic stricture dilation and stenting Removal of mobile pancreatic stones ≤ 5 mm Hilar tumor stenting Treatment of hilar and intrahepatic biliary stricture Sphincter of Oddi manometry Limited pancreatic sphincterotomy Removal of migrated pancreatic stents
Grade IV Removal of impacted and larger pancreatic stones Pseudocyst drainage or necrosectomy Ampullectomy ERCP in patient with altered anatomy (<i>e.g.</i> , status post Billroth II surgery) Minor papilla therapy
Grade V “Rendezvous” procedure to access and stent the biliary and pancreatic systems - requires endoscopic ultrasound training

Adapted with modifications from Cotton^[3]. ERCP: Endoscopic retrograde cholangiopancreatography; CBD: Common bile duct.

training in EUS, ERCP or both, but applicants are generally more interested in ERCP, which is a more highly valued and marketable skill.

Under the milestones paradigm, most advanced GI fellows achieved cognitive and technical goals, and were judged ready for independent practice^[53], but the rate of skill acquisition was highly variable^[42,45,48,49]. Number of ERCPs is deemed relevant only as a threshold to initiate formal assessment of achieving milestones for ERCP skills^[45].

Various endoscopic simulators, including mechanical devices, virtual (computer-generated) models, organ explants, and live animals can help teach and train GI fellows in ERCP^[51]. An inexpensive, simple, fabricated device boosted trainee confidence in performing actual ERCPs^[54], while an elaborate, expensive European mechanical simulator was also helpful^[55]. Computer simulators can improve ERCP skills^[56]. Trainees can practice cannulation, sphincterotomy, and stent deployment using neo-papillae and neo-bile duct fashioned from chicken heart and trachea, respectively^[57]. Simulators are useful adjuncts to formal training, but cannot replace actual clinical experience. Experienced ERCP operators can further improve their hands-on skills with workshops, such as those offered by the ASGE, especially for training in new and emerging technologies^[58,59].

Credentialing

Credentialing is potentially contentious. A gastroenterologist without ERCP privileges is barred from performing ERCP. One-time denial is potentially tantamount to lifelong denial of this privilege because ERCP skills generally atrophy over time with disuse. Denial may decrease professional reputation because ERCP is perceived as a prestigious endoscopic procedure, and may decrease referrals for standard GI endoscopies because the gastroenterologist may be perceived as incapable of performing complex endoscopies.

Credential committee members have legitimate concerns about patient safety and potential malpractice litigation if applicants with borderline credentials are granted ERCP privileges, but the committee members could theoretically be biased against granting ERCP privileges to newly graduating GI attendings to stifle competition. However, institutional manpower needs and economic incentives may trump such

concerns because patients with pancreatobiliary diseases could be rerouted or transferred by ambulance to other hospitals if a given hospital has too few GI attendings with ERCP privileges.

A recent survey demonstrated that 21% of United States hospitals lack formal guidelines for initial credentialing for ERCP privileges, 59% of them lack formal guidelines for renewal of such privileges, 67% of them do not collect data on sphincterotomy rate or volume, and 85% of them do not collect data on rates of successful biliary cannulation^[60]. After performing this survey, Cotton *et al*^[60] reiterated his plea for adherence to credentialing guidelines, and establishing standardized national certification for ERCP. He recommended different criteria for initial credentialing for ERCP after completing GI fellowship, credentialing after one year of GI practice, and subsequent credentialing for renewal of ERCP privileges. Clinical studies suggest that 40 to 50 ERCP with sphincterotomies annually is a reasonable number to maintain ERCP proficiency, as evidenced by such high volume operators having a lower risk of ERCP complications than low volume operators^[61,62]. The accompanying editorial endorsed Cotton's proposal, called the current credentialing process "alarming", and urged credential committees to analyze more data on ERCP outcomes and hospital course^[63]. Publications on ERCP competency including original articles, position papers, recommended guidelines, and editorials are listed in Table 5. Most authorities believe that endoscopists performing high volumes of ERCPs generally provide higher quality ERCPs and improve patient outcome compared to endoscopists performing low volumes of ERCPs^[31,64-66]. Low-volume operators derive less personal satisfaction from performing ERCP, possibly because of greater stress, and may be viewed less favorably by endoscopy personnel^[65].

GI endoscopists who perform ERCPs at several hospitals pose another problem. How can endoscopists who rarely perform ERCPs at a given hospital be evaluated for re-credentialing based on the limited data available at this given hospital? Who manages patient complications after ERCP when the performing gastroenterologist is away at another hospital? Should all endoscopists with ERCP privileges be compelled to participate in on-call rotations for emergency ERCPs that must be performed at night or on weekends, and should all of them be compelled to participate in a rotation to perform ERCPs on patients without medical insurance? At Beaumont Hospital at Royal Oak, renewal of privileges has been linked to enrolling in an on-call rotation for emergency ERCPs and in a rotation for uninsured patients requiring ERCPs.

Manpower needs

Few studies analyze United States manpower needs for ERCP. The approximately 350000-500000 ERCPs performed annually in the United States^[3,5] are mostly performed by endoscopists without advanced endoscopy training, and this predominance will likely persist for years to come. In Cotton's survey published in 2017^[60,63], only one-quarter of surveyed ERCP operators in the United States had advanced ERCP training, and these practitioners typically practiced in academic urban or suburban hospitals. Rigorous vetting of applicants for ERCP privileges could limit the number of operators. Rigorous vetting should work well in densely populated urban areas with high concentrations of ERCP operators, but may be problematic in rural and inner-city hospitals that are likely underserved in number of ERCP operators. This phenomenon may explain the reluctance of some hospitals to rigorously follow professional ERCP guidelines. Transferring patients from inner city or rural hospitals to academic medical centers for emergency ERCPs, for indications such as acute cholangitis or bile leaks, is problematic. Gastroenterologists at low-volume ERCP centers may solicit medical advice by telephone or video communications from ERCP experts at high-volume centers^[67]. To adapt to local shortages of gastroenterologists performing ERCPs, surgeons could increase their rate of performing intraoperative cholangiography and could potentially perform ERCP themselves^[68,69], while interventional radiologists could perform transhepatic cholangiography as a substitute for ERCP.

The duties of the individual GI fellow applying for ERCP privileges, of the supervisory attending, and of the credentialing committee at which the GI fellow is applying for ERCP privileges upon completion of the fellowship are summarized in Table 5. Upon graduation of a GI fellow, training programs should issue a nationally standardized certificate regarding ERCPs that provides quantitative data on numbers of ERCPs and percentages of successful therapeutic interventions (proposed ERCP report card illustrated in Table 6). Credentialing should grant preference to trainees who performed an extra year of GI fellowship mostly devoted to ERCP training.

This work has proposed that national criteria be mandatory rather than recommended. One reasonable method of enforcement is for chairs of credentialing committees to certify that the physician was granted ERCP privileges in accord with

Table 5 Determining competency for endoscopic-retrograde-cholangiopancreatography

Duties of GI fellow applying for ERCP privileges at a hospital	Duties of GI supervisor of ERCP training/GI fellowship program director	Duties of hospital committee voting on ERCP privileges for applying physician
Contemporaneously sign each ERCP note in which actively participated	Ascertain GI fellow signs ERCP notes when the fellow actively participated in case	
Can contemporaneously sign each note in which merely observed ERCP, but observer status should be reflected in note	Allow fellow to sign on note as an observer (not active participant) in cases in which fellow was passive observer	Passive observation of an ERCP should be meaningful in enhancing cognitive skills for ERCP, but cannot count towards minimum threshold for performed ERCPs
ERCP note in which GI fellow participated should specify what technical procedures performed during ERCP: <i>e.g.</i> , sphincterotomy, stone extraction, dilation of stenosis, and <i>etc.</i>	Ascertain that endoscopy report includes all technical aspects of the performed ERCP	Ascertain that received data is complete
Collate all numbers performed for ERCP: Number performed, number (%) cannulated, number with sphincterotomy, number with stone retrieval, number of strictures dilated, and <i>etc.</i>	Review total numbers of ERCPs and number of ERCPs in which special techniques were employed as appropriate. Record rate (%) of success of special techniques.	Review total numbers of ERCPs and number (%) of ERCP special procedures and determine whether these data satisfy minimal numbers and minimal % of successful result required for competency
Make sure packet with ERCP numbers and recommendations is submitted in a timely manner at hospital applicant is applying for ERCP privileges	Sign form containing total number of ERCPs, and write whether GI fellow is recommended for independent privileges in ERCP	Decide in a timely manner whether physician granted ERCP privileges. If decision is negative, provide internal due process to appeal decision

Duties of graduating gastrointestinal fellow, endoscopic-retrograde-cholangiopancreatography supervisors during fellowship training, and credentialing committee at hospital to which applicant is applying for endoscopic-retrograde-cholangiopancreatography privileges. ERCP: Endoscopic retrograde cholangiopancreatography; GI: Gastrointestinal.

the national criteria. This certification may, however, prove to be an inadequate remedy. An ultimate solution is to establish a Board for ERCP certification similar to the American Board of Internal Medicine that would remove politically difficult decisions on privileging from hospital committees. Cappell has personal experiences of enduring political pressures during 6 cases of applicants denied ERCP privileges and in 1 case of an applicant approved ERCP privileges despite borderline credentials (personal unpublished data, Cappell). Requiring certification by a national board would dissociate deliberations from local political considerations and would avoid flouting of the numerous recommended guidelines, position papers, and recommendations promulgated during the past 30 years.

MRCP and EUS

The advent of MRCP and EUS has improved the landscape so that ERCP is now rarely indicated solely for diagnosis. Current diagnostic ERCP indications are restricted to subtle primary sclerosing cholangitis, chronic pancreatitis, and indeterminate biliary strictures^[70]. MRCP is limited by contraindications from implanted metal devices, high imaging cost, technical expertise required for performance and interpretation, and occasionally claustrophobia. EUS is often performed by the same operator who would perform the contemplated ERCP. Acquisition of endoscopic skills in both ERCP and EUS is therefore highly desirable during advanced GI fellowship training. A “negative” MRCP or EUS can obviate the need for ERCP^[71] in about 70% and 50% of cases, respectively^[72]. Such avoidance of ERCP is desirable because patients without evident malignancy or choledocholithiasis may be more susceptible to ERCP-induced pancreatitis^[73].

CONCLUSION

ERCP training and credentialing has become a growing concern during the last thirty years. ERCP differs from most other endoscopic procedures in its predominantly therapeutic intent, necessity for typical performance in hospitals, steep learning curve, and penchant for occasionally causing severe complications. ERCP training has undergone several paradigm shifts during the past 50 years including: (1) Change to not requiring ERCP training during standard GI fellowship; (2) Recommendation for training in advanced endoscopy fellowships to obtain privileges in ERCP; (3) Recent exponential growth in number of advanced endoscopy fellowships; and (4) recent shift in ERCP training from an apprenticeship to milestone model, which emphasizes progressive milestones in competence until ultimately achieving independent practice at graduation. Advanced fellows and advanced fellowships have been increasingly

Table 6 Proposed standardized gastroenterology fellowship report card for endoscopic-retrograde-cholangiopancreatography training and performance**Proposed standardized gastroenterology fellowship report card for ERCP****Achievements:**

- _____ Number of ERCPs in which trainee was only a passive observer.
- _____ Number of ERCPs in which trainee actively participated (excludes ERCPs in which trainee was only a passive observer)
- _____ Number and _____ % of ERCPs in which trainee personally successfully cannulated at least one duct (includes either common bile duct or pancreatic duct)
- _____ Number and _____ % of ERCPs in which trainee personally successfully performed sphincterotomy
- _____ Number and _____ % of ERCPs in which trainee successfully personally performed stone retrieval by basket or balloon pull through
- _____ Number of ERCPs in which trainee successfully dilated a biliary or pancreatic stricture
- _____ Number of ERCPs in which trainee successfully personally deployed a stent
- _____ Number of ERCPs in which trainee successfully retrieved a stent
- _____ Number of ERCPs in which trainee successfully used daughter endoscope (*e.g.*, Spyscope) technology

Adverse events:

Number and percent of total ERCPs in which trainee participated in which adverse events occurred:

For fatal complication: Number _____ Percent of total _____

For major adverse events: Number _____ Percent of total _____

For minor adverse events: Number _____ Percent of total _____

Has the trainee been a defendant in a medical malpractice suit in any ERCP in which the trainee participated? _____ Yes _____ No.

Has the trainee had privileges in ERCP revoked or restricted or received a written warning? _____ Yes _____ No

Has the trainee voluntarily given up ERCP privileges in lieu of these privileges being revoked or restricted? _____ Yes _____ No

ERCP: Endoscopic retrograde cholangiopancreatography.

scrutinized regarding ERCP skills, as reflected by at least 12 publications on this subject during the past 5 years (Table 1), including analysis of trainee learning curves and criteria for ultimate competency. ERCP authorities frequently call to improve standardization of ERCP competence and performance, including quality metrics, such as high rates of successful biliary cannulation and low rates of procedural complications. The advanced endoscopy-trained pool remains relatively limited, and most ERCP operators have been trained during a standard GI fellowship or by other means. Hospital credentialing committees have to balance patient safety and risk of medical malpractice litigation versus real-world needs for available ERCP operators and desire for increased hospital revenue from treating patients requiring ERCPs. Credentialing in ERCP by any route other than advanced endoscopy training is expected to become increasingly difficult.

All hospitals need to establish or adopt written criteria for ERCP privileges that are standardized according to national guidelines. Hospitals should be granted a transition period to implement these criteria. Criteria should include minimum number of ERCPs required to apply for privileges and minimum annual volume to maintain privileges. These criteria may specify numbers required for specialized ERCP procedures, including sphincterotomy, stricture dilatation, stent deployment, stone extractions, and per-oral cholangiopancreatography. Hospitals will have to develop criteria for minimally acceptable rates of successful biliary cannulation, sphincterotomy, and gallstone extraction. Hospitals may also have to determine maximal acceptable rates of major post-ERCP complications, especially for ERCP-induced pancreatitis, clinically significant post-sphincterotomy bleeding, and bile leaks. These criteria would benefit hospitals by establishing firm criteria for granting versus denying ERCP privileges, protect applying physicians from being denied ERCP privileges for competitive rather than professional reasons, and protect patients from inadequately trained ERCP operators. Institutional GI morbidity and mortality committees should review all mortality from major ERCP complications including ERCP-induced pancreatitis, post-sphincterotomy bleeding, bile leaks, or duodenal perforations.

Implementing and following stricter ERCP regulations would likely introduce new direct costs from the work required to closely monitor ERCP practitioners, and indirect costs from reduction in the number of ERCP operators. Public health administrators need to realize that increased regulation is costly and budget these inherent costs to benefit patient care. Criteria for ERCP competency still remain controversial in 2019 and are sometimes flouted by hospitals despite the numerous

studies, position papers, editorials, and recommended guidelines for ERCP competency. Mandatory criteria monitored by a national board, similar to the National Board of Medical Examiners or American Board of Internal Medicine, would provide nationally uniform criteria, which would be divorced from local political considerations of individual practitioners, their GI groups, competing GI groups, and given hospital, and would avoid widespread flouting of recommended guidelines.

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