This article aims to serve as a template for practitioners seeking to formally establish an office-based surgery and use an office-based endoscopy service (OBE) as an example. We have drawn from Gastroenterological Society guidelines and our local experience.1,2

**Scope of practice**
- Gastrointestinal endoscopy – upper GI, small bowel, sigmoidoscopy, colonoscopy, including biopsy, ablation, dilatation
- Bronchoscopy
- ENT – rigid and fibre-optic endoscopy, laryngeal surgery
- Urology – flexible cystoscopy, ultrasound-directed prostate biopsy
- Gynaecology – hysterectomy, endometrial biopsy (ablation, laparoscopy).

**Reimbursement**
In the current era of managed care there are formidable shifting relationships that we must deal with. The OBE offers greater comfort and satisfaction at a lower cost than traditional treatment facilities. Is it ethical for surgeons or gastroenterologists to own the facility in which they work, to self-refer and to charge for the use of the facility? Yes, but there are safety, quality-of-care and ethical constraints.

The current fee structure has lagged far behind endoscopy practice costs. Activities by legislative bodies and managed care organisations continue to stress the economic viability of the office environment. The initial investment in OBE can be daunting.

One effort currently underway is to ‘rebase’ practice costs and facility fees to reflect the actual costs of providing services (so-called national health reference price list (NHRPL)) rather than on historic charges. An alternative proposal is to use the fees developed for hospitals and apply these to OBS and OBE as a classification system for grouping procedures for facility payment (assignments purportedly would be based on clinical characteristics and resource utilisation). Grouping and reimbursement levels are current issues being discussed by the National Health Insurance (NHI) task teams.

Along legislative lines, there are also impediments of outdated legislation, talks of Certificate of Need (CON) restrictions and the trend towards accreditation of facilities. Accreditation is a natural evolution as payers, managed care organisations and regulators place increasing emphasis on quality, safety and patient satisfaction. It will also become increasingly important, if not essential, for obtaining facility reimbursement.

**Functional plan and architectural issues**

**Size and volume**
It is important to have a clear understanding of the expected volume of procedures and the number of doctors sharing the facility.
Endoscopy

Separate space for cleaning equipment between procedures and a separate recovery area will avoid delays in room turnover. If many patients are 'first visits' on the day of their procedure, consultation space and time must be factored in. Endoscopic case mix can also influence volume.

Location

Locating in an existing professional building on your primary hospital campus has several advantages over a totally free-standing facility. Patient trust may be higher when entering a professional hospital complex. In the event of a complication, response time is rapid. And since no hospital wants to lose your endoscopy business, the hospital can see some rental return. Corporate and hospital governance issues place additional pressure to ensure safety compliance.

There are also strong arguments for a free-standing, geographically separate facility: neutral turf, both politically and geographically, might be best.

Construction basics and work flow

Plumbing, air conditioning, sound proofing, ventilation and electricity are beyond the gambit of this article, but some basics are as follows:

• Construction costs for endoscopic space tend to be 2 - 3 times as expensive as standard office space. Several nuts-and-bolts issues will be dictated by local building codes and licensing regulations. Make sure you are aware of regulations.

• Adequate sound-proofing between endoscopy rooms, patient recovery area and waiting rooms is essential. The sounds related to endoscopy can be disturbing to patients waiting to undergo procedures, as well as those recovering.

• Temperature regulation is desirable. Waiting rooms have fully clothed people; pre-operation areas have nervous, undressed people; endoscopy rooms have sedated people and others hard at work with heat-generating equipment.

• The endoscopy rooms and endoscopy cleaning areas must be well-ventilated.

• The most desirable patient flow pattern is a simple, one-directional movement. Consider the movement flow in the procedure room – the number of people, where they stand, endoscope and monitors, beds and trolleys, supplies, cleaning facility.

Patient trust may be higher when entering a professional hospital complex.

• Patents often arrive for endoscopy anxious and confused. If possible, send careful instructions, and have signs posted in the immediate vicinity. There must be wheelchair, stretcher and bed access.

• The reception area must have adequate room for patients’ families. As a general rule, 1 - 2 people accompany each endoscopy patient. Use individual chairs instead of couches; people do not like to sit with strangers in stressful situations. A toilet facility should also be available.

• The pre-op (prep) area should be private. IVs are started and patients are undressed. Nursing and doctor interviews are performed here. Bathrooms should be easily accessible.

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• Consider the use of television or music in the reception and prep area.

• Procedure rooms have high electrical needs and the building must have power back-up in both procedure and recovery rooms. Dimmers are excellent, as well as spotlights over areas of paper work and biopsy handling. Telescopic lights or headlamps are useful.

• The endoscope cleaning area should be near the procedure room, and should be spacious and well-ventilated. The standard of practice is moving to automatic endoscope reproprocessors, but they are expensive and require lots of space and hot water.

• The recovery area requires more planning than one might think. There must be adequate space for recovery beds. Time in recovery can be considerable and could create a ‘log jam’. Until patients are fully recovered and exit this unit, there is no way to bring new patients through the system. A standard scenario may be as follows: patient goes from procedure to recovery room on a stretcher; once alert he/she sits up and gets dressed, then proceeds to a recliner before reaching full ambulatory status. This frees up the stretcher area and allows observation of nearly ambulatory patients prior to discharge.

• Have a transfer agreement with a hospital to handle emergency admissions.

• Strongly consider training and accreditation in advanced life support for doctors and staff.

• Do not compromise on quality of staff or endoscopic equipment simply for economic reasons. You must be at least as comfortable working in your OBE as you are at the hospital. The quality of care and quality improvement process should address all areas, including access, reception, procedures, storage, waste disposal, pathology, transfer policy, housekeeping, administration, clinical records, billing as well as continuing professional development (CPD).

• A note about the doctor’s office: it is a great advantage to have the office area adjacent
to the procedure room. The doctor can then easily go from seeing patients to performing procedures.

Checklist for office-based endoscopy set-up (office set-up)
(Note: these are illustrative and form the basis of local accreditation processes that are under development.)

Regulations
- All office-based endoscopy practices must adhere to local and state laws and regulations, including occupational health and safety and infection control.
- Endoscopes must be cleaned to a high level of disinfection. Reprocessing of endoscopes and other contaminated equipment should be done in a room separate from where endoscopic procedures are performed.
- There must be adequate ventilation.
- Regular staff orientation and refresher training on policy and procedures are important.
- There must be an appropriate plan for disposal of human waste, blood and other potentially infectious materials.
- Compliance must be monitored.

Good clinical practice
Any office endoscopy setting where a patient receives intravenous conscious sedation must comply with guidelines, accreditation and laws.

Indications/appropriateness
- Office-based procedures are to exclude: stent placement, endoscopic retro-grade cholangiopancreatography (ERCP), removal of a foreign body, therapeutic haemostatic control of acute bleeding, procedures deemed emergencies, procedures carrying a considerable risk of bleeding or major complication.
- Patients with an American Society of Anesthesiologists (ASA) score of IV are not eligible to undergo office endoscopy.
- Patients with an ASA score of III are further assessed for their appropriateness.

Physical environment
- There should be appropriate patient facilities which include disabled access.
- A private patient changing area is needed, as well as a storage locker or equivalent for patient belongings.
- The bathroom should not be in a common area.
- A waiting area for accompanying family or others should be provided.
- Acceptable patient privacy should be maintained at all times throughout the pre-procedure, procedure and recovery care.
- All patient records and materials must be filed in a safe and confidential area.

Patients with an ASA score of IV are not eligible to undergo office endoscopy.

Exam room criteria
The endoscopy room should be at least 10 m². One should be able to reduce illumination from ambient light, to fit a rolling stretcher through all doorways, and move freely on both sides of the patient. The doctor should have an unimpeded view of all monitoring equipment, and there should be sufficient storage for supplies and equipment, adequate ventilation, auditory and visual privacy, and a mechanism to summon additional assistance to the room.

The following equipment must be in the room, functioning and readily available: oxygen, endoscopes, suction, electronic monitors of pulse, BP, oxygen saturation and ECG. There should be a written policy for equipment checks and maintenance and a log to monitor compliance.

Emergency supplies, equipment and procedures
- The following equipment should be functioning and readily available with properly trained staff: oxygen, suction, airway, laryngoscope, Ambu bag, defibrillator, electrocautery, power backup.
- The defibrillator must be checked at the start of each work day, and other equipment checked according to manufacturers’ recommendations.
- Safety provisions must be in place to evacuate a patient.
- All medications and devices must be stored in a secure and environmentally controlled location.
- Relevant provisions of the Controlled Substances Regulations must be adhered to. Controlled substances must be stored in a double-locked cabinet and counted and signed for daily. Pharmaceutical agents must be monitored for date of expiration and a log must be kept.

Procedure information and documentation
- Patients are given face-to-face pre-procedure instructions.
- Informed consent must be taken by the doctor prior to the procedure and documented in the patient’s medical record.
- There must be written discharge instructions.
• A medical record system must be kept and there must be a procedure for reporting results to the patient and referring doctor.

**Administration of conscious sedation (sedation and analgesia)**

- All patients should have a documented anaesthesia risk assessment.
- Conscious sedation should be administered in accordance with accepted policy.
- Intravenous access must be maintained until the patient has fully recovered.
- Reversal agents must be readily available.
- Once sedation has begun at least one certified doctor or nurse trained to monitor and assess the patient’s well-being should be physically present in close proximity to the patient at all times.
- A trained assistant should be present in the room throughout the endoscopic procedure. If the procedure is particularly complex, so that the assistant’s attention may become diverted from monitoring, a second assistant may be necessary.
- Pre-sedation and post-procedure stabilisation must include baseline heart rate, blood pressure, respiratory rate and oxygen saturation, and ECG for high-risk patients.
- A registered nurse must be present in the recovery area at all times.
- Patients must be continuously monitored in the recovery area and should be discharged only after they have been assessed and all criteria have been met.
- Written discharge criteria are established to include: evaluation of responsiveness, vital signs, ability to tolerate fluids and swallow. Patients who have undergone conscious sedation must be accompanied by an adult upon discharge.

**Documentation**

Initial findings are documented in the patient chart on the day of the procedure. Subsequently, a signed report of the procedure should be completed. The report must include: date of procedure(s), procedure(s), extent of examination, duration, findings, tissue sampling, therapeutic intervention, procedure-related and sedation-related complications, limitations, copies of photographs or digital images.

**Training and office management**

- Doctor and staff must be properly trained and certified.
- To achieve quality assurance, regular peer review of the appropriateness of procedures performed and their outcomes should be done.
- A log or database of all procedures and outcomes should be kept. Recognised procedure-related and sedation-related complications must be tabulated and regularly reviewed.
- A written office policy and procedure manual must be maintained and updated.
- Staff should receive orientation and continuous training in all policies and procedures.

**In a nutshell**

- Many endoscopic procedures are suitable for the office.
- There are challenging reimbursement issues.
- Calculate expected volume of procedures and number of doctors sharing.
- Plan work flow, access (including disabled) and trolleys and beds.
- The doctor should be able to easily move between seeing patients and doing procedures.
- Do not compromise on quality of staff or endoscopic equipment.
- Adequate sound proofing, ventilation and temperature regulation are important.
- The endoscope cleaning area should be separate and well-ventilated.
- The recovery area requires careful planning.
- There should be a transfer agreement with a hospital to handle emergency admissions.
- Accreditation of the facility is advisable.
- Training and accreditation in advanced life support for doctors and staff is necessary.
- There should be a checklist for an office-based endoscopy set-up.

**References**