CHAPTER 2

Design and management of gastrointestinal endoscopy units

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Synopsis

The specialty of gastrointestinal endoscopy has evolved to the point where it requires specific attention to many aspects of facility design and unit management. Important design elements that require consideration include regulatory mandates, space planning, and infrastructure for health-care facilities, with specific attention to water supplies, forced air, vacuum capability, and waste disposal. Experience has generated numerous specific recommendations for design of the individual portions of the endoscopy suite to enhance both quality and efficiency. Administrative oversight is required for issues specific to physician, nursing, and business concerns. Besides those tasks common to most of health care (such as licensure, competency, and personnel issues) administrative arenas include scheduling of procedures and staff; purchasing of endoscopes, therapeutic devices, and endoscopic databases; reprocessing of endoscopes and related infection control issues; accreditation; efficiency and quality improvement efforts.

Introduction

The growth of gastrointestinal endoscopy as a specialized activity within health care has increased the need for specialization in both facility design and management skills. Historically, endoscopic facilities grew within hospital environments, often using existing patient rooms or wards and the existing skills of generic hospital personnel. Administration was commonly assumed by hospital-based departments responsible for surgical suites or emergency departments, with academic attachments to departments of medicine or surgery. The increasing demand for greater volume and complexity of services commonly strained these original arrangements. This led to the design of purpose-specific facilities and greater specialization by staff and administrators. The subsequent evolution from specialized hospital-based units to office endoscopy and accredited ambulatory surgical centers led to further complexity in the planning and

administration of endoscopy units. This chapter will review the broad elements of facility design and unit administration that are important for successful development of a gastrointestinal endoscopy unit today.

Some elements particular to ambulatory surgical centers (ASCs) will be mentioned or referenced. Ambulatory endoscopy centers (AECs) are ASCs specific to one specialty, but they share essentially the same regulatory and design issues. There are extensive published and commercial guides regarding development of such units and professional consultation is typically useful during their planning [1]. This outline should not be considered definitive guidance on issues pertinent to their establishment or administration.

Unit design

A variety of external standards dictate the design of facilities for endoscopic services [2]. Architectural guidelines pertaining to construction of health-care facilities, including ambulatory centers, come from local and state building and fire codes, medicare mandates, accrediting organizations, and the industry standards espoused by the American Institute of Architecture [3]. They vary in specificity, but are generally coherent and well-known to architects working in the health-care field. Facility licensure and medicare certification require strict attention to the details of design [4]. Inquiry about requirements and guidance regarding details should be sought from state agencies that will be providing licensure. In many states there is a requirement to obtain a certificate of need (CON) prior to construction. This approval process confirms the regional or local need for an additional new facility.

Important elements requiring close attention pertain to infrastructure, people, equipment, supplies, and services. Table 2.1 delineates many of the various elements that fall into these categories. Most of them are generic to health care, while some are highly peculiar to sedation-based endoscopy practices, training environments, etc. Each should be considered both separately and as part of the whole. While not all are pertinent in every endoscopy unit, their consideration will ensure that major needs are not overlooked.

Space planning

Architectural form has a major influence on the function of a facility. Considerations given to the space allocated to specific activities, and their adjacency or proximity, greatly affect the resulting efficiency, and even safety, of the services delivered in the environment.

When considering development of a new or remodeled facility, two of the most important considerations pertain to the space available for the project and

Table 2.1 Design and space considerations

Consideration and planning is required for the following elements pertaining to the infrastructure, people, equipment, supplies, and services during design and planning of an endoscopy facility. Many elements require specifically designated locations and space.

Space
- Space: to efficiently accommodate people, current activities, growth (see Table 2.2)
- Adjacency, proximity
- Flow: of patients, staff, equipment, biologic samples, waste, etc.
- Entries and exits for patients and staff

Infrastructure
- Utilities: electrical, HVAC, wet and dry (clean/soiled) vacuum; oxygen, compressed air, anesthesia gases
- Communications: internet, intranet, phone, dictation, call systems for emergency or assistance, visual systems (lights) for monitoring current room use, endoscope or patient status, alarm systems

People
- Patients and family: arrival, waiting rooms, restrooms
  - Specific accommodation may be required for patients with various disabilities, paralysis, overweight, etc.
  - Secure, tamper-evident storage for patient belongings
- Staff: nursing, physicians, receptionists, administrative, housekeeping, transcription
  - Private phone/work space: nursing, physicians, fellows
  - Lockers, changing, coat/personal item storage
  - Break area
  - Conferences/training
- Professional/academic visitors
- Vendors

Equipment
- Endoscopes, light sources, image processors
  - Accommodation for equipment care and upkeep
  - Specialized storage, closets, etc.
  - Space for repair or shipping and receiving
- Image recording/printing devices vs. infrastructure
- Reprocessing machines for endoscopes/devices
- Disposable vs. reusable endoscopic devices
- Stretchers: in use and spare
- Wheelchairs, lifts
- Fluoroscopy equipment
- Anesthesia equipment: in use, storage
- Resuscitation equipment: code cart

Supplies
- Linens: clean, dirty, hamper space per room
- Biological samples, containers: prep, storage, and transport
- Reprocessing fluids
- Disposables: i.e. personal protective ware, etc.
- Medications: controlled and non-controlled substances

Continued p. 6

Table 2.1 (*cont'd*)

Services
- IV starts, lab drawing
- Colon preparation
- Documentation of care
- Consultation
- Conferences/education
- Emergency care/resuscitation
- Fluoroscopy
- Procedural components
  - Check-in, procedure, recovery
  - Changing area
  - Patient lockers or tamper-evident bags to secure clothing storage
  - Procedure waiting: ambulatory or inpatient; chairs vs. stretchers
  - Sedation and analgesia; anesthesia services
- GI endoscopy vs. mixed services/specialties
  - Colonoscopy/EGD
  - ERCP; other fluoro based
  - EUS
  - Capsule endoscopy
  - Esophageal/other manometry
  - Breath testing
  - Pancreatic function testing
  - Bronchoscopy/other non-GI testing

the spectrum and volume of services that must be provided by the facility. Space projections should include the likelihood for growth in volume and potential expansion of services over 5–8 years, allowing for construction of a facility that can either accommodate growth or expand into adjacent space. Considerations of space are among the most difficult and carry the greatest implications for overall construction costs.

Anticipated procedure volumes provide useful space estimates based on planned procedure-room utilization rates and ratios of procedure rooms to waiting spaces and recovery beds [2]. Facilities intended for modest numbers of procedures can utilize space more flexibly than those with significant requirements for patient throughput and efficiency of personnel (Fig. 2.1). Small units often share public and clinical space with other departments that require similar accommodations for waiting, reception, pre- and postprocedure patient care, and administrative services. Examples include small emergency departments, outpatient surgery services, cardiology, pulmonary, or urological procedural areas. Note that ASC guidelines strictly detail which spaces can be shared, with which type of service, and which must be distinct. For instance waiting rooms, entries, and patient care areas must be distinct and separate from contiguous office space, but some staff facilities/break rooms, etc. can be shared [2].

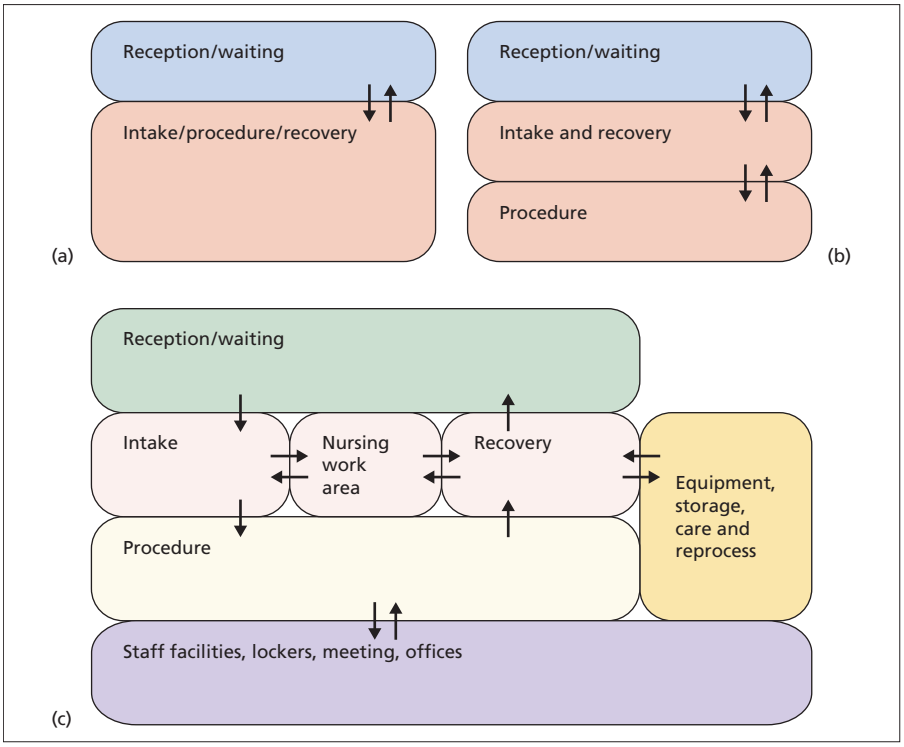


Fig. 2.1 Generic proximity considerations for (a) small, (b) medium, and (c) large units.

Hospital endoscopy is typically less efficient and more space consuming than practice in ambulatory settings due to the mix of inpatients and outpatients and the greater intensity of services required. A variety of ratios pertaining to ancillary activities (such as waiting room capacity per procedure room, recovery capacity per procedure room, etc.) have been used to assist with estimating space needs (Table 2.2) [5].

Daily room volumes

Daily procedure volumes per room vary greatly by type of procedure, patient characteristics, ancillary staffing levels, and process issues such as whether an individual endoscopist works out of one room or two. For high-volume general gastrointestinal endoscopy, daily volumes *per room* can vary from 6 to 10 when physicians use dual rooms and up to 12 or more when they work out of a single room. This equates to 1500–3000 procedures per room, annually [6]. Detailed analysis of procedure types and their mean durations are helpful for estimating

Table 2.2 Ratios for estimating space needs of ancillary functions

Ancillary function	Ratio
Waiting room chairs per procedure room	4–5
Intake beds or stretcher bays per procedure room	1–2
Recovery beds per procedure room based on standard moderate sedation with narcotic and benzodiazepine	1.5–2
Procedure rooms per endoscopist	1–2 colons 1–3 EGD 1 ERCP, EUS
Annual volume per procedure room	≥1000+
Space per procedure room: EGD, colonoscopy	220 sq. ft (20 m^2)
Space per procedure room: miscellaneous complex	350+ sq. ft (33+ m^2)
Space per procedure room: ERCP, fluoroscopy	400+ sq. ft (37+ m^2)
Space per recovery bed	60–80 sq. ft (5.6–7.4 m^2)
Space per waiting room chair	15 sq. ft (1.4 m^2)
Space per office	90–120 sq. ft (8.4–11.1 m^2)
Space per examination/consultation room	100–120 sq. ft (9.3–11.1 m^2)

realistic capacities per procedure room and, globally, per unit [5]. For AECs this is straightforward due to the narrow spectrum of procedures performed on relatively well patients. In the hospital setting considerations for both basic and complex procedures in frail and ill patients make estimating more challenging. Procedure and room turnover times specific to the facility and physician mix should be used if available.

Procedure room size

Similarly, space requirements per procedure room vary based upon the anticipated activity it will need to accommodate [7]. General procedures employing standard moderate sedation without the need for anesthesia monitoring are efficiently accomplished in about 220 square feet (20 m^2). Complex procedures require more equipment and room for more personnel, and are best planned for rooms of 300–350 square feet (28–33 m^2). Fluoroscopy-based procedures can be accommodated in 400 square feet (37 m^2) but often benefit from even larger rooms due to the need for extra rolling equipment, storage for devices, and accommodation for anesthesia. Further comments on individual room design are provided below.

Preparation and recovery ratios

Higher-volume units employing traditional sedation and analgesia work efficiently with one intake space per endoscopist and 1.5–2 recovery beds per procedure

room. Adoption of sedation practices utilizing rapidly metabolized sedation agents (propofol, and others) can reduce the need for recovery space but may require larger procedure rooms, depending on the involvement of anesthesia personnel and their equipment requirements in the given facility. Larger-volume units with need for greater efficiency require relatively greater space to accommodate thoroughfares for optimal patient and staff flow. Ideally, alert preprocedure and sedated postprocedure patients are separated in waiting, recovery, and transport areas. The benefit of dual hallways for this purpose is rarely realized due to space constraints.

Separate entrances

Separate entrances for staff access to and from patient-occupied areas help achieve staging for patient care while avoiding unnecessary staff traffic in view of waiting patients and families. In addition, should a problem occur, the separate staff paths for entry and exiting the suite can be utilized for emergency personnel entering the unit or to transport patients from the unit.

Common space problems

Space-planning inefficiencies that are sometimes foisted on staff in endoscopic procedure facilities include:

1 overconsumption of space for very routine procedure rooms, with lost and inefficient square footage between walls and equipment;

2 inadequate space in rooms designed for complex procedures, especially those employing fluoroscopy or other varieties of portable devices or carts;

3 inadequate storage for bulky spare or intermittently utilized equipment (patient lifts, extra monitors, portable recording equipment, argon plasma devices, lasers, etc.);

4 inadequate space for anesthesia staff and equipment at the head of the bed and for storage of anesthesia equipment;

5 inadequate allowance for dictating, conferencing, and downtime of staff and professional visitors.

Physical infrastructure

Most of the infrastructure required for an endoscopy unit, such as electrical, plumbing, and HVAC services, is standard for health-care facilities or ASCs. Infrastructure for communication systems and networking for electronic medical records, image documentation, intranet, etc. is becoming standard.

Particular enhancements must be provided for adequacy of ventilation in reprocessing areas and of vacuum suction in the procedure rooms. Ventilation air exchange rates must maintain ambient levels of reprocessing agent fumes below rigidly defined levels. Vacuum capacity may need local boosters or auxiliary units to accommodate the number and spectrum of active rooms in a unit at any one time. Most facilities use standard 'medical' or 'clean' in-wall vacuum suction attached to disposable waste traps in the room. A useful alternative that may reduce supply expenses, room clutter, and nursing tasks is use of a wet vacuum system which evacuates fluid waste directly into the sewage system. These systems eliminate the need for suction canisters and the infection control issues related to their emptying or disposal. Periodic flushing of lines (1–3 times per week) with a cleaning agent is recommended. Systems can be purchased for a single room or for a suite, floor, or building.

Most endoscope reprocessors are equipped with relatively expensive micron pore filters for removal of bacteria from rinse water. The useful life of these filters can be lengthened with the installation of one or two inexpensive sediment filters in the water supply line to remove larger particles before the water reaches the micron filter. Financial savings can be achieved by having the sediment filters installed on water lines coming to the suite as opposed to lines feeding each endoscope reprocessor.

Intake and recovery areas

The design of facilities for patient intake and recovery varies greatly, based on available space and whether or not the patients are ambulatory. In many units these two activities are combined in one area to allow mobility of space and staff between them. This approach yields maximal flexibility in limited space. We have long maintained separate areas for these activities in order to maintain simplicity and specificity of design, patient confidentiality, and space conservation in the intake area.

Intake areas

Like all hospital-based units, many ambulatory facilities also perform their intake activities while patients are recumbent on a stretcher in hospital attire. This relegates the individual to an unfamiliar and less comfortable patient status early in his or her visit. In contrast we believe it is both efficient and respectful to have patients check-in while still clothed. Subsequently, they change to hospital attire and await their procedure separated by gender in a typically chairbased lounge. They are then escorted to the procedure room where identification is again confirmed before they assume a recumbent position. This

approach facilitates family participation in the preprocedure interview and saves on space in the preprocedure area, utilizing about 15 square feet (1.4 m^2) per chair as opposed to 60–80 square feet (5.6–7.4 m^2) per stretcher.

Check-in cubicles can be relatively small (30–40 square feet (2.8–3.7 m^2)) and clustered in close proximity to the entry and changing areas. Their design is analogous to other stations in our institution for performance of phlebotomy or check-in at blood banking areas. They must be designed to preserve confidentiality and to accommodate wheelchairs and an accompanying individual. Requirements include a partial desk or counter for writing and sit-down access to a computer terminal and two chairs. Partial enclosure with three solid walls for improved sound proofing plus one curtain wall can suffice. Full four-walled rooms with doors are generally unnecessary and inefficient.

Managing clothes and valuables

To minimize the space requirement for lockers in the changing area and the need for a patient and nurse escort to return to the check-in changing area prior to departure, patients retain their clothing and accompanying valuables in a tamper-evident plastic bag throughout their visit. In the procedure room the bag is placed in a lockable pouch attached to each stretcher (PHS West, Hanover, MN) where it remains until they redress in the recovery area.

Recovery facilities

Recovery areas can utilize reclining chairs, stretcher bays, or hospital beds. For many years our recovery practice was primarily chair-based due to space constraints, but with the increasing depth of sedation, the frailty of some patients, and enhanced space in new units we have changed to predominantly stretcher-based recovery. Further evolution to propofol sedation could stimulate a return to brief observation intervals in reclining chairs. Facilities serving ambulatory patients with relatively fast turnaround do well with narrow stretcher bays separated by curtains, in which accompanying family members are not well accommodated. Each bay must have monitoring capabilities, emergency call systems and full electronic access to databases and the electronic medical record. Confidential conversations are not pursued in this environment, so a neighboring room for consultation with patients and family is necessary. One bathroom for approximately six recovery bays should be available for changing to street clothes.

In our practice patients undergoing ERCPs and liver biopsy recover in a shared 'short-stay' or 'ambulatory' surgery recovery facility, where family members can easily join the patient for up to several hours of observation. Similar space

accommodations can be made in dedicated GI units for those patients in whom observation will be prolonged.

Procedure room reprocessing and storage

The design of individual procedure rooms should be based on careful considerations of their intended use, the tasks of each of the staff members working in the room, need for proximity of equipment and staff to the patient, need for maintenance of relatively clean vs. soiled areas, and patient considerations for safety and ambience. Space requirements are discussed above.

Standard procedure rooms

Generic upper and lower gastrointestinal endoscopy is efficiently performed in relatively smaller rooms with most equipment and storage positioned against the walls [5]. Physician/endoscopist and nurse/assistant areas of activity can be delineated around the patient, who is located in the center of the room. These regions overlap but are largely distinct (Fig. 2.2). Requisite equipment for each individual's activities should be positioned within or accessible to their regions of work. Both endoscopist and nursing areas encompass soiled and clean areas. Separate computer terminals should be provided for the nursing and physician functions. The endoscopist's terminal can be within or just outside of the room,

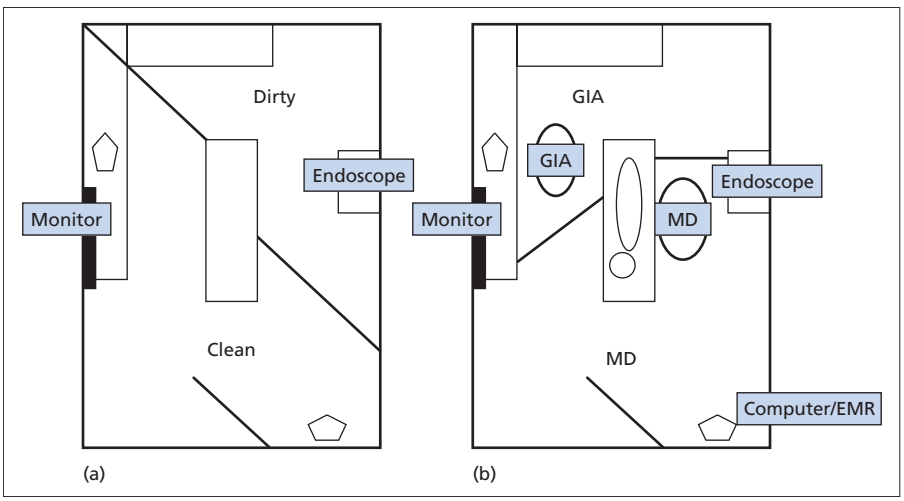


Fig. 2.2 Room design considerations. (a) Clean and dirty regions of the endoscopy room. (b) Functional physician and nursing areas. Note dual computer terminals for electronic medical record and endoscopy database.

(a)

(b)

Fig. 2.3 Room pictures of nursing and physician workstations. Note proximity of the nurse's terminal to the patient for ongoing documentation of clinical details of patient monitoring and procedural elements.

but a nurse's terminal should be in close proximity to the patient and should not require turning away from the patient to access patient medical records or to complete documentation required in the course of the exam (Fig. 2.3). Phones and hand-washing sinks should be accessible to both staff.

Scope reprocessing and storage

Decisions regarding the desired flow of patients and endoscopes influence the design and space requirements. Current architectural standards dictate that endoscope reprocessing areas be located outside of the procedure room. Many

units locate endoscope cleaning and reprocessing in nearby anterooms serving only 1–3 procedure rooms (Fig. 2.4), while others employ single dedicated cleaning rooms for the entire suite. The lapsed time from extubation to scope reprocessing will be affected by the location and distance to the reprocessing area as well as by staffing patterns. When the reprocessing room is distant from the procedure room, sinks and space for initial rinsing of soiled equipment

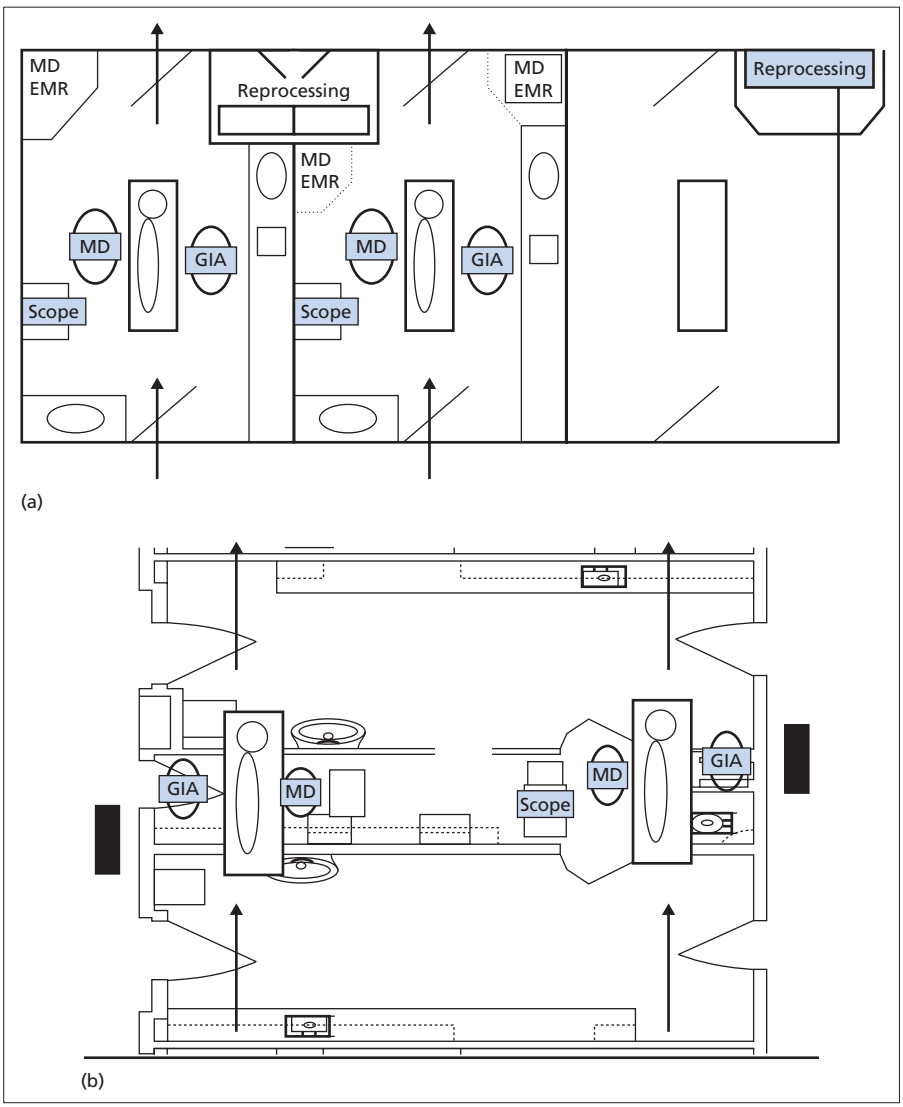


Fig. 2.4 Pass through room design with local reprocessing anterooms. (a) Design options. (b, c) Final design and photo of our reprocessing corridors, which are located between every two general procedure rooms. (d, e, f) Other reprocessing anterooms employed in our units.

(c)

(d)

(e)

(f)

Fig. 2.4 (*cont'd*)

(precleaning) should be available in the procedure room. A 'dirty-to-clean' flow of endoscopes and equipment should be maintained in the reprocessing and equipment areas to avoid cross-contamination between soiled and newly cleaned instruments. Adequate counter space on both sides of cleaning areas must be available to accommodate one or more instruments. Counter space with compressed air for drying should be nearby.

Endoscope storage requires a location where instruments can be hung freely without coiling or risk of entrapment by drawers or doors. This does not require significant space. Proprietary cabinets incorporating ventilation and temperature control are available. We employ shallow cabinets lined with brackets that

are embedded in the walls of hallways for greater accessibility to all staff. In-room storage is only used for specialty procedure rooms (ERCP and EUS) and storage of prototype and study instruments (Fig. 2.5).

Patient flow issues

Patient flow within the procedure room is largely dictated by door and equipment location. Large units seeking to separate pre- and postprocedure patients employ separate doors at each end of the room for arrival of alert ambulatory patients and departure of wheeled sedated patients on gurneys (Fig. 2.4). This requires additional space for dual hallways. Similarly, larger rooms for complex or fluoroscopic procedures should have an entry at each end for arrival and departure of staff or equipment during the procedures.

Complex procedure rooms

Complex and fluoroscopy-based procedures generally employ greater varieties and numbers of additional devices, often each with their own mobile console. The ability to move additional systems near or far requires adequate space to accommodate movement of ancillary staff around the outside of the equipment near the perimeter of the room (Fig. 2.6). The placement of utilities serving the equipment becomes problematic in larger rooms, as the presence of electrical cords and suction devices on the floor or spanning throughways generates risks to the staff. Options for provision of the utilities to the bedside include mid-floor and ceiling-based utility pillars serving mobile endoscopy carts or semi-mobile hanging bays for stacks of equipment, as has become standard in modern surgical suite. The latter approach keeps the floor clear but requires an even greater space allowance. Anesthesia utilities may be supplied via ceiling attachments for flexible hoses when their use will be relatively intermittent, or via the semimobile hanging bays typical in the operating room. The latter requires greater accommodation for space.

Storage of supplies and medications

Several options are available for in-room storage of linens, commonly used disposables, and other supplies. Adequate quantities of the generic moderate- to high-volume items should be kept in the room to serve only 1–2 days of practice, with daily restocking. This practice can minimize the potential for overstocking and ordering. It will also minimize the potential waste of accessories by an improved rotation of stock, with the ability to check expiration dates in the primary storage area. Rarely used non-emergency items that may be required

(a)

(b)

(c)

Fig. 2.5 (a, b) Endoscope storage in-wall option. (c) Detail demonstrating protective barrier for endoscope tips and placement of paper towels for daily assessment of overnight water dripping. Any evidence of water stains prompts repeated reprocessing in the morning before use.

Fig. 2.6 Large complex room design.

in any of several rooms should be kept in a common storage area for the entire suite. Both low- and high-volume specialty items used in only a single room (as with ERCP or EUS equipment) should be efficiently accessible within or very near that specific room. Fluoroscopy rooms dedicated to ERCP practice have the greatest need for organized accessible storage of innumerable devices. Organization can be accomplished with bins, peg-board hanging storage, slotted cupboards, and drawers (Fig. 2.7), or proprietary inventory management systems analogous to pharmaceutical systems noted below. Labeling and lighting should accommodate identification of equipment in dim rooms employing fluoroscopy.

Locked storage and access to pharmaceuticals for both regular and infrequent use should be carefully considered. Options include in-room locked drawers or cabinets with supplies checked out to each nurse for each shift and in-room or unit-wide computerized dispensers (Pyxis Products, Cardinal Health, Inc., San Diego, CA) that are commonly networked to hospital-wide pharmacy systems. Non-controlled medications and intravenous fluid supplies should be kept locked either in the room or in a central storage area, depending upon the frequency and urgency of use.

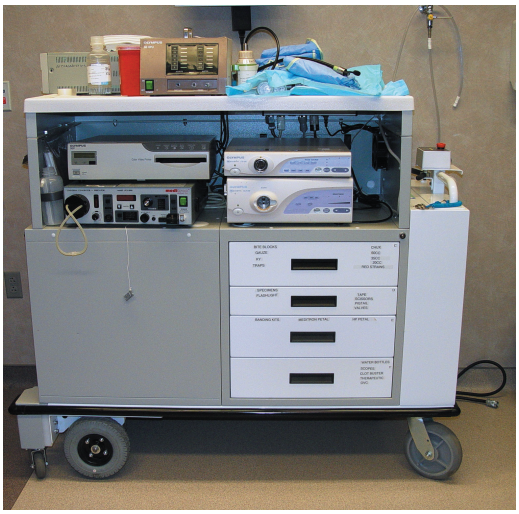
(a)

(b)

Fig. 2.7 (a, b) Storage for ERCP devices, employing slotted cabinets with recessed doors and labeling for daily 'par' stock control using electronic wands.

Travel carts for emergencies

Mobile carts are available for transporting the essential elements of the procedure suite to the bedside in the emergency room or intensive care unit. We utilize a self-powered (motorized) design that allows a single nurse to safely drive all equipment to distant locations of the hospital (PHS West, Hanover, MN) (Fig. 2.8). A larger primary cart carries the light source, endoscopes, devices, drugs, and most accessories. A smaller non-powered cart for the monitor and disposable protective equipment links to the larger cart during transportation and separates for positioning across the bed from the endoscopist during the procedure. Vacuum capabilities are generally available in all patient



(a)

(b)

Fig. 2.8 Mobile cart used for transport of endoscopic services to distant areas throughout the hospital. (a) The main self-powered module containing most equipment. (b) Smaller non-powered module that is linked to the larger unit during travel and unlinked for procedure performance.

areas served. Databases can be linked to the central servers via wireless systems or via hospital-wide intranet jacks.

Unit management

With the trend toward specialization of procedure units there has been a corollary specialization of the administrative tasks for optimal function of such units. Administrative structures will vary greatly depending upon the business model, ownership, and setting of the unit. A variety of structures can function well, as long as the major areas of responsibility are adequately addressed and sufficient communication occurs between the respective roles. Most administrative structures incorporate significant overlap in responsibilities and rely on collaboration in the administration of medical/physician, nursing, and business arenas.

Major areas of responsibility

The major responsibilities of the administrative team are delineated in Table 2.3. Specific comments pertaining to several of these areas of responsibility are

Table 2.3 Major administrative responsibilities for a gastrointestinal endoscopy unit

Medical administration
- Physician credentialing, privileging, calendars
- Definition and maintenance of professional standards
- Sentinel events; complication/outcome tracking; proctoring

Nursing and allied health staff administration
- Hiring, credentialing, training of staff
- Maintenance/demonstration of competency
- Staffing
- Nursing care planning
- Policies and procedures

Other responsibilities variably assigned between physician, nursing, and business administrators
- Purchasing
  - Capital equipment (endoscopes, computers, communications, fluoroscopy, etc.)
  - Software (databases, image management)
  - Devices
- Schedules/calendars
- Medication control
- Equipment maintenance, repair
- Infection control/instrument reprocessing
- Coding and billing
- Accounting
- Accreditation
- Quality Improvement

provided below. Those commonly delegated to the medical administrator include credentialing, privileging, and maintenance/oversight of professional standards for the physician or other professional endoscopists. Many of these issues are managed by a central medical staff office of physician affairs for hospital-based units, while freestanding ambulatory facilities need to attend to them individually.

Responsibilities commonly delegated to the nursing administrator include development and maintenance of nursing care plans, hiring, credentialing, privileging, training, staffing, and maintenance of competencies for nurses and other allied health staff. This individual or their assistant will have significant responsibility for personnel management of the nursing staff. In a hospital setting this is often shared with professionals from the human resources department. Smaller units often place both overall unit management and nursing administration in the hands of the same individual, whereas this would exceed the capacity of one individual in larger units. Reprocessing and repair of equipment is commonly overseen by this member of the team or another staff member with focused expertise.

Administrative tasks that may fall to the medical administrator, head nurse, or a trained business administrator are numerous. They include purchasing (of capital equipment, reusable or disposable devices, and consumables), coding, billing, accounting, image management and electronic medical record databases, and general unit function. Management of non-nursing personnel may fall to this individual as well.

Staffing design

Major staffing issues that influence both efficiency and costs pertain to the level of caregivers employed for varying tasks and the number of staff assigned per room, per physician, or per volume of procedures. Many units staff all procedure rooms with a full-time registered nurse (RN) to administer sedation and monitor the patient and a full-time licensed practical nurse (LPN) or technician as a gastrointestinal assistant (GIA) for assisting with endoscopic interventions. Nursing functions must be in line with state 'scope-of-practice' laws relative to patient monitoring vs. assessment and medication administration. Such rules may vary between settings and states. We staff 1.5 LPNs per general procedure (EGD and colonoscopy) suite, where one staff member monitors patient comfort, vitals, response to medication, and procedural interventions; one joins in to assist with endoscopic interventions; and an RN is available to respond at a moment's notice via a call system in each room. The physician retains global responsibility for assessment, medication management, and initial medication administration. In our advanced procedure suites (ERCP, EUS, miscellaneous

complex procedures) and for general procedures in high-risk patients, an RN performs both the monitoring and assessment tasks, an LPN serves as the technical GIA, and the physician retains the responsibility for medication management but not administration.

Nursing staff are also required for the preprocedure assessment and the recovery/dismissal tasks. Other personnel commonly employed in larger units include technical assistants for endoscope reprocessing, skilled technicians for endoscope and other equipment servicing and minor repairs, patient scheduler, and reception and secretarial staff.

Overall staffing levels for endoscopy units can be managed based on indices of productivity, such as procedure unit volume per employee, average total employee hours per procedure [8] or procedure relative value units (RVUs) per non-physician employee. Many varied staff schedules can be used to cover shift responsibilities. Flexibility in staffing for the extremes of high and low demand is useful for the unit manager.

Staffing emergencies

Plans should be made for staffing emergency procedures, both during the workday and during off hours of nights and weekends. If unscheduled procedures are infrequent this activity may be easily absorbed into the existing workday calendar. Many units leave the after-hours technical role of set-up, reprocessing, and procedural assisting to the endoscopist or trainee plus available float staff; however, this diminishes both quality and safety of the procedure and potentially the efficacy of reprocessing. Some units schedule a part time late shift that routinely covers those scheduled procedures that run late plus all emergencies until the morning. We schedule one LPN/GIA to cover emergencies at all times of the day and night for 3–4 day stretches (two per week). They are responsible for transporting the mobile endoscopy cart when necessary, and for the usual elements of procedure set-up, cleaning, and reprocessing. A maximum of 12 individuals rotate through this assignment for after-hour and daytime coverage in order to maintain monthly exposure. They are joined by an RN from the local area being served (emergency room, surgical suite, ICU, floor unit) or from the hospital float pool. During the workday the on-call GIA is available to staff in an unscheduled room or to float as an assistant in the scheduled rooms. During the evenings and on weekends they are available by page for initiation of procedures within 30–45 min.

Weekend ERCP coverage may require specially trained nurses. Historically we required all on-call nurses to have ERCP skills, but the frequency of bleeding and the relative infrequency of weekend ERCPs (~30–40 per year) have prompted us to restrict ERCP call to a smaller group.

Procedure schedules

Attention to the design and completion of daily procedure calendars is critical for unit efficiency and profitability. The major considerations for calendar design include the number of rooms per endoscopist, the time scheduled per procedure of a given type, and the time required for turnover between procedures. When the number of procedure rooms is the predominant constraint for a given unit, efficiency is maximized by utilizing one room per endoscopist while tightly managing room turnover time. In contrast, a surplus of space and procedural demand requires maximizing efficiency of the professional staff by minimizing their between-procedure downtime—usually by provision of multiple rooms per endoscopist. Efficient calendars are more easily designed using block scheduling of endoscopists performing basically similar or uniform procedures. Serial performance of brief EGDs, for instance, allows calculation of average procedure time, average reprocessing and room turnover times, and therefore, the ideal number of rooms per endoscopist—usually two or three depending upon their personal efficiency and the need to intermix other clinical activities or consultative tasks. Outpatient colonoscopies entail longer procedure times but similar turnover times, with two rooms adequate for maximal endoscopist efficiency.

Relative time requirements

We assign a relative time requirement of 1.0 to average risk EGDs in a non-teaching assignment, which we schedule every 15 min—but could just as well list for 10, 12, 18, or 20 min, depending upon the desired pace, documentation requirements, and patient care duties between procedures. In the same system, non-teaching colonoscopies are weighted for a time value of 2.0 (30 min each), and ERCP and EUS procedures, which are always teaching assignments, are assigned a value of ~5 (75–80 min each), including room turnaround. Other complex therapeutic procedures are weighted anywhere between two and five. Thus mixed procedure calendars can be scheduled with some anticipation of workload and appropriate staffing.

Barriers to efficiency

Despite excellent processes, efficiencies can be affected by procedures that go over the time allotted, patients that do not show for appointments, procedures that are cancelled due to inadequate preparation or current health risks, unfilled appointment slots, open blocks in the schedule, or late arriving endoscopists.

Purchasing

Endoscopes

The major purchasing decisions pertain to capital equipment (endoscopes, fluoroscopy units, electrosurgical generators, patient gurneys, databases, etc.). Of these, endoscopes, light sources, and image management systems (endoscopy 'set-ups') are most central to the function of the endoscopy suite. While there are only limited numbers of endoscope vendors in the marketplace and the basic functional aspects of their products are quite similar, endoscopists often develop strong and divergent opinions regarding ergonomics and functionality of each line of equipment. Hence both physician preferences and contractual stipulations are important in the selection of endoscopy equipment. The major options for acquisition of endoscopes are outright purchase of new, refurbished, or used equipment and leasing, typically for terms of 3 or 4 years. The latter approach is often quoted on a price-per-procedure (PPP) basis. Units that purchase endoscopes may do so on a rolling basis, replacing 20–25% of their stock every year, or in bulk fashion every 4–6 years, with amortization/depreciation schedules then spread out over that interval. Purchase with extended use beyond 3–4 years is typically more cost effective than leasing. This approach risks undesirable delays in acquiring new technology and may yield increasingly worn instruments and rising repair costs toward the end of their term. Price-per-procedure leases tend to be more expensive, but they are potentially desirable and cost effective if equipment exchange is planned after shorter time frames of 3 years or so. As with auto leasing, a direct comparison of costs requires quotations for per procedure costs, estimated (contractual) procedure volumes, specific delineation of types and numbers of endoscopes, and contractual residual values at the termination of the contract. Some vendors will not specify all of these elements at the outset, particularly a residual buyout value. Buy-out options for some of the instruments should be considered and negotiated at the time of the lease as they may be useful for subsequent back-up use.

How many endoscopes? For both the purchase and lease options, accurate planning of endoscope requirements contributes to cost constraint, as efficiently reusing fewer instruments is far less costly than having extra instruments hanging largely unused in closets. Appropriate estimates must accommodate instrument breakdowns, repairs, dual procedures, etc. We have successfully utilized the following ratios during equipment planning for several large and small units. One colonoscope, gastroscope, and sigmoidoscope for every 350 procedures per year; one duodenoscope and EUS scope for each 150 procedures per year; one light source and processor per endoscopic procedure room; and

one scope reprocessor for each 1000 procedures per year. Some specialty endoscopes, such as pediatric and therapeutic instruments, may be needed to provide complete basic services. Others may not be economically wise if they require a skill set or instrument that would be infrequently used.

Endoscope repair costs. Endoscope repair costs are a major element of unit finances. Repairs can be purchased on a piecemeal basis, with or without volume discounts, or on a prospective contract basis. Like endoscope leases, prospective repair contracts may be negotiated on a per-procedure basis, whether the equipment is purchased or leased. For cash flow purposes this provides useful averaging of expenses over an anticipated range of costs. One typical contract design covers cumulative costs for the department over a range of 90–120% of the face value of the contract. Cumulative actual costs below 90% of the contract value yield a rebate to the unit while costs exceeding 120% yield a liability to the unit. Such contracts typically don't stipulate the cost schedule for various repairs, such that the unit may be unaware they are actually purchasing top-drawer services but paying for them over time. It is useful to have right of acceptance and decline for individually advised repairs, much like that afforded to customers by the service department of a reputable auto dealer. The acceptance or decline option should be delegated to an individual with knowledge of instrument use and design. This allows staff to learn of instrument frailties and mistreatments that lead to repairs, and provides an avenue for negotiating the price and purpose of some repairs.

Databases. Modern databases for reporting of gastrointestinal endoscopic procedures are available from several vendors as well as via collaboration with the national endoscopy database (CORI System) developed by the University of Oregon and the American Society of Gastrointestinal Endoscopy (ASGE) and funded by the National Institutes of Health. Several major institutions, like ours, employ databases of their own design for meeting documentation requirements, [9] reporting, and unit management. With the growing emphasis on quality improvement and the coming utilization of pay for performance reimbursement, computerized databases are becoming inevitable necessities for the endoscopy unit.

Most databases employ, or map to, some version of the internationally developed minimum standard terminology (MST) for endoscopy [10,11]. Most are used for basic scheduling, reporting, billing, and correspondence. Some also provide means of documenting all clinical and nursing care. In our department, the endoscopic database, coupled with interfaces to the institutional electronic medical record and several other systems, provides a completely paperless environment for all aspects of clinical practice, business management, quality

assurance, and research. The sophistication and complexity of interfaces needed will be a function of the practice setting and the independence of the unit from a larger institution. Adequate interactivity should negate the need for dual entry of names, numbers, or any variety of data in more than one record or system.

Devices. Next to the cost of personnel, devices are becoming a dominant expense within many endoscopy units, particularly those that deliver complex therapeutic procedures and ERCP and EUS services. The major device decisions any unit faces are: (1) whether to predominantly use reprocessable and reusable devices or single use disposable devices [12,13], and (2) if any devices are reprocessed and reused, whether to do this internally or via a reprocessing vendor.

A variety of considerations may influence these decisions. Single-use devices are typically high quality and sometimes unique in their capabilities. They simplify infection control considerations while generally risking higher costs than reusable devices. Many commonly used devices such as biopsy forceps and single-channel sphincterotomes have reached a commodity status, in that their function and design by different manufacturers are all similar and adequate. This has driven unit costs for single-use designs down to the point where they are cost competitive with the reusable alternatives. Reusable devices typically reduce costs, but require ongoing administration of reprocessing capabilities, including training, quality assurance, risk, etc.

Device costs can be constrained by:

1 the willingness of endoscopists to designate which items are commodities and which are not;

2 willingness to use the lowest cost commodity items;

3 use of an open bid process for competing vendors to propose their best offers based on projections of both uniform large-volume purchasing and single-unit purchasing;

4 purchasing through one of several purchasing collaboratives, which many hospitals participate in across multiple specialties and types of equipment and supplies;

5 concerted effort by physicians and nurses to avoid intraprocedural wastage of expensive items.

Endoscope reprocessing

Endoscope cleaning and reprocessing is perhaps the Achilles heel of the endoscopy suite, as its reliable performance following every procedure is critical for patient safety, yet it is typically performed by the least educated and lowest paid members of the unit team in a fast paced and demanding environment. Lapses in endoscope reprocessing can jeopardize both individual patients and

the entire practice, as those incidents that culminate in serious sequelae are often widely publicized.

Cleaning standards are promulgated by the Society of Gastrointestinal Nurses and Associates (SGNA) [14] as well as by many national and international endoscopy societies [15,16]. A number of guidelines are available. All emphasize 'adequate' initial manual cleaning employing soap and enzymatic solutions, rinsing, disinfection in an approved agent for the appropriate duration stipulated in the labeling for the given agent, rinsing, and drying. Most units employ automated reprocessing machines that accomplish reliable flushing of high-level disinfectants, contact times, rinsing, and final alcohol flushes for drying [17].

Written unit standards and processes must be in place for several aspects of the reprocessing task, including:

1 the training of personnel responsible for cleaning and reprocessing equipment;

2 the frequency of strength testing for the disinfectant solutions (usually daily);

3 testing and maintenance of the reprocessing machines;

4 ideally, intermittent and random culture testing for confirmation of the reprocessing outcome.

An individual with a sophisticated understanding of the intricacies of endoscope design and channels is helpful in maintaining optimal cleaning and reprocessing practices in a unit.

Unit design and staffing patterns both influence the efficiency, and hence the safety, of endoscope reprocessing. In our experience, the lapsed time from extubation to placement of the washed instrument in a reprocessing machine is about 8 min when instruments travel directly into a reprocessing room without entering a corridor. When taken to a central reprocessing room the average time is 18 min and when procedures are performed outside of the endoscopy unit, as in an ICU or emergency room, the time to reprocessing can approach a full hour. In the setting of the contiguous reprocessing anteroom, individuals assigned to scope reprocessing can be given visual clues as to when a scope is in need of reprocessing; prompting their proactive retrieval of the soiled instruments. In the alternative scenarios, the endoscope is precleaned locally, but may not be transported for reprocessing until numerous other tasks related to the patient, specimens, or medications are completed.

Coding and billing

Accurate identification of services is the responsibility of the endoscopist. However, endoscopy unit staff, the business manager, and the physician support staff are generally responsible for transfer of the information to the

responsible coding and billing personnel [18]. While final coding review and/or billing services may be provided by a department serving a larger institution, expertise in the coding and billing issues specific to the specialty should reside within the endoscopy group. National specialty societies, such as the ASGE [19], and many vendors have useful coding hotlines and/or websites [20,21]. Most endoscopy units utilize a relatively narrow spectrum of billing codes; however, there are nuances and intricacies involved in their selection or combination for some patients and some environments, the details of which are beyond the scope of this review.

Accreditation

Accreditation is the sine qua non for presumed base-level quality and safety of a health care facility. It is also a prerequisite for medicare and some third party reimbursement of both ambulatory and inpatient services. Accreditation for AECs can be obtained through either the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) (Oakbrook Terrace, IL) [22] or the Accreditation Association for Ambulatory Healthcare (AAAHC) (Wilmette, IL) [23,24]. In addition to accreditation, AECs require medicare certification, which may be presumptively granted in so-called 'Deemed Status' when accreditation is received by one of these two organizations. Most hospital and inpatient facilities are accredited as part of their institutional accreditation process with the JCAHO. Elements of an accreditation survey are spread across the spectrum of all administrative and practice functions of a facility. Accreditation therefore requires active attention from all administrative partners in the endoscopy suite, including the medical director, the nursing director, and the business manager. Preparation for an accreditation visit may require 6–12 months of effort. The survey visit itself generally takes 1–2 days, depending on the size and complexity of the unit. For a large institution this may extend over 1–2 weeks. In the past accreditation was typically granted for 3-year intervals; however, the current practice is to require accreditation readiness at all times and to anticipate unannounced accreditation survey activities at any time of the year without advance notice.

Outstanding issues and future trends

The practice of gastrointestinal endoscopy will undoubtedly continue to evolve. Several potential trends can now be anticipated that may influence the size, use, and staffing of our endoscopy units. Many of these trends risk such major change that our current space and capital-heavy investment in existing units will become a liability. Anticipation and planning for how they interact with traditional endoscopy should lessen these risks.

Capsule endoscopy

Capsule endoscopy is now established in the investigation of the small intestine. While this practice does not require an endoscopy environment, the needs for focused nursing skills, billing mechanisms, and a location for computer equipment is prompting its placement in many endoscopy suites. For the most part this has added to the tasks of the suite. Similarly, esophageal capsule exams can be performed almost anywhere, but will end up in many endoscopy suites by convenience. Adoption of the esophageal capsule, however, risks incurring significant erosion of standard upper endoscopy volumes if it proves adequately efficacious and cost-saving. Both remain to be seen at this time. Wireless colon capsule devices for cancer and polyp screening are currently under development.

Colon screening technologies

Colon screening technologies (CT colonography or virtual colonoscopy, stool gene testing, and wireless capsule endoscopes), may significantly erode current screening volumes, while adding lesser numbers of planned therapeutic procedures based on their identification of polyps or other uncertain findings. CT colonography and stool gene testing are both currently available, but remain less adequate than standard colonoscopy. It is likely only a matter of time and almost certain technical advances before they assume a significant role in primary screening. Some gastroenterology practices are investing in their own on-site CT machines to retain the screening practice. Undoubtedly this will lead to difficult interspecialty issues pertaining to quality and competence-based reimbursement.

Endoscopy by non-specialists

Endoscopy by non-specialists is an additional trend that risks eroding volumes and/or reimbursement for high-volume general endoscopy. Both general physicians (GPs, FPs) and licensed non-physicians (RNs, nurse practitioners, and physician assistants) are entering the practice. Arguments about inadequate training of non-specialist physicians are hard to sustain when specialists are training licensed assistants for the same tasks in some practices.

Growth of advanced endoscopy

Growth of advanced endoscopy on the other end of the spectrum encompasses more highly specialized and invasive procedures, including endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), and transgastric

intra-abdominal procedures. The latter are becoming known as natural orifice transenteric surgery (NOTES) procedures. At the present time, basic EMR is growing in the form of saline-assisted polypectomy; however, more advanced EMR of very large lesions and ESD of superficially malignant lesions requires lengthy procedures that are not easily adapted to existing Western practices and will likely remain in the hands of tertiary endoscopists. Transgastric NOTES procedures remain highly investigational and many anticipate they will be adopted by general laparoscopic surgeons more readily than by gastroenterologists. For the foreseeable future advanced EMR, ESD, and NOTES procedures are unlikely to greatly influence general endoscopy unit needs. Tertiary centers may need expanded capacity for complex procedures. The NOTES procedures will mostly likely require facilities analogous to operating room suites.

Lastly, two trends of greater immediacy for the general endoscopist, those entering training, and unit personnel are the adoption of simulators for training and of alternative approaches to sedation. Both are beyond the scope of this discussion, but will require some accommodation for space and/or nursing skills.

Summary

Gastrointestinal endoscopy has become a specialty endeavor for physicians and nurses, a primary screening modality for public health purposes, an essential diagnostic and therapeutic service for outpatient and intensive hospital settings, and a big business. Optimal design of facilities and services and professional administration for safety, quality, and efficiency are important to its success on each of these levels.

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