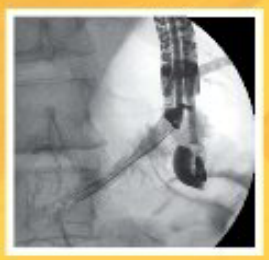

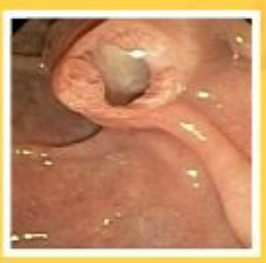

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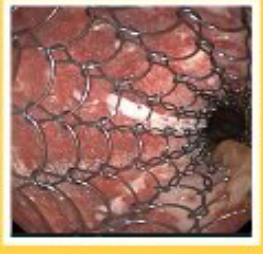

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CLINICAL GASTROINTESTINAL ENDOSCOPY, THIRD EDITION ISBN: 978-0-323-41509-5

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Library of Congress Cataloging-in-Publication Data
Names: Chandrasekhara, Vinay, editor. | Elmunzer, B. Joseph, editor. | Khashab, Mouen, editor. | Muthusamy, V. Raman, editor.
Title: Clinical gastrointestinal endoscopy / [edited by] Vinay Chandrasekhara, B. Joseph Elmunzer, Mouen A. Khashab, V. Raman Muthusamy.
Description: Third edition. | Philadelphia, PA : Elsevier, [2019] | Includes bibliographical references and index.
Identifiers: LCCN 2017056974 | ISBN 9780323415095 (hardcover : alk. paper)
Subjects: | MESH: Endoscopy, Gastrointestinal | Gastrointestinal Diseases–therapy | Biliary Tract Diseases–therapy | Pancreatic Diseases–therapy
Classification: LCC RC804.E64 | NLM WI 190 | DDC 616.3/407545–dc23 LC record available at https://lccn.loc.gov/2017056974

Executive Content Strategist: Dolores Meloni
Senior Content Development Specialist: Rae Robertson
Publishing Services Manager: Catherine Jackson
Project Manager: Tara Delaney
Design Direction: Renee Duenow

Printed in China

Last digit is the print number: 9 8 7 6 5 4 3 2 1

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PREFACE

Welcome to the third edition of *Clinical Gastrointestinal Endoscopy*. Gastrointestinal endoscopy is a continuously evolving field with the advent of new technologies, refined techniques, and new applications. The prior editions of this book have been universally regarded as a comprehensive guide to the latest endoscopic techniques. Understanding and adoption of such practices leads to optimal outcomes with endoscopy. This text is unique because of the breadth of topics covered by experts in every discipline of gastrointestinal endoscopy from across the globe. *Clinical Gastrointestinal Endoscopy* has been an essential resource for anyone interested in learning about endoscopic procedures, as one can access a variety of topics in succinct, easily understood chapters from content specialists.

This edition marks the transition to a new editorial team and builds on the success of the two prior editions. The previous editions achieved great accolade due to the efforts of the editorial board lead by Gregory Ginsberg and coedited by Michael Kochman, Ian Norton, and Christopher Gostout. The new editorial team was selected due to their expertise in gastrointestinal endoscopy, enthusiasm for disseminating best practices to a worldwide audience, and diverse background of training and experience from different premiere institutions. Commensurate with the change in the editors, we were excited to invite a new set of content experts who share their insights into recent advances in endoscopy and the impact these innovations have had on improving patient care. This has led to an exciting, comprehensive textbook from today's most prestigious specialists.

Clinical Gastrointestinal Endoscopy, third edition, is divided into three main sections covering Equipment and General Principles of Endoscopy, Luminal Gastrointestinal Disorders, and Pancreaticobiliary Disorders. Section I elegantly describes the history of gastrointestinal endoscopy and then provides primers on how endoscopes, endoscopic devices, and endoscopy units function. There are many applicable practice-changing pearls of wisdom in this section. Section II: Luminal Gastrointestinal Disorders covers both benign and malignant disorders as well as emerging endoscopic areas. Section III: Pancreaticobiliary Disorders details standard and advanced techniques in ERCP and EUS for the diagnosis and management of benign and malignant disorders of the pancreaticobiliary systems.

Each chapter has been meticulously crafted to present relevant updates to the topic in a manner that is easy to read and readily retained. These chapters are filled with tips that will help deliver optimal care for your patients. In addition, the content has been enhanced with new images and illustrations to highlight recent major advances in endoscopic techniques and applications for the latest technologies. These images and pictures can be downloaded from the book's website so that you can use them in your presentations. Furthermore, most topics have accompanying videos demonstrating the diagnostic and therapeutic endoscopic procedures. This media platform allows the reader to experience endoscopic procedures firsthand when accessing the content from their handheld device or computer. Each video clip has been meticulously edited to maximize the educational value.

The authors and editors draw upon their collective experience to provide you with the most current, authoritative, and impactful content for the sole purpose of enhancing the education of gastrointestinal endoscopy for years to come.

Vinay Chandrasekhara, MD

DEDICATION

To my parents Bina and Kota and my sister Sheila, who provided a nurturing environment and encouraged me to dream big. The values that you instilled from an early age will forever remain with me.

To my wife Meghana and our children Siddhant and Adya, who have allowed me to pursue my dreams even if it meant being away from home. Every professional accomplishment is only possible because of your love and support.

To my colleagues, friends, trainees, and professional acquaintances: I appreciate everything you have taught me over the years. I am especially ever grateful to Drs. Gregory Ginsberg and Michael Kochman for providing me with unbelievable opportunities, including serving as an editor for this textbook.

—Vinay Chandrasekhara

To my parents, Carol and Hadi, for showing me the right path and to my wife, Alli, for taking it with me. To our patients, without whom there would be no progress.

—B. Joseph Elmunzer

This book is dedicated to my family, trainees, nurses, colleagues and mentors. It took a tremendous effort and commitment to put this comprehensive endoscopy book together. I am grateful to both my personal family and my work family who allowed me to have the focus, dedication, and time to be a coeditor of this book.

—Mouen A. Khashab

I dedicate this book to my teachers, colleagues, and trainees who continue to challenge me to question what is felt to already be known. To my patients for their inspiration in motivating me to continually improve on the care we deliver. To my entire family, I thank you for your constant love and support. Specifically, to my mother, who has always encouraged me to follow my own path, and to my father, who left a medical school faculty position in India 45 years ago to start over as a resident in the USA with nothing other than $20 in his pocket and the American Dream, for the many opportunities I have had in my life and to whom I owe everything. Finally, to my wife Nanda and daughter Sonali for your substantial patience, compassion, warmth, and most importantly for bringing so much joy and laughter into my life.

—V. Raman Muthusamy

VIDEO CONTENTS

SECTION III Pancreaticobiliary Disorders

1

The History of Gastrointestinal Endoscopy

James L. Achord and V. Raman Muthusamy

CHAPTER OUTLINE

INTRODUCTION

The role of the physician is to observe, detect anatomic abnormalities or disease, and conceive ways and means by which discovered deficiencies in function can be corrected or ameliorated. To extend the physical examination to areas hidden from external view, such as within body orifices, presents a problem of safe and effective access. In insatiable attempts to accomplish these goals, there is no human orifice along with its recesses that has not been inspected, probed, prodded, and otherwise examined over the centuries. It was a compelling necessity to develop safe, nonsurgical methods to accomplish this purpose. Before the 20th century, numerous attempts to access these hidden cavities were plagued by instrumentation that was inadequate and dangerous. The history of every science or technical development is invariably a series of small discoveries or innovations, often in fields remote from those under investigation. Small improvements, each resulting in incremental gains, lead toward the idealized goal. Often, changes that appear to be an advance are found to be an impediment by further discoveries, and we recognize that a different way is better. Therefore, the task is never ending.

The term *endoscopy* comes from the Greek prefix *endo-* ("within") and the verb *skopein* ("to view or observe"). In this chapter, we summarize major developments over the years in gastrointestinal (GI) endoscopy to the present. As in any summary, the contributions of some individuals inevitably are not cited, and we offer our apologies to these individuals.

SEQUENTIAL HISTORY OF ENDOSCOPY

The visual exploration and examination of body orifices date to at least Egyptian and later Greco-Roman times, during which mechanical specula for viewing the vagina and anus were developed and used to a limited extent. Further progress was delayed by lack of sufficiently strong metals and the ability to form them into usable instruments, as well as the lack of adequate illumination. These initial efforts were directed at the genitourinary (GU) tract, with cavities that were only a short and relatively straight distance from the exterior.

Bozini (1805) is credited with the earliest known attempt to visualize the interior of a body cavity with a primitive endoscope (Fig. 1.1).[1–3] Bozini devised a tin tube illuminated by a candle from which light was reflected by a mirror; this was a device he called a *lichtleiter* (light conductor). He used this device to examine the urethra, urinary bladder, and vagina, but it was an impractical instrument that never gained wide acceptance. Although there were multiple attempts to develop more usable instruments, all directed toward the GU tract, none were widely used. The most notable efforts were by Segalas in France in 1826 and Fisher in Boston in 1827,[2] both using straight metal tubes, but the lack of a satisfactory light source remained a major impediment.

The next significant development was the instrument of Desormeaux in France.[2] Desormeaux's contribution in 1855 was a better, although still inadequate, light source using a lamp fueled with alcohol and turpentine ("gazogene") (Fig. 1.2). His instrument was based on that of Segalas. Others continued with efforts to improve the light source and the means to deliver it, but the devices were unsatisfactory for the more inaccessible areas of the GI tract.

Rigid Gastrointestinal Endoscopes

Kussmaul is credited as being the first to perform a gastroscopy in 1868, using a straight rigid metal tube passed over a flexible obturator and a cooperative sword swallower (Fig. 1.3).[1–4] For a light source, he used a mirror reflecting light from the

Abstract

The development of endoscopy is a testimony to human ingenuity. Instruments have evolved from dangerous straight tubes, illuminated by light reflected from candles, to more flexible and safer instruments with an image transmitted through a series of prism lenses and illumination by an electric light bulb, to images transmitted through fiberoptic bundles with illumination transmitted by fiber bundles from an external source, to our present remarkably safe electronic instruments with digital images transmitted to a video screen through wires and processed by computers. Most recently, we can visualize the lumen of the gut without touching the patient. Now we not only can visualize, biopsy tissue, and perform procedures within the hidden cavities of the body, but also directly and indirectly see beneath the mucosa and into immediately adjacent organs. The evolution of gastrointestinal endoscopy is a truly remarkable story, and advances in the diagnostic and therapeutic capabilities of these instruments continue to be made at a rapid pace. To know and understand what has occurred previously lends strength to efforts toward achieving what is to come.

Keywords

gastrointestinal endoscopes
fiberoptics
videoendoscopy
capsule endoscopy
gastroscopy
sigmoidoscopy
colonoscopy
endoscopic retrograde cholangiopancreatography (ERCP)
endoscopic ultrasonography (EUS)
enteroscopy

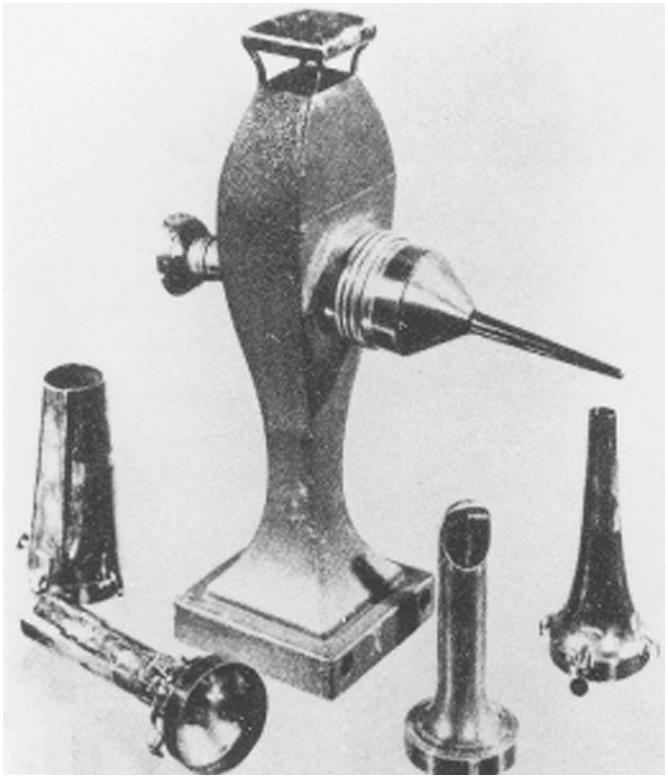

FIG 1.1 Bozzini's lichtleiter, 1805. (From Edmonson JM: History of the instruments for gastrointestinal endoscopy. *Gastrointest Endosc* 37[Suppl 2]:S27–S56, 1991.)

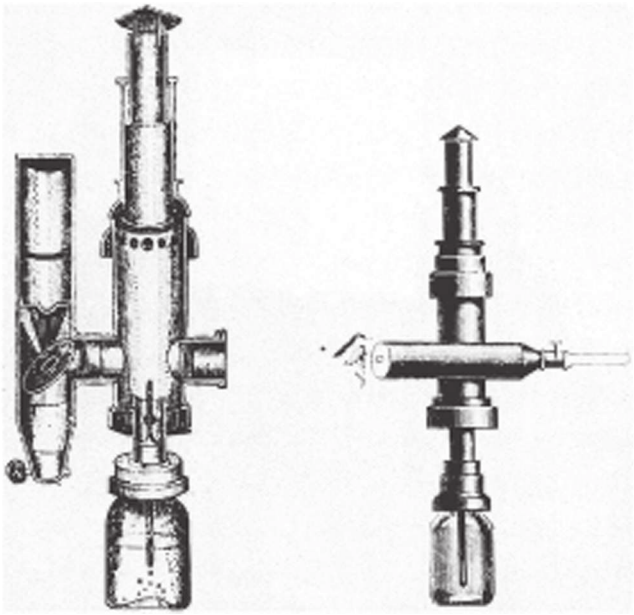

FIG 1.2 Desormeaux's endoscope, 1853. (From Edmonson JM: History of the instruments for gastrointestinal endoscopy. *Gastrointest Endosc* 37[Suppl 2]:S27–S56, 1991.)

Desormeaux device but found it inadequate. He also quickly discovered that gastric secretions were a problem, despite using a flexible tube he had developed earlier to empty the stomach before the procedure. The value of his efforts was the demonstration that the curves and bends of the esophagus and esophagogastric junction could be traversed with careful manipulation and that the gastric pouch could be visualized. Kussmaul apparently demonstrated his "gastroscope" several times, but the illumination was too poor to allow a clinically useful image,[4] and he abandoned his efforts.

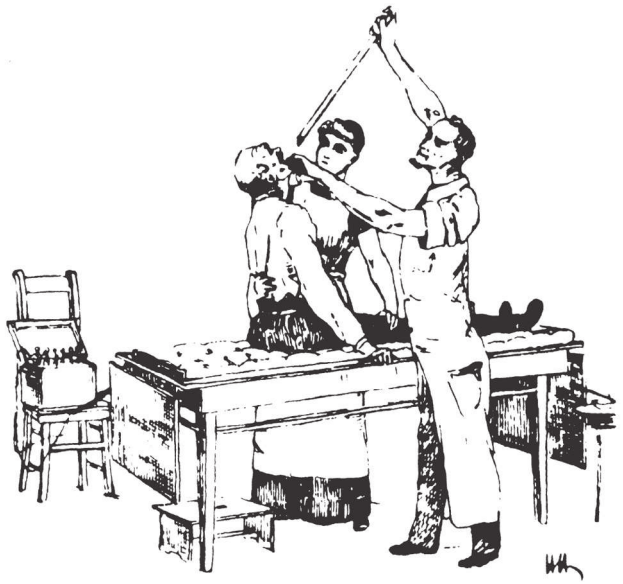

FIG 1.3 Kussmaul's gastroscope, 1868. (From Edmonson JM: History of the instruments for gastrointestinal endoscopy. *Gastrointest Endosc* 37[Suppl 2]:S27–S56, 1991.)

Encouraged by the efforts of Kussmaul, others switched their attention to developing esophagoscopes because the esophagus is much easier to visualize, and a less complex design than the gastroscope was required. The problems of perforation, at that time usually fatal, and of illumination, remained major obstacles. Before the late 19th century, illumination of light reflected by a mirror into a straight metal tube continued to be used. As noted earlier, several light sources were developed, but the intensity left much to be desired. Several innovations were developed to solve this problem, including a burning magnesium wire, which produced a brilliant light but unacceptable heat and smoke. The most promising device seemed to be the brilliant light from a loop of platinum wire charged with direct current, introduced simultaneously by Bruck in Breslau and Milliot of Paris in 1882.[2] Although the illumination was adequate, major difficulties were encountered with the considerable heat generated, necessitating a water cooling system and the cumbersome batteries used for a power source. Nevertheless, the platinum wire device was an encouraging development and was used in several instruments that saw relatively widespread use.

These instruments were made obsolete just a few years later by Edison's incandescent electric light bulb, introduced in 1879. In 1886, Leiter, an instrument maker, was the first to use the electric incandescent light bulb in a cystoscope just 7 years after Edison introduced it. With a few short-lived exceptions, all instruments used Edison's invention after 1886. Working with Leiter, von Mikulicz developed an unsuccessful gastroscope but a practical esophagoscope that he used extensively until distracted by his many other medical interests.

At the turn of the 20th century, Jackson, an otolaryngologist, also examined the esophagus and the stomach using a straight rigid tube and a distal electric light bulb, but few could match

his talents in the GI tract. Under his influence, esophagoscopy was considered the exclusive province of ear, nose, and throat (ENT) departments in many community hospitals in the United States as late as the 1950s. The design of the esophagoscope remained a straight rigid tube, usually with a rubber finger-tipped obturator to make insertion safer. With the later addition of a 4 × power lens on the proximal end and a distal incandescent bulb, various models were popular until the introduction of fiberoptics in 1961. The Eder-Hufford rigid esophagoscope (Fig. 1.4), introduced in 1949, was popular and still in use in the early 1960s.

It was not until after 1900 that persistent efforts to develop a usable gastroscope were successful. All attempts to build a flexible instrument using a multiplicity of lenses were designed to be straightened after introduction and were fragile, easily damaged, and cumbersome. Straight tubes with simpler optics were useful, but perforations were still a problem.[1] In 1911, Elsner introduced a rigid gastroscope with an outer tube through which a separate inner optical tube with a flexible rubber tip and side-viewing portal could be passed (Fig. 1.5). The rubber tip, previously used in the esophagoscope obturator, was more crucial than it might appear, for it seemed to be, along with the later addition of a flexible metal coil proximal to it, the single feature that reduced the rate of perforation. Elsner's instrument worked as designed and was widely used, especially by Schindler, then in his native Germany, who called it the "mother of all instruments until 1932."[5]

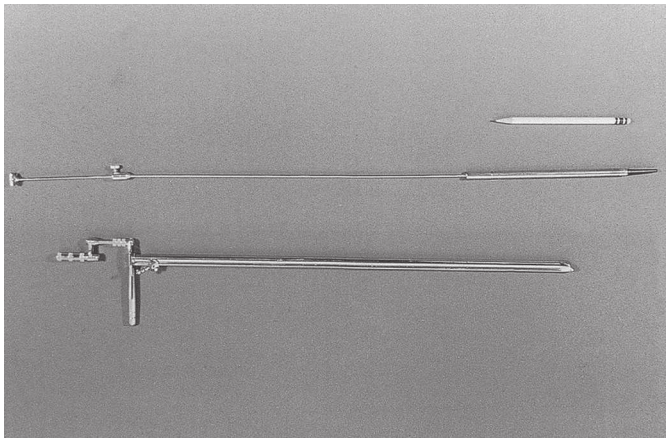

FIG 1.4 Eder-Hufford esophagoscope, the result of multiple attempts to develop a clinically useful instrument, 1949.

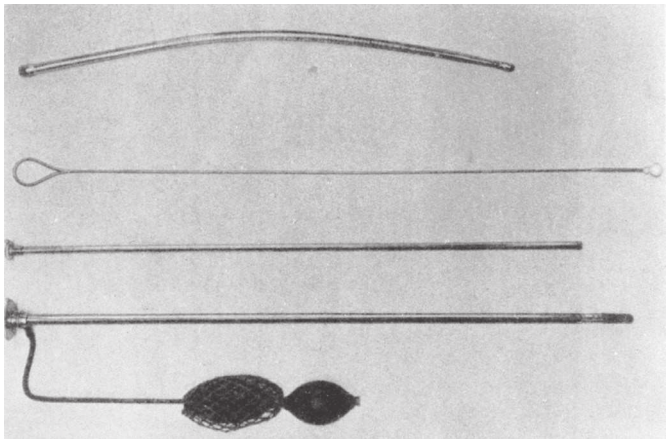

FIG 1.5 Elsner's gastroscope, 1911. (From Edmonson JM: History of the instruments for gastrointestinal endoscopy. *Gastrointest Endosc* 37[Suppl 2]:S27–S56, 1991.)

In 1922, Schindler introduced his own version of the Elsner gastroscope, the major innovation of which was the important addition of an air channel to clear the lens of secretions. With the Elsner gastroscope, Schindler examined the stomachs of several hundred patients and meticulously recorded his findings in each procedure. He published *Lehrbuch und Atlas der Gastreoskopie* in 1923, with descriptions and remarkably accurate drawings. He trained others in the technique and was responsible for wide acceptance of gastroscopy. The procedure began with emptying the stomach using a nasogastric tube, followed by sedation. The patient was placed on the left side, and an assistant held the head rigidly extended to produce a straight path into the esophagus and the stomach (the "sword swallower's technique"). The role of the assistant was crucial. Schindler's effort was impressive and convinced many of the value of an expert examination of the stomach.

Semiflexible Gastroscopes

It became apparent that straight, rigid tubes were not ideal for examination of the stomach. Fatal perforations continued to the detriment of acceptance of the procedure. Visualization of the surface of the stomach was incomplete at best, with many consistent blind spots. These problems stimulated investigation of methods to manufacture safer, "flexible" instruments. The use of the term *flexible* here is problematic in view of what we think of today as flexible instruments. Although these early instruments were not flexible by our standards, they were more flexible than the straight, rigid instruments that came before. *Semiflexible*, with passive angulation of the distal portion of 34 degrees and sometimes more, was a more appropriate term.

In 1911, Hoffman showed that an image could be transmitted through a curved line by linking several short-focus prisms. Using this principle, several instruments were constructed, but these were unsatisfactory or were not widely accepted. Schindler, working with Wolf, the renowned instrument maker, constructed a semiflexible instrument with a rigid proximal portion and a distal portion made elastic by coiled copper wire and terminating with first a rubber finger and later a small rubber ball. Illumination was with a distal incandescent light bulb. Air insufflation was made possible with a rubber bulb, expanding the stomach wall to beyond the focal length of the prisms, which were manufactured by Zeiss. In 1932, the sixth and final version was patented. This instrument, known as the Wolf-Schindler gastroscope, greatly improved the safety and efficacy of gastroscopy and was used throughout the world (Fig. 1.6).

Thanks to the published meticulous work and enthusiasm of Schindler, whose designation as the "father of gastroscopy" is well deserved, the procedure was finally widely accepted as a valuable extension of the physical examination. The era of the semiflexible gastroscope from 1932 to 1957 has been called *the Schindler era*. Schindler was chiefly responsible for transforming gastroscopy from a dangerous and seldom used procedure to one that was relatively safe and indispensable for evaluation of known or suspected disease of the stomach. He insisted that all clinicians who planned to use the instrument be properly trained and that "… no manipulation inside of the body is without danger; therefore no endoscopic examination should be done

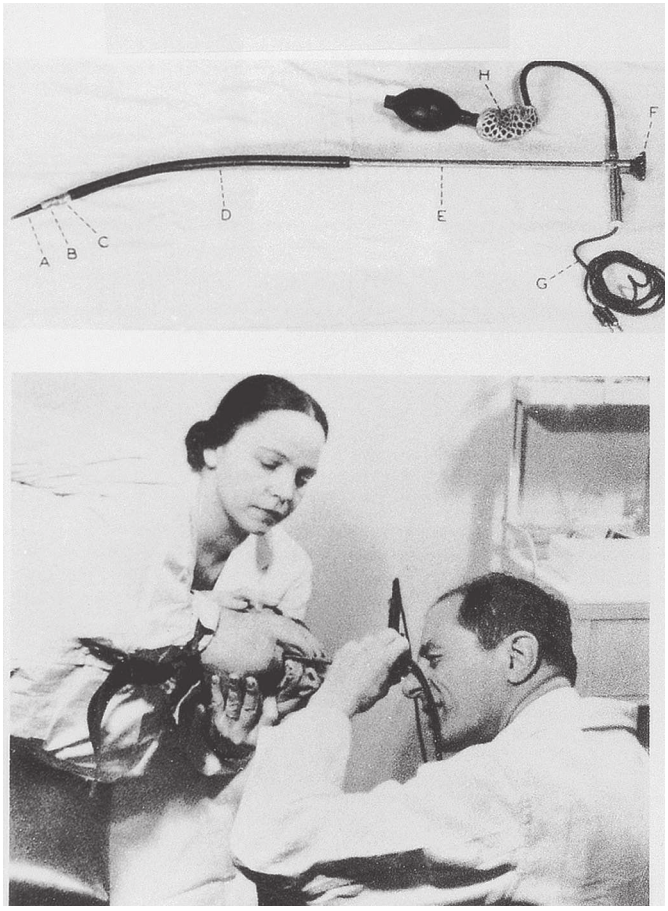

FIG 1.6 Wolf-Schindler "flexible" gastroscope *(top)* being used by Schindler *(bottom)* with his wife as the head holder. (From Edmonson JM: History of the instruments for gastrointestinal endoscopy. *Gastrointest Endosc* 37[Suppl 2]:S27–S56, 1991.)

without reasonable indication."[6] In today's vernacular, the risk approaches infinity if the benefit approaches zero.

Schindler was born in Berlin in 1888. He gained considerable experience as an Army physician in World War I, where he became convinced that gastritis, then an often-disparaged cause of symptoms, was a bona fide disease. His interest in gastritis lasted throughout his career and undoubtedly stimulated his interest in gastroscopy. The Wolf-Schindler endoscope of 1932 and Schindler's publications with drawings further enhanced what thereafter rapidly became a discipline. His enthusiasm for and talent in using the gastroscope led to what has been called his *gospel of gastroscopy*, which he and others spread throughout academia and to the community of practicing physicians. Because of his Jewish background, Schindler was put in "protective custody" by the Nazis, but with the help of the physicians Ortmeyer and Palmer and philanthropists in Chicago, he was able to immigrate to the United States in 1934.[1–4,7]

Chicago became the hub of GI endoscopy, and it was here, in Schindler's home, that the first discussions were held about forming a new organization for GI endoscopy, now known, after several name changes, as the *American Society of Gastrointestinal Endoscopy*. In 1943, just 9 years after his arrival in the United States, Schindler left Chicago for Loma Linda University. In 1958, he accepted an appointment as Professor of Medicine at the

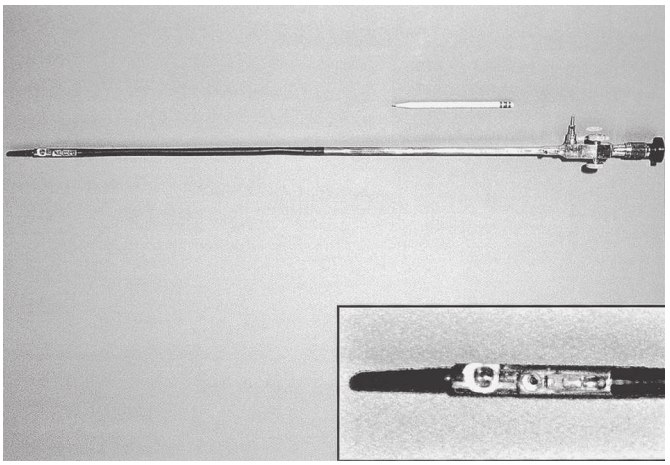

FIG 1.7 Benedict operating gastroscope.

University of Minas Gerais in Belo Horizone, Brazil. He came back to the United States in 1960 because of an eventually fatal illness of his wife and returned to his native Berlin in 1964, where he died in 1968 at the age of 80.[1] Despite his acclaim in endoscopy, Schindler insisted that one must be a physician first and an endoscopist second. He was very knowledgeable in the field of general gastroenterology and published, without coauthors, a synopsis of the entire field in 1957.[6]

The Wolf-Schindler endoscope was introduced into the United States by Benedict, Borland, and many others. Schindler's immigration to Chicago inspired a surge of interest in the United States, but with the outbreak of war in Europe, the German source of instruments disappeared. Several US companies working with Schindler and others produced many popular gastroscopes that were significant variations on the Wolf-Schindler model, including Cameron Co., which produced its first instrument in 1940.[8] The Eder-Hufford semiflexible gastroscope followed in 1946,[9] and American Cystoscope Makers, Inc. (ACMI) produced a gastroscope in 1950. A combination of the Eder-Hufford esophagoscope with a semiflexible gastroscope to be passed through it was the Eder-Palmer transesophagoscopic flexible gastroscope produced by the Eder Company in 1953. Each gastroscope had its proponents.

Biopsy

With the availability of instruments for visualization, it became apparent that tissue must be obtained to identify the nature of the observed abnormalities. Instruments for blind biopsies were used early on, but a device was needed that would allow the operator to obtain a biopsy specimen of abnormal tissue directly when seen at endoscopy. The Benedict Operating Gastroscope was produced in 1948 based on a 1940 model by Kenamore (Fig. 1.7).[10] The Benedict instrument was a popular instrument that was widely used. In the debates about the necessity for biopsy, Benedict, a surgeon who switched entirely to endoscopy, stated that gastroscopy was not a routine procedure and should be reserved for those with a complex differential diagnosis, but "gastroscopic examination is not complete unless the gastroscopist has some means of biopsy readily available."[11] It soon became clear that the correlation between histology and a diagnosis based on visualization alone was often widely discrepant, and certain diagnoses could not be reliably made without tissue examination.

Efforts such as wash and brush cytology continued and have persisted in various forms to the present time.

Fiberoptics

By the 1950s, the ideal of a totally flexible GI endoscope with good visualization that could withstand the rigors of clinical use had not been realized, although the semi-flexible instruments with their biopsy capabilities were satisfactory for most clinical purposes. In fact, these instruments were not rapidly abandoned by all with the introduction of the remarkably flexible fiberscope. The development of the science of fiberoptics and its application to endoscopes truly revolutionized the diagnostic and, later, the therapeutic abilities of endoscopy. Its importance in the development of this field cannot be overstated.

The principle of internal reflection of light along a conduction pathway was used by Lamm in October 1930.[1] The image was severely degraded by light escaping from the thin fibers of quartz he used, although the potential for total flexibility was present. Lamm could not interest Schindler or others in his efforts, and the experiment was discontinued. Almost 25 years later, in 1954, Hirschowitz, in fellowship training at the University of Michigan, visited Hopkins and Kapany in London to review their work[12] with glass fibers, which totally confirmed the work of Lamm and his predecessors. Hirschowitz became convinced that application of this principle could be used to develop a totally new and superior endoscope. He began work with a graduate student, Curtiss, who developed a technique of coating glass fibers with glass of a different optical density, preventing the escape of light and degradation of the image. This was the critical discovery that made the principle of internal reflection through glass fibers workable.

In 1957, Hirschowitz demonstrated his fiberscope, and he published his work in 1958 (Fig. 1.8).[13] His audience was not impressed, and it took another 3 years, working with ACMI, to produce a marketable scope, which he called the *Hirschowitz Gastroduodenal Fiberscope*. This was a very flexible side-viewing instrument with an electric light on its distal end, an air channel, and an adjustable focusing lens proximally. The tip lacked what was by then the "obligatory" rubber finger, and this omission was a source of criticism; one was added on a later model. Although some individuals criticized the quality of the image, most believed the size and brightness were superior to the semiflexible scopes. This model, the ACMI 4990, was introduced to the market late in 1960 after being tested by Hirschowitz on himself and numerous patients. In 1961, the senior author of this chapter was in a gastroenterology fellowship at the Emory University Clinic with Schroder. He vividly recalls Schroder's reaction after the first use of the new fiberscope around March 1962 (Fig. 1.9). Upon finishing the initial examination using the new device, he turned to him and said, "Anybody want to buy a used Benedict operating scope?" The senior author does not recall it ever being used again, as the Hirschowitz Gastroduodenal Fiberscope was clearly superior in his view, and he finished his training with that instrument.

There were problems with the fiberscope noted by users. The distal light source would become so heated that thermal injury to the gastric mucosa was possible unless the tip was continuously moved. In prolonged procedures, protein in gastric secretions would coagulate on the bulb and the adjacent visualizing port, totally obscuring the lens. As the number of procedures with a single instrument increased, some glass fibers would break, producing small black dots in the visual field. This was a persistent problem with fiberscopes during their entire history and especially apparent in training programs where a single scope was used by several trainees on many patients. The side-viewing lens prevented visualization of the esophagus, and the scope had to be passed blindly through the pharyngeal orifice. The previous semiflexible scopes in use shared this problem, and it was not considered a defect at the time. The flexibility itself resulted in some difficulty in advancing because attempts to push the instrument through the pylorus and into the gut resulted in more bowing in the gastric pouch (Fig. 1.10). Although one could sometimes visualize the duodenum, this was done by overinflating the stomach and looking through the pylorus without actually entering it. If one managed to introduce the tip into the duodenum, as occasionally happened, the visual field was inside the focal length of the instrument, and only a "red-out" was observed.[4]

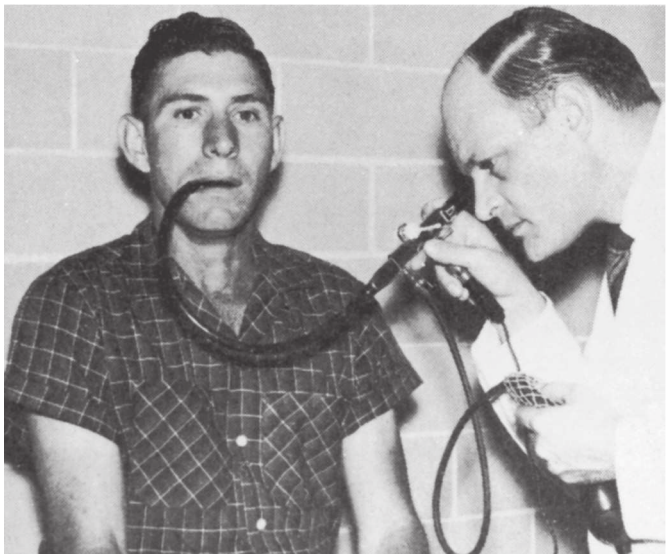

FIG 1.8 Hirschowitz examining the stomach of an outpatient. (From Hirschowitz BI: Endoscopic examination of the stomach and duodenal cap with the fiberscope. *Lancet* 277[7186]:1074–1078, 1961.)

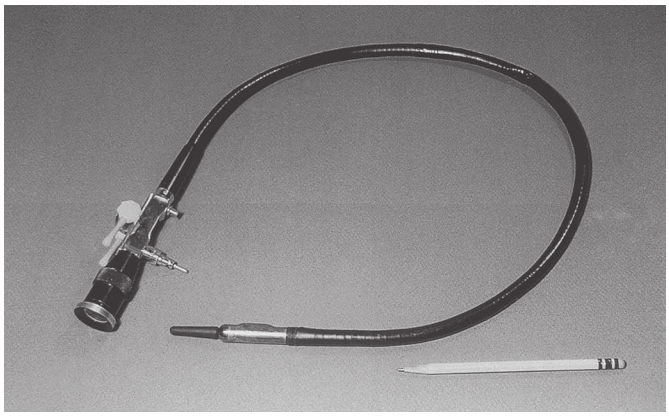

FIG 1.9 ACMI fiberscope, 1962.

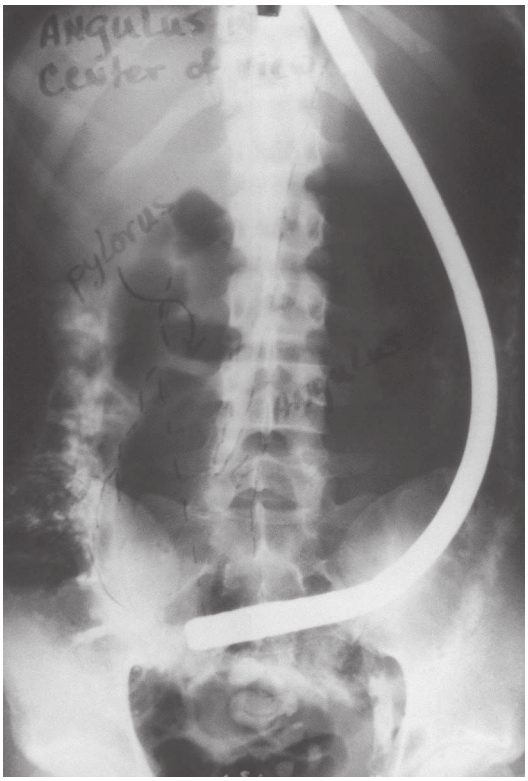

FIG 1.10 Visualization of duodenum was sometimes obtained by overinflating the stomach.

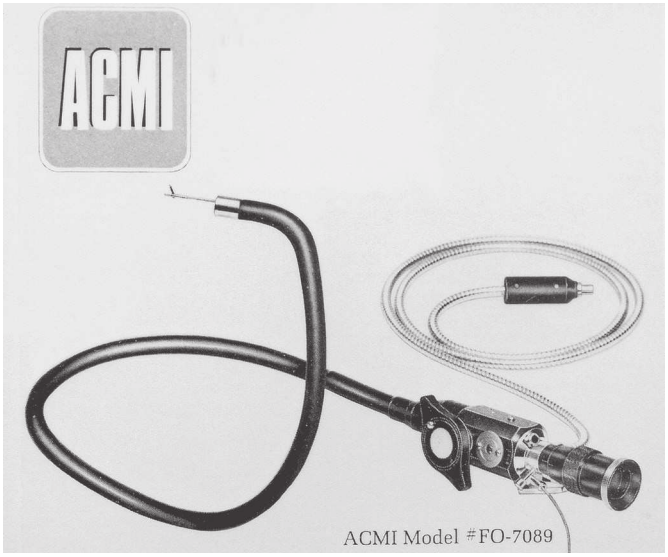

FIG 1.11 LoPresti forward-viewing esophagogastroscope. (From advertisement in *Gastrointest Endosc* 16:79, 1970.)

Many clinicians did not believe the additional expense of replacing the older, beloved instruments with which they had been successful for many years was warranted. Even ACMI officials did not see the fiberscope as totally replacing the instruments with a lens system.[2] Despite reservations, comparison and experiential studies showed the advantages of the new fiberscopes.[14–17] Following the flagship ACMI model 4990, several models of the fiberscope were introduced by ACMI and other companies, each with significant improvements, including the controllable tip in the side-viewing ACMI model 5004. Visualization of the gastric pouch, including retroflexed views of the cardia, was now complete. The major objection to these instruments was the inability to pass the instrument under direct vision and examine the esophagus; in addition, the area beyond the pylorus could not be consistently examined.

Most clinicians were already fully trained in use of the Eder-Hufford esophagoscope, and in the absence of a forward-viewing fiberscope, use of the Eder-Hufford esophagoscope continued. A forward-viewing scope was mandatory. LoPresti modified the tip of the fiberscope to create the foroblique fiberoptic esophagoscope in 1964.[18] Passing the instrument under direct vision was possible, and clinicians immediately discovered that they could examine not only the esophagus, but also a large portion of the proximal stomach. At a length of 90 cm, however, one could not reach the duodenum. Working with ACMI, LoPresti produced the longer Panview Mark "87" gastroesophageal endoscope in 1970. By about 1971, the instrument had been lengthened to 105 cm with a four-way controllable tip capable of 180 degrees of deflection (Fig. 1.11).

The aptly named *panendoscope* was now a reality. Japanese and American manufacturers began to produce new models with such rapidity that endoscopists hardly had time to become thoroughly familiar with one before another, significantly improved (and more expensive) model was on the market. Patient comfort was greatly improved, and the relative safety of the fiberoptic endoscopes rapidly became apparent. By 1970, most gastroscopic examinations were done with fiberscopes. The development of a "teaching head" fiberoptic bundle with a light splitter and attached eyepiece and attachment to the eyepiece of the scope allowed two people to visualize the image. Dividing the light from the endoscope considerably diminished the brightness of the image, however, to both the operator and the observer. This device saw limited use and was utilized primarily in teaching institutions.

Endoscopic Retrograde Cholangiopancreatography (ERCP)

With access to the duodenum, the ampulla of Vater became visible. It followed that one should be able to inject contrast material into the bile and pancreatic ducts and increase diagnostic capabilities. Initial attempts in 1968 by McCune et al[19] to modify an existing scope were only partially successful, but did show that endoscopic visualization by injection of radiologic contrast agents into ducts was possible. In 1970, Machida and Olympus in Japan produced usable, side-viewing scopes with controllable tips and elevators to move the injection tube to the ampulla.

Japanese endoscopists[20] developed the technique of endoscopic retrograde cholangiopancreatography (ERCP) with an 80% success rate. Vennes and Silvis[21] showed the utility of ERCP in the United States and taught many physicians to use it.[4] It was immediately apparent that if clinicians could visualize the biliary and pancreatic ducts endoscopically (i.e., nonsurgically), they should be able to apply by some means long-established surgical techniques for treatment of choledocholithiasis and pancreatitis, such as sphincterotomy and stone removal. In 1974, just 4 years after the demonstration of the diagnostic utility of the new ERCP

scopes, Kawai et al in Japan[22] and Classen and Demling in Germany[23] independently developed methods of endoscopic electrosurgical sphincterotomy for extraction of biliary calculi in the common duct. This procedure requires great skill; in 1976, Geenen[24] reported that only 62 operative procedures had been done by four endoscopists, and seven of the procedures were failures. In 1983, Schuman[4] reported that several thousands of patients had undergone ERCP, and by now, hundreds of thousands of ERCP procedures have been done. Because of advances in radiologic techniques, ERCP is now seldom used for purely diagnostic purposes.

Photography

It is one thing to describe to others what one may see through any device and another to be able to show them. The large impact of Schindler's early publications was related, in part, to the excellent color drawings he presented. Early on, neither cameras nor photographic films were advanced enough to allow good color reproduction or sharp, accurate images in relatively poor lighting. Such documentation is essential for widespread appreciation of endoscopy by individuals who do not perform the procedure. The first clinically useful photography came with improvements in film by Kodak and the construction of an external integrated camera by Segal and Watson in 1948.[25,26] Although these authors reported that approximately 61% of the images were of good quality, this was not the experience of all clinicians.[4]

Although an intragastric camera was developed as early as 1848 by Lange and Meltzung, a clinically useful device was not available until 1950, when Uji, Sugiura, and Fukami, working with Olympus Corp. (Center Valley, PA),[27] developed the Gastrocamera with synchronized flash, which took good intragastric pictures and had a controllable distal portion. By following a prescribed pattern of rotation and flexion, a series of pictures was obtained that included the entire surface of the stomach. The big disadvantage was that the operator could not see through the instrument and had to await development of the very narrow (5-mm) film before the results could be seen. Photographs for demonstration required additional time in the photo laboratory while enlargements were made.

After the introduction of fiberoptic scopes in 1961, Olympus introduced a combination Gastrocamera fiberscope (GTF-A) in 1964, but, as Schuman[4] commented, "it was *just* a gastroscope" and never attained popularity. Simultaneously, rapid development and physician acceptance of fiberscopes with the ability to use technically advanced 35-mm cameras with an external adapter made the Gastrocamera obsolete, and it was abandoned.

Sigmoidoscopy and Colonoscopy

The problems presented by examination of the anus and rectum were relatively easy. Straight metal tubes were used and found in the ruins of Pompeii.[2] The basic design of the anoscope has not changed in the past century or more except that it is now made of disposable plastic. It remains a tapering short tube with an obturator that is removed after introduction through the anal sphincter. Examination of the rectum and sigmoid required a longer tube, but no truly satisfactory device was available until 1894, when Kelly[28] at Johns Hopkins developed a 30-cm rigid tube with light reflected down the tube from a head lamp. Tuttle[29] incorporated a distal light source in his proctosigmoidoscope of 25 cm in 1903. These instruments have remained the basic design for the past 100 years. For the past 25 years or so, disposable clear plastic tubes have been widely used. These are essentially a plastic version of the Kelly and Tuttle tubes with a distal electric light source, but visualization is possible through the clear plastic. With the application of fiberoptics to sigmoidoscopy in the late 1960s, examination of the sigmoid colon became not only satisfactory, but also much more comfortable for the patient.

Overholt,[30] who later went on to be the principal developer of colonoscopy using similar technology, presented his results of flexible sigmoidoscopy in 250 patients in 1968. Although early flexible sigmoidoscopes were made in variable lengths, the current length of 60 cm came to be the preferred one. Examination of the colon above the sigmoid presents obvious additional problems of multiple curves and angulations amenable only to highly flexible instruments and trained operators. Attempts, all unsuccessful, were made using semiflexible instruments, and these are reviewed by Edmonson.[2] Satisfactory examination of the length of the colon was impossible until the introduction of the flexible fiberscope. Attempts to use forward-viewing gastroscopes were not technically satisfactory, although several clinicians tried. Turell[31] presented his attempts in 1967 using a modified gastroscope, but he concluded that the instrument was not ready for routine clinical use. By 1970, several manufacturers produced instruments specifically designed for colonoscopy, including ACMI working with Overholt in the United States and Olympus Corporation in Japan.

The primary problem with regularly completing examinations to the cecum was not the instruments so much as it was the techniques necessary for passage of the scopes into the more proximal portions of the colon. Earlier pioneers in developing successful techniques still in use include, among others, Overholt, Wolf, Shinya, and Waye in the United States; Niwa and colleagues in Japan; Salmon and Williams in England; and Dehyle in Germany.[4] Many of these early efforts were accomplished with the guidance of fluoroscopy to negotiate the more difficult turns and to identify the actual area being observed, but, as experience was gained, fluoroscopy was no longer required. Learning under expert guidance and experience continues to be more necessary in colonoscopy (and ERCP) than in upper endoscopy. By 1971, the diagnostic advantage of fiberoptic colonoscopy over single-contrast barium enema was firmly established,[32] and the efficacy and safety of polypectomy were established by 1973.[33]

Digital Endoscopy (Videoendoscopy)

In 1984, barely 20 years after introduction of the endoscopic fiberscope, Welch Allyn, Inc. (Skaneateles Falls, NY), replaced the coherent fiberoptic image bundle in a colonoscope with a light-sensitive computer chip or charge-coupled device on which the image was focused by a small lens (see Chapter 3).[34] The digital signal was fed to a video processor, which generated an image to a television monitor. The image did not occupy the entire screen, leaving space for information to be typed in by a keyboard. The resolution of the image was at least equal to that of the fiberscope.

It was unnecessary to change the basic mechanics of the fiberscope. The fiberoptic light bundle remained unchanged, as did water, suction, and biopsy channels; in addition, the deflection and locking mechanisms were the same. The basic elements of the videoendoscope have not changed, although a magnified image is now available. Since the original introduction of the videoendoscope by Welch Allyn, which no longer produces the Video Endoscope, the market has been supplied by Olympus, Pentax, and Fujinon. The technology was rapidly adapted to

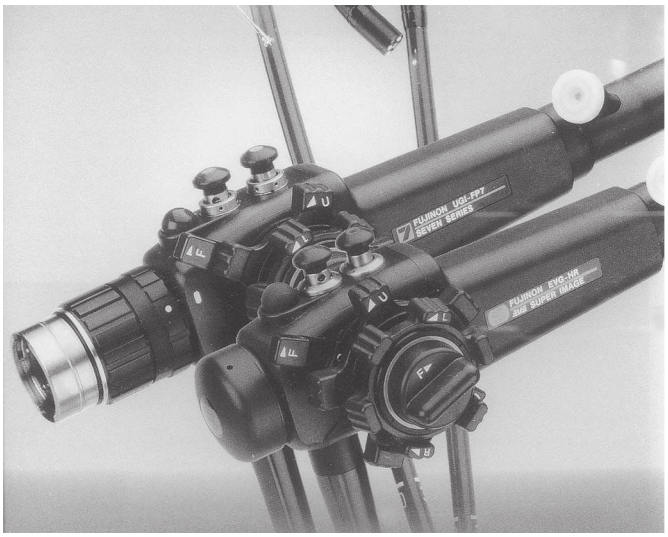

FIG 1.12 Fujinon fiberoptic panendoscope *(top)* and its successor, the Videopanendoscope *(bottom),* 1990, showing the two kinds of operating heads. (From advertisement in *Gastrointest Endosc* 36:240–241, 1990.)

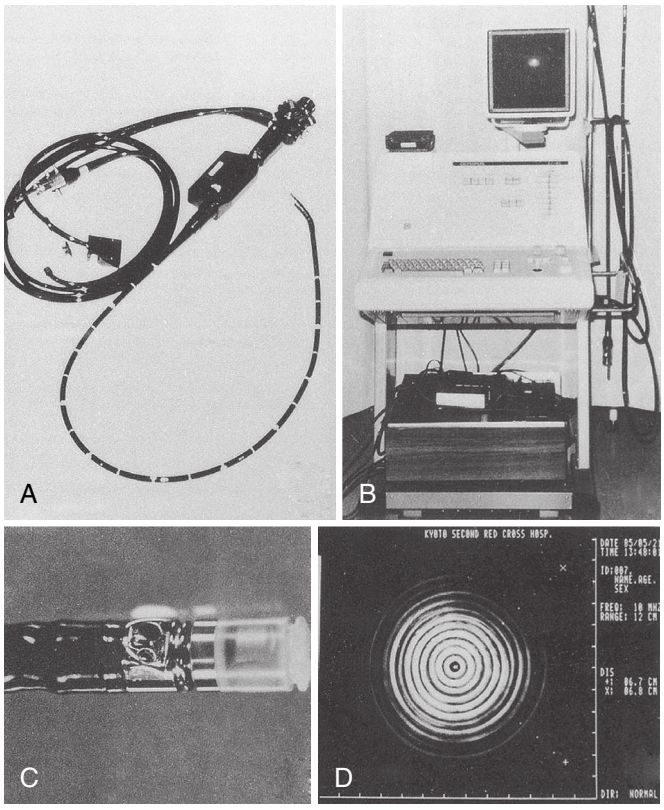

FIG 1.13 **A** to **D,** Ultrasonic endoscope system, model IV, made by Olympus Corp., 1986. (From Yasuda K, Mukai H, Fujimoto S, et al: The diagnosis of pancreatic cancer by endoscopic ultrasonography. *Gastrointest Endosc* 34:1–8, 1988.)

all endoscopes, used not only in gastroenterology but also in other fields.

Advantages of the electronic instruments include an image that can be seen not only by the operator, but also by anyone with access to a connected monitor in the same or another room. This feature greatly enhanced the ability to teach others about the procedure and to inform other interested physicians about the findings in the individual patient. If desired, recording of procedures could be accomplished with videotape machines, and good-quality pictures of individual frames could be made immediately with externally integrated digital equipment. Individual endoscopists found that no adjustment of techniques was necessary when videoendoscopes were used, although they had to become accustomed to looking at the monitor screen rather than through an optical system with one eye (Fig. 1.12). This feature added to the useful length of the instrument because the whole scope could be held at the waist rather than being brought to eye level.

More recent innovations in colonoscopy instruments by Olympus include the ability to make a portion less flexible to facilitate navigation of difficult bends and turns. In addition, an enlarged image is now available that is an improvement in vision and ease of manipulation. A major disadvantage of videoendoscopes is cost. Fiberoptic endoscopes, when they were still in use, could be purchased for less than $6000 and did not require processors or monitors, whereas the latest videoendoscopes are priced at more than $20,000, and initial purchase of the entire package of endoscope, processing computer, monitors, and attachments may exceed $30,000. Initially, many questioned the wisdom of this added cost, which is passed on to the patient and their insurance companies.

Endoscopic Ultrasonography (EUS)

Although the improvements in GI endoscopy are remarkable in the synthesis of diverse but complementary technologies, the information gained remains confined to what one can see from within the lumen of the gut. Simultaneous with these developments were those of computed tomography and external ultrasonographic tomograms. Conceptually, it was not only logical but also compelling to look beneath the mucosa of the gut by incorporating miniaturized models of ultrasonographic transducers already in use into GI endoscopes. The ability to noninvasively explore tissue and organs in proximity to the gut had exciting implications for diagnosis and therapy.

In Germany in 1976, working with Siemens Co., (Berlin, Germany) Lutz and Rosch[35] reported the use of a 1-cm ultrasonographic 4-MHz probe that could be passed through the biopsy channel of an Olympus TGF. They used it in two patients to successfully differentiate between pancreatic pseudocysts and tumors.[7] In 1980, Classen's group in Germany[36] and DiMagno et al[37] at the Mayo Clinic reported EUS devices that were incorporated onto the tip of conventional fiberscopes, one using a 5-MHz transducer and the other using a 10-MHz transducer. These probes had good resolution at an acoustic focus depth of 3 cm. Others incorporated the transducer in the distal shaft of fiberoptic scopes and primarily explored the gut wall.[33,38] By 1985, ultrasonic transducers with variable frequencies incorporated into videoendoscopes were readily available, although expensive (> $100,000 for initial setup) (Fig. 1.13). It was immediately apparent that this procedure could accurately evaluate known or suspected intramural lesions of the gut,[39,40] and it was rapidly expanded to include the esophagus; problems

of diagnosis and recurrence of neoplasia, especially in the pancreas; portal hypertension; the colon and rectum; and bile ducts.[41] In 1991, Wiersema et al[42,43] showed that EUS could be used to obtain fine-needle aspiration cytology of mediastinal nodes and of nodes and lesions of the upper and lower GI tract. The addition of Doppler technology has now made possible the study of the flow through various structures, including the thoracic duct and blood vessels. EUS is increasingly being used to provide therapy, leading to the development of "interventional EUS." EUS-guided interventions include celiac plexus block/neurolysis, placement of fiducial markers to facilitate radiotherapy, direct injection of alcohol or chemotherapeutic agents for the treatment of tumors or cystic lesions, drainage of the pancreatic or biliary ductal systems, and the creation of gastrojejunal anastomoses using lumen-apposing metal stents. The techniques of using EUS instruments differ only slightly from using videoendoscopes, but dedicated training is necessary to interpret the sonographic images obtained accurately. EUS is not amenable to self-instruction. EUS training centers have been established in academic centers, but retraining of practicing physicians is challenging due to the duration of training necessary to achieve competence.[44]

Capsule Endoscopy (Wireless Endoscopy)

In 2000, Iddan et al[45] reported the development of a capsule containing a tiny CMOS camera that could be swallowed, obtain images (at 2 frames per second), and transmit the images over 7 hours to a receiving digital storage unit worn by the patient as he or she goes about his or her normal activities. These frames are downloaded to a computer from which they are projected onto a monitor at a rate that can be controlled by the observer. Pictures can be printed of areas of interest. Gastroenterologists in Israel conducted randomized trials comparing the efficacy of the wireless capsule with push enteroscopy and obtained superior results with the capsule.[46–48]

Wireless capsule endoscopy caught the imagination of gastroenterologists over the world, and capsule endoscopy has been adopted as a part of standard practice for small bowel imaging. The findings are virtually unanimous in demonstrating better results in identifying lesions in the small bowel with capsule endoscopy when compared to push enteroscopy.[49] The capsule avoids the discomfort and need for sedation inherent with push enteroscopy. In addition to lack of biopsy capability, an additional disadvantage is the time needed to review the study, but this has been overcome by a variety of methods including software advancements, improved training techniques, and utilizing non-physician personnel to initially review the obtained images. The major use of the capsule to date has been in elucidating the cause of occult bleeding from small bowel sources, where it seems to be superior to other methods. Future applications, such as in the colon, are continuing to be investigated in large, multicenter comparative studies. The future of wireless capsule endoscopy is bright. It will be interesting to see how the principle of wireless endoscopy is incorporated into videoendoscopes, such as the potential for a wireless connection between the endoscope and the image processor.

Enteroscopy

The small intestine has traditionally been regarded as the final frontier of GI endoscopy. Although capsule endoscopy provides remarkable images of the small bowel mucosa, tissue acquisition and therapy with a capsule-based instrument is many years away. Surgically assisted small bowel enteroscopy may be performed via either the transoral or anal route or via a mid–small bowel enterotomy incision. The disadvantage of this technique is its invasive nature.[50] Endoscopic examination of the small intestine has remained technically difficult. The many loops of the small intestine prevent progression of the instrument tip by simple pushing. This problem was overcome initially with the use of the Sonde enteroscope,[51] which is a very fine, floppy instrument with a balloon at the tip. The Sonde enteroscope progressed through much of the small bowel under peristalsis, and then the proceduralist would slowly withdraw the instrument, assessing the mucosa while pulling back. This technique was thought to visualize 50% to 70% of the mucosal surface.[52] However, the procedure was uncomfortable, time-consuming, and did not permit therapeutics, all of which limited its use.

The concept of small bowel enteroscopy was revolutionized by Yamamoto with the introduction of the double-balloon enteroscope in 2001.[53] This technique uses traction between a balloon at the tip of the enteroscope and another balloon on a flexible overtube to fix the loops of small bowel and provide traction for forward movement. The procedure requires peroral and anal procedures to examine the entire small intestine, and even then only in a minority of Western patients is the whole small bowel visualized. Nonetheless, double-balloon–assisted enteroscopy permits endoscopic therapeutics to most of the small bowel without the need for surgical assistance. A single balloon version is also available.

Natural Orifice Transluminal Endoscopic Surgery (NOTES) and Peroral Endoscopy Myotomy (POEM)

A new development in endoscopy is natural orifice transluminal endoscopic surgery (NOTES), in which the endoscope is inserted into the abdominal cavity via an incision in an accessible organ. The first report appeared in 2002. Incisions have been made in the stomach, vagina, and colon with successful tubal ligation, liver biopsies, biopsy of peritoneal metastases, oophorectomy, cholecystectomy, and nephrectomy procedures having been performed. Most published articles report experimental use in animals, but more recent reports have described the simultaneous use of NOTES with laparoscopic techniques. Comparative studies are ongoing. A difficulty with the technique has been overcoming the lack of instrument "triangulation"; that is, approaching a surgical site from two or more directions to create countertraction, tie sutures, and so forth. Although NOTES is an exciting development, its remarkable potential will have to await the development of new instruments and the acquisition of additional expertise. At a minimum, it appears the development of NOTES will result in marked improvements in mucosal and transmural closure devices. Recently, flexible endoscopes have also been used to tunnel into the submucosal space of the esophagus and perform a myotomy, resulting in a treatment for achalasia termed peroral endoscopy myotomy, or POEM. First performed by Inoue in 2008 and reported by Inoue in 2010, this procedure has gained widespread popularity worldwide and has been performed thousands of times to date with impressive short- and long-term results and an excellent safety profile.[54,55] Additional applications of "submucosal" endoscopy include performing a similar procedure in the antrum to treat gastroparesis (G-POEM) and to perform resection of intramural lesions of the GI tract.[56,57]

SUMMARY

The development of endoscopy is a testimony to human ingenuity. Instruments have evolved from dangerous straight tubes illuminated by light reflected from candles, to more flexible and safer instruments with an image transmitted through a series of prism lenses and illumination by an electric light bulb, to images transmitted through fiberoptic bundles with illumination transmitted by fiber bundles from an external source, to our present remarkably safe electronic instruments with digital images transmitted to a video screen through wires and processed by computers. Most recently, we can visualize the lumen of the gut without touching the patient. Now we can not only visualize, biopsy tissue, and perform surgical procedures within the hidden cavities of the body, but also directly and indirectly see beneath the mucosa and into immediately adjacent organs. The evolution of gastrointestinal endoscopy is a truly remarkable story, and advances in the diagnostic and therapeutic capabilities of these instruments continue to be made at a rapid pace. To know and understand what has occurred previously lends strength to efforts toward achieving what is to come.

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2

Setting Up an Endoscopy Facility

Klaus Mergener and Barry Tanner

CHAPTER OUTLINE

INTRODUCTION

The safe and efficient performance of gastrointestinal (GI) endoscopy has the following requirements:

- A properly trained endoscopist[1] with appropriate privileges to perform specific GI endoscopic procedures[2,3]
- Properly trained nursing and ancillary personnel
- Operational, well-maintained equipment
- Adequately designed and equipped space for patient preparation, performance of procedures, and patient recovery
- Cleaning areas for reprocessing endoscopes and accessories
- Trained personnel and appropriate equipment to perform cardiopulmonary resuscitation
- A robust quality assurance/improvement program[4,5]

Many of the previously listed requirements for safe and efficient GI endoscopy depend on the careful planning and design of the endoscopy facility. This chapter describes that process, beginning with laying the groundwork, including the development of a business plan and review of regulatory issues; site selection; facility planning and design (including patient flow and space needs); equipment requirements; staffing needs; and scheduling considerations. Some additional issues, such as endoscope cleaning and storage, tissue specimen processing and handling, record keeping and documentation, and quality assurance and improvement, are discussed briefly but are covered in more detail in subsequent chapters of this book (see Chapters 4, 5, and 10).

EXPLORING POSSIBILITIES

Type of Facility

There are different types of endoscopy facilities, including hospital endoscopy units, single-specialty or multispecialty ambulatory surgery centers (ASCs), and office endoscopy suites. Each model has a unique set of advantages, disadvantages, and regulatory issues. The hospital and ASC environments are highly regulated by state and federal agencies and by third-party accreditation bodies. In the United States, these include The Joint Commission (JC), the Accreditation Association for Ambulatory Healthcare (AAAHC), and the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF). Commercial payers sometimes impose their own specific requirements. Office endoscopy suites, previously less regulated, have been subjected to more controls by state and federal agencies in recent years.

The decision regarding which type of facility to establish is affected by the practice environment (solo practitioner, small or large group, single-specialty or multispecialty group, independent or hospital-based) and local economics and politics. Regardless of the service location, high-quality care must be maintained. The American Society for Gastrointestinal Endoscopy (ASGE) has stated that the "standards for out-of-hospital endoscopic practice should be identical to those recognized guidelines followed in the hospital."[6] The hospital-based unit poses the fewest financial risks and demands for the endoscopist during the early phases of operation, and its use avoids alienating hospital administration by preserving hospital case volume. This environment, however, affords the endoscopist little control over operations, and offers him or her the lowest financial return. Office endoscopy offers control and convenience with better financial return for the physician, but it poses some safety and liability concerns.[7,8] A single-specialty endoscopic ambulatory surgery center (EASC) provides the best of control, efficiency, convenience, and reimbursement for the physician owners and is extremely popular with patients, referring physicians, and payers.[9,10] A major ASC payment reform implemented by the

Abstract

Since its introduction into clinical use in the early 1960s, GI endoscopy has transformed the discipline of gastroenterology and has become a crucial tool in cancer prevention and the management of GI disorders. The growing use of increasingly complex endoscopic procedures and the evolution of endoscopy in the outpatient setting have fostered the careful development of endoscopy facilities that enable the delivery of endoscopic services in a safe, efficient manner that is reassuring to the patient and produces good outcomes.

The process of setting up an endoscopy facility begins with exploring the types of facilities, developing a business plan, and researching relevant regulatory and certification issues. With those objectives accomplished, attention turns to planning the facility, including site selection, choosing equipment, and planning the physical environment and flow of patients and staff. Finally, the general plans for the facility are turned into specific architectural designs which form the basis for construction of a pleasant, efficient facility. Once the facility is constructed, careful attention to appropriate staffing, scheduling, documentation, and quality improvement activities promotes efficient and effective care as well as optimal patient outcomes.

Keywords

endoscopy
ambulatory surgery center
hospital endoscopy unit
office endoscopy
efficiency
cost
quality

Centers for Medicare and Medicaid Services (CMS) in 2008 resulted in drastic cuts of facility payments for endoscopic services.[11] Subsequently, the passage of the Affordable Care Act in 2010 led to massive hospital consolidation, which, in turn, resulted in significant increases in the prices hospitals demand for endoscopic services provided in hospital-based facilities.[12–14] How all of these changes will affect both the efforts and the ability to provide beneficial GI services to patients at a reasonable cost remains to be seen. More information about recent and ongoing health care reform efforts is available elsewhere.[15] Regardless of the type of facility being developed, formulating a business plan and understanding various regulatory issues are usually the first steps in the process.

Business Plan

The decision to set up an endoscopy facility should be made only after detailed data gathering and the formulation of a business plan (e.g., market analysis, financial pro forma, implementation time line).[16–18] For a hospital-based unit or academic medical center, facility planners and accountants often perform these functions. For an office-based suite or an EASC, the tasks fall to the physician owners, aided by numerous consultants, contractors, or corporate partners. Even with skilled help, however, development of an accurate and reliable business plan and pro forma are highly dependent on physician estimates, insights, and work habits. Physician input into the business plan makes the difference between a perfunctory exercise and an accurate predictor of future performance. Endoscopy facilities represent significant investments requiring substantial financial resources and staff. Procedure volume must be sufficient to produce adequate revenue to cover the costs of building and running the facility and to generate a profit on investment.

Many factors influence the financial performance of an endoscopy facility, including the size of the initial investment, expected volumes of service, revenue per unit of service, fixed operating costs, and variable costs per unit of service. The initial investment includes the cost of construction, equipment, and working capital for the first few months of operation. Strategic planning is important to anticipate group growth and demand for services in the next 5 to 10 years.[16,18] The impact on the GI practice of local competition and consolidation of health systems or major health plans must also be anticipated. In addition, population changes, demographics, and the possibility of new disruptive technologies might affect case volume for the practice and the endoscopy facility.

A pro forma is a calculation examining the financial feasibility of a project based on anticipated investment and operating costs and revenues. The purpose of the pro forma is to reliably predict cash flows and profitability for the project. Initial investment costs have been defined previously. Estimated total costs per case based on estimated fixed and variable costs and expected case volume are also incorporated in the pro forma. Fixed costs are costs that remain constant regardless of the number of procedures performed and include rent, interest, depreciation, taxes, insurance, amortization, and management fees. Staffing costs (salaries and benefits) are also largely fixed as most facilities operate with full-time staff for quality and efficiency reasons. Variable costs, including medical supplies, medications, equipment maintenance and repair, administrative supplies, etc., typically make up approximately 20% (i.e., a relatively minor portion) of the overall costs. Stated differently, doing one additional procedure adds a relatively small incremental cost for a significant financial benefit. This is why optimizing efficiency as well as minimizing "no-shows" and empty slots on the schedule are critically important to the economics of an endoscopy unit.

Break-even volumes can be determined by subtracting the variable expense per procedure from the average payment per procedure to indicate the contribution available to be used for overhead and profit. Dividing fixed costs by the contribution margin per procedure indicates the number of procedures needed to pay the fixed costs, also known as the break-even point. Additional service units above that level constitute profit. Vicari and Garry[16] provided a simple example of a pro forma. The business plan and pro forma are mandatory in assessing the financial feasibility of the proposed endoscopy unit before construction. They further aid discussions in obtaining financing and help the architect design the unit for anticipated volumes.

Regulatory and Certification Issues

Before planning and designing the facility, one must understand the relevant regulatory and certification issues. As with the business plan, units developed in a hospital or academic medical center usually benefit from administrators and planners familiar with these complex issues. Physician owners of an office endoscopy suite or EASC must gain their own understanding. Various agencies provide myriad rules and regulations concerning endoscopy facilities.[19–23] Legislation can come from federal, state, or local authorities. Regulations may come from federal agencies, state departments of health, third-party accreditation organizations, and private payers. Although these rules and regulations can seem excessive and needlessly costly, their intent is to ensure safe and successful outcomes for patients. Regulations and certification issues for endoscopy facilities can be divided into six main categories, as follows:[19]

- General federal regulatory laws and rules
- Facility state licensure
- Medicare certification
- Third-party accreditation
- Physician credentialing
- Private payer requirements

General Federal Health-Related Laws

Federal regulatory laws and rules include fraud and abuse statutes (also known as antikickback laws), which are laws designed to prevent excessive or inappropriate payments. Endoscopy centers typically fall into a specific "safe harbor," a designation that protects EASC investors or shareholders from allegations of fraud or abuse. The safe harbor applies if the physician participants are surgeons or specialists engaged in the same surgical or medical practice specialty, including gastroenterology. These physicians can refer patients directly to their center and perform procedures on them as both an extension of and significant part of their practices.

Additional requirements of the safe harbor apply. Ownership of the facility, or remuneration from it, cannot be related to volume of referrals, services furnished, or the amount of business otherwise generated from that physician to the EASC. The amount of payment to physician owners from facility revenues must be directly proportional to the amount of each owner's capital investment. There must be no requirement that a passive investor make referrals to the EASC, and the EASC or any investor cannot make loans or guarantee a loan for a physician if these funds are used to purchase ownership in the EASC. Each physician must agree to treat Medicare and Medicaid patients. Finally, the

physician owner must derive at least one-third of his or her medical practice income from the performance of procedures that require an EASC or hospital endoscopy unit setting.

Other general federal health-related laws and rules relevant to endoscopy facilities include the False Claims Act, copayment waivers, Stark provisions, Health Insurance Portability and Accountability Act (HIPAA) provisions, and labor and employment issues. The False Claims Act was designed to prevent false billings, claims that are medically unnecessary, and billings for inappropriately high payment. Copayment or deductible waivers may also be illegal if the government suspects such waivers are likely to induce referrals. Stark provisions stem from the Ethics in Patients Referrals Act. They are closely related to fraud and abuse statutes, but are civil rather than criminal laws. The regulatory body overseeing Medicare has ruled that a physician does not make an illegal referral for a procedure when he or she either personally performs the service or refers a patient to a partner to perform the service. HIPAA provisions are rules and regulations covering patient health information disclosed by any covered health care entity, provider, or facility. Regarding labor and employment issues, numerous rules and regulations cover discrimination, harassment, protection of the disabled, and workplace safety. The Occupational Health and Safety Act (OSHA) of 1970 seeks to protect employees from recognized work hazards that might cause death or serious harm. For endoscopy centers, OSHA requirements of major importance cover cleaning of endoscopic equipment, disinfection, and appropriate ventilation.

State Licensure

The state department of health licensing authority is interested in several features of a potential endoscopy facility. First, before any design and construction is undertaken, a careful review of the state's certificate of need (CON) requirements is needed. Some states do not allow construction of new facilities unless need is demonstrated. This process can be difficult and prospective physician owners of endoscopy facilities may encounter opposition from hospitals fearing competition and seeking to maximize use of their own facilities. Regarding specific construction guidelines, state regulators are most often interested in patient safety, the flow of the facility, cleanliness, and control of infection within the procedure areas. Many states follow guidelines from the Facility Guidelines Institute (FGI), but individual states recognize different versions of these FGI guidelines. Many states will also have their own set of regulations that must be followed and may relate to specific room sizes, acoustic regulations, door and hall size requirements, handicapped access provisions, requirements for exhaust systems, and specific fire codes.

Medicare Certification

Medicare certification is usually sought after obtaining state licensure and is required for any facility seeking reimbursement for Medicare and Medicaid work. Medicare regulations and requirements are usually more extensive than regulations of the state and address governance of the facility, transfer agreements with a nearby hospital, continuous quality improvement activities, Medicare architectural requirements, and medical records. Additional standards concern organization and staffing, administration of drugs, and procurement of laboratory and radiology services. Two other requirements warrant special attention as they relate to EASCs. First, the facility must be used exclusively for providing "surgical" services, a definition that includes GI endoscopies but not services like manometry. This requirement also mandates a separation from other health care activities, separate staffing, and maintenance of special medical and financial records. Finally, the facility must comply with state licensure laws, which is potentially difficult in some states because of restrictive CON requirements. Medicare will survey under the ASC regulations for compliance[24] and the Medicare-adopted code set of the National Fire Protection Association (NFPA).[25]

Third-Party Accreditation

After state licensure and Medicare certification have been obtained, some states or specific payers may require a third-party accreditation before authorizing payments to an endoscopy facility. This accreditation can be provided by inspection from JC, AAAHC, or AAAASF. Although these accreditations are typically achieved after state licensure, they can sometimes be pursued simultaneously with Medicare inspection. Under certain circumstances, Medicare accepts accreditation from one of the third-party accreditation authorities in lieu of its own survey; this is known as attaining "deemed status." In a deemed-status survey, the surveyors will survey for both state regulatory compliance as well as Medicare regulatory compliance. Third-party accreditations focus on patient-related and organizational functions and, in the case of an EASC, concentrate on the "environment of care" or "facilities and environment."

Third-party inspection of a facility can be challenging and demands that the owners and operators fully understand the standards of each specific accrediting organization. A JC survey scrutinizes a variety of domains including Environment of Care, Emergency Management, Human Resources, Infection Prevention and Control, Information Management, Leadership, Life Safety, Medication Management, National Patient Safety Goals, Provision of Care, Record of Care, Rights and Responsibilities, and Waived Testing and Performance Improvement. AAAHC and AAAASF inspections assess similar functions, although these may be grouped under different organizational headings.

Physician Credentialing

Credentialing and privileging of physicians using an EASC may be mandated by federal, state, local, or third-party organizations and include a formal application process, verification of licensure and drug enforcement administration status, malpractice history, admitting privileges, advanced cardiac life support status, and documentation of training. Additional requirements may be outlined in the center's medical staff bylaws (for example, board certification of providers).

Payer Requirements

Individual health plans or insurers may have their own requirements, and these may vary significantly from payer to payer. Careful attention to local payer mix and any special requirements is necessary before designing and building an endoscopy facility to ensure qualification for payment. As outlined previously, the regulatory and certification issues for endoscopy facilities are "complex, detailed, and broad."[19] Any physician wishing to develop an endoscopy facility must understand these rules of regulation and certification. Appropriate legal counsel should be considered essential.

Choosing a Site

For hospital-based endoscopy facilities, the location of the facility is usually determined by the hospital's own planners. Although some hospitals have developed separate units for outpatient and

inpatient endoscopies, most hospitals operate a single endoscopy unit. Choosing its location requires careful consideration of patient transport issues; the flow of inpatients and outpatients in and out of the unit; and the proximity to radiology, the emergency department, intensive care units, and inpatient wards. With office-based endoscopy or EASCs, physician owners choose the site. The site size and location require careful consideration because most office-based facilities or EASCs later expand to accommodate more physicians and patients. Preliminary land requirements are determined from space estimates (discussed later), parking requirements, appropriate landscaping or "green areas," and anticipated expansion. For an office endoscopy suite or EASC, proximity to a hospital is desirable to minimize travel for patients requiring hospital transfer and for physician convenience. The site should be near but perhaps not on a major street to ease patient parking. Many patients coming to an EASC or office-based facility are elderly or may be anxious about their upcoming procedures. Access should be easy. Locating the physician offices adjacent to the EASC should be strongly considered because it may be very efficient for staff and patients.

Facility Planning and Design

After forming a realistic business plan and acquiring an understanding of relevant regulatory and certification issues, attention turns to the planning and design of the facility. Although the remainder of this chapter includes some remarks about issues specifically related to hospital units, the main focus of the discussion is on the development of an outpatient endoscopy facility, details of which are equally applicable to hospital units. Objectives must be articulated to the design professionals to ensure that the facility meets the needs of patients, endoscopists, and staff. Some points to keep in mind are the following:

- Allow adequate time for planning.
- Set aside a regular block of time for discussion, review, and program development.
- Choose experienced design professionals with health care experience and knowledge of state and local health care building regulations.
- Involve staff to ensure attention to their needs and wishes.
- Prepare a statement of needs and goals to aid the architect in preparing a detailed program.
- Prepare an inventory of equipment needed and its location for the architect to be able to install the proper electrical system and plumbing.
- Visit other facilities to gather ideas worth incorporating.
- Use flow studies to evaluate placement of functional elements.
- Review preliminary drawings carefully.
- If questions arise about the size or shape of a space, lay it out with tape on the floor and simulate work practices.

Planning and design of the facility is a team project. The team mainly involves a physician representing the endoscopists who will use the facility; two staff people, including the nurse responsible for patient care activities within the unit and the appropriate administrator; the architect; engineers; and the builder. The responsible physician must be given adequate time away from clinical duties to devote to planning, design, and oversight of the construction of the facility. Designated time must be set aside because the process is ongoing and cannot be relegated to lunch hours and brief sessions whenever time can be stolen from clinical activities. The architect is the primary professional involved in overseeing the entire project. It is wise to select an architect who specializes in medical buildings, particularly one who has experience in designing endoscopy facilities. Similarly, selection of a contractor who has experience in medical construction, particularly construction of endoscopy facilities, is important. Both the architect and the contractor must thoroughly understand the requirements of regulatory and certifying bodies and local and state building codes. Sometimes the design and contracting can be provided by one company with both design and building capabilities.

Although the physician representative, designated staff persons, architect, and contractor compose the major elements of the planning and design team, additional input may be needed from engineers (mechanical, electrical, plumbing), telephone contractors, information technology experts, and attorneys. Consideration might also be given to involving a layperson or "patient" to ensure sufficient attention to issues of patient comfort, dignity, and privacy.

PLANNING

The planning stage is concerned with deciding what activities will be conducted in the facility, what equipment will be needed, and how space will be allocated.

Scope of Activities

The first consideration is which endoscopic procedures and other services will be performed in the facility. The type of facility will, to a great extent, answer this question. For a hospital unit that must provide a wide range of endoscopic services, one or more rooms must be large enough and appropriately equipped to accommodate the special equipment required for complex procedures (e.g., endoscopic retrograde cholangiopancreatography [ERCP], endoscopic ultrasound [EUS], balloon enteroscopy, laparoscopy, anesthesia cart). In some community hospitals, endoscopy units are shared with other specialties, such as cardiology or pulmonology, and have to accommodate procedures such as transesophageal echocardiography or bronchoscopy. If the hospital is part of an academic medical center, the unit may serve additional purposes, including teaching and research, requiring further modifications in space, equipment, and staffing.

For an office suite and EASC, services offered will be based on clinical considerations, safety, and logistics. In these out-of-hospital facilities, procedures are usually limited to individuals and stable patients undergoing "routine" high-volume procedures with predictable turnaround and recovery times, utilizing standard equipment and accessories. In an EASC, it is crucial that all procedures done be on the Medicare approved list to qualify for facility reimbursement. For both the office suite and the EASC, procedures are often limited to upper GI endoscopy, esophageal dilation, and colonoscopy, including polypectomy. Predictably, rapid turnaround time is crucial for an efficiently functioning EASC or office facility. Whereas EUS, ERCP, and other complex endoscopic examinations are also done in some EASCs, it is generally advisable to perform long procedures or procedures that are unpredictable in duration or clinical outcomes in the hospital. Procedures requiring prolonged recovery times, such as liver biopsy, are also best done in a hospital environment.

The question sometimes arises whether it is better to have a multispecialty or single-specialty ASC. From the standpoint of services offered and equipment, a single-specialty EASC has the advantage of being the "focus factory."[26,27] In this environment,

endoscopists, skilled GI nurses, technicians, and administrative staff maximally use standardized equipment, performing predictably timed procedures with a rapid turnaround. A single-specialty EASC avoids the problem of a multispecialty facility in which highly specialized equipment lies idle much of the time while physicians from differing specialties are performing their individual procedures.

Equipment

The greatest capital expense after the basic construction is equipment. Some tabulation of the equipment needed is necessary in the early planning stages and facility design. The basic equipment needed for an endoscopy unit is listed in Box 2.1. A detailed discussion of individual items is not presented here, but a few points are useful in integrating the equipment needs into planning and design. Generally, examining or procedure tables have been replaced by height-adjustable, rolling procedural stretcher carts that allow patients, once properly gowned for endoscopy, to mount the movable cart and not leave it until ready to leave the facility. These carts allow patients to be shuttled from preparation areas to procedure rooms and back to recovery areas, and also serve as procedure tables. This capability is very important to overall system efficiency and adds to patient safety by avoiding transfer to and from a procedure table.

Another major determinant of overall system speed and efficiency is the availability of endoscopes. Adequate numbers of endoscopes, high-level disinfection systems (automatic endoscope reprocessors [AERs]), and adequate storage for extra endoscopes are required. Adequate numbers of endoscopes must be available to prevent inefficient downtime in the unit. Staff salaries, wages, and benefits make up a significant percentage of total costs of providing endoscopic services, and it is inefficient and fiscally unwise to have highly paid physicians and staff waiting for endoscopes. Regarding dilating devices and other accessories, decisions (e.g., whether to use a Savary dilator system versus dilating balloons) should first and foremost be made on clinical grounds. This decision will, however, also have economic consequences as the cost of accessory devices is bundled into the facility payment and the endoscopy center will not be able to procure additional reimbursement for higher-cost devices. Finally, with the growing use of propofol and anesthesia services for endoscopic procedures, additional medications and equipment are often required for this service.[28,29]

BOX 2.1 Endoscopy Facility Basic Equipment List

I. Major endoscopic and electrosurgical equipment
  A. Endoscopes, light sources, video processors, and monitors
  B. Electrocautery units and accessories
  C. Hemostasis unit (e.g., heater probe, gold probe, argon plasma coagulator)
  D. Physiologic monitoring devices including pulse oximetry, blood pressure, and cardiac monitoring
II. Catheters, snares, forceps, and brushes
  A. Polypectomy snares
  B. Biopsy forceps
  C. Brushes
    1. Cleaning
    2. Cytology
  D. Graspers
  E. Retrieval baskets
III. Endoscopic report writer with photo generator and image manager
IV. Esophageal dilators
  A. Wire-guided (e.g., Savary)
  B. Balloon
V. Rolling procedural stretcher carts with adjustable heights
VI. Suction equipment
VII. Pharmaceuticals
  A. Sedation and analgesia agents
    1. Benzodiazepines
    2. Narcotic analgesics
    3. Miscellaneous preference
  B. Benzodiazepine antagonists
  C. Narcotic antagonists
  D. Glucagon
  E. Atropine
  F. Topicals
VIII. Intravenous equipment, solutions, needles, and syringes
IX. Chemicals
  A. Formalin
  B. Disinfection solutions
X. Emergency cart, resuscitation equipment, supplies, and medications
XI. High-level disinfection equipment (cleaning trays, sinks, automatic endoscope washers, and autoclave)
XII. Instrument storage cabinets
XIII. Blanket warmer
XIV. Audio/music system
XV. Eyewash station

Physical Environment

Before beginning specific planning and design, some issues affecting space efficiency should be considered. It is the goal for physicians and staff to work as quickly and efficiently as possible while giving patients the assurance that they are receiving appropriate and safe care. System speed in the endoscopy facility usually comes from the following three delivery components:

1. Preparation and recovery of the patient.
2. Reprocessing and return of endoscopes to the procedure room.
3. Physician work habits.

If the first two components operate properly, the number of procedure rooms available is not as important as the practice habits of the physician in starting their schedule on time, performing procedures in an efficient manner, talking to patients and their families, completing medical records, and returning to the procedure room.[28] In an efficient facility, physician discipline is needed because room turnover and equipment reprocessing time can be rapid.

Flow

Architects use flow diagrams to plan movement patterns in arranging space before actual design plans. Physician and nurse input is crucial in arranging the flow relationships within the endoscopy facility to maximize efficiency, minimize travel distance, and achieve economy of movement. A basic flow diagram showing patient flow through a simple endoscopy unit is shown in Fig. 2.1. The patterns of movement may be more complicated in a hospital department. Simple flow diagrams such as these can be elaborated into a functional schematic drawing diagram as shown in Fig. 2.2. This type of functional schematic diagram shows the way that patients, staff, physicians, and equipment can move through the facility. A functional schematic diagram can be turned into a floor plan by assigning actual space requirements to the rooms that are represented. A 40% circulation allowance must be added at the end of the tabulation to account for wall thicknesses, corridors, and so forth.[30]

For hospital-based units, specific patient flow issues must be considered. Separate entrances for sick, bedridden patients and

ambulatory individuals should be considered. The monitoring and treatment requirements for sick inpatients must be taken into consideration. Separation of inpatients and outpatients in waiting or holding areas, preparation areas, and recovery areas may also be helpful. If an endoscopy facility is constructed adjacent to a clinic facility, the regulations require a firewall separation between the EASC and the clinic. Shared waiting rooms are no longer permitted. This separation may require a 1- or 2-hour fire rated wall-door construction system depending on the state and/or the building in which the facility is located. When fire-rated walls are required, it is important that the proper rating of the wall is considered, making sure the fire-rated gypsum board on either side of the structural wall extends through the ceiling to the roof of the structure above and all penetrations through the wall are properly sealed.

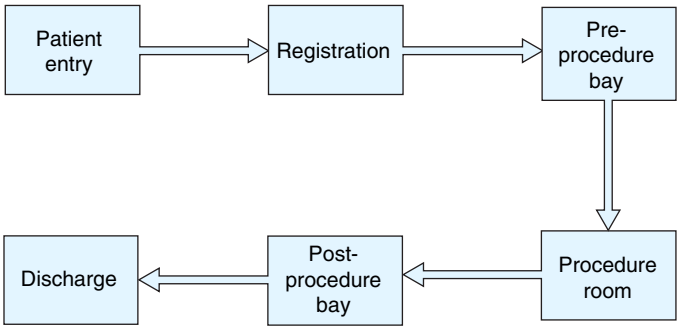

FIG 2.1 Basic endoscopy unit flow diagram.

Designing the Endoscopy Facility

The *Guidelines for Design and Construction of Health Care Facilities (FGI Guidelines),* published by the American Society for Healthcare Engineering, include a section on the design and construction of GI endoscopy facilities.[31] The document is updated on a 4- to 5-year revision cycle with the latest edition published in 2014. Many states have not yet adopted this newest version and some have not officially adopted any version. A state map outlining FGI adoption is also available.[32] The *FGI Guidelines,* which are referenced by many federal and state jurisdictions, were originally conceived as minimum construction requirements for hospitals. Over time, the document has evolved to include engineering systems, infection control, and safety and architectural guidelines

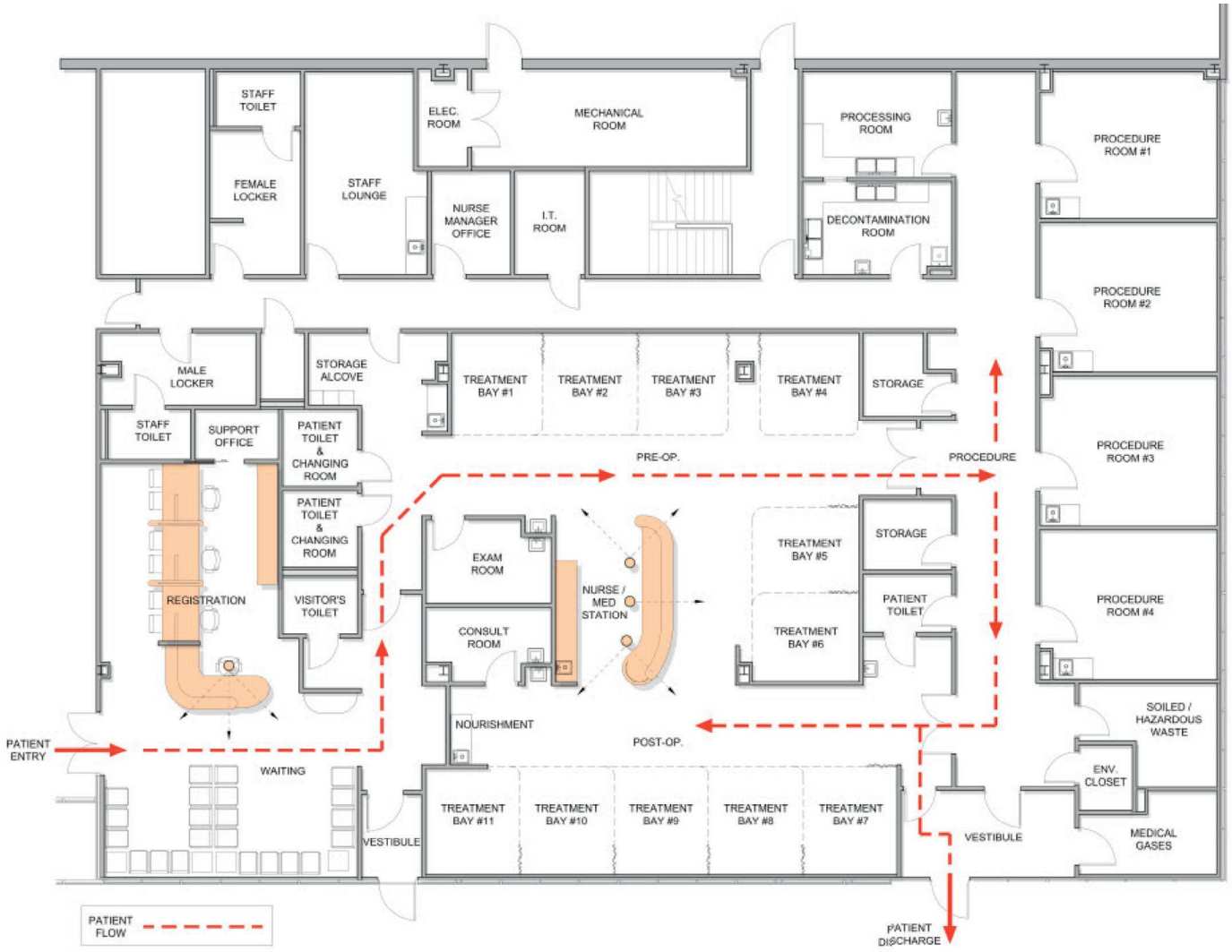

FIG 2.2 Functional relationship diagram for an ambulatory endoscopy center.

TABLE 2.1 Space Considerations

Room	Components	Considerations
Waiting	Seating Beverage counter Public restroom	Calculate the amount of seating in the waiting room based on the number of procedure rooms being constructed. Typically, 3 chairs per procedure room are needed.
Reception/business area	Registration bays needed. Billing area Medical record storage	The number of registration bays may vary depending on the number of procedure rooms. If billing functions are outsourced, less space is needed for this function. If the facility is using an EMR, medical record storage can be reduced to locking millwork.
Pre/post procedure area	Pre/post procedure bays Nurse station Nutrition area Medication area Patient belongings Handwashing sinks Restrooms/patient changing Exam/consult room	Number of procedure bays will vary with State regulations. Typically, 2–3 bays are required per procedure room. Pre- and post-op bays can be used interchangeably, provided the minimum monitoring, electrical and medical gas components are included. Nurse station must have visualization of all bays. One nurse station for all bays provides a more efficient staffing model. Medication area may be provided behind nursing station in locking millwork if State allows. Small purse lockers can be provided to secure patient belongings. Handwashing sinks typically required = 1 sink per every 4 bays.
Procedure area	Corridor Procedure rooms	The number of procedure rooms will drive the project. This calculation will be based on number of physicians and physician volume. Minimum size requirements for these rooms will vary by State. A corridor separating the pre/post area from the procedural area may be required by State. Scrub sinks – may be required in some States.
Reprocessing area	Soiled scope Reprocessing area	Separation of the soiled scope area and reprocessing area are essential. A pass-through window will allow these rooms to have two separate and distinct functions. Eyewash should be provided in the reprocessing area due to the chemicals used for reprocessing.
Staff area	Locker room(s) Shower Staff restrooms	Number and size of locker rooms will vary depending on the number of procedure rooms/staffing. Staff shower is required in some States.
Supporting functions	Storage Environmental functions Utility rooms IT room Biohazard/soiled linen/trash room	Minimum storage requirements must meet State requirements. Two environmental closets are typically required.
Mechanical	Medical gases Water heater/boiler UPS/generator Electrical room Vacuum pump room HVAC	Medical gas room is required to be rated. Depending on the number of gases, storage in this room may be required to meet certain ventilation requirements. Consider adding CO_2 to the manifold to allow for CO_2 insufflation in the procedure rooms. Work closely with the engineers to determine mechanical requirements.
Exterior	Parking Canopy	Adequate parking spaces must be provided. Number of spaces required will depend on local jurisdiction. Handicap spaces must be provided. Canopy extending to the curb may be required by some States.

EMR, electronic medical record; UPS, uninterruptible power supply.

for design and construction of hospitals and other types of health care facilities. It provides an invaluable resource for the construction of a new EASC, the construction of a hospital-based endoscopy unit, or the renovation of existing units. The *FGI Guidelines* can be purchased through the American Hospital Association.[33]

Table 2.1 provides a list of areas and components of a typical endoscopy unit as well as some key considerations for each area. The following sections highlight some of these considerations.

Arrival and Waiting Areas

The patient's experience of the endoscopy facility often begins outside the building in the parking lot. Patients arriving for endoscopy are often anxious and sometimes frightened. Maps with careful driving instructions and signs posted in the vicinity of the endoscopy facility can minimize confusion and offer reassurance. An all-weather canopy and automatic opening doors are helpful to elderly, ill, or disabled patients. The reception and waiting room area provides an early impression of the endoscopy facility and should project friendliness and efficiency. Wheelchair storage should be available in this area, with wheelchairs stored out of sight. There must be adequate room for patients' escorts because one or two people usually accompany each patient scheduled for endoscopy. If the clinic area is adjacent to the endoscopy center, there are very specific mandates in regard to separate and distinct waiting rooms. As an example, per CMS manual, the endoscopy center "must provide a waiting area for its patients within the perimeter of its 1-hour fire-rated barrier and ensure said barrier is free of penetrations."[24] Waiting areas should be well appointed and equipped with a television set and reading material. A toilet should be available near, but not directly off, the waiting room. Drinking water should be provided, either via a drinking fountain (required in some states) or bottled water (allowed in some states). The general waiting area for Northern New Jersey Endoscopy Center, Englewood Cliffs, NJ is shown in Fig. 2.3.

FIG 2.3 General waiting area for Northern New Jersey Endoscopy Center, Englewood Cliffs, NJ. (Photograph by Andrea Brizzi, facility designed by RSC Architects, Hackensack, NJ, http://www.rscarchitects.com.)

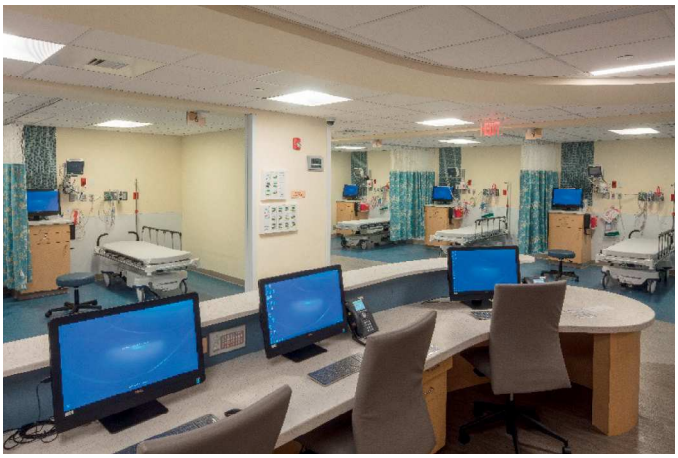

FIG 2.4 Nursing control station for preparation-recovery area, Northern New Jersey Endoscopy Center, Englewood Cliffs, NJ. (Photograph by Andrea Brizzi; facility designed by RSC Architects, Hackensack, NJ; http://www.rscarchitects.com.)

Business-Reception Area

The business-reception area includes the reception desk, registration bays, billing stations, and medical records storage. If billing functions are outsourced, square footage can be eliminated for this function. With the adoption of electronic medical records, the space needed to store paper copies of medical records can be kept at a minimum. Often this space is limited to locking cabinets located in this area.

Pre/Postprocedure Area

The preparation-recovery area of the endoscopy facility requires constant patient surveillance from the nursing staff. This area usually contains a nursing control station (Fig. 2.4), which allows unobstructed viewing of patients during the preparation and recovery stages of their visit. The most efficient arrangement for preparation and recovery is to have them occur in the same place and to set up the patient bays so they can be used interchangeably. Patient clothing can be stored in a locked cabinet in the preparation-recovery area or can accompany the patient during transport to the procedure room and back, stored in a belonging bag underneath the rolling procedural stretcher cart. Patient valuables should be left with the patient escort or secured in a locker during the procedure. Patients can be rolled into procedure rooms on properly designed stretchers that are also used as procedure tables. In this way, patients can move from preparation to procedure and back to recovery requiring no mounting or dismounting from wheelchairs or carts. This is not only more efficient but also safer for the patient.

Per the FGI 2010 guideline, one preparation and two recovery rooms or curtained bays are required per procedure room, but state requirements may vary and need to be checked. Some patients who need additional recovery time after they are able to dismount the procedure cart can recover in recliner chairs. A few curtained recliner chair areas can provide this extra recovery space. The number and type of required recovery bays may also vary depending on the type of sedation used. Corridors between procedure areas and preparation-recovery spaces should be wide enough to provide easy patient cart movement. Toilets should be close to both preparation-recovery and procedure areas.

Procedure Room Area

The number of procedure rooms is determined by the caseload of the endoscopy facility. This number is often overestimated. More important than the number of procedure rooms is the amount of recovery space available. In an efficient facility where turnaround time is quick, the number of procedure rooms can be minimized. Turnaround between cases should be very rapid. Using procedure rooms for recovery compromises efficiency by tying up a specialized procedure room. To determine the required number of procedure rooms, consider the number of physicians and the anticipated procedural volume. An average efficient procedure room should be able to accommodate 16 to 20 endoscopy procedures per day, depending on the types of procedures being performed. Allowances should be made for anticipated growth in numbers of physicians and patients over the subsequent 5 years. By using the patient load anticipated 5 years hence, and dividing this load by the number of procedures per room per year, the number of required rooms can be calculated.

The minimum size for an endoscopy room is approximately 200 clear square feet according to the *FGI Guidelines;* however, this may vary according to state specific regulations. Clearances shall permit a minimum clearance of 3 feet 6 inches at each side, head, and foot of the stretcher/table. A hand-washing station shall be available to each procedure room. Approximately 300 square feet may be needed for higher complexity endoscopy procedures. Sometimes state licensing departments or Medicare mandates a minimum size for an "operating room" that is inappropriately large for an endoscopy room. In that instance, a variance can be requested, but it is not automatically granted.

In an endoscopy procedure room layout, placement of the light source, the video processor, video monitor(s), and electrocautery must be carefully considered. Many variations are possible to fit the preferences of the endoscopists and nursing staff. Rooms should be planned with equipment and supplies integrated into the layout and positioned strategically around the site of the patient on the procedural stretcher. An example of such a procedure room layout is provided in Fig. 2.5. The floor should be free of cables and wiring; these can be arranged along the perimeter of the room or preferably above ceiling, below the

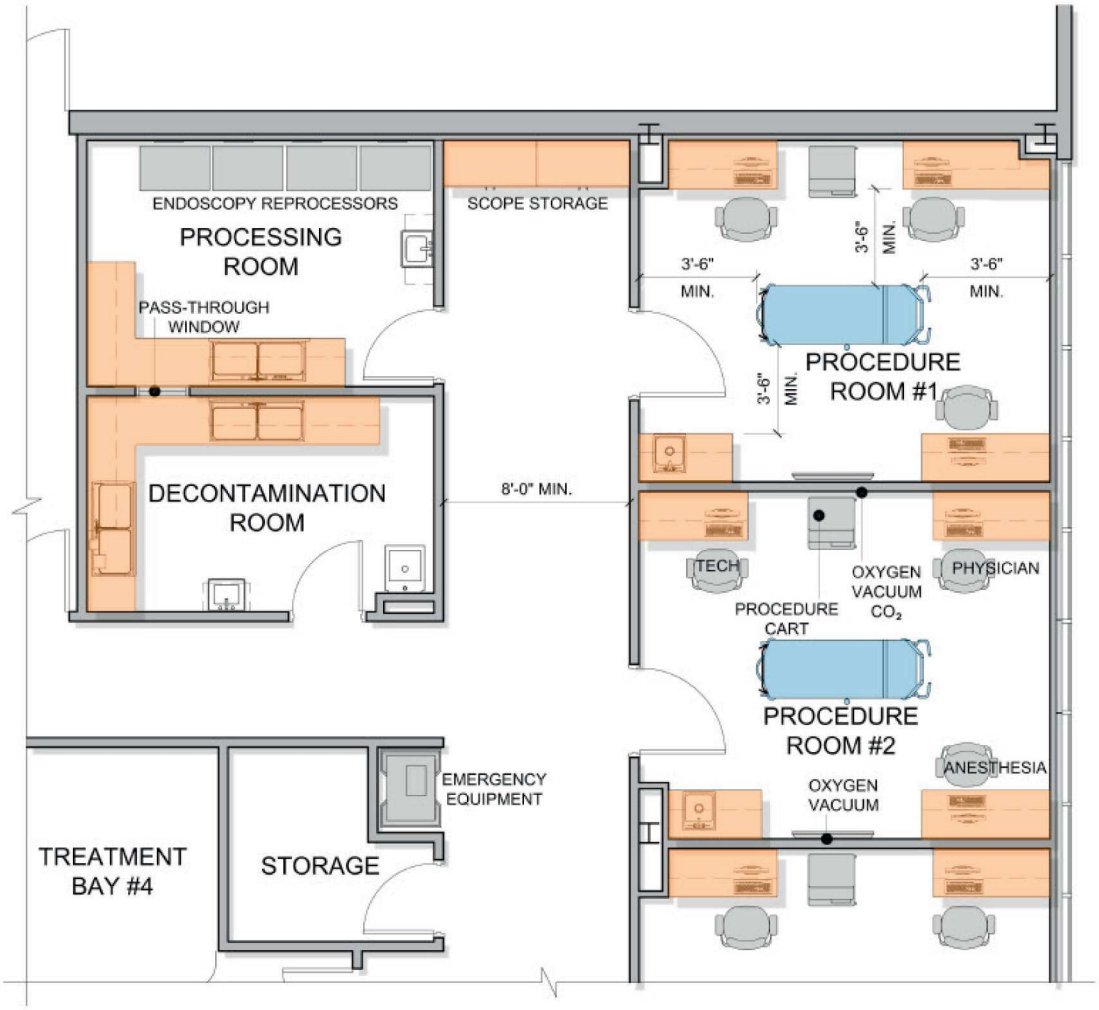

FIG 2.5 Example of procedure room and reprocessing room layout.

floor, or via conduits in the walls. This allows physicians, staff, and equipment to move unfettered by cords and cables, and it avoids damaging these sensitive components. Preplanning should include consideration of the type of endoscopes used, as this will affect the cabling needed. All endoscopic accessories, suction, oxygen, supplies, and all resuscitation equipment should be at hand. An emergency call button is required in each procedure room, and an emergency (crash) cart should be stored nearby. A typical endoscopy procedure room is shown in Fig. 2.6.

Reprocessing Areas

Efficient equipment turnover time can be achieved by having appropriate equipment for rapid cleaning and high-level disinfection. In this scenario, the speed of the endoscopy facility is determined by the efficiency of the physician between procedures rather than by the number of procedure rooms. Instrument cleaning and high-level disinfection can be accomplished by strategically placing the cleaning area between two procedure rooms or having an efficient large cleaning area within a short distance of several procedure rooms. Adequate numbers of endoscopes stored properly and reprocessed effectively and efficiently ensure that the most expensive cost elements of the endoscopy facility—the physicians and nursing staff—are not kept waiting for equipment.

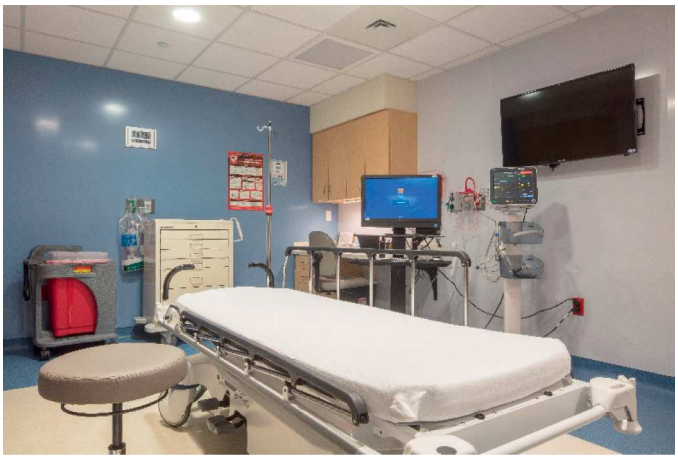

FIG 2.6 Typical endoscopy procedure room, Northern New Jersey Endoscopy Center, Englewood Cliffs, NJ. (Photograph by Andrea Brizzi; facility designed by RSC Architects, Hackensack, NJ; http://www.rscarchitects.com.)

FIG 2.7 High-level disinfection processing room for multiple endoscopes. Northern New Jersey Endoscopy Center, Englewood Cliffs, NJ. (Photograph by Andrea Brizzi; facility designed by RSC Architects, Hackensack, NJ; http://www.rscarchitects.com.)

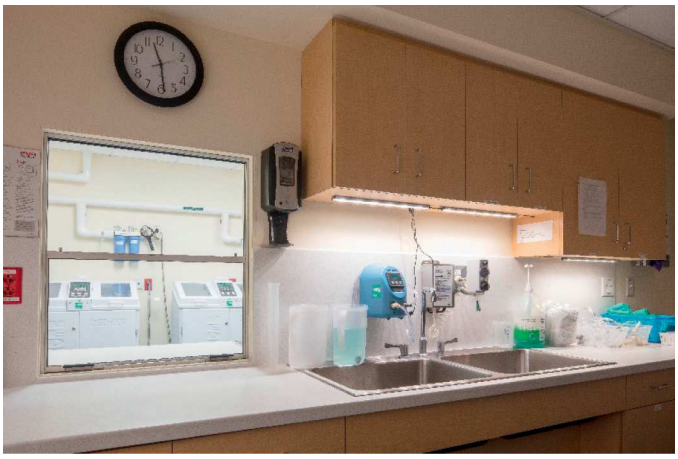

FIG 2.8 Pass-through window maintains separation of "clean" and "dirty" areas. Northern New Jersey Endoscopy Center, Englewood Cliffs, NJ. (Photograph by Andrea Brizzi; facility designed by RSC Architects, Hackensack, NJ; http://www.rscarchitects.com.)

The soiled scope cleaning room and the reprocessing room should be large and appropriately ventilated, with ample plumbing and power provisions for future changes. Oversized sinks are required, and there should be a place for soiled endoscopes to be placed while waiting to be cleaned. Automated endoscope-reprocessing machines with multiple endoscope compartments provide an efficient way of reprocessing endoscopes (Fig. 2.7). Different instrument-reprocessing units vary in the chemicals used and their cleaning time, which has an impact on the number of endoscopes required by a busy unit. A "pass-through" window from soiled to clean processing areas, as shown in Fig. 2.8, can help maintain separation of clean and dirty areas.

A closed cabinet with proper ventilation for the storage of the clean endoscopes is essential. Endoscope storage cabinets that circulate air through the endoscope channels provide added protection against moisture and bacterial growth within channels. A storage unit with channel air circulation is shown in Fig. 2.9. It is essential that proper ventilation follow the standards to meet infection control and safety guidelines.

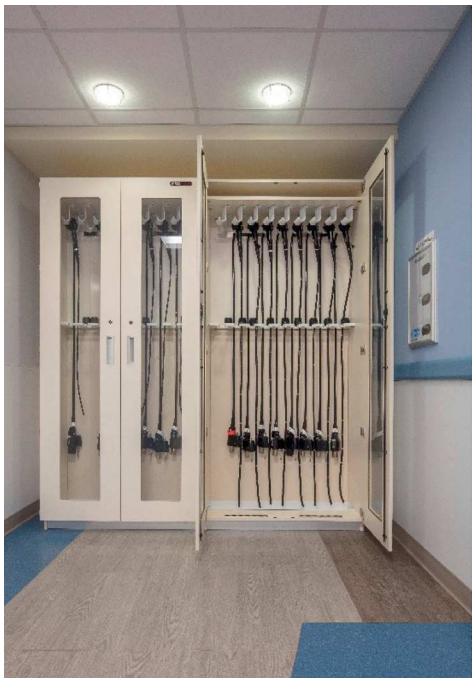

FIG 2.9 Endoscopy storage cabinet providing air circulation through endoscopy channels. Northern New Jersey Endoscopy Center, Englewood Cliffs, NJ. (Photograph by Andrea Brizzi; facility designed by RSC Architects, Hackensack, NJ; http://www.rscarchitects.com.)

Support Areas

General storage for supplies must meet all temperature/humidity guidelines and be readily accessible to the preparation-recovery areas and the procedure rooms. An adequately rated room should be provided for biohazardous waste. Space should also be allocated for soiled linen and regular trash. Environmental closets are also required for this space.

Mechanical Areas

Mechanical rooms are needed to supply the medical gas manifold, vacuum pump, water heater, HVAC unit and other mechanical equipment. An alternative power source (Essential Electrical System), such as a battery backup system or generator, is necessary to ensure uninterrupted power. Providing the correct power source will be dependent on the type of anesthesia used, the type of facility, and Medicare and state regulations.

Staff Area

Requirements for dressing room spaces are different in regulated and unregulated endoscopy facilities. Rules for the EASC or hospital may be quite different from the office. It is wise to know the regulations from the state department of health and from certification agencies. Male and female locker areas are generally required, but variances can be requested to eliminate the need for unnecessary shower facilities. Fig. 2.10 shows a convenient

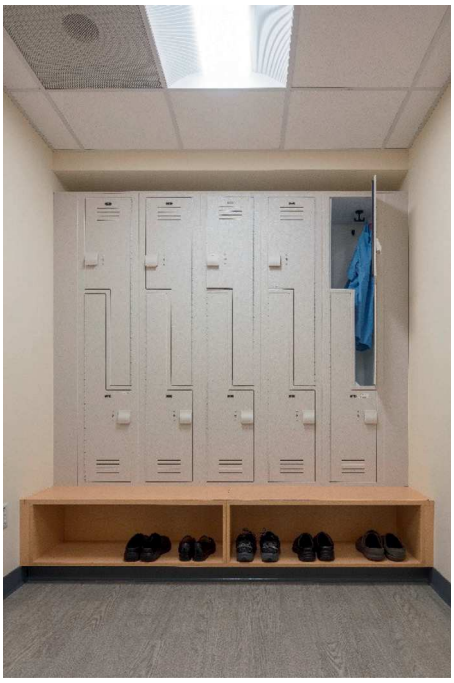

FIG 2.10 Staff changing room and lockers. Northern New Jersey Endoscopy Center, Englewood Cliffs, NJ. (Photograph by Andrea Brizzi; facility designed by RSC Architects, Hackensack, NJ; http://www.rscarchitects.com.)

locker/bench/shoe storage area in a staff locker room. An additional part of the staff area is the break room. Some state departments of health or certification bodies require a break room within the confines of the endoscopy facility. Careful attention to state and federal regulations is warranted to ensure that licensure and certification requirements are met.

Summary of Planning and Design

The design of an efficient endoscopy facility is facilitated by a functional relationship diagram showing the flow of patients through the facility. An architectural space program is developed by tabulating the areas necessary and assigning space required. This architectural space program determines the size of the facility. A procedure room utilization calculation determines the number of procedure rooms and other areas necessary to handle the patient caseload, and provisions should be made for caseload growth. Careful attention to planning and design results in the construction of a pleasant, efficient endoscopy facility that meets the needs of patients, physicians, and staff.

STAFFING AND SCHEDULING

Decisions regarding staffing and scheduling are critical to the safe and efficient operation of the endoscopy facility, have a major impact on patient outcomes, and affect the financial viability of the endoscopy unit.

Staffing

Decisions regarding staffing hinge on regulatory requirements, volumes of procedures, and case mix (disease acuity). Numerous federal and state regulations affect staffing decisions, and a thorough knowledge of these requirements is necessary to ensure compliance with state licensing requirements, Medicare certification regulations, and third-party accreditation standards.[34,35]

Medicare guidelines stipulate that a registered nurse (RN) must be available on site during all hours of operation of a hospital or ASC endoscopy facility. The nurse practice act of each individual state also affects staffing decisions. A state nurse practice act defines the scope of practice for RNs, licensed practical nurses (LPNs), and other assistants or technicians. These nurse practice acts may limit who can start intravenous (IV) lines, administer IV medications, or provide other clinical services. To determine the number of full-time equivalents (FTEs) needed for staffing, one must quantify the time needed to care for a single patient, multiply this by the number of procedures scheduled daily, and divide by the work hours per day of a full-time employee. Some factors that influence the decision to use RNs versus LPNs versus technicians include scope-of-practice regulations, salary costs, and availability. Regardless of the mix, care should always be directly supervised by an on-site RN.[36]

Scheduling

Most facilities use block scheduling to maximize efficiency and convenience.[34,35] Block scheduling also allows for time allotments based on the performance characteristics of individual endoscopists. Examples of block scheduling and tools for use in block scheduling have been published by McMillin.[34]

Time allotments for procedures vary from facility to facility. Some facilities allow 45 minutes for colonoscopy and 30 minutes for upper GI endoscopy,[34] whereas others schedule more tightly, often using 30 minute slots for all upper and lower endoscopies (Digestive Health Specialists, Tacoma, WA, unpublished data). The tighter scheduling can be accommodated by efficient endoscopists, good staffing, adequate equipment, rapid turnaround time, and ample preparation-recovery space. Careful staffing and scheduling are imperative to ensure high quality care, good patient outcomes, and optimal fiscal performance of the endoscopy facility.

DOCUMENTATION AND INFORMATION TECHNOLOGY

An accurate and complete medical record for each patient and a log of the unit's overall activities must be kept (see Chapter 10). The endoscopy report and nursing notes may include, but may not be limited to: date, patient identification data, endoscopist, specific instruments used, endoscopic procedure, indications, informed consent, extent of examination, duration of procedure, findings, notation of tissue sampling, therapeutic interventions, complications, limitations of the examination, conclusions, and recommendations. Photographs, electronic images, and biopsy reports should also be part of the record. Quality indicators and patient outcomes should be tabulated, and a method of regular peer review should be developed.[5] Information management in an endoscopy facility affects all aspects of the operation, including scheduling, billing and reimbursement, patient medical records, procedure reports, clinical laboratory and anatomic pathology reports, imaging, pharmacy, patient education, performance improvement data, financial management, materials management and inventory, budgeting and forecasting, payroll and personnel, and staffing and scheduling.[37] Modern information technology may allow more efficient and effective operations within the facility.

Information technology is changing medical practice at a rapid pace and may allow for more efficient and effective operations within the endoscopy facility.

To minimize repetitive data entry and difficulties with sharing and analyzing data across different systems, the modern endoscopy unit should plan ahead and install an information technology system that provides compatibility between the office electronic medical record (EMR), the endoscopic facility, the billing department, the endoscope manufacturer, the cardiac monitor manufacturer/model, and possibly the local hospital. The interface should allow prompt transfer of demographic data and pertinent components of the medical history and physical examination. Bidirectional transfer of information ensures that the procedure report and billing information are transmitted to the individuals who need access to it. Further increases in functionality can be envisioned. For example, the use of wireless networks and voice-recognition software for endowriters and EMRs are possible. Electronic systems can also be used to enhance service offerings to patients and families. The system can generate automatic reminder letters or offer educational material and resources for the patient and family if a new diagnosis has been made. The pathology request, endoscopy report, referral letter, discharge instructions, plans for follow-up, and billing information can be generated from the base examination and completed before the patient leaves the facility. Many of the documents can be sent electronically.

QUALITY MEASUREMENT AND IMPROVEMENT

Increasing health care costs, constrained resources, and evidence of variations in the quality of care rendered have triggered a renewed emphasis on quality measurement and improvement. Two reports by the Institute of Medicine advocate widespread changes in health care, including paying for performance as a means of achieving the delivery of high quality care.[38,39] Medicare regulations and third-party accreditors require endoscopy facilities to engage in an ongoing comprehensive self-assessment of the quality of care provided. This process includes quality improvement efforts directed toward numerous facets of the operation of the facility. Reasons for quality improvement activities include ensuring that patients receive the highest quality of care possible; providing a competitive edge when seeking contracts; and addressing the recent emphasis of legislators and regulators on quality improvement activities as part of the licensure, certification, and accreditation process. Johanson[40,41] described continuous quality improvement in the EASC. The philosophies and tools presented in this article provide a framework for quality improvement activities in all endoscopic facilities. A 2015 publication by a joint task force from the ASGE and the American College of Gastroenterology provides an excellent resource with recommendations and ranking of quality indicators that can be used as a starting point in quality measurement and improvement efforts.[5]

ACKNOWLEDGMENTS

The authors gratefully acknowledge the work of James T. Frakes, MD who authored and coauthored the previous versions of this chapter. The text of the current revision draws substantially from those previous versions. The authors are also very grateful to MaryAnn Gellenbeck for her suggestions and input related to the current revisions.

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