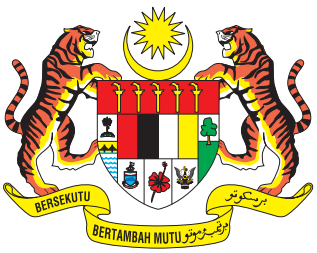
MOH/P/PAK/316.16(BP)

Gastroenterology Services

Operational Policy

MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA



GASTROENTEROLOGY SERVICES OPERATIONAL POLICY

Medical Development Division
Ministry of Health Malaysia

This policy was developed by the Medical Services Unit, Medical Services Development Section of the Medical Development Division, Ministry of Health Malaysia and the Drafting Committee for the Gastroenterology Services Operational Policy.

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FOREWORD

DIRECTOR-GENERAL OF HEALTH MALAYSIA

It is my pleasure to introduce the Gastroenterology Services Operational Policy that has been meticulously prepared by the gastroenterology committee. I am proud to see the gastroenterology team to set a standard for the practice of gastroenterology in Malaysia. The need for a standard has never been greater in this modern age where globalization and access to information becomes easier for the end user, where the end user now is able to carry out a full discussion with the doctors.

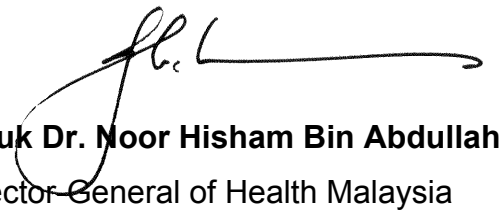
As healthcare professionals, it is our duty to continually improve ourselves and ensure that the standard of treatment and care extended to the patients adheres to a strict international standard. The Ministry of Health has always encouraged its personnel to keep improving their level of care and to follow the standards put forth by our peers in the international arena. Therefore, I am glad to see the gastroenterologist have taken it upon themselves to create a standard operational policy which will guide the practice of gastroenterology amongst the doctors at the national level, encompassing all the practitioners both in public as well as the private sector.

The guidance of this standard operational policy I am sure will elevate the standard of practice of gastroenterology and make Malaysia a country that excels in the provision of health services. This practice of high quality standardized service is in par with what the Ministry Of Health has always extolled in its mission and vision together with the direction of Ministry Of Health.

I am sure that the publishing of this standard operational policy augurs well for the training of gastroenterology. The setting of high standards in training eschewed by this standard operational policy will breed competent, efficient gastroenterologists who will subsequently practice with a high level of competence that will improve the delivery of health care to the population.

Lastly I would like to congratulate the gastroenterology committee on the job of publishing this standard operational policy I wish them all the best in the implementation of the policy.

Thank you.



Datuk Dr. Noor Hisham Bin Abdullah
Director-General of Health Malaysia

NATIONAL ADVISOR FOR GASTROENTEROLOGY, MINISTRY OF HEALTH MALAYSIA

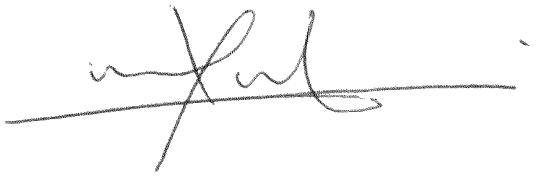
I would first like to thank all my colleagues In the JKK gastroenterology for a job well done in preparing and publishing this very important standard operational policy, especially to Datuk Dr. Jayaram, whose stewardship of this standard operational policy committee was instrumental in getting it off the ground. A note also to Dr Rosaida whose persistence made it sure that it stayed on course to the end. Needless to say, I would like to acknowledge the huge support MOH gave to the gastroenterology subcommittee in the drafting of this very important standard operational policy what will change the practice of gastroenterology in Malaysia.

Standard operational policy are important and internationally recognized as a vital mechanism that when made available to the MOH, will be able to guide MOH to benchmark practice and training to ensure a high quality of care which is at par with global standards of care. The provision of high quality care to patients is the core value of KKM and the presence of this standard operational policy will be a huge stepping stone in ensuring that the delivery of care will be elevated and adhered to by all the practitioners of gastroenterology. The end result will be a healthier population and a more productive country.

The standard operational policy is also an important arsenal which will be used in the training of gastroenterology. The observance to global standards during training by the trainees will result in competent gastroenterologists with better skill set that I am confident will elevate the standard of gastroenterology in Malaysia in the long run.

Finally, the fruition of this standard operational policy will help in achieving the vision and mission of MOH that has been laid out, and to ensure that MOH will continue to deliver high quality health services.

Thank you.



Dato' Dr. Muhamad Radzi Abu Hassan
National Advisor for Gastroenterology (16th October 2014 till present)
Ministry of Health Malaysia

CHAIRMAN OF WORKING GROUP GASTROENTEROLOGY SERVICES OPERATIONAL POLICY

It is with great pride that I write this foreword for this inaugural book of Gastroenterology Services Operational Policy. Gastroenterology as a discipline has evolved in depth and complexity over the years. Gastrointestinal endoscopy is an essential part of the therapeutic armamentarium for all gastroenterologists. Endoscopy has developed by leaps and bounds over the past few years. Endoscopy units in Malaysia offer a wide variety of services including gastroscopy, colonoscopy, endoscopic retrograde cholangiopancreatography, endoscopic ultrasonography and enteroscopy amongst others. The practice of endoscopy is governed by strict standards. There needs to be an emphasis on quality delivery of care and patient safety at all levels in endoscopy units. The gastroenterology fellowship programme as well as the post-basic endoscopy nursing programme of the Ministry of Health are initiatives to ensure the highest standard of care in gastroenterology and endoscopy in this very rapidly developing field.

In keeping with this quality initiative, the Ministry of Health has drawn up this book of operational policies to guide the practice of endoscopy in Malaysia. These guidelines cover a wide range of issues concerning endoscopy. It is hoped that these policies will set the standards for the practice of gastroenterology and endoscopy in Malaysia.

I would like to take this opportunity to thank the gastroenterology subspecialty training committee for their untiring efforts in drawing up these comprehensive guidelines. It is hoped that these policies will be updated in due course.

Thank you.

Datuk Dr. Jayaram Menon
Head of Gastroenterology Unit, Queen Elizabeth Hospital, Kota Kinabalu
National Advisor for Gastroenterology
(6th September 2012 till 6th September 2014)
Ministry of Health Malaysia

ARTICLES

1.0 INTRODUCTION

Gastroenterology is a rapidly evolving subspecialty of Medicine. It has a clinical component as well as a procedural component. Both are governed by exacting standards. Gastrointestinal endoscopy is the primary procedural component . There is a plethora of diagnostic and therapeutic endoscopic procedures available today. Many of the accredited centres for Gastrointestinal endoscopy in Malaysia do provide a wide range of diagnostic and therapeutic services. In addition a few centres provide gastrointestinal physiology studies as well. In view of the rapid developments in diagnosis and management of gastroenterological disorders a multidisciplinary approach encompassing radiology, pathology, oncology and surgery may be required. It is hoped that the clinical service, endoscopy service and ancillary services adhere to the standards set by these operational policies.

2.0 OBJECTIVES OF SERVICE

2.1 To provide a comprehensive gastroenterology service encompassing clinical gastroenterology, gastrointestinal endoscopy and gastrointestinal physiological studies in the Ministry of Health, Malaysia.

2.2 To promote the development of gastroenterology including diagnostic and therapeutic gastrointestinal endoscopy as well as the expansion of gastroenterological services in the Ministry of Health, Malaysia.

2.3 To provide teaching and training in the form of structured programmes for all categories of staff in the gastroenterology service including Gastroenterology Fellows, Gastroenterologists, Gastrointestinal assistants (Endoscopy nurses) and allied health personnel .

2.4 To collaborate with all stakeholders in the Ministry of Health, academic institutions, the private sector and non-governmental organisations to promote the development of gastroenterological services in Malaysia.

2.5 To ensure that the practice of gastroenterology and gastrointestinal endoscopy is current and evidence-based with emphasis on patient safety.

2.6 To promote research in all aspects of gastroenterology.

2.7 To network with overseas centres of excellence and international gastroenterology organisations in the field of gastroenterology with particular emphasis on training and research.

2.8 To increase the awareness of the prevention, screening , detection and treatment of gastrointestinal disorders through close collaboration with primary care and public health practitioners.

3.0 SCOPE OF SERVICES

3.1 Gastroenterology service consists of:

3.1.1 Inpatient and daycare endoscopy services.

3.1.2 Gastroenterology and hepatology clinics.

3.1.3 Inpatient gastroenterology consults.

3.1.4 “Out of hours” emergency endoscopy services.

3.1.5 Hospital networking.

3.2 Training and research.

3.2.1 Gastroenterology fellowship training programme.

3.2.2 Post-basic endoscopy nursing programme.

3.2.3 Research in gastroenterology and hepatology.

3.3 Patient registries (Ministry of Health).

3.3.1 Malaysian gastrointestinal registry.

3.3.2 National endoscopy registry.

3.3.3 Colorectal cancer registry.

3.4 Screening programmes (Ministry of Health).

3.4.1 Colorectal cancer screening.

3.4.2 Screening for hepatitis B and C.

3.5 Patient advocacy and health promotion.

4.0 COMPONENTS OF SERVICE

4.1 Outpatient Services:

4.1.1 Clinics

- General Gastroenterology
- Hepatology
- Multidisciplinary (eg GI Oncology, Nutrition)
- Research

4.2 Endoscopy services (including Ambulatory Care services):

4.2.1. Upper GI Endoscopy :

- Oesophagogastroduodenoscopy (OGDS)
  – Diagnostic and therapeutic

4.2.2 Small bowel enteroscopy

- Device-assisted enteroscopy/endoscopy
  – Diagnostic and Therapeutic

4.2.3 Lower GI Endoscopy:

- Sigmoidoscopy – Diagnostic and therapeutic
- Colonoscopy – Diagnostic and therapeutic

4.2.4 Endoscopic retrograde cholangiopancreatography (ERCP)
– Therapeutic

4.2.5 Endoscopic ultrasound (EUS) – diagnostic and therapeutic

4.2.6 Cholangioscopy

4.2.7 Endoscopic Mucosal Resection

4.2.8 Endoscopic Submucosal dissection

4.2.9 Enteral feeding

4.2.10 Video Capsule Endoscopy

4.2.11 Other endoscopy services

4.3 Gastrointestinal physiological services

4.3.1 pH monitoring

4.3.2 Impedance studies

4.3.3 Manometry

4.3.4 Other physiological studies

4.4 Inpatient Services

4.4.1 Care of patients with gastrointestinal disease

4.4.2 Care of patients with hepatobiliary disease

4.4.3 Care of post-liver biopsy patients

4.4.4 Care of transplant patients

4.4.5 Care of patients with gastrointestinal and hepatobiliary cancers

4.4.6 Emergency inpatient endoscopy

4.4.7 Abdominal paracentesis

4.4.8 Ultrasound-guided drainage

4.4.9 Interventional radiology

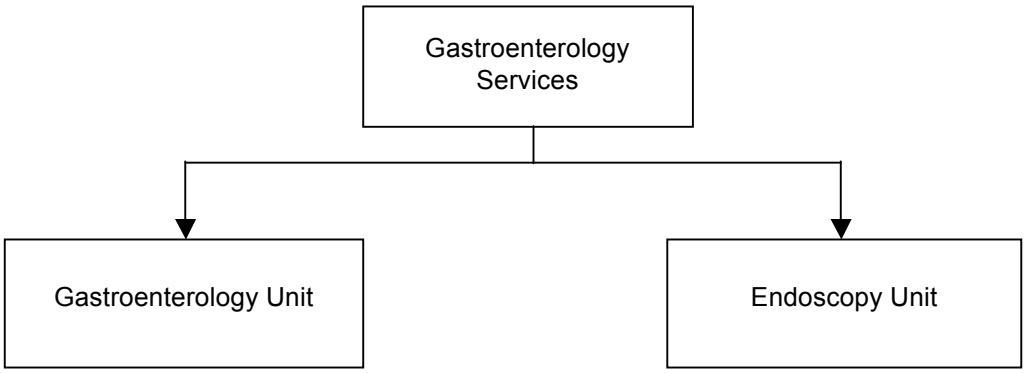
4.5 Advocacy:

4.5.1 Prevention of gastrointestinal and liver disorders

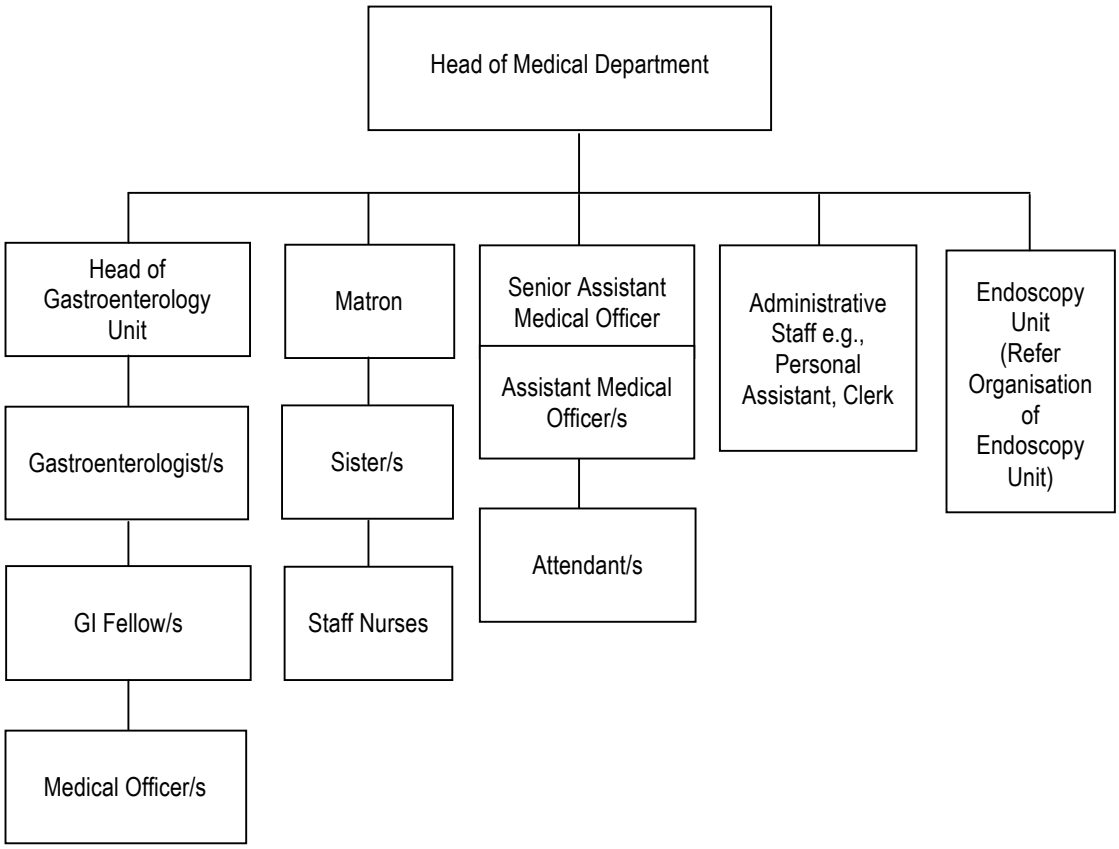
4.5.2 Screening for gastrointestinal and liver cancers

5.0 ORGANISATION

5.1 A gastroenterology service is essentially divided into clinical gastroenterology and GI endoscopy.



5.2 Organisation chart of gastroenterology services



5.3 Roles and Responsibilities of Gastroenterology Personnel

5.3.1 National advisor for gastroenterology, Ministry of Health

5.3.1.1 Roles and responsibilities.

a) Policies and procedures.

- To advise on and develop operational policies in gastroenterology.
- To assist in setting the standards for credentialing in gastroenterology and endoscopy.
- To advise on and develop clinical practice guidelines (CPG) in gastroenterology.

b) Manpower.

- To advise on manpower needs and requirements for gastroenterologists and gastrointestinal assistants (GIAs) in the Ministry of Health.
- To advise on posting of gastroenterologists and GI fellows to various hospitals in Malaysia.

c) Equipment, drugs and consumables.

- To advise on the urgent needs for equipment, consumables and drugs for all accredited gastroenterology centres.

d) Budget.

- To plan and advise on annual budgetary requirements for gastroenterology centres in the Ministry of Health.

e) Planning.

- To advise on the planning and design of new gastroenterology centres and endoscopy units.

- To advise on the development of gastroenterology and gastroenterological services in Malaysia.

- To advise on and coordinate registries of gastrointestinal diseases.

f) Training.

- To chair the national gastroenterology subspecialty services committee.

- To oversee and lead the gastroenterology fellowship training committee.

- To plan, coordinate and regulate the entire gastroenterology fellowship training programme.

g) Research.

- To actively promote and coordinate research in gastroenterology among gastroenterologists and GI fellows.

h) Quality Assurance (QA).

- To promote the implementation of QA indicators in endoscopy and gastroenterology.

i) Networking.

- To network with all state hospitals and gastroenterologists throughout Malaysia in the interest of advancement of gastroenterology services.

5.3.2 Head of gastroenterology unit/department.

5.3.2.1 Administrative.

a) To advise the hospital director on matters pertaining to gastroenterology.

b) To participate in task forces and committees as advised by the hospital director.

c) To participate in QA activities.

d) To plan, implement and monitor the department's activities according to the policies and procedures of the department, hospital and Ministry of Health. Heads of departments of state hospitals shall also be responsible for the planning, implementation and monitoring of gastroenterology services in their respective state.

e) To be a member of the gastroenterology subspecialty training programme committee of Ministry of Health.

f) To oversee the planning and development of the unit.

g) To prepare the budget for the department and be responsible for effective use of resources.

h) To advise on the drugs, consumables and reagents required in providing a safe, effective and efficient gastroenterology service.

i) To advise on equipment needs in providing a safe, effective and efficient gastroenterology and endoscopy service.

j) To participate in national gastroenterology registries and research activities.

k) To implement and monitor QA activities.

l) To conduct regular meetings with all department personnel.

m) To organise continuous professional development (CPD) activities for the department including gastroenterology courses and endoscopy workshops.

n) To audit the department's activities and performance, and prepare its annual report for submission to the hospital director and national advisor of gastroenterology.

o) To conduct yearly assessments of all medical staff within the department.

p) To mentor and train gastroenterology fellows.

q) To advise and oversee the hospital privileging of gastroenterologists.

5.3.2.2 Clinical.

a) To ensure effective, efficient, safe and professional management of gastroenterology patients in the clinics and wards.

b) To conduct weekly gastroenterology grand rounds.

c) To perform endoscopic procedures.

d) To provide professional clinical leadership and supervision of specialists and MOs.

e) To organise and undertake the teaching and training of GI fellows, specialists, MOs, GIAs, nurses and AMOs.

f) To undertake call duties.

g) To be up-to-date with trends and developments in Gastroenterology.

5.3.3 GI fellows.

5.3.3.1 Administrative.

a) To assist the head of department in carrying out administrative duties.

b) To orientate new MOs to the department on their roles and responsibilities.

c) To participate in and organise continuous medical education (CME) for personnel of the department (MRCP/masters trainees, MOs, nurses, assistant medical officer [AMOS]).

d) To participate in and implement the department's CPD, research and QA activities.

e) To prepare the rosters for calls and bleeder rotas.

5.3.3.2 Clinical.

a) To provide services for gastroenterology patients in the clinics and wards.

b) To provide a full range of endoscopic services.

c) To perform invasive procedures in the ward when necessary.

d) To supervise and train junior specialists and MOs in gastroenterology.

e) To organise multi-disciplinary gastroenterology meetings (e.g., pathology, oncology, radiology).

f) To undertake bleeder on-call duties as per rota.

g) To participate in CPD, gastroenterology national registries, research and clinical audit.

h) To participate in gastroenterology courses and workshops organised by the department.

5.3.4 Medical Officer.

a) To provide patient care under specialist supervision in the clinic and ward.
b) To perform invasive procedures in the ward.

c) To participate in CPD activities.

d) To participate in research and clinical audit.

e) To participate in gastroenterology courses and workshops.

5.3.5 Gastroenterology wards nurse.

a) To provide nursing care and ensure patient well-being.

b) To recognize complications, take remedial measures and inform the doctor.

c) To assist doctors in clinical procedures.

d) To monitor and record patients' vital signs.

e) To trace laboratory investigations, previous hospitalisation case notes and radiological investigations.

f) To adhere to infection control policies.

g) To communicate effectively with colleagues, patients and their families with respect to patient care.

h) To document the nursing report in the patients' case notes or EMR.

i) To attend continuous nursing education (CNE) activities.

j) To comply with ward protocols and related guidelines.

k) To comply with the care bundle protocols.

5.3.6 Gastroenterology clinic nurse.

a) To communicate effectively with colleagues, patients and their families with respect to patient care.

b) To set appointment dates for patients.

c) To receive referrals and register patients.

d) To facilitate patients for laboratory investigations and imaging procedures.

e) To trace investigation results and previous records.

f) To assist doctor during consultation.

g) To dispatch reply letters.

h) To document, record and perform data entry for statistical purposes.

i) To contact patients when necessary.

j) To assist in clinic audit, research and national registries.

k) To participate in CPD activities.

5.3.7 Gastrointestinal Endoscopy Nursing Services

Roles and responsibilities of the GIA include but are not limited to the following**:**

5.3.7.1 Administrative.

a) Documenting patient data to ensure continuity in the provision and coordination of patient care.

b) Contributing to the planning, implementation and evaluation of patient care.

c) To perform an inventory every month to ensure adequate supply of consumables and drugs.

d) To conduct audit activities.

e) Data collection for research using evidence-based practice to improve patient outcomes.

f) To be involved in training activities and act as a mentor for others.

g) To participate in CME activities including endoscopy workshops.

h) To achieve certification in post-basic gastrointestinal endoscopy nursing and subsequent accreditation.

i) Participating as an active member in professional and consumer organisations, contributing to professional publications, and presenting at professional meetings.

5.3.7.2 Clinical.

a) To establish priorities and make ethically sound decisions to ensure safe patient care.

b) To set appointment dates for endoscopic procedures.

c) To register patients for endoscopic procedures.

d) To trace patients' records before the procedures.

e) To provide health education and information on endoscopic/GI procedures to patients.

f) To ensure that endoscopes and equipment are functioning.

g) To prepare drugs and equipment required for endoscopic procedures.

h) To prepare the endoscopic rooms before the procedures.

i) To prepare the trolleys for equipment used during the procedure.

j) To receive and prepare patients for endoscopic procedures and establish a nursing diagnosis.

k) To position patients before and after the endoscopic procedures.

l) To monitor patients before, during and after the endoscopic procedures.

m) To observe, record and report changes requiring intervention.

n) Assisting the endoscopist during diagnostic and therapeutic procedures to promote optimal patient outcome by team collaboration.

o) Handle endoscopy equipment properly while maintaining cleanliness.

p) To be very conversant with guidelines on infection control, disinfection and reprocessing in endoscopy.

q) To ensure endoscopy rooms are always clean, tidy and organized.

r) To replenish stocks of consumables and drugs in the endoscopy rooms.

s) To check that the resuscitation trolley is fully equipped and to respond urgently to emergency situations to promote optimal patient outcome.

t) Evaluating outcomes of nursing intervention and initiating change when appropriate.

u) Performing diagnostic studies as ordered by the gastroenterologist/endoscopist.

v) Serving as a mentor for other nurses and to monitor supporting staff in performing their clinical duties.

w) Participating in continuing education and achieving/ maintaining certification.

x) Monitoring performance by developing and participating in performance improvement and QA activities.

6.0 OPERATIONAL POLICIES

6.1 THE GASTROENTEROLOGY UNIT

6.1.1 The unit shall be headed by a consultant gastroenterologist who:

a) Is responsible for the management of all components of the service.

b) Collaborates with the national advisor for gastroenterology in formulating a plan of service development, policies and procedures.

c) Works closely with the relevant stakeholders such as the hospital director, nursing managers and the heads of other clinical services.

6.1.2 The head of gastroenterology service serves as the national advisor to the Ministry of Health on all matters pertaining to gastroenterological services.

6.1.3 The organisation of the unit depends on the category of the hospital, level of patient care and the scope of the service provided. All state hospitals shall provide daycare endoscopy services, outpatient gastroenterology and hepatology clinics, inpatient gastroenterology consults and , if manpower allows, “out of hours” on call services for endoscopy .

6.1.4 The head of the gastroenterology unit of the respective state hospital shall advise on the following matters:

a) Posting of medical officers (MOs) and specialists to the gastroenterology unit as well as their job description.
b) Clinical management.
c) Procurement of drugs, equipment and consumables.
d) Development of local clinical policies, standard operating procedures and guidelines.

6.1.5 For non-specialist hospitals or hospitals where there is no resident consultant gastroenterologist, the gastroenterology service shall come under the responsibility of consultant surgeons or physicians.

6.1.6 Multidisciplinary meetings.

6.1.7 The following multidisciplinary meetings are recommended to be held at least on a monthly basis:

a) Gastroenterology-radiology conference
b) Gastroenterology-clinical pathology conference (CPC).
c) Multidisciplinary team (MDT) gastroenterology-oncology meeting.
d) Gastroenterology research meeting.

6.2 THE GASTROENTEROLOGY WARD

6.2.1 It is recommended that all accredited gastroenterology centres have dedicated gastroenterology wards.

6.2.2 The gastroenterology ward shall be under the overall charge of the head of the gastroenterology unit.

6.2.3 The ward personnel shall provide the best care to all patients who are admitted for gastroenterology problems or endoscopic procedures.

6.2.4 Recommended patient-to-nurse ratio:

a) The safety and quality of patient care is directly related to the size and experience of the nursing workforce.

b) The proposed patient-to-nurse ratio in the gastroenterology ward ranges from 4:1 to 5:1.

c) The ideal nurse to patient ratio shall:
   - Improve patient care.
   - Improve patient satisfaction.
   - Ensure patient safety.
   - Encourage shorter length of stay.
   - Reduce medical errors, including medication errors.
   - Reduce morbidity and mortality.
   - Improved nurse morale.

6.2.5 Admission policy

6.2.5.1 Patients admitted to the gastroenterology ward are categorized as follows:

a) Elective admission from clinic for further investigation and management.

b) Elective admission from the clinic for endoscopic procedures.

c) Urgent admission from the emergency department (ED) for gastrointestinal (GI) bleed/GI emergencies.

d) Urgent admission from ED for other gastroenterology and hepatology diseases.

e) Post-endoscopy complications that might require close monitoring, surgical intervention, intravenous antibiotics and/or urgent imaging.

6.2.5.2 Approval must be obtained from the gastroenterologist before admitting any patient to the gastroenterology ward.

6.2.5.3 All patients shall be seen within half an hour of admission by the attending MO.

6.2.5.4 It is the responsibility of the MO to inform the ward specialist, GI fellow or gastroenterologist regarding the admission.

6.2.5.5 The ward specialist, GI fellow or gastroenterologist shall review the patient (acute admission) within the next 1-2 hours.

6.2.6 Discharge policy

6.2.6.1 Patients shall be discharged when:

a) Appropriate investigations, procedures and management have been deemed to be completed.

b) Complications have settled.

c) Patients are stable and safe to be discharged.

6.2.6.2 The decision to discharge a patient shall be made by the gastroenterologist. Patient shall be given a discharge plan which includes:

a) Discharge summary.

b) Medication prescription.

c) Appointment in follow-up clinic.

d) Appointment for imaging if indicated.

e) Endoscopy appointment if indicated.

6.2.7 Visiting policy

6.2.7.1 Visiting hours for the gastroenterology ward shall be based on existing hospital policy.

6.2.8 Ward round policy

6.2.8.1 For ill cases, ward rounds shall be conducted three times a day on normal working days, and twice daily on

weekends and public holidays. For stable patients, the ward round shall be conducted twice daily on normal working days, and once daily on weekends and public holidays.

6.2.8.2 The ward round shall be led by a gastroenterologist or GI fellow. Night rounds shall be led by the specialist on call.

6.2.8.3 A weekly grand ward round led by the consultant gastroenterologist is encouraged.

6.2.8.4 During the ward round, patients shall be informed regarding their:

a) Clinical progress.

b) Results of the investigations that have been done.

c) Management plan including imaging and endoscopic procedure(s).

d) Plan for subsequent discharge and follow-up.

6.2.8.5 All clinical data shall be updated and documented in the patients' folder and/or electronic medical record (EMR).

6.2.9 High Dependency Ward (HDW)

6.2.9.1 The HDW shall be under the overall charge of the head department of medicine/head of gastroenterology unit or head of intensive care/anaesthesiology.

6.2.9.2 It shall provide critical care for patients who need joint management between the gastroenterologist and intensivist.

6.2.9.3 HDW admission policy.

a) Patients may be admitted to HDW if clinically indicated and this is determined by the gastroenterologist/ intensivist.

b) A patient-to-nurse ratio to 2:1 is encouraged.

c) Patients will be closely monitored, with every bed equipped with a bedside monitor.

d) All clinical data of each patient shall be entered directly into the patient's clinical notes or EMR.

e) Strict aseptic technique according to the hospital infection control policy shall be maintained throughout.

6.2.9.4 HDW round policy.

a) The ward round shall be conducted three times a day on normal working days and twice daily on weekends and public holidays. The frequency may be increased for critically ill patients.

b) The ward round will be led by the consultant intensivist, gastroenterologist or GI fellow.

6.2.9.5 HDW visiting policy.

a) Visiting hours for the HDW shall be based on existing hospital policy.

6.2.9.6 HDW discharge policy.

a) Decision to transfer or discharge patients will be jointly made by the intensivist and gastroenterologist.

6.3 THE GASTROENTEROLOGY CLINIC

6.3.1 The gastroenterology clinic shall be under the overall charge of the head of the gastroenterology unit.

6.3.2 The gastroenterology clinic shall provide the following services:

6.3.2.1 Specialist referral.

6.3.2.2 Follow-up.

6.3.3 Referrals

6.3.3.1 All gastroenterology patients are to be referred by:

a) Physicians, surgeons, specialists or MOs from other disciplines/hospitals.

b) Family physicians or MOs from health centres.

c) General practitioners (GPs).

6.3.3.2 All referrals should be made to gastroenterologists or GI fellows.

6.3.3.3 All referrals should be made by MOs or specialists.

6.3.3.4 All inpatient referrals between departments in the hospital or between hospitals should be discussed with gastroenterologist or GI fellow.

6.3.3.5 Referring doctors should discuss all urgent referrals with the gastroenterologist or GI fellow.

6.3.4 Appointments.

6.3.4.1 The number of appointments per day shall be decided by the head of the gastroenterology unit in consultation with the gastroenterologists and nursing sister in charge of the clinic.

6.3.5 Gastroenterology clinic policy.

6.3.5.1 Every accredited gastroenterology centre shall have at least two clinic days per week.

6.3.5.2 The clinic should run for 3-4 hours for the morning session and 2-3 hours for the afternoon session.

6.3.5.3 All new referrals shall be screened by the gastroenterologist or GI fellow.

6.3.5.4 All new referrals (excluding suspected malignancy) shall be seen within 8 weeks.

6.3.5.5 All referrals for suspected GI malignancy shall be seen within 2 weeks.

6.3.5.6 For urgent referrals, the cases shall be seen immediately (on the same day) or on the next clinic day.

6.3.5.7 Early appointments should be given to all patients who had undergone endoscopic procedures and biopsy for review of the pathology report.

6.3.5.8 Patients who miss their appointment for two consecutive visits have to be referred again as new cases.

6.3.5.9 Waiting time to see a doctor shall be less than 90 minutes and this shall be one of the key performance indicators (KPI) for the gastroenterology unit. In order to achieve the KPI, staggered appointments are suggested.

6.3.5.10 Every gastroenterology clinic shall be provided with a dedicated clinic nurse and personnel.

6.3.5.11 For each gastroenterologist, a suggested maximum of 2-3 new cases and 10-15 follow-up cases shall be seen in a session allowing 20-30 minutes per new case and 15-20 minutes per follow-up case.

6.3.5.12 Patients shall be seen and examined by the gastroenterologist. If patients are seen either by a GI fellow or MO, the cases should be discussed and reviewed by the gastroenterologist.

6.3.5.13 The gastroenterologist shall discuss in detail with the patient (and relatives) regarding the possible diagnosis and differential diagnoses.

6.3.5.13 The gastroenterologist shall formulate a care plan for every patient in term of further investigation, imaging, date of admission and type of endoscopic procedure if indicated. The management plan shall be explained and discussed with patient and relatives, and this includes the indications, benefits, possible risks (complications) of the planned procedure(s) and other available alternatives.

6.3.5.14 All clinic data shall be updated and documented in the patient's folder and/or EMR.

6.3.5.15 Where indicated involvement of the appropriate GI nurse, dietician and pharmacist is encouraged in the running of the gastroenterology clinic.

6.3.5.16 Regular clinic audit is encouraged e.g., clinic waiting time and waiting time for endoscopy appointments.

6.3.5.17 Hospital networking (including gastroenterology district visits) - providing gastroenterology services to selected hospitals without resident gastroenterologists.

6.3.5.18 Scheduling of patients shall be done using the hospital resource scheduling system.

6.3.5.19 The gastroenterology clinic service shall be provided by the visiting consultant gastroenterologist. MOs may be allowed to assist in the clinic with supervision.

6.3.5.20 The referral letter shall be screened by the doctor in-charge of the clinic.

6.3.5.21 Appointments are based on urgency. For non urgent cases an appointment date shall be given within eight weeks.

6.3.5.22 Urgent referrals shall be discussed by the referring doctors and cases may be admitted directly if needed or may be given an early outpatient appointment date.

6.3.5.23 The clinic staff shall be responsible for updating relevant patient information from time to time.

6.4 THE ENDOSCOPY UNIT

6.4.1 Design of an endoscopy unit

6.4.1.1 General principles.

a) Endoscopic procedures can be stressful to both patients and relatives, and the flow of the unit should progress a patient without looping back.

b) Suitable disabled access as well as facilities for patients with visual and mobility disabilities should be available.

c) The unit should be calm with noise level kept to a minimum.

d) All areas should follow fire and general safety principles.

e) There should be adequate natural as well as general and clinical lighting available.

f) A combination of natural and mechanical ventilation should be available.

g) Gender separation facilities should be available if possible.

6.4.1.2 The design of an endoscopy unit can be divided into several main areas.

a) Patient-related accommodation.

- Entrance/ reception.
- Preparation room.
- Treatment room.
- Recovery area.
- Sanitary facilities.
- Special patient needs.

b) Staff facilities.

- Male/female changing room.
- Rest room.
- Office.
- Teaching/training.

c) Support services.

- Endoscope cleaning.
- Storage space.
- Clean/dirty utilities.
- Waste disposal.
- Electricity/water room.

6.4.1.3 Entrance, reception and waiting area (Figure 3 and 5)

a) The reception desk should be situated at an accessible area in the reception. The reception desk should be low enough to cater for patients on wheelchair.
b) A phased admission system with patients arriving at intervals is best to reduce patient waiting time, the size of the waiting area and prevent crowding.
c) The waiting area must have enough chairs with designs suitable for the elderly, children as well as obese patients.
d) Toilet facilities should be available in the waiting area.

6.4.1.4 Preparation room (Figure 3 and 5).

a) The preparation room should include a separate room for interviewing the patient and allow confidential discussion and consent taking.
b) Toilet facilities should be available in the preparation room especially when enemas area given pre-procedure.
c) Separate changing facilities for gender separation should be encouraged if possible.
d) The waiting area should be comfortable.

e) A method of handling patients' property should be instituted with a safe storage area available or moving it with the patient.

6.4.1.5 Procedure room requirements (Figure 3 and 5).

a) The room should be of sufficient size to carry out the procedure comfortably.
b) It should allow easy access at all sides and allow trolleys.
c) Space enough for endoscopist, two GIAs as well as fellows.
d) Space for endoscopy equipment and wiring.
e) Clinical preparation space for equipment.
f) Desk space for reporting system and computers.
g) Controlled drug cupboard.
h) Foot operated bins.
i) Hand washing sink.
j) Emergency call system.
k) Patient monitoring system.
l) Space for anaesthetic staff and equipment if procedures under anaesthesia are undertaken.
m) Piped oxygen and wall vacuum.
n) Fluoroscopic equipment as well as lead protective gear for procedures done under fluoroscopy, e.g., ERCP. Appropriate lead shielding of walls according to radiation guidelines should be instituted.
o) The number of procedure rooms in an endoscopy unit should be based on estimated number of procedures, type of procedures undertaken as well as planned expansion in the future.

6.4.1.6 Recovery area (Figure 3 and 5).

a) The recovery area normally comprises 2 spaces. The first stage recovery area involves the patient recovering in the trolley with an access to their own curtained space.

b) Each recovery area should have access to a wall oxygen port, vacuum suction equipment as well as clinical monitors for saturation and blood pressure.
c) There should be a gap between trolleys (ideally 1.2 m minimum) to allow access to emergency resuscitation equipment if needed.
d) The number of beds needed generally is around 3 to 4 beds per procedure room.
e) The second stage recovery area is a communal seated area where refreshments may be served to patients who have recovered sufficiently from sedation.
f) Recovery areas should have access to toilets and washing facilities.
g) Both recovery areas should be easily monitored by staff based within the recovery area.

6.4.1.7 Staff facilities (Figure 3 and 5).

a) The following should be available within the unit including male/female changing rooms, and male/ female toilets.
b) A staff rest room and adjoining pantry/kitchen should also be available.
c) The number of staff as well as anticipated staff increases should dictate the size and number of staff facilities.
d) A teaching room should be available in bigger endoscopy units to facilitate staff education.

6.4.1.8 Support services.

a) Endoscopic cleaning/reprocessing room.
   - Ideally the cleaning area should be accessible to the endoscopy rooms and designed in such a way to include both clean area (scope storage) as well as dirty area (scope reprocessing area).

- The dirty area should at a minimum contain an automated endoscope disinfector, sinks, work surface with cupboard space and drainers.
- The area should be safe and dry with easily cleaned surfaces.
- Ventilation and extraction facilities must be available to ensure staffs are not exposed to hazardous chemicals.
- For details on endoscopic reprocessing refer section 14.0 on infection control in endoscopy.

b) A stock room and also disposal area for hazardous materials should be available.

6.4.2 Equipment in the endoscopy unit (Figure 4 and 5)

a) The type of capital equipment in the endoscopy unit depends on the type of procedures performed there. Of these, endoscopes, light sources, and image management systems are most central to the function of the endoscopy suite.

b) Some of the typical capital equipment in the endoscopy unit include:
   - Various endoscopes including gastroscopes, colonoscopes, duodenoscopes, enteroscopes and endoscopic ultrasonography (EUS) scopes (radial and linear).
   - Endoscope systems including processors and monitors.
   - Gurney beds.
   - Fluoroscopy units.
   - Databases (endoscopy reporting systems).
   - Electrosurgical generators.
   - Monitoring devices

c) Accurate planning of endoscope requirements would contribute to cost savings as efficiently reusing few equipment would be far less costly than having unused equipment in the storage. Appropriate estimates must accommodate instrument breakdown and repair. Endoscope repair and payment would be in accordance with Ministry of Health/hospital policy.

d) Purchase of accessories and devices also accounts for a big amount of the unit's expenditure. It would be up to the individual endoscopy unit to decide on the type of devices required as well as choosing either single use devices or reprocessable multiple use devices.

6.4.3 The endoscopy service (Figure 2)

6.4.3.1 Introduction.

- This policy provides information for all staff within the multi-disciplinary team working in the endoscopy unit.
- The endoscopy unit delivers care by providing an outpatient and inpatient service for patients who require treatment for gastrointestinal conditions, either electively or as an emergency.

6.4.3.2 Service summary

a) The service is provided in an integrated unit with a multidisciplinary approach to patient care. The majority of patients using the service are seen on a daycare basis. In general, the unit is open 8 am to 5 pm on working days. A 24 hour on-call service is available in selected units. There is an increasing demand for emergency endoscopy in most established centres.

b) The unit will provide a variety of procedural care which includes:

1) Endoscopic procedures.
   - OGDS (gastroscopy).
   - Colonoscopy.
   - ERCP.

- EUS.
- PEG.
- Device assisted balloon enteroscopy (DBE or SBE).
- Capsule endoscopy.

2) Other services.
   - Manometry.
   - pH monitoring.
   - Breath testing.

c) The unit has a dedicated nursing team covering all sessions.

d) Endoscopies are performed by accredited endoscopists including gastroenterologists, gastroenterology fellows, surgeons and surgical fellows. The unit may provide accredited training for doctors, gastroenterology fellows and GI endoscopy nursing staff.

6.4.3.3 Staffing arrangements (refer chapter 5.0)

a) Medical staffing.

- The unit is staffed by both gastroenterologists and surgeons.

b) Nurse staffing.

- The facility is staffed by full time GIAs including a unit manager.

c) Management.

- The unit sits within the medical/surgical directorate and is managed by a clinical nurse manager. Any

financial issues will be referred to the head of service and the hospital director.

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d) Staffing design

1) Nursing and ancillary staff.
   - This includes the nurse in charge (unit manager), GIAs (qualified nurses, AMOs, trained paramedics) and administrative staff.

2) Medical staff.
   - This includes doctors trained in endoscopy (gastroenterologists and surgeons).

e) Staffing requirements

- Staffing requirements for the performance of GI endoscopy should be based on what is needed to ensure safe and proficient performance of the individual procedure. It should relate to the workload of the endoscopy unit including that after hours. This is affected by the population served and by local methods of practice such as the provision of open access. The number of staff required for endoscopy must take account of staffing in the endoscopy room, preparation and recovery areas and in administration. Currently, staffing may vary as determined by local practice, patient characteristics, and the type of endoscopic procedures being performed.

f) The endoscopy unit manager.

- All units should have a person managerially in charge. Although it is usual for a clinician to be in overall charge

of an endoscopy unit, the role of manager or head nurse is vital to the everyday smooth running of the unit.

- This person is usually a senior registered nurse (RN) or AMO, who has overall responsibility for the unit including:

  i) Day to day organisation and running of the unit
  ii) Training of endoscopy assistants
  iii) care of equipment and the maintenance of high standards of patient care.
  iv) Arrangement of appointment. This appointment must be made in consultation with the clinician in charge of the unit who should have overall control of the endoscopy service.

- Close co-operation between the endoscopy unit manager, clinician and the medical director is essential.

g) The unit hierarchy (Figure 6).

- The gastrointestinal assistant (GIA) may be an RN or AMO, with specific training and credentialing in endoscopy and who is involved in patient and equipment care.
- The clerical/secretarial staff is responsible for the clerical and administrative side of the unit (patient notes, appointments, etc.).
- Ancillary or supporting staff such as portering, scientific officers (endoscopy technicians) and domestic services has a support role within the unit, and may or may not come under direct control of the manager.

h) 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 RN to administer sedation and monitor the patient and a trained community nurse or technician as a GIA for assisting with endoscopic interventions. The physician/endoscopist retains global responsibility for assessment, medication management, and initial medication administration. In advanced procedure suites (ERCP, EUS, miscellaneous complex procedures) and for general procedures in high-risk patients, a GIA performs both the monitoring and assessment tasks. The physician retains the responsibility for medication management but not necessarily its administration.

i) Nursing staff are also required for the pre-procedure assessment and the recovery 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, reception and secretarial staff.

j) Depending on the number of lists and the workload, the staffing requirements for an endoscopy unit are as follows:
   - Endoscopy assistants.
     Generally a staffing ratio for endoscopy is a minimum of ***qualified-to-trained** ratio of 7:3

     *** Note: 'qualified' refers to staff holding a professional qualification (e.g., RN), whilst 'trained' refers to staff who have had specific training in endoscopy.**

- Requirements per list.

1) Endoscopy room.

   - Minimum two staff, at least one of which should be a RN or AMO. The RN will administer sedation and monitor the patient. The GIA will assist in the endoscopic procedure.

2) Recovery area.

   - Depending on number of patients to be recovered at any time.
   - One to six patients - one RN.
   - Seven to twelve patients - two RNs or one RN and one HCA.
   - Thirteen to eighteen patients - three RNs or two RNs and one HCA.

3) Admissions area.

   - One or two RNs are required for this area. It is essential that RNs are employed in this area because of both the knowledge required assessing a patient's medical and psychological condition, and also that needed to answer any questions regarding the patient's endoscopy or medical condition.

4) Reception/clerical staff.

   - Larger endoscopy units need two or more receptionists/clerical staff due to the increased work load.

5) Ancillary staff.

- Portering assistants.
  Larger units with a high inpatient workload require two porters, perhaps working opposite shifts and overlapping at the busiest times, to provide this service.
- Endoscopy technicians.
  The majority of units will require at least one such person, and it may be that this role is part of a multiskilled role within the unit. These technicians or scientific officers may be involved in endoscope reprocessing and minor repairs.

6.4.3.4 Types of endoscopic services available

1. Endoscopy without sedation.

   - A significant number of GI endoscopic procedures are performed with sedation. However, OGDS and sigmoidoscopy are often performed without sedation. Sometimes colonoscopy is also performed without sedation. In this setting, 1 endoscopy staff member is required to assist with various technical aspects, such as obtaining biopsy specimens. An appropriately trained health care assistant may perform these tasks.

2. Endoscopist-directed sedation.

   - Refer section 6.9 on sedation in endoscopy.

3. Endoscopy with an anaesthesia provider.

- Refer section 6.9 on sedation in endoscopy.

6.4.3.5 Education.

1) Non-endoscopist training.

- Training of medical students undertaking medical and surgical placements.
- Training of nursing students undertaking both post-basic and diploma level training.
- The unit supports a proactive approach to staff development and research based practice.
- Induction programmes are in place to support newly appointed or newly qualified staff.
- All staff will also be offered the opportunity to undertake the post-basic gastrointestinal endoscopy nursing course (post-basic course).

2) Trainee endoscopists/GI Fellows.

- The unit supports training of gastroenterology and surgical endoscopists. Training is carried out in accordance with Ministry of Health standards.

6.4.3.6 Patient referral, vetting and booking process - for outpatients and inpatients.

a) The Process for Gastroenterology Endoscopy Referrals

b) OGDS/Colonoscopy.

- Patients are given a procedure specific

information leaflet that contains information about the endoscopy unit, procedural details, guidance on preparation for the procedure and information on consent.

c) PEG referrals.

- All PEG referrals are seen by or discussed with a member of the gastroenterology team and will be given an appointment date.

6.4.3.7 Cancellation.

- All patients are given the next available date.
- If a patient's appointment is cancelled or postponed, they will be contacted by phone and a new date given.

6.4.3.8 Emergencies

a) Office hours.

- Each case is discussed with a gastroenterology specialist and scheduled for the procedure as appropriate.
- The unit runs a fixed number of scheduled lists per week plus lists for emergencies.

b) Out of hours.

- A GI bleed rota is operational in major centres. The rota consists of specialists and consultants, and a minimum of 3 members of the endoscopy unit nursing team. The majority of referrals go through the GI specialist on call. If the patient requires an endoscopy the on call GIA/nurse is

contacted to come in and prepare the equipment and assist with the procedure. The majority of GI bleeders are scoped in the endoscopy unit but if required they may also be done by the bed-side or in the operating room (OT).

6.4.3.9 Admission and discharge

a) Ward patients.

- The respective wards phone the unit in the morning to confirm that the patient is on the list. They are then sent to the unit by the ward nurse.
- Following the procedure the ward is informed and the nurse returns to take the patient back to the ward.
- All patients who have a blood transfusion in progress must be accompanied by an RN. A patient ID and checklist will be undertaken in conjunction with the nurse.
- Inpatients are admitted in the recovery area and interviewed by the unit nurse prior to the procedure. Care is taken to ensure patient's privacy is maintained and curtains are drawn during the discussion about their care.
- The consent process must be carried out by the endoscopist.
- The endoscopy findings are noted in the patient's file or records with a copy in the endoscopy unit.

b) Tertiary referrals.

- Patients are transferred by ambulance and are

escorted by a qualified nurse and/or doctor throughout their transfer, admission and discharge. A copy of the endoscopy report is filed in the patient's notes and a reply letter to the referring doctor written prior to discharge.

c) Daycare patients.

- All patients booked for a procedure will report to the endoscopy reception upon arrival at the unit. All patients undergo a pre-endoscopic assessment by a GIA in a private area. The pre-endoscopic interview is documented on a clinical assessment form.
- Patients will be assessed and consent taken by the endoscopist.
- Patients booked for upper GI endoscopies are not required to change into gowns; however those booked for lower GI endoscopy procedure do change into hospital gowns. The patient's property will remain with them or the family members or designated staff in charge of safe keeping at all times.
- The patient will then be escorted into the procedure room by the staff.
- The procedure room is always set up prior to the patient entering the room and is staffed by the endoscopist and at least two GIAs. A 4th member of staff will be required for complex therapeutic procedures.
- Post-procedure, patients will be transferred to the recovery area by trolley by the team for a formal handover to recovery staff.
- Patients who have sedation will be closely

monitored in the recovery area until the patient has recovered from sedation.

- Prior to discharge the patient will be informed of the outcome of their procedure by the endoscopist. The unit operates a policy of endoscopist-led discharge. Patients should be reviewed by the endoscopist when fully awake. In selected or complicated cases admission into the ward may be deemed necessary by the endoscopist.

6.4.3.10 Anticoagulation.

- Refer section 6.12 on antiplatelets and antithrombotics in endoscopy.

6.4.3.11 Antibiotic prophylaxis.

- Refer section 6.11 on antibiotic prophylaxis in endoscopy.

6.4.3.12 Consent (refer Appendices section 2.0).

- Informed consent is obtained by the endoscopist.

6.4.3.13 Endoscopy reporting system.

- All units are encouraged to use an endoscopy reporting system with electronic medical records (EMR).

6.4.3.14 Process for informing patients of possible malignancy.

- Following the procedure the endoscopist will discuss the findings with the patient. If the lesion is highly suspicious of malignancy, the patient may be admitted to expedite the management. Otherwise the patient should be given an early follow up appointment within 2 weeks to review the histopathology findings.

6.4.3.15 Pathology reports.

- All pathology reports are sent to the GI clinic where they are reviewed by the gastroenterologist / gastroenterology fellows.

6.4.3.16 Complaints.

- All complaints are investigated by the head of unit as per departmental policy.

6.4.3.17 Visitors.

- All visitors will be required to report to the unit reception area.

6.4.3.18 Relatives/carers.

- Relatives and carers may accompany patients into the department and will then return to the ward/reception area. A quiet area will be provided for the purpose of communication with relatives/carers.

6.4.3.19 Cleaning and decontamination of endoscopes (refer section 6.10).

6.4.3.20 Supplies.

- All orders for stock items and consumables are delivered via a top up system. Other non stock items are ordered as and when required. All items ordered are delivered to the unit in accordance with hospital policy.

6.4.3.21 Domestics.

a) Cleaning Service.

- The cleaning service is provided by the hospital support service. The cleaning of the unit occurs during office hours.

b) Linen.

- The unit has a delivery of linen each day and a number to call for ad hoc stock.

6.4.3.22 Waste collection.

- The cleaning service is responsible for household waste collection. Staffs are responsible for the proper disposal of clinical waste.

6.4.3.23 Medical gas.

- The department is supplied with oxygen cylinders or piped medical gases.

6.4.3.24 Security services.

a) All staff are issued with a name tag on induction.

b) The operating hours for the unit are 8 am to 5 pm on working days. At all other times the unit is locked and not accessible to patients and visitors except during emergency endoscopies.

6.4.3.25 Fire evacuation.

a) All staff are required to attend mandatory fire training each year. In the event of a fire in the unit, all staff will follow the evacuation procedures in accordance with hospital policy.

6.4.3.26 Pathology specimen collection.

a) Pathology specimens are sent to the pathology lab by the unit staff at least once a day. Urgent samples will be taken immediately and marked as urgent.

6.4.3.27 Resuscitation.

a) All staff are required to undertake mandatory basic life support (BLS) training.

b) Resuscitation trolleys are available in the unit and in the recovery bay. The trolleys are checked on a daily basis by designated staff.

c) In the event of an emergency “code blue” procedures should be initiated.

Table 1 Type of procedure and time required

Procedure	Time Required (min)
Upper GI	15
Colonoscopy	30
ERCP	45
Therapeutic procedure or EUS	45

ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasonography; GI, gastrointestinal

Table 2 Capacity per room

Procedure	Services list (*n*)	Trainees list (*n*)
Upper GI	12	8
Colonoscopy	6	4
ERCP / Therapeutic	4	3

ERCP, endoscopic retrograde cholangiopancreatography; GI, gastrointestinal

Figure 1: Volume calculator for an Endoscopy Unit

- Daily Projected Volume $= \frac{\text{ANNUAL PROJECTED VOLUME}}{\text{WORKING DAYS PER YEAR}}$
- Capacity per Room (RC) $= \frac{\text{NUMBER OF WORKING HOURS}}{\text{AVERAGE PROCEDURE TIME + TURNABOUND TIME}}$
- Number of Endoscopy Rooms (ER) $= \frac{\text{DAILY PROJECTED VOLUME (DV)}}{\text{CAPACITY PER ROOM (RC)}} \times 0.7 \text{ (ACTIVITY FACTOR)}$

Figure 2: Work flow of an Endoscopy Unit

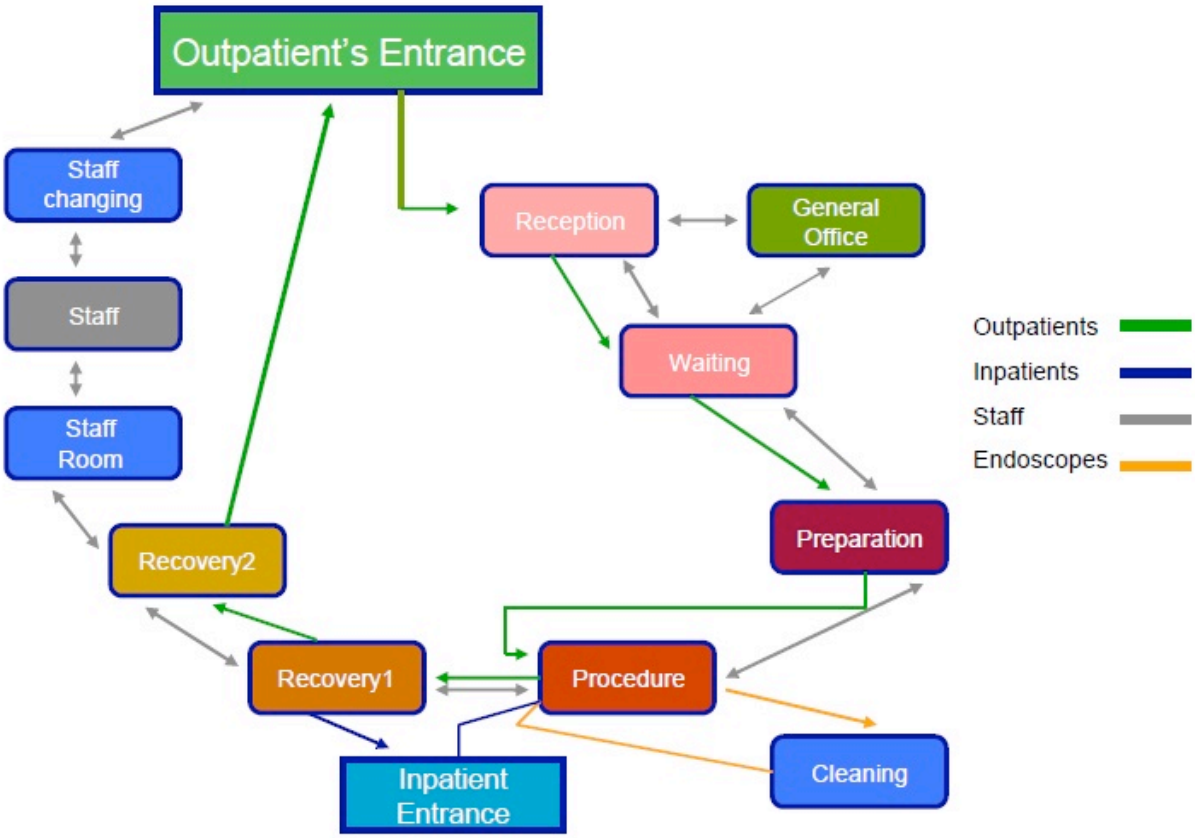


Figure 3: Example of a modern endoscopy unit with integrated staff facilities and an outpatient clinic situated around the endoscopy unit for easy hands-on supervision

Figure 4: Sample layout of endoscopy room

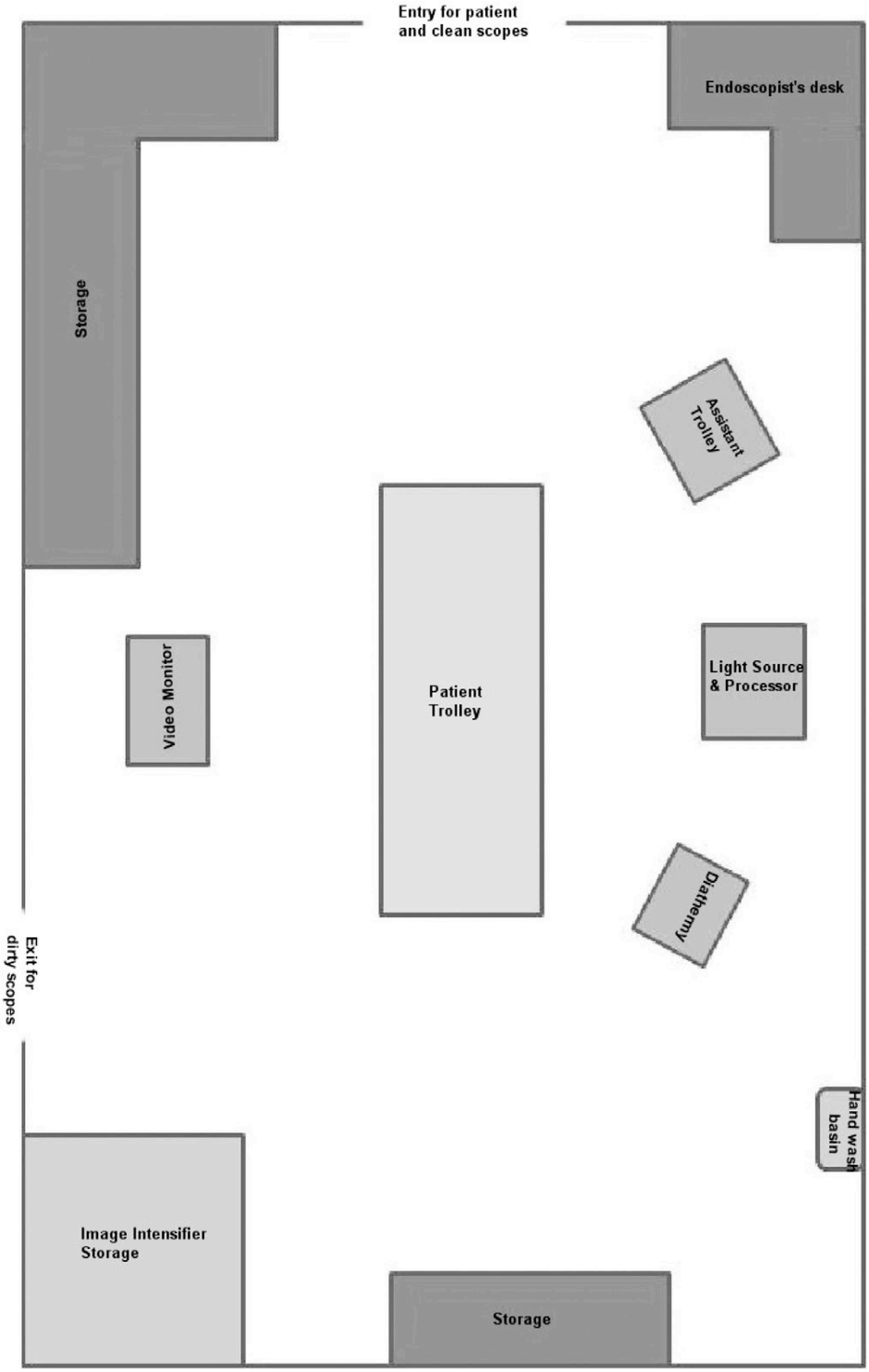


Figure 5: Summary of essential and desirable components of a JAG compliant endoscopy environment

	Essential	Desirable
3	**Reception and waiting**	
3.1	Toilet facilities within or immediately nearby the waiting area without going into the restricted clinical area	Appointments allowing phased admission of patients
3.2		A low and open reception desk, with a lower counter area for wheelchair access
3.3		A waiting area with immediate access to the reception desk
3.4	Sufficient seating to house throughput	Appropriate seating for patients with special requirements. Patients may require additional seating space to accommodate their needs.
3.5	Relatives remain outside clinical area unless there are exceptional reasons to enter	
3.6	Access to the clinical area (post reception) via doors accessed only by clinical staff	A second entrance for in patients
4	**Patient assessment and preparation areas**	
4.1	At least one separate room to undertake patient assessments and discharge for privacy	
4.2	En suite toilet and washing facilities in one preparation room if enemas are given. A suitable alternative would be if this could be provided in a nearby clinical area.	
4.3	Separate gender specific changing facilities, with their own dedicated washing and toilets	Patients in a gown should be offered dignity shorts, and wearing of footwear and a dressing gown should be promoted.
4.4	A method of handling patients property throughout their endoscopy	

	Essential	Desirable
5	**Patients prepared in the same area they are recovered in post procedure**	
5.1	A patient space for assessment, and later recovery should be curtained or screened	Patients who have not been treated do not meet patients who have been treated.
5.2		Food aromas do not pervade the area.
6	**The endoscopy room**	
6.1	Easy access and room for the patient trolley with accessibility to all sides Floor space for the endoscopist, two endoscopy assistants and a trainee Minimum of endoscopy equipment and cables on the floor or trailing, and a risk assessment undertaken to provide an achievable action plan. Space for a resuscitation trolley and emergency team to access the patient Clinical preparation space for procedural equipment Controlled drug cupboard. Clinical grade storage space for endoscopy supplies required during the session Foot operated bins or sack stands Hand washing sink	Desk space for the Endoscopy Reporting System and equipment, and record keeping

	Essential	Desirable
	Emergency call system Oxygen and suction facilities Patient monitoring for pulse, blood pressure and Sa02	
6.2	Complete range of modern endoscopy equipment available for use, with the ability to take still photography	
6.3	Endoscopy reporting system	
6.4	Register of trainees allowed to perform specified procedures independently	No thoroughfare to storage or unnecessary equipment
	Minimum entry to the room whilst patient within	Minimum of required staff in the room
7	**Fluoroscopy within the unit**	
7.1	For radiological guided procedures, a trolley suitable for a " C " arm to be used	
7.2	Lead aprons stored on a medical grade hanging frame	
8	**Recovery and discharge**	
8.1	Oxygen and suction supply, and clinical monitor to each curtained recovery space	Call system
8.2	Minimum gap of 1.2m between recovery trolleys.	3-4 beds per procedure room
8.3	Separate recovery rooms for males and females or room dividers. Room dividers fixed to the building structure and high enough to make	

	Essential	Desirable
	the patients feel as if they are in a separate room.	
8.4	If a second stage recovery base, is used, additional clinical monitors are required	
8.5	Each 1st stage recovery area should have toilet and washing facilities. If there are two recovery areas for gender separation, each should have its own toilet.	
8.6	1st stage recovery areas should have a hand washing sink. If any clinical procedures are undertaken in the second stage, e.g. removal of cannulas an additional sink is required, unless accessible room dividers are used	Dedicated base for patient records and general communications
8.7	Disposable crockery or crockery washed in an organisation approved dishwasher. Individual biscuits packs	Hand wipes
9	**Resuscitation area**	
9.1	Dedicated area within the unit should be identified to house the resuscitation trolley, oxygen, suction and emergency drug box	
10	**Off the unit endoscopy**	
10.1	Rooms, equipment and processes to the same standard for off unit or out of hours endoscopy, including decontamination	
10.2	Registered nurse or an anaesthetic practitioner remains with patient post sedation with oxygen, suction and patient monitoring	
11	**The decontamination environment**	

	Essential	Desirable
11.1	Dedicated decontamination facilities with clear separation of dirty and clean equipment and processes.	Door to have code locks
11.2	Medical grade surfaces Disinfectant storage Personal protective equipment Spillage kit Ventilation and extraction facilities according to chemicals used Doors shut at all times	
11.3	Sinks for manual cleaning should be of adequate height to prevent back related injuries for all staff	Adjustable height sinks or sinks of multiple heights
11.4	Double sink with a double drainer to fully submerge the largest scope cleaned. A system to check the detergent, water concentration and temperature. Manual leak testing facilities	Automated water, detergent and temperature systems
11.5	Automated endoscope reprocessing. AERs in good working order, and CFPP compliant, maintained in accordance with the manufacturers instructions	Pass through system of AERs
11.6	Endoscopes storage in a lockable medical grade storage cabinet	Endoscope drying and storage cabinets
11.7	Hand washing sink in decontamination area (two sinks if separate rooms for dirty and clean processes)	

	Essential	Desirable
11.8	Scope trays identifying a clean or dirty instrument. Hard lid for movement outside the unit. Lockable case or tray if moved outside the hospital.	
11.9	Tracking system Storage for any dirty equipment for sterile services	
12	**Stock room and disposal area**	
12.1		Storage for laundry, major supplies. Dedicated area nearby for safe disposal of general and hazardous waste. Access to a sluice and facilities for use and disposal of urinals and bedpans
13	**Staff changing rooms and staff room**	
13.1		Staff access to a dedicated changing area, with secure property storage, toilet and washing facilities on the unit or nearby Dedicated staff room.
14	**Additional facilities**	

	Essential	Desirable
14.1	Video photography for trainee lists	Nearby seminar room with a video link to the endoscopy unit. Complete range of equipment for therapeutic and advanced technique endoscopy. Imagers, models or simulators, are available or readily accessible.
15	**Children and endoscopy**	
15.1	Separate dedicated endoscopy list for children if own facility not available Visible separation of adult and child patients in the unit if concurrent lists undertaken Children admitted and recovered directly in a paediatric facility.	Children treated within own unit. For concurrent adult/ child lists, communal areas (admission, recovery, pre discharge) divided by movable screens.

Figure 6: The unit hierarchy

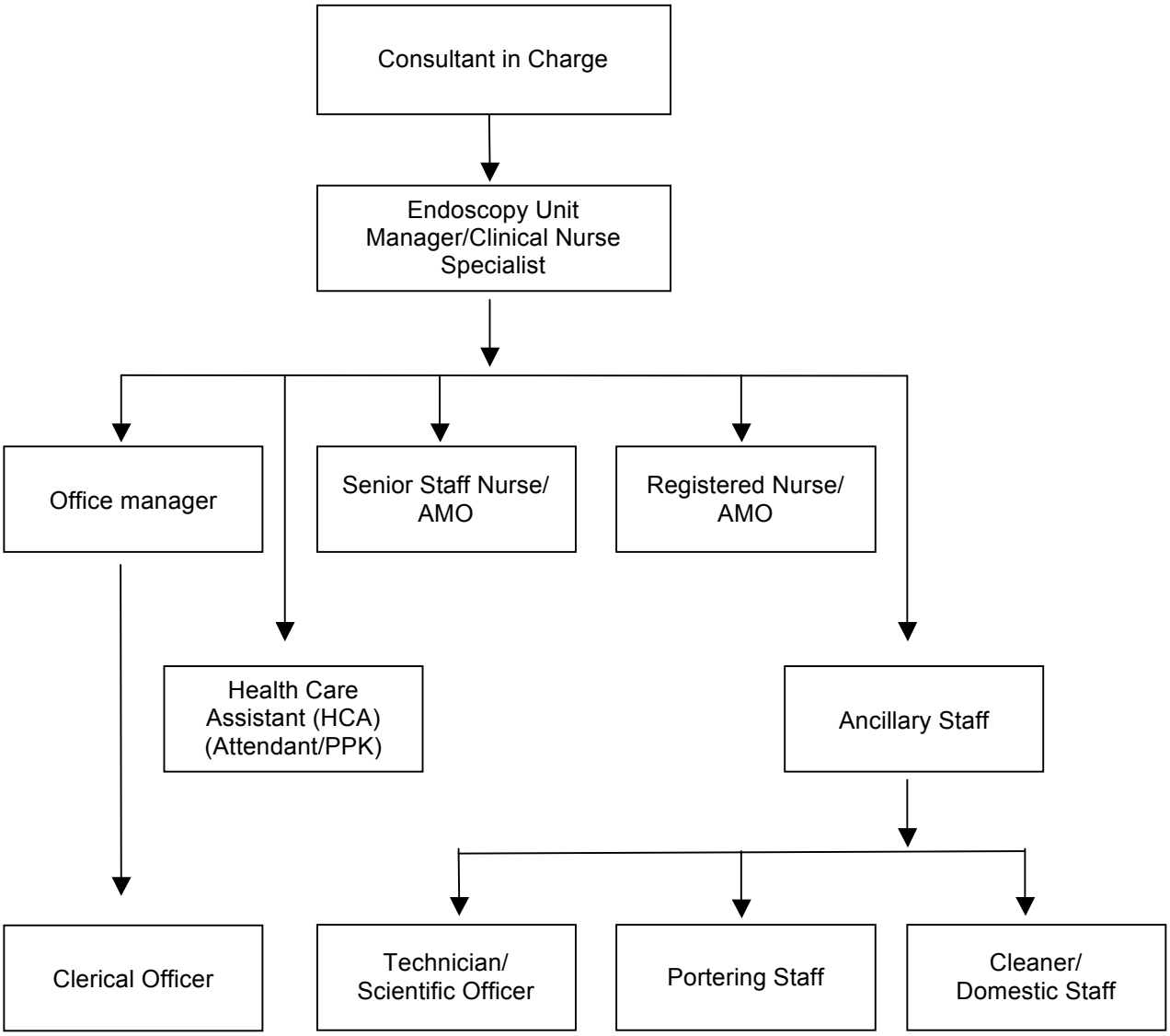


Figure 7: The process for Gastroenterology Endoscopy referrals

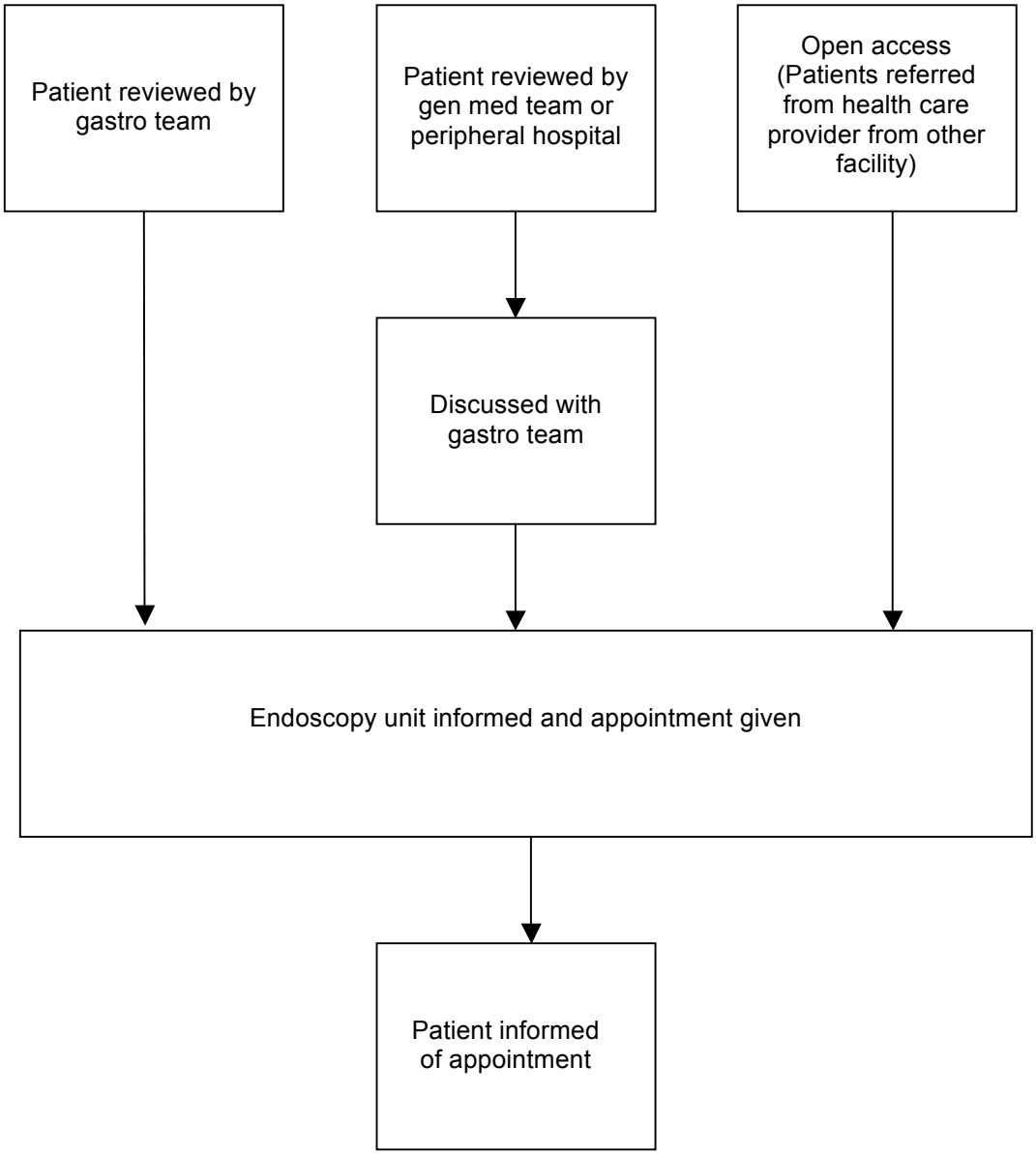
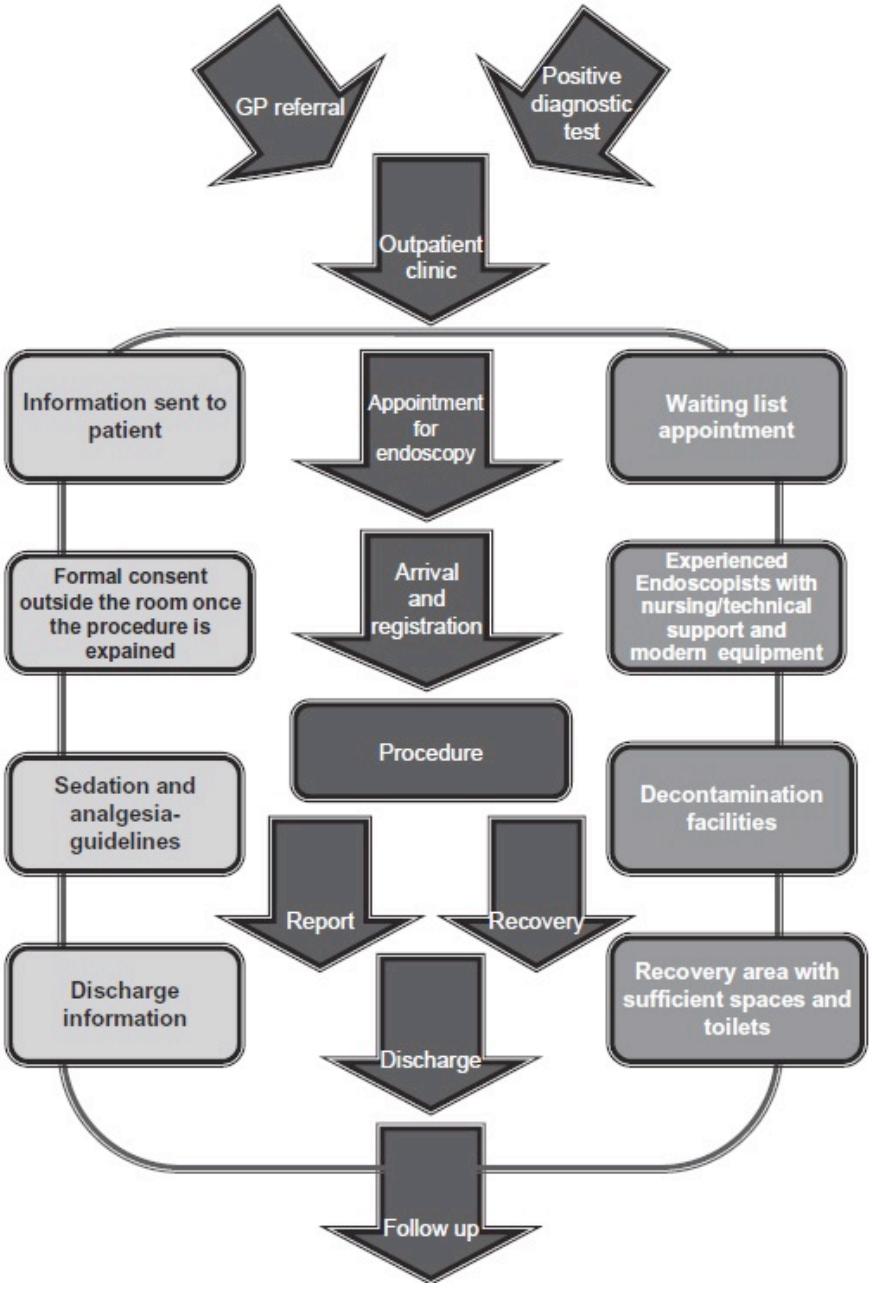


Figure 8: Endoscopy pathway



6.5 INDICATIONS AND QUALITY INDICATORS FOR ENDOSCOPY

6.5.1 Grades of recommendation

Grade of recommendation	Clarity of benefit	Methodologic strength/evidence	Implications
1A	Clear	Randomised trial without important limitations	Strong recommendations. Can be applied to most clinical setting
1B	Clear	Randomised trials with important limitations	Strong recommendations. Can be applied to most practice settings
1C+	Clear	Overwhelming evidence from observational studies	Strong recommendations; can be applied to most practice settings in most situations
1C	Clear	Observational studies	Intermediate strength recommendation; may change when stronger evidence is available
2A	Unclear	Randomised trial without important limitations	Intermediate strength recommendation; best action may differ depending on patients or societal values
2B	Unclear	Randomised trials with important limitations	Weak recommendation; alternative approach may be better under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; alternative approach likely to be better under some circumstances
3	Unclear	Expert opinion	Weak recommendation; likely to change as data become available

6.5.2 Oesophagogastroduodenoscopy (OGDS).

6.5.2.1 Indications and contraindications.

- OGDS is generally indicated for evaluating:

a) Upper abdominal symptoms that persist despite an appropriate trial of therapy.
b) Upper abdominal symptoms associated with other symptoms or signs suggesting serious organic disease (e.g., anorexia and weight loss) or in patients >45 years old.
c) Dysphagia or odynophagia.
d) Oesophageal reflux symptoms that are persistent or recurrent despite appropriate therapy.
e) Persistent vomiting of unknown cause.
f) Other diseases in which the presence of upper GI pathologic conditions might modify other planned management (examples include patients who have a history of ulcer or GI bleeding who are scheduled for organ transplantation, long-term anticoagulation, or long-term non-steroidal anti-inflammatory drug therapy for arthritis, and those with cancer of the head and neck).
g) Familial adenomatous polyposis syndromes
h) For confirmation and specific histologic diagnosis of radiologically demonstrated lesions.
    1. Suspected neoplastic lesion.
    2. Gastric or oesophageal ulcer.
    3. Upper tract stricture or obstruction.
i) GI bleeding.
    1. In patients with active or recent bleeding.
    2. For presumed chronic blood loss and for iron deficiency anaemia when the clinical situation

suggests an upper GI source or when colonoscopy results are negative.

j) When sampling of tissue or fluid is indicated.
k) In patients with suspected portal hypertension to document or treat oesophageal varices.
l) To assess acute injury after caustic ingestion.
m) Treatment of bleeding lesions such as ulcers, tumours, vascular abnormalities (e.g., electrocoagulation, heater probe, laser photocoagulation, or injection therapy).
n) Banding or sclerotherapy of varices.
o) Removal of foreign bodies.
p) Removal of selected polypoid lesions.
q) Placement of feeding or drainage tubes (peroral, percutaneous endoscopic gastrostomy, percutaneous endoscopic jejunostomy).
r) Dilation of stenotic lesions (e.g., with transendoscopic balloon dilators or dilation systems using guide wires).
s) Management of achalasia (e.g., botulinum toxin, balloon dilation).
t) Palliative treatment of stenosing neoplasms (e.g., laser, multipolar electrocoagulation, stent placement).

- OGDS is generally not indicated for:

a) Symptoms that are considered functional in origin (there are exceptions in which an endoscopic examination may be done once to rule out organic disease, especially if symptoms are unresponsive to therapy).
b) Metastatic adenocarcinoma of unknown primary site when the results will not alter management.
c) Radiographic findings of:
    1. Asymptomatic or uncomplicated sliding hiatal hernia.

2. Uncomplicated duodenal ulcer that has responded to therapy.
3. Deformed duodenal bulb when symptoms are absent or respond adequately to ulcer therapy.

- Sequential OGDS may be indicated in:

a) Surveillance for malignancy in patients with premalignant conditions (i.e., Barrett's oesophagus).

- Sequential OGDS generally not indicated for:

a) Surveillance for malignancy in patients with gastric atrophy, pernicious anaemia, or prior gastric operations for benign disease.
b) Surveillance of healed benign disease such as oesophagitis or gastric or duodenal ulcer.
c) Surveillance during repeated dilations of benign strictures unless there is a change in status.

6.5.2.2 Summary of proposed quality indicators in OGDS.

- Quality indicators and grade of recommendation.
  a) Accepted indication(s) is provided before performance of OGDS. Grade 1C +
  b) Informed consent is obtained, including specific discussion of risks associated with OGDS. Grade 3
  c) Prophylactic antibiotics are given in patients with cirrhosis with acute upper GI bleeding who undergo OGDS. Grade 1A

  d) Prophylactic antibiotics are given before placement of a PEG. Grade 1A
  e) Complete examination of the oesophagus stomach

and duodenum, including retroflexion in the stomach. Grade 2C

f) Biopsy specimens are taken of gastric ulcers. Grade 1C
g) Barrett's oesophagus is measured when present, with the location of the gastroesophageal junction and squamocolumnar junction in centimetres from the incisors being documented. Grade 3
h) Biopsy specimens are obtained in all cases of suspected Barrett's oesophagus. Grade 3
i) Type of upper GI bleeding lesion is described and location is documented. For peptic ulcers, at least one of 3 the following stigmata is noted: active bleeding, non bleeding, non bleeding visible vessels (pigmented protuberance), adherent clot, flat spot, cleaned based. Grade 3
j) Unless contraindicated, endoscopic treatment is given to ulcers with active bleeding or with non bleeding visible vessels. Grade 1A
k) In cases of attempted haemostasis of upper GI bleeding lesions, whether haemostasis has been achieved is clearly documented. Grade 3
l) When epinephrine injection is used to treat non variceal upper GI bleeding or non bleeding visible vessels, a second treatment modality is used (e.g., coagulation or clipping). Grade 1A
m) Variceal ligation is used for endoscopic treatment of oesophageal varices. Grade 1A
n) Written instructions, which include particular signs and symptoms to watch for after OGDS, are provided to the patient on discharge. Grade 3
o) In patients undergoing dilation for peptic oesophageal strictures, PPI therapy is recommended. Grade 1A
p) Patients diagnosed with gastric or duodenal ulcers are

instructed to take PPI medication or an H2 antagonist. Grade 1A

q) Patients diagnosed with gastric or duodenal ulcers have documented plans to test for the presence of H pylori infection. Grade 1A
r) Rebleeding rates after endoscopic haemostasis are measured. Grade 1C+

6.5.3 Colonoscopy

6.5.3.1 Indications for colonoscopy.

a) Evaluation on barium enema or other imaging study of an abnormality that is likely to be clinically significant, such as a filling defect or stricture.
b) Evaluation of unexplained gastrointestinal bleeding.
    1. Haematochezia.
    2. Maelena after an upper gastrointestinal source has been excluded.
    3. Presence of faecal occult blood.
c) Unexplained iron deficiency anaemia.
d) Screening and surveillance for colonic neoplasia.
    1. Screening of asymptomatic, average-risk patients for colonic neoplasia.
    2. Examination to evaluate the entire colon for synchronous cancer or neoplastic polyps in a patient with treatable cancer or neoplastic polyp.
    3. Colonoscopy to remove synchronous neoplastic lesions at or around time of curative resection of cancer followed by colonoscopy at 3 years and 3-5 years thereafter to detect metachronous cancer.
    4. After adequate clearance of neoplastic polyp(s) survey at 3-5 year intervals.

5. Patients with significant family history.
    - Hereditary non polyposis colorectal cancer: colonoscopy every 2 years beginning at the earlier of age 25 years or 5 years younger than the earliest age of diagnosis of colorectal cancer. Annual colonoscopy should begin at age 40 years.
    - Sporadic colorectal cancer before age 60 years: colonoscopy every 5 years beginning at age 10 years earlier than the affected relative or every 3 years if adenoma is found.
6. In patients with ulcerative or Crohn's pancolitis 8 or more years' duration or left-sided colitis 15 or more years' duration every 1-2 years with systematic biopsies to detect dysplasia.

e) Chronic inflammatory bowel disease of the colon if more precise diagnosis or determination of the extent of activity of disease will influence immediate management.
f) Clinically significant diarrhoea of unexplained origin.
g) Intra-operative identification of a lesion not apparent at surgery (e.g., polypectomy site, location of a bleeding site).
h) Treatment of bleeding from such lesions as vascular malformation, ulceration, neoplasia, and polypectomy site (e.g., electrocoagulation, heater probe, laser or injection therapy).
i) Foreign body removal.
j) Excision of colonic polyp.
k) Decompression of acute nontoxic megacolon or sigmoid volvulus.
l) Balloon dilation of stenotic lesions (e.g., anastomotic strictures.

m) Palliative treatment of stenosing or bleeding neoplasms (e.g., laser, electrocoagulation, stenting).
n) Marking a neoplasm for localization.

6.5.3.2 Summary of proposed quality indicators for colonoscopy.

- Quality indicators and grade of recommendation.
    a) Appropriate indication. Grade 1C+
    b) Informed consent is obtained, including specific discussion of risks associated with colonoscopy. Grade 3
    c) Use of recommended post-polypectomy and post-cancer resection surveillance intervals. Grade 1A
    d) Use of recommended ulcerative colitis/Crohn's disease surveillance intervals. Grade 2C
    e) Documentation in the procedure note of the quality of the preparation. Grade 2C
    f) Caecal intubation rates (visualization of the caecum by notation of landmarks and photo documentation of landmarks should be present in every procedure). Grade 1C
    g) Detection of adenomas in asymptomatic individuals (screening). Grade 1C
    h) Withdrawal time: mean withdrawal time should be >6 minutes in colonoscopies with normal results performed in patients with intact anatomy. Grade 2C
    i) Biopsy specimens obtained in patients with chronic diarrhoea. Grade 2C
    j) Number and distribution of biopsy samples in ulcerative colitis and Crohn's colitis surveillance. Goal: 4 per 10 cm section of involved colon or approximately 32 specimens per case of pancolitis. Grade 1C
    k) Mucosally based pedunculated polyps and sessile

polyps >2 cm in size should be endoscopically resected or documentation of unresectabiltiy obtained. Grade 3

l) Incidence of perforation by procedure type (all indications vs. screening) is measured. Grade 2C
m) Incidence of post-polypectomy bleeding is measured. Grade 2C
n) Post-polypectomy bleeding managed non-operatively. Grade 1C

6.5.4 ERCP

6.5.4.1 Indications for ERCP.

a) Jaundice thought to be the result of biliary obstruction.
b) Clinical and biochemical or imaging data suggestive of pancreatic or biliary tract disease.
c) Signs or symptoms suggesting pancreatic malignancy when direct imaging results are equivocal or normal.
d) Pancreatitis of unknown aetiology.
e) Preoperative evaluation of chronic pancreatitis or pancreatic pseudocyst.
f) Sphincter of Oddi manometry.
g) Endoscopic sphincterotomy.
    1. Choledocholithiasis.
    2. Papillary stenosis or sphincter of Oddi dysfunction causing disability.
    3. Facilitate biliary stent placement or balloon dilatation.
    4. Sump syndrome.
    5. Choledochocele.
    6. Ampullary carcinoma in poor surgical candidates.
    7. Access to pancreatic duct.

h) Stent placement across benign or malignant strictures, fistulae, postoperative bile leak, or large common bile duct stones.
i) Balloon dilatation of ductal strictures.
j) Nasobiliary drain placement.
k) Pseudocyst drainage in appropriate cases.
l) Tissue sampling from pancreatic or bile ducts.
m) Pancreatic therapeutics.

6.5.4.2 Summary of proposed quality indicators for ERCP

- Quality indicators and grade of recommendation.
    a) Appropriate indication. Grade 3
    b) Informed consent. Grade 3
    c) Assessment of procedural difficulty. Grade 3
    d) Prophylactic antibiotics. Grade 2B
    e) Cannulation rates.
        i. Desired duct. Grade 1C
        ii. Use of precut. Grade 2C
    f) Extraction of common bile duct stones. Grade 1C
    g) Biliary stent placement. Grade 1C
    h) Complete documentation. Grade 3
    i) Complication rates: pancreatitis, bleeding, perforation, and cholangitis. Grade 1C

6.5.5 Endoscopic ultrasound (EUS)

6.5.5.1 Indications for EUS.

a) Staging of tumours of the GI tract, pancreas, bile ducts, and mediastinum.
b) Evaluating abnormalities of the GI tract wall or adjacent structures.
c) Tissue sampling of lesions within, or adjacent to, the wall of the gastrointestinal tract.

d) Evaluation of abnormalities of the pancreas, including masses, pseudocysts, and chronic pancreatitis.
e) Evaluation of abnormalities of the biliary tree.
f) Providing endoscopic therapy under ultrasonographic guidance.

6.5.5.2 Summary of proposed quality indicators for EUS.

- Quality indicators and grade of recommendation.
  a) Proper indication. Grade 3
  b) Proper consent. Grade 3
  c) Prophylactic antibiotics. Grade 2c
  d) Visualization of structures. Grade 3
     i. In EUS for non obstructing oesophageal cancer, visualization of the celiac axis.
     ii. In EUS for evaluation of suspected pancreatic disease, visualization of the entire pancreas.
  e) Description of abnormalities. Grade 3
     i. Gastrointestinal cancers should be staged with the TNM staging system.
     ii. Pancreatic mass measurements should be documented.
     iii. The wall layers involved by subepithelial masses should be documented.
  f) When celiac axis lymph nodes are seen during EUS staging of a thoracic oesophageal cancer, FNA is performed. Grade 2 C
  g) The incidence of pancreatitis after EUS-FNA of the pancreas. Grade 1C

6.5.6 Deep/device-assisted enteroscopy

6.5.6.1 Indications for deep/device-assisted enteroscopy.

a) Treatment of small intestinal lesions such as angiodysplasia.
b) Biopsies of lesions/ulcer seen on capsule endoscopy.
c) Removal of retained objects in small intestine.
d) Small intestinal polypectomy in hereditary syndromes.
e) Balloon dilatation of small bowel stricture.
f) Gaining access in patients with surgically altered small bowel anatomy.

6.6 ASSESSMENT OF PATIENTS FOR ENDOSCOPY

6.6.1 Endoscopy is part of a comprehensive evaluation of the gastrointestinal tract. It is the responsibility of the endoscopist to risk stratifies patients before endoscopy. The endoscopist should evaluate and optimize the patients before the procedure.

6.6.2 A standard assessment form (appendix 1.0) is needed to gather relevant clinical history from the patients. This information will help risk stratify the patient before the relevant procedure. It is recommended that all endoscopic unit use an assessment form.

6.6.3 The assessment of patient fitness for endoscopy and mortality risk of procedure can be assessed with American Society of Anaesthesiologists (ASA) grading system.

American Society of Anesthesiologists (ASA) Grading System

ASA	Assessment of Fitness	% mortality predicted
Class I	Healthy patient	0.05
Class II	Mild systemic disease, no functional limitations, no acute problems (e.g., controlled hypertension, mild diabetes, chronic bronchitis, asthma)	0.4
Class III	Severe systemic disease, definite functional limitation (e.g., brittle diabetes, frequent angina, myocardial infarction)	4.5
Class IV	Severe systemic disease with acute, unstable symptoms (e.g., recent [3 months] myocardial infarction, congestive heart failure, acute renal failure, diabetes ketoacidosis, uncontrolled asthma)	25
Class V	Severe systemic disease with imminent risk of death, moribund	50

6.7 CONSENT

6.7.1 Theory of informed consent.

a. The ethical and legal requirement to obtain informed consent prior to a procedure comes from the concept of personal patient autonomy and is rooted in the theory of patient self-determination. Against such a backdrop, a person's right to self-determination warrants that a physician obtains informed consent.

b. The competent patient, after receiving appropriate disclosure of material risks of the procedure in question, and understanding the risks, benefits and alternative approaches, then makes a voluntary and uncoerced informed decision of whether to proceed.

c. Obtaining informed consent is a process that includes more than placing a signature on a standardized consent form. It involves mutual communication and decision making and can advance the physician-patient relationship.

6.7.2 Principles of consent.

a. Informed and signed consent is obtained from the patient before the procedure.
b. The patient has the right to be given sufficient information and sufficient time to allow an informed decision to be made.

c. Written consent is documentary evidence that an explanation of the proposed procedure or treatment was given and that consent was sought and obtained.

d. It is the duty of the endoscopist to ensure that the patient understands the following before deciding whether to consent to a procedure, treatment or investigation:

    - Nature of the condition and test results.
    - Purpose of the proposed treatment (including sedation) and aftercare.
    - The reason or indications for the procedure.
    - The likely benefits of the procedure.
    - The risks (complications and side effects) associated with the treatment or procedure, including their relative incidences and severities.
    - The taking and retention of tissue samples.
    - The possible alternative treatments both to the proposed intervention and the alternative of no treatment.
    - The patient's prognosis if the treatment or test is declined.

e. Patients should be provided with written information warning of the risks of diagnostic and therapeutic endoscopic/ interventional procedures.

f. Consent must be taken by the endoscopist who shall be performing the endoscopic/interventional procedures.

g. In the case of a patient who is incompetent or incapacitated, the endoscopist has a duty to obtain informed consent from a parent, legal guardian or surrogate.

h. Consent for endoscopic procedures for patients who are under the age of 18 shall be obtained from the parents or legal guardian.

i. Patients with language barriers shall need a translator for the consent.

j. Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves and no-one else can give consent on their behalf, two consultants can provide the consent in accordance with hospital policy.

k. All informed refusals shall be documented clearly in the event the patient decides to refuse any form of treatment after having discussed the possible treatment options with the endoscopist.

l. If the patients have already signed a consent form, but then change their mind, it shall be documented in the form and case record.

6.7.3 Exceptions to informed consent.

a. There are several exceptions to the informed consent process. These include:

    - Emergencies where the patient is incapacitated to a degree that consent cannot be obtained and delay would put the patient at risk and may be life threatening.

- Incompetency, where the patient is unable to make a decision and that responsibility is given to the patient's legal guardian.

6.7.4 Informed refusal.

a. A patient who refuses a procedure or treatment must do so in a well informed way and that it is the endoscopist's duty to ensure that such refusal is informed.

6.8 BOWEL PREPARATION FOR COLONOSCOPY

6.8.1 Introduction.

6.8.1.1 The ideal oral bowel cleansing agent would be convenient to administer, well tolerated, effective in cleansing, with an acceptable side-effect profile.

6.8.1.2 Polyethylene glycols (PEG) or macrogols are non-absorbable isoosmotic solutions that pass through bowel without net absorption or secretion. Thus, significant fluid and electrolyte shifts are attenuated.

6.8.1.3 Oral sodium phosphate preparations (OSP) are hyperosmotic and promote colonic evacuation by drawing large volumes of water into the colon (1-1.8 litres of water per 45 ml of preparation).

6.8.1.4 Picosulphate is a prodrug that is metabolized within the bowel lumen to a stimulant that promotes peristalsis. It is often combined with magnesium salts, which act synergistically through their osmotic effects.

6.8.2 Recommendations.

6.8.2.1 Adjunctive measures to improve bowel preparation.

a) A low-fibre diet on the day preceding colonoscopy is recommended.

b) The use of low-fibre diet for more than 24 hours prior to the examination is not currently recommended.

c) The routine use of enemas in addition to oral bowel preparation is not recommended.

d) The routine use of prokinetic agents as adjuncts to bowel preparation is not recommended.

6.8.2.2 Precautions when administering oral bowel prep agents.

a) Absolute contraindications for the use of all oral bowel cleansing preparations:

- Gastrointestinal obstruction, perforation, ileus, or gastric retention.
- Acute intestinal or gastric ulceration.
- Severe acute inflammatory bowel disease or toxic megacolon.
- Reduced levels of consciousness.
- Hypersensitivity to any of the ingredients.

- Inability to swallow without aspiration (in this situation a nasogastric tube may be used for administration).

- Ileostomy.

b) Renal function should be measured (using an estimated GFR from serum creatinine concentration) in all patients in whom the use of oral bowel cleansing agents is considered.

c) Renal function should be checked as close to the colonoscopy appointment as practically possible, but in any case within 3 months.

6.8.2.3 Patients taking particular medications.

a) Angiotensin-converting enzyme (ACE) inhibitors/ angiotensin receptor blockers (ARB)/ non-steroidal anti-inflammatory drugs (NSAIDs).

    - Are discontinued on the day of administration of oral bowel cleansing agents and are preferably not reinstated until 72 hours after the procedure.

b) Diuretics.

    - Are discontinued on the day of administration of oral bowel cleansing agents and are preferably not reinstated until 72 hours after the procedure.

    - If there is a significant risk of pulmonary oedema and diuretics have to be continued, the patient's hydration status is assessed prior to administration of oral bowel cleansing preparations. In patients taking diuretics sodium picosulphate preparations should not be used.

c) Medications known to induce the syndrome of inappropriate anti-diuretic hormone (SIADH) secretion.

    - Serum urea and electrolytes should be checked prior to administration of oral bowel cleansing preparations in patients taking such medications.

d) Aspirin.

    - May be continued.

e) Iron tablets.

    - Should be stopped 1 week before the procedure.

6.8.2.4 General recommendations for healthy patients with no comorbidities and risk factors.

a) A split regimen of 3-4 litres PEG solution (or a same-day regimen in the case of afternoon colonoscopy) for routine bowel preparation is recommended.

b) The initial 2-3 litres PEG on the night before the procedure and the remaining 1-2 litres the following morning is recommended. To improve both tolerability and efficacy, consideration should be given to splitting the dose of oral bowel cleansing agent over 12 hours when polyethylene glycol preparations are utilised.

c) A split regimen (or same-day regimen in the case of afternoon colonoscopy) of 2 litres PEG plus ascorbate or of sodium picosulphate plus magnesium citrate may be valid alternatives, in particular for elective outpatient colonoscopy.

d) Sodium picosulphate preparations and magnesium salt preparations can be used as alternatives.

e) The routine use of oral sodium phosphate for bowel preparation is not advised in the following risk groups:

- Chronic kidney disease (CKD).
- Cardiac failure.
- Advanced cirrhosis.
- Pre-existing electrolyte disturbances.
- Hypertension.
- Hypovolemia.

f) Oral sodium phosphate may be advised in:

- Individuals assessed by physicians to be at low risk of oral sodium phosphate-related side-effects.
- Selected cases of specific needs that cannot be met by alternative products (e.g., other products are contraindicated or have proven ineffective or intolerable).

g) An evaluation of the kidney function should be available before prescribing oral sodium phosphate.

h) If oral sodium phosphate is used for bowel preparation, two 45 ml doses 12 hours apart are recommended. They are typically diluted in about 250 ml of water.

i) An alternative regimen of a 45 ml dose followed by a 30 ml dose 24 hours later may be used. This regimen reduces the incidence of clinically relevant hyperphosphataemia (>2.1 mmol/L) without compromising efficacy.

j) Contraindications to oral sodium phosphate (OSP).

- Absolute contraindications are:
    - Pregnancy.
    - Age <18 years.
    - Stage 3-5 CKD.
    - Inability to maintain adequate fluid intake.
    - Pre-existing electrolyte disturbances.
    - Ascites.
    - Symptomatic congestive heart failure.
    - Recent (within <6 months) symptomatic ischemic heart disease (unstable angina or myocardial infarction).
- Relative contraindications are:
    - Active inflammatory bowel disease.
    - Parathyroidectomy.
    - Delayed bowel transit.

k) Risk factors for acute phosphate nephropathy following the use of OSP are:
    - Age> 55 years.
    - Hypovolemia.
    - Baseline kidney disease.

- Bowel obstruction.
- Active colitis.
- Diuretics, angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers and possibly non-steroidal anti-inflammatory drugs.

l) Timing of colonoscopy.

- The period of bowel cleansing should not exceed 24 hours.
- The delay between the last dose of bowel preparation and colonoscopy should be minimized and no longer than 4 hours.

6.8.2.5 Special risk groups.

a) Stage 1-3 chronic kidney disease.

- In patients with renal failure, PEG is the only recommended bowel preparation.
- Alternatives include sodium picosulphate preparations, magnesium salt preparations.
- Oral sodium phosphate preparations are best avoided.

b) Stage 4 and 5 pre-dialysis CKD.

- PEG is recommended if patient is able to tolerate fluids.

- Sodium picosulphate preparations should be avoided, but can be used cautiously in those who cannot tolerate fluids/PEG.

- Magnesium salt preparations should be avoided, but can be used cautiously in Stage 4 CKD. It is absolutely contraindicated in CKD 5.

- Oral sodium phosphate preparations are absolutely contraindicated.

c) Chronic haemodialysis.

- Discussion with nephrologist is necessary.

- Admission to hospital to co-ordinate and oversee dialysis prescription.

- PEG should be used.

- Sodium picosulphate, or magnesium salts can be used as alternatives.

d) Peritoneal dialysis.

- Discussion with nephrologist is necessary.

- Admission to hospital to oversee administration of oral bowel cleansing agents should be considered in those considered to have important residual renal function.

e) Renal transplant.

- Discussion with nephrologist is necessary.
- OSP should not be used.
- Admission to hospital may be advisable on an individual patient basis when concerns exist over the absorption of immunosuppressants during concomitant administration of oral bowel cleansing agents.

f) Hypovolemia.

- PEG is recommended.
- Sodium picosulphate preparations and OSP should not be used.

g) Advanced cirrhosis.

- PEG is recommended.
- Sodium picosulphate preparations should not be used, but in selected cases, it can be used cautiously.
- Magnesium salt preparations and oral sodium phosphate preparations are contraindicated.

h) Heart failure.

- PEG is recommended.

- Sodium picosulphate preparations and magnesium salt preparations should not be used, but in selected cases, it can be used cautiously.

- Oral sodium phosphate preparations are absolutely contraindicated in patients with significant congestive cardiac failure (NYHA class III or IV, or an ejection fraction below 50%) but can be used cautiously in other heart failure patients.

i) Pre-existing electrolyte disturbances.

- PEG is recommended.

- Sodium picosulphate preparations and magnesium salt preparations should not be used, but in selected cases, it can be used cautiously.

- Oral sodium phosphate preparations are absolutely contraindicated.

j) Hypertension.

- PEG, sodium picosulphate preparations or magnesium salt preparations can be used.

- Oral sodium phosphate preparations are not recommended.

6.8.2.6 Advice regarding regular medications:

a) Regular oral medications should not be taken one hour before or after administration of bowel cleansing preparations due to the possibility of impaired absorption.

b) Patients taking the oral contraceptive pill should be advised to take alternative precautions during the week following the administration of the oral bowel cleansing agent.

c) Patients with diabetes mellitus receiving treatment with insulin will also require specific advice.

6.8.2.7 The appropriate doses of oral bowel cleansing preparations should not be exceeded.

6.8.2.8 Hypovolaemia must be corrected prior to administration of oral bowel cleansing preparations.

a) Patients with co-morbidities indicating a predisposition to hypovolaemia should be assessed prior to commencing administration of oral bowel cleansing agents.

- Chronic or severe diarrhoea.
- Chronic vomiting.
- Dysphagia.
- Those with persistent hyperglycaemia.
- Those taking high-dose diuretics.

b) Admission to hospital for hydration may be necessary.

c) Where intravenous fluid replacement is undertaken, isotonic fluid (for example, Hartmann's solution) may be preferable.

d) Hypovolaemia must be prevented during administration of oral bowel cleansing preparations.

e) Patients should receive clear instructions regarding oral fluid intake and these instructions should also be provided in writing.

f) Oral and written information about bowel preparation is recommended.

g) Admission for intravenous fluid replacement should be considered in all patients who may be unable to maintain adequate oral intake at home (for example, the elderly and those with reduced mobility).

6.8.3 Specific scenarios.

6.8.3.1 Poor bowel prep.

a) In patients with inadequate bowel cleansing, the use of endoscopic irrigation pumps or repeating colonoscopy on the following day after additional bowel preparation is recommended.

6.8.3.2 Pregnancy/breastfeeding.

a) In pregnant/breastfeeding women, PEG regimens may be considered.

6.8.3.3 Inflammatory bowel disease.

a) The use of PEG for bowel preparation in patients affected by or at risk of inflammatory bowel disease is recommended. Other agents may cause mucosal abnormalities that mimic inflammatory bowel disease.

6.8.3.4 Lower gastrointestinal bleeding.

a) PEG is recommended if urgent colonoscopy is scheduled for lower gastrointestinal bleeding.

6.8.4 Colonoscopy report.

6.8.4.1 It is recommended that the colonoscopy report include an evaluation of the quality of colon cleansing, with the adoption of a validated scale.

6.8.5 Oral bowel preparation agents.

6.8.5.1 PEG (electrolyte lavage solution).

a) Dosing.

- No solid food for at least two hours before ingestion of the solution.
- Divided-dose PEG regimens (2-3 litres given the night before the colonoscopy and 1–2 litres on the morning of procedure) are recommended.
- 3-4 litres are consumed are acceptable alternative regimens.
- Dosage for nasogastric administration is 20 to 30 ml per minute (1.2–1.8 l/hr).
- Special care must be taken to avoid altering the osmolarity of the preparation or adding substrates to the preparation, which can metabolize into

explosive gases or alter the amount of water and salts absorbed.

- Avoid eating raw fruit and vegetables, particularly those with fine seeds, e.g., grapes, raspberries, currants, strawberries, kiwi, dragon fruits, figs, tomatoes, cucumbers, and the preserves made from them.

- Avoid eating beetroot, wholegrain bread, and poppy seed.

6.8.5.2 Oral sodium phosphate (OSP).

a) Dosing.

- Only clear liquids can be consumed on the day of preparation.
- Two doses of 30 to 45 ml (2-3 tbsp) of oral solution are given at least 10 to 12 hours apart with one of the doses taken on the morning of the procedure.

- Each dose is taken with at least 8 oz of liquid followed by an additional minimum of at least 16 oz of liquid.

- The second dose must be taken at least three hours before the procedure.

6.8.5.3 Sodium picosulpate.

a) Dosing for adult including the elderly.

- Split-dose regimen (evening pre- and post-colonoscopy).

- On the day pre-procedure: 1 sachet in the evening (e.g., 5-9 pm) followed by at least five 250 ml drinks of clear liquids spread over several hr.
- On the day of the procedure: 1 sachet in the morning (5-9 hr pre-procedure) followed by at least three 250 ml drinks of clear liquids spread over several hr.

- Day-before regimen (evening before the procedure only).
  - On the day pre-procedure: 1 sachet in the afternoon or early evening (e.g., 4-6 pm) followed by at least five 250 ml drinks of clear liquids spread over several hr.
  - Take another sachet in the late evening (e.g., 10:00 pm-12:00 am) followed by at least three 250 ml drinks of clear liquids spread over several hr.

AN ADVICE SHEET FOR PATIENTS WHO HAVE BEEN PRESCRIBED AN ORAL BOWEL CLEANSING AGENT

You have been prescribed an oral bowel cleansing agent (sometimes also called ‘bowel prep’). Its role is to clear out your bowels. This is important to ensure the safety and effectiveness of the planned procedure. There is a risk of developing dehydration, low blood pressure or kidney problems with this medication. The doctor prescribing the oral bowel cleansing agent will have assessed your risk and identified the most appropriate medication for you. You should also have had a blood test to check your kidney function. A number of oral bowel cleansing agents are available. You should refer to the manufacturer’s instructions when taking your preparation. However, the following rules apply in all cases.

The prescribed dose of oral bowel cleansing agent should not be exceeded. The oral bowel cleansing agent should not be taken over a period longer than 24 hours.
Oral bowel cleansing agents predispose to dehydration. You should maintain a good fluid intake whilst taking these medications. If you develop the symptoms of dehydration, and cannot increase your fluid intake, then you should seek medical attention. These symptoms include dizziness or light-headedness (particularly on standing up), thirst, or a reduced urine production.

You should follow any specific advice you have been given with regard to your regular medications. Medications that you may have been asked to temporarily discontinue include:

- **Antihypertensives** (to lower your blood pressure) such as ACE inhibitors like ramipril®.

- **Diuretics** (‘water tablets’, such as furosemide).
- **Non-steroidal anti-inflammatory drugs** (a type of pain killer, such as ibuprofen).

- **Iron preparations** (for anaemia, such as ferrous sulphate).

- **Aspirin, dipyridamole, clopidogrel or warfarin** (these agents thin your blood out; you may have been asked to discontinue them depending on the nature of the procedure that is planned).

If you have not received specific advice regarding your regular medications then you should continue to take them as normal. However, you may need to amend the timing as it is preferable to avoid taking them less than one hour either side of any dose of oral bowel cleansing agent.

Patients taking the oral contraceptive pill should take alternative precautions during the week following taking the oral bowel cleansing agent.

If you experience problem, advice from a healthcare professional is available on (tel no).

ORAL BOWEL CLEANSING AGENT PRESCRIPTION

ORAL BOWEL CLEANSING AGENT PRESCRIPTION CHECKLIST

NAME:
HOSPITAL NO:
DATE OF BIRTH:

STEP 1: ABSOLUTE CONTRAINDICATIONS

GI Obstruction, ileus or perforation	Y/N
Severe IBD	Y/N
Toxic megacolon	Y/N
Reduced conscious level	Y/N
Hypersensitivity to any ingredients	Y/N
Dysphagia (unless via NGT)	Y/N
Ileostomy	Y/N

If yes to any question, do not continue

STEP 2: Review the **BLOOD RESULTS**

Na ……
K ……
eGFR ……

eGFR 30-60 = CKD 3
eGFR 15-29 = CKD 4
eGFR 0-14 = CKD 5

STEP 3: Review **MEDICATIONS**

ACEI/ARB	Y/N	Safe to stop for 72 hrs?	Y/N
Diuretics	Y/N	Safe to stop for 24 hrs?	Y/N
NSAIDs	Y/N	Safe to stop for 72 hrs?	Y/N

STEP 4: Consider CO-MORBIDITIES & RISK FACTORS

Co-morbidities	Optimal	Acceptable	Avoid
Kidney Disease			
CKD 3	PEG/Pico/Mag		OSP
CKD 4	PEG (if fluid status allows)	Pico, Mag	OSP
CKD 5	PEG (if fluid status allows)	Pico	OSP, Mag
Haemodialysis	Discuss with nephrologist		
Peritoneal dialysis	Discuss with nephrologist		
Renal transplant	Discuss with nephrologist		
Electrolyte Imbalance	PEG	Pico, Mag	OSP
Cardiac Failure	PEG	Pico, Mag	OSP
Liver Cirrhosis	PEG	Pico	OSP
Hypertension	PEG/Pico/Mag		OSP

STEP 5: TYPE OF BOWEL PREP ISSUED?
PEG/Pico/Mag/OSP

STEP 6: INSTRUCTIONS PROVIDED TO THE PATIENT
Verbally Y/N
Leaflet Y/N

STEP 7: OTHER COMMENTS

STEP 8:

SIGNATURE ……

KEY: **ACEI** Angiotensin converting enzyme inhibitors, **ARB** Angiotensin-II receptor blockers, **CKD** Chronic kidney disease, **OSP** Oral sodium phosphate preparations (Fleet Phospho-soda), **PEG** polyethylene glycol, **Pico** Sodium picophosphate preparations, **Mag** Magnesium salt preparations

6.9 SEDATION IN ENDOSCOPY

6.9.1 Background.

6.9.1.1 Sedation may be defined as a drug-induced depression in the level of consciousness.

6.9.1.2 The purpose of sedation and analgesia is to relieve patient anxiety and discomfort, improve the outcome of the examination, and diminish the patient's memory of the event.

6.9.1.3 Four stages of sedation have been described, ranging from minimal to moderate, deep, and general anaesthesia (Table 1).

TABLE 1: Levels of Sedation and Anaesthesia

	Minimal sedation (anxiolysis)	**Moderate sedation (conscious sedation)**	**Deep sedation**	**General anaesthesia**
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response after repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

6.9.1.4 Most endoscopic procedures are performed with the patient under moderate sedation (‘‘conscious sedation’’).

6.9.1.5 A patient undergoing deep sedation cannot be easily aroused but may still respond purposefully to repeated or painful stimulation. Airway support may be required for deep sedation.

6.9.1.6 At the level of general anaesthesia, the patient is unarousable to painful stimuli, and cardiovascular function may be impaired. The level of sedation should be titrated to achieve a safe, comfortable, and technically successful endoscopic procedure.

6.9.1.7 Patients may require different levels of sedation for the same procedure and patients may attain varying levels of sedation during a single procedure. Therefore, practitioners should possess the skills necessary to resuscitate or rescue a patient whose level of sedation is deeper than initially intended.

6.9.2 Pre-procedure preparation and assessment.

6.9.2.1 Patients should be informed of and agree to the administration of sedation/analgesia/anaesthesia, including discussion of its benefits, risks, and limitations and possible alternatives.

6.9.2.2 There are no absolute guidelines as to timing of cessation of oral intake before administering of sedation because of the absence of supporting data with regard to a direct relationship between duration of fasting and risk of pulmonary aspiration.

6.9.2.3 Patients should not consume fluids or solid foods for a sufficient period of time so as to permit adequate gastric

emptying but patients should fast a minimum of 2 hours after consuming clear liquids and 6 hours after consuming light meals before the administration of sedation.

6.9.2.4 In situations where gastric emptying is impaired or in emergency situations, the potential for pulmonary aspiration of gastric contents must be considered in determining:

a) The target level of sedation.

b) Whether the procedure should be delayed.

c) Whether the airway should be protected by endotracheal intubation.

6.9.2.5 All patients undergoing endoscopic procedures require pre procedural evaluation to assess the risk of sedation and to manage problems related to pre-existing medical conditions.

6.9.3 Prior to endoscopy:

6.9.3.1 The following historic details should be sought:

- Abnormalities of major organ systems.
- Snoring, stridor, or sleep apnoea.
- Drug allergies, current medications, and potential for drug interactions.
- Prior adverse reaction(s) to sedatives or anaesthetics.
- Time of and type of last oral intake.

- Tobacco, alcohol, or substance use.

6.9.3.2 The physical examination should include:

- Measurement of vital signs.
- Determination of baseline level of consciousness.
- Examination of the heart and lungs and airway anatomy.

6.9.3.3 All women of childbearing age should be queried about the possibility of pregnancy. Pregnancy testing may be considered in women of childbearing age.

6.9.3.4 The pre-procedure assessment should be documented. This includes verification of patient identification and confirmation of the correct procedure by the procedural team.

6.9.4 Unsedated endoscopy.

6.9.4.1 Selected patients may be able to undergo endoscopic procedures without sedation.

6.9.4.2 Topical anaesthesia is used during unsedated endoscopy.

6.9.4.3 Colonoscopy may be performed in selected patients without sedation.

6.9.4.4 Preparation should be the same as described for sedation in the event that sedation is administered.

6.9.5 Topical anaesthesia.

6.9.5.1 Topical pharyngeal sprays with lidocaine are often used for anaesthetic purposes during upper endoscopy, particularly when unsedated endoscopy is performed.

6.9.5.2 Topical anaesthetic agents have been associated with serious adverse effects, including aspiration, anaphylactoid reactions, and methaemoglobinemia.

6.9.6 Sedation and analgesia agents used for endoscopy.

6.9.6.1 The level of sedation required to perform a successful procedure ranges from minimal sedation to general anaesthesia.

6.9.6.2 Patient age, health status, concurrent medications, pre-procedural anxiety, and pain tolerance influence the level of sedation.

6.9.6.3 The procedural variables include the degree of invasiveness, the level of procedure-related discomfort, the need for the patient to lie relatively motionless and the duration of examination.

6.9.6.4 Diagnostic and uncomplicated therapeutic upper endoscopy and colonoscopy are successfully performed with moderate sedation.

6.9.6.5 Deeper levels of sedation may be considered for longer and more complex procedures, including, but not limited to ERCP and EUS.

6.9.6.6 Additionally, deep sedation or general anaesthesia should be considered for patients who have been difficult to manage with moderate sedation and are anticipated to be poorly

responsive to sedatives. (This includes patients who have had long-term use of narcotics, benzodiazepines, alcohol, or neuropsychiatric medications).

6.9.6.7 The choice of sedative is largely operator dependent and is based on maximizing patient comfort while minimizing risks.

6.9.6.8 The choice of sedatives consists of benzodiazepines used either alone or in combination with an opiate.

6.9.6.9 The most commonly used benzodiazepines are midazolam. (fast onset of action, short duration of action, and high amnestic properties).

6.9.6.10 Opioids, such as pethidine and fentanyl administered intravenously, provide both analgesia and sedation.

6.9.6.11 Fentanyl has a more rapid onset of action and clearance and has a lower incidence of nausea compared with pethidine.

6.9.6.12 Combinations of benzodiazepine and opioid agents are frequently used for synergism.

6.9.6.13 Specific antagonists of opiates (naloxone) and benzodiazepines (flumazenil) should be available in every endoscopy unit.

6.9.7 Propofol.

6.9.7.1 Propofol (2, 6-diisopropyl phenol) is an ultra short-acting hypnotic agent that provides sedative, amnestic, and hypnotic effects with no analgesic properties.

6.9.7.2 Propofol rapidly crosses the blood-brain barrier and causes a depression in consciousness.

6.9.7.3 Propofol is contraindicated in patients with propofol allergy or hypersensitivity to eggs or soybean.

6.9.7.4 It is a pregnancy category B drug and should be used with caution during lactation.

6.9.7.5 Propofol is metabolized primarily in the liver, excreted by the kidney.

6.9.7.6 The time from injection to the onset of sedation is 30 to 60 seconds with duration of effect of 4 to 8 minutes.

6.9.7.7 The pharmacokinetic properties do not significantly change in patients with renal failure or moderately severe chronic liver disease.

6.9.7.8 Dose reduction is required in patients with cardiac dysfunction and in the elderly as a result of decreased clearance of the drug.

6.9.7.9 Negative cardiac inotropy and respiratory depression can be seen with the use of propofol. These effects reverse rapidly with dose reduction or interruption of drug infusion and rarely require temporary ventilator support.

6.9.7.10 There is no reversal agent for propofol.

6.9.7.11 Personnel specifically trained in the administration of propofol with expertise in emergency airway management must be present during use of this agent, and the patient's physiologic parameters must be continuously monitored (Table 2).

TABLE 2: Recommendations for Propofol Use During Endoscopy

- A sedation team with appropriate education and training. At least 1 person who is qualified in advanced life support skills (i.e., airway management, defibrillation and the use of resuscitative medications).

- Trained personnel dedicated to the uninterrupted monitoring of the patient's clinical and physiologic parameters throughout the procedure.

- Physiologic monitoring must include pulse oximetry, electrocardiography, and intermittent blood pressure measurement. Monitoring oxygenation by pulse oximetry is not a substitute for monitoring ventilatory function. Capnography should be considered because it may decrease the risks during deep sedation. Continuous monitoring will allow recognition of patients who have progressed to a deeper level of sedation.

- Personnel should have the ability to rescue a patient who becomes unresponsive or unable to protect his or her airway or who loses spontaneous respiratory or cardiovascular function.

- Age-appropriate equipment for airway management and resuscitation must be immediately available.

- An anaesthesiologist should be present throughout propofol sedation and remain immediately available until the patient meets discharge criteria.

6.9.8 Who is qualified to give propofol?

6.9.8.1 The narrow therapeutic window of propofol that distinguishes it from conventional sedative hypnotics used for endoscopy increases the risk for cardiopulmonary complications if it is not administered appropriately.

6.9.8.2 Hence, specific training in the administration of propofol and patient monitoring during use of this agent are required.

6.9.8.3 The appropriate personnel and equipment for propofol administration are listed in Table 2.

6.9.9 Administration of propofol.

6.9.9.1 Initial bolus doses of propofol of 10 to 60 mg are typically administered; additional bolus doses are administered after a minimum interval of 20 to 30 seconds.

6.9.9.2 The amount of dosing and depth of sedation are titrated as appropriate for the procedural goals.

6.9.9.3 Propofol does not possess analgesic properties so deep sedation may be required to keep the patient comfortable.

6.9.9.4 Propofol may be used as the sole sedation agent or in combination with other sedative-hypnotics (multidrug propofol sedation).

6.9.9.5 Precise titration of propofol is possible when lower bolus doses of propofol are used. In addition, the ability to reverse the concomitantly administered opioid and benzodiazepine medications can be maintained with naloxone and flumazenil.

6.9.9.6 When propofol is used alone for sedation, higher doses are typically required to achieve adequate sedation, which results in a level of deep sedation. Thus, dose-related propofol effects including hypotension, respiratory depression, or bradycardia are more likely to occur.

6.9.10 Propofol efficacy/safety for endoscopic sedation.

6.9.10.1 Studies have demonstrated an advantage of sedation with propofol for endoscopy over sedation with an opioid/ benzodiazephine combination for several important outcomes, although there are some disadvantages to its use (Table 3).

6.9.10.2 Data do support that propofol administration is superior to other agents with regard to recovery time and physician satisfaction.

6.9.10.3 Additionally, at discharge, propofol-sedated patients have better scores on psychomotor testing, reflective of greater learning, memory, and mental speed.

6.9.10.4 Similarly propofol use provides similar or higher levels of patient satisfaction.

6.9.10.5 Propofol monotherapy and combination therapy compare favourably with conventional sedative agents with respect to safety.

6.9.10.6 The use of propofol in appropriate patients with trained personnel is associated with an excellent safety profile. Transient hypoxia occurs in 3% to 7% of cases and transient hypotension in 4% to 7%.

6.9.10.7 Time to recovery ranges between 14 and 18 minutes.

TABLE 3: Advantages and Disadvantages of Propofol for Sedation

Advantages

- Rapid onset.
- Favourable pharmacodynamics.
- Mild antiemetic properties.
- Potentially more effective.
- Rapid termination of effect.
- Expedited recovery.

Disadvantages

- Potency.
    - Potential to induce general anaesthesia.
    - Potential to cause hemodynamic and respiratory depression.
    - No pharmacologic antagonist.

6.9.11 Propofol use for complex GI procedures.

6.9.11.1 Propofol may have clinically significant advantages compared with conventional sedative-hypnotic agents when used for prolonged or complex therapeutic procedures where deep sedation is the targeted level of sedation.

6.9.11.2 For complex procedures propofol is comparable in efficacy and safety to conventional sedation.

6.9.12 Intra-procedural monitoring.

6.9.12.1 For both moderate and deep sedation, the level of consciousness must be periodically assessed in addition to documentation of heart rate, blood pressure, respiratory rate, and oxygen saturation.

6.9.12.2 These physiologic parameters should be assessed and recorded.

- Before the procedure is begun.
- After administration of sedative-analgesic agents.
- At regular intervals during the procedure.
- During initial recovery.
- Just before discharge.

6.9.12.3 Equipment and medications for emergency resuscitation should be immediately available when sedation and analgesia are being administered.

6.9.12.4 An individual, other than the physician performing the endoscopy who understands the stages of sedation, has the ability to monitor and interpret the patient's physiologic parameters, and possesses the skills to initiate appropriate intervention in the event of an adverse event should monitor the patient throughout the procedure.

6.9.12.5 This person must be certified in basic or advanced cardiac life support. If deep sedation is undertaken, this individual should have no procedure related responsibilities other than observation and monitoring of the patient. When deep sedation is administered, at least one other person in the room should have advanced cardiac life support certification, be able to provide a secure airway, and be able to provide bag ventilation.

6.9.13 Monitoring techniques.

6.9.13.1 Continuous electrocardiogram (ECG) monitoring recommended in patients with significant cardiovascular disease or arrhythmia during moderate sedation.

6.9.13.2 Other patients who may benefit from ECG monitoring include those with a history of significant pulmonary disease, elderly patients, and those in whom prolonged procedures are anticipated.

6.9.13.3 In addition, all patients receiving intravenous sedation should be monitored with non-invasive blood pressure devices.

6.9.13.4 Oximetry effectively detects oxygen desaturation and hypoxemia in patients undergoing sedation and analgesia.

6.9.13.5 Risk factors for hypoxemia include a baseline oxygen saturation of less than 95%, an emergency indication for the

endoscopic procedure, a procedure of long duration, difficulty with oesophageal intubation, and the presence of co-morbid illness.

6.9.13.6 Administration of supplemental oxygen should be considered for moderate sedation and should be administered during deep sedation unless specifically contraindicated for a particular patient or procedure.

6.9.13.7 Capnography should be considered for all patients receiving deep sedation and for patients whose ventilation cannot be observed directly during moderate sedation.

6.9.13.8 Capnography is a non-invasive measure of respiratory activity and more readily detects hypoventilation compared to pulse oximetry and therefore provides an opportunity for early recognition of depressed respiratory activity.

6.9.13.9 After completion of endoscopic procedures, patients are to be observed for adverse effects from either instrumentation or sedation. Standardized discharge criteria should be used to assess recovery from sedation.

6.9.14 Anaesthesiologist assistance for endoscopic procedures.

6.9.14.1 Sedation-related risk factors, the depth of sedation, and the urgency and type of endoscopic procedure play important roles in determining whether the assistance of an anaesthesiologist is needed.

6.9.14.2 Patient risk factors include significant medical conditions such as extremes of age; severe pulmonary, cardiac, renal, or hepatic disease; pregnancy; the abuse of drugs or alcohol; uncooperative patients; a potentially difficult airway for

positive-pressure ventilation; and individuals with anatomy that is associated with more difficult intubation.

6.9.14.3 Airway management may be difficult in patients with the following situations:

- Previous problems with anaesthesia or sedation.
- A history of stridor, snoring, or sleep apnoea.
- Dysmorphic facial features, such as Pierre-Robin syndrome or trisomy 21.
- Oral abnormalities, such as a small opening (<3 cm in an adult), edentulous, protruding incisors, loose or capped teeth, high arched palate, macroglossia, tonsillar hypertrophy, or a non visible uvula.
- Neck abnormalities, such as obesity involving the neck and facial structures, short neck, limited neck extension, decreased hyoid-mental distance (<3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, or advanced rheumatoid arthritis.
- Jaw abnormalities such as micrognathia, retrognathia, trismus, or significant malocclusion.

6.9.14.4 The presence of one or more sedation-related risk factors coupled with the potential for deep sedation will require consultation with an anaesthesiologist to provide sedation (Table 4).

TABLE 4: Guideline for Anaesthesiology Assistance During GI Endoscopy

Anaesthesiologist assistance may be considered in the following situations:

- Prolonged or therapeutic endoscopic procedures requiring deep sedation.
- Anticipated intolerance to standard sedatives.
- Increased risk for complication because of severe comorbidity (ASA greater than class III).
- Increased risk for airway obstruction because of anatomic variant.

6.9.15 Recommendations (with grade of recommendation)

6.9.15.1 Adequate and safe sedation can be achieved in most patients undergoing routine OGDS and colonoscopy by using an intravenous benzodiazepine and opioid combination (1B).

6.9.15.2 Sedation providers must have a thorough understanding of medications used for endoscopic sedation and the skills necessary for the diagnosis and treatment of cardiopulmonary complications (3).

6.9.15.3 Non-invasive blood measurement and pulse oximetry are supplemental to and do not replace clinical observation of the patient during endoscopic sedation (2B).

6.9.15.4 When deep sedation is planned, this individual should be dedicated to observation and monitoring and have no other procedure-related responsibilities (3).

6.9.15.5 Extended monitoring techniques may provide sensitive measures of patient's ventilatory function (capnography) and level of sedation; Automated monitoring for apnoea (capnography) should be considered for patients receiving deep sedation and for all patients in whom ventilatory function cannot be observed adequately (1B).

6.9.15.6 Propofol has the advantages of more rapid onset of action and shorter recovery time compared with traditional sedative regimens. However, clinically important benefits in average-risk patients undergoing upper endoscopy and colonoscopy have not been consistently demonstrated. Therefore, the routine use of propofol in average-risk patients cannot be endorsed (1B).

6.9.15.7 Propofol can be safely and effectively given by non-anaesthesiology physicians and nurses provided they have undergone appropriate training and credentialing in administration and rescue from potential pulmonary and cardiovascular complications (1C).

6.9.15.8 A patient targeted for one level of sedation may become more deeply sedated than planned. Therefore, an individual administering sedation/analgesia should be trained to and possess the skills necessary to rescue a patient who has reached a level of sedation deeper than that intended. Thus, a physician targeting moderate sedation must be able to rescue a patient who is deeply sedated. Similarly, an ability to rescue a patient from general anaesthesia is necessary when providing deep sedation (3).

6.9.15.9 The assistance of an anaesthesia specialist should be considered for ASA physical status III, IV, and V patients. Other possible indications for involvement of an anaesthesia professional during sedation include emergency endoscopic procedures, complex endoscopic procedures, and patients with a history of (1) adverse reaction to sedation, (2) inadequate response to moderate sedation, (3) anticipated intolerance of standard sedatives (e.g., alcohol or substance abuse), and (4) those at increased risk for sedation-related complications, such as patients with severe comorbidities or with anatomic variants predictive of increased risk for airway obstruction or difficult intubation (e.g., morbid obesity or sleep apnoea) (3).

6.9.15.10 An anaesthesia specialist is not required for average-risk patients undergoing routine upper and lower endoscopic procedures (3).

SEDATION AND ANALGESIA

DRUG	DOSE	COMMENTS
Midazolam	Initial dose: 0.5-2 mg iv	▪ Sedative/hypnotic ▪ Non analgesic ▪ Induces amnesia ▪ Good for prolonged sedation; may result in very prolonged sedation, particularly in the elderly ▪ Increase the risk of respiratory depression when in association with opioid ▪ Maximum effect at 3-5 minutes after administration ▪ Duration of effect: 1-3 hours ▪ Side-effects: respiratory depression, hypotension
Pethidine	Initial dose: 20-50 mg iv	▪ An analgesic opioid with mild sedative effect ▪ Maximum effect: at 10 minutes after administration ▪ Duration of effect: 2-3 hours ▪ Side effects: respiratory depression, hypotension, nausea, vomiting
Propofol	Initial dose: IV infusion 25 mcg/kg/min Bolus: initial 0.5 mg/kg Repeat doses: 0.25-0.50 mg/kg Mean use of 200-400 mg in 30 minutes procedures	▪ Short-acting sedative, amnestic and hypnotic drug with minimal analgesic effect ▪ Maximum effect: 30-60 seconds after administration ▪ Half-life: 1.8-4.1 minutes ▪ Side-effects: pain in injection site, respiratory depression, hypotension-collapse, acute pancreatitis, anaphylactic shock in allergies to soy and eggs ▪ Care in hypovolaemia ▪ Rapid recovery

Fentanyl	Initial dose: 50-100 mcg iv Dose: 25-50 mcg, repeated after 3-5 minutes if necessary, maximum of 100 mcg	▪ An analgesic opioid with mild sedative effect ▪ Rapid onset of effect ▪ Rapid recovery ▪ Maximum effect: 5-8 minutes ▪ Duration of effect: 1-3 hours ▪ Side effects: respiratory depression ▪ Less accumulation in renal failure
Flumazenil	Initial dose: 0.2 mg iv over 15 sec. If after 45 sec, no response, administer 0.2 mg again over 1 min; may repeat at 1 min intervals; not to exceed total dose of 1 mg	▪ Reverse benzodiazepine-induced sedation ▪ Doubtful or late efficacy in reversing benzodiazepine-induced respiratory depression ▪ Maximum effect: 3-5 minutes ▪ Duration of effect: 1-2 hours ▪ Side-effects: re-sedation, seizures
Naloxone	0.4–4 mg IV initial dose Repeat q2–3 min PRN; not to exceed 0.01 mg/kg	▪ Reverses opioid-induced analgesia, opioid effects on the CNS, and respiratory depression ▪ Maximum effect: 1-2 minutes ▪ Duration of effect: 1-3 hours ▪ Side-effects: pain, agitation, nausea, vomiting, tachycardia, arrhythmias, lung oedema, deprivation syndrome, renarcotization

6.10 INFECTION CONTROL IN GI ENDOSCOPY

6.10.1 CLEANING AND DISINFECTION

6.10.1.1 Introduction.

a) Quality assurance in GI endoscopy mandates the appropriate reprocessing of endoscopes and accessories. In addition to other procedure-related risks, the risk of infection due to endoscopic procedures has always to be taken into consideration. Endoscope-associated infections risks are categorized as follows:

- Endogenous infection.

- Exogenous infection caused by inadequately reprocessed equipment. (Endoscopes and accessories can be vehicles for pathogens or facultative microbes that are transmitted from previous patients).

- Risks of infection to endoscopy staff.

b) Microorganisms may be spread by inadequately reprocessed equipment, from one patient to another, or from patients to staff. All patients should be considered potentially infectious. This guideline aims to set the standards for the reprocessing of endoscopes and endoscopic devices prior to each procedure. It will focus on flexible endoscopes and accessories used in gastrointestinal endoscopy.

6.10.1.2 Definitions.

a) **Automated Endoscope Reprocessor (AER)** refers to machines designed for the purpose of cleaning and disinfecting endoscopes and accessories. Meticulous manual cleaning must precede the use of AERs. AERs are also known as washer-disinfectors.

b) **Biofilm** refers to a matrix of different types of bacteria and extracellular material that can tightly adhere to the interior surfaces of endoscopes.

c) **Clean conditions:** Conditions where surfaces have been cleaned satisfactorily and/or known to contain minimal levels of organic and/or inorganic substances.

d) **Detergent:** A compound, or a mixture of compounds, intended to assist cleaning.

e) **Dirty conditions:** Conditions where surfaces are known to or may contain organic and/or inorganic substances.

f) **Disinfectants:** Antimicrobial agents that are applied to non-living objects to destroy microorganisms.

g) **Disinfection:** Reduction of the number of viable microorganisms on a device by irreversible destruction, to a level appropriate for safe use on a patient, where sterilization of the device is not necessary. Disinfection is a prerequisite to sterilization. Disinfection is carried out immediately after cleaning.

h) **Endoscope** refers a tubular instrument used to examine the interior of the hollow viscera. In this document, endoscope refers only to flexible gastrointestinal endoscopes.

i) **Endoscopic accessories**: All devices used in conjunction with an endoscope to perform diagnosis and therapy.

j) **Enzymatic detergent** refers to low-foaming detergents which add enzymes capable of digesting organic material such as blood and mucous.

k) **High-level disinfectant (HLD)** refers to a chemical germicide capable of destroying all microorganisms including viruses, vegetative bacteria, fungi, mycobacterium and some, but not all, bacterial spores.

l) **Material Safety Data Sheet (MSDS)** refers to a descriptive sheet that accompanies a chemical or chemical mixture and provides information regarding the identity of the material; physical hazards, such as flammability; and acute and chronic health hazards associated with contact with or exposure to the compound.

m) **Minimum effective concentration (MEC)** refers to the lowest concentration of active ingredient necessary to meet the label claim of a reusable high-level disinfectant/sterilant.

n) **Reprocessing** refers to the process of cleaning and disinfecting endoscopes and accessories.

o) **Reusable accessories**: Reusable accessories should be sterilized. Sterilization is carried out after cleaning. Manufacturers provide validated standard reprocessing

parameters (e.g., temperature and time) for cleaning, disinfection, and sterilization.

p) **Reuse life** refers to the maximum number of days a reusable high-level disinfectant / sterilant might be effective.

q) **Single-use accessories:** Also called “disposable” accessories. These are provided sterile, ready for use. The opening of a sterile package implies immediate use. After a single-use device has been employed, all materials should be appropriately disposed of. Under no circumstances should a single-use device be processed.

r) **Standard operating procedures (SOPs):** Describe each step of the reprocessing process in detail including:

- What manual handling processes must be carried out in each individual step in the correct sequence?
- Who should carry out these steps?
- Which tools must be used?
- Which process chemicals must be applied and under what conditions, e.g., of concentration, temperature, contact time?

s) **Sterilant** refers to a chemical germicide capable of destroying all microorganisms, including all bacterial spores.

t) **Sterile** refers to the state of being free from viable microorganisms.

u) **Sterilization** refers to a process resulting in the complete elimination or destruction of all forms of microbial life including bacterial spores. The Spaulding classification identifies sterilization as the standard for medical devices

(e.g., biopsy forceps) that enter the vascular system or sterile tissue.

v) **Surfactant** is a substance that has both a hydrophilic group and a hydrophobic group. Surfactants are a broad class of molecules that function to bind and lift soil. They may be natural such as soap (anionic) or synthetic, derived from petroleum products. Some types of surfactants serve as wetting agents to lower the surface tension of the cleaning solution.

w) **Washer-disinfectors:** Washer-disinfectors are intended to clean and disinfect medical devices, e.g., flexible endoscopes, within a closed system.

Table 1: Potential Weaknesses and Deficiencies in Endoscope Reprocessing (ESGE-ESGENA Guideline)

a. Inadequate reprocessing of endoscopes and accessories

- Inadequate cleaning (e.g., inadequate manual cleaning and brushing of endoscope channels).
- Contaminated cleaning accessories (e.g., cleaning brushes).
- Use of unsuitable or incompatible detergents and disinfectants.
- Inadequate concentrations, contact time of agents and temperature.
- Contaminated or time-expired solutions.
- Contaminated rinsing water.
- Fixed organic material in endoscopes or washer-disinfectors.
- Use of nonsterile accessories in invasive diagnosis and treatment (e.g., nonsterile biopsy forceps, polypectomy snares).
- Inadequate reprocessing of water bottles (e.g., no sterilization).
- Use of tap water in water bottles.

b. Inadequate transport and storage of endoscopes

- Insufficient drying before storage (resulting in Pseudomonas infection).
- Inappropriate storage conditions.

c. Contaminated or defective washer-disinfector

- Contaminated pipes, containers, etc.
- Contaminated final rinsing water.
- Biofilms in water pipes, containers or washer-disinfectors.
- Mechanical/electronic defects of washer-disinfector.
- Incorrect use of washer−disinfector (e.g. wrong connections).
- Incorrect or inadequate load (i.e. bottles, flasks).
- Lack of regular maintenance of washer-disinfector according to manufacturer’s recommendations.
- Lack of self-disinfection cycle run.

d. Design limitations and damaged endoscopes

- Small lumina and branched channels not accessible to cleaning brushes.
- Damage to the surfaces (internal and external) of the endoscope, providing potential for contamination.

e. Contaminated water in the endoscopy unit

- Contaminated mains water pipes/supply.
- Contaminated or inadequate water supply systems (filtration etc.).

f. Contaminated ultrasonic cleaner

g. Insufficient drying and storage

h. Shortcuts due to insufficient number of endoscopes and/or reprocessing resources for the clinical workload

6.10.1.3 Principles of Infection Control.

a) As the carrier status of patients is often unknown:
   - All patients should be treated as potentially infectious.
   - All endoscopes and accessories should be reprocessed following every endoscopic procedure, using a uniform, standardized reprocessing protocol.

b) Patients undergoing digestive endoscopy should be examined and treated without the risk of transmission of infection or side effects that may result from inadequate reprocessing of endoscopic equipment.

c) Regular quality control and the institution's adherence to validated reprocessing procedures is the responsibility of both endoscopists and clinical service providers and should be monitored by the hospital-based infection control department.

d) Infection control in endoscopy includes:
   - Cleaning, disinfection, and sterilization of medical equipment.
   - Correct use of personal protective equipment.
   - Personal hygiene.
   - Engineering controls (ventilation, building design, clean water supply).
   - Cleaning, disinfection of environmental surfaces.
   - Adequate administrative control and support.
   - Training and continuing education.
   - Adequate written standardized operating procedures (SOPs).
   - Documentation.

e) Flexible endoscopes are complex instruments which require thorough reprocessing before use on patients. Failure to adhere to reprocessing guidelines is a factor that may cause bacterial and viral transmission.

f) Dr. Earl Spaulding developed a classification system that divides medical instruments into categories based on the risk of infection involved in their use. The Spaulding classification is as follows:

- Critical: devices that enter normally sterile tissue or the vascular system and should be sterilized, such as reusable biopsy forceps, laparoscopes, percutaneous cholangioscopes.
- Semi-critical: devices that come into contact with intact mucous membranes and do not ordinarily penetrate sterile tissue. These devices (e.g., endoscopes) should receive a minimum of high-level disinfection, defined as the destruction of all vegetative bacteria, viruses and fungi, immediately before use.
- Non-critical: devices that come into contact with only intact skin and do not ordinarily touch the patient and should receive low-level disinfection or cleaning. Examples of non-critical devices are such as, blood pressure cuffs, stethoscopes etc.

g) Endoscopes are considered as semi-critical items and should be reprocessed by at least using a high-level disinfectant approved by the FDA. Complex endoscope design features may allow organic debris and microorganisms to accumulate, making manual cleaning essential. Biofilm formation may harbour microorganisms, making strict and meticulous adherence to reprocessing guidelines imperative in order to prevent cross-contamination between patients and hospital-

acquired infections. Prompt efficient cleaning processes are the best defence against biofilm formation.

h) A department-specific policy on infection control must be available. The following topics are infection control standards that all healthcare professionals must adhere to:

- Health and safety of endoscopy personnel

i. Contamination-related hazards come in two forms:
   - From cross-infection from patients or equipment.
   - From chemicals used in cleaning and disinfection.

ii. Micro-organisms may also be transmitted directly from patients to endoscopy personnel. Therefore protection from direct contact with contaminated endoscopes, accessories and body fluids is essential .Protection against chemicals used for reprocessing is of the utmost importance to avoid toxic and allergic reactions.
   - Personnel assigned to reprocess endoscopes must be well trained in the technique of endoscope reprocessing. These personnel must adhere to infection control principles.
   - Competency testing of personnel reprocessing endoscopes should be done on a regular basis. Temporary personnel should not be allowed to reprocess endoscopes until competency has been established.
   - All personnel who use chemicals should be educated about the biologic and chemical hazards present while performing procedures that use disinfectants.

- Personal protective equipment.

  i. Personal protective equipment such as gloves, gowns (long-sleeved, moisture-resistant), eyewear (protective glasses), respiratory protection devices (face masks), and protective full-face visors should be readily available and should be used, as appropriate, to protect staff from exposure to chemicals, blood, or other potentially infectious material.

  ii. A department-specific policy covering spillages chemicals, detergents and body fluids should be available. This policy should cover sharps and contaminated devices.

  iii. Staff known to be disease carriers should avoid duties that could potentially transmit their disease to patients.

  iv. Regular health surveillance for staff is recommended.

  v. Staff should be vaccinated against hepatitis B.

- Reprocessing room.

  i. There must be a designated and dedicated area for reprocessing of endoscopes.

  ii. The reprocessing room should be designed to provide a safe environment for healthcare personnel and patients. Air exchange equipment e.g., ventilation system with exhaust hoods should be used to minimize the exposure of all persons to potentially toxic vapours.

iii. The reprocessing room must be purpose built consisting of a clean and dirty area. There should be filtered water for use during the cleaning process.

- Reprocessing standards.

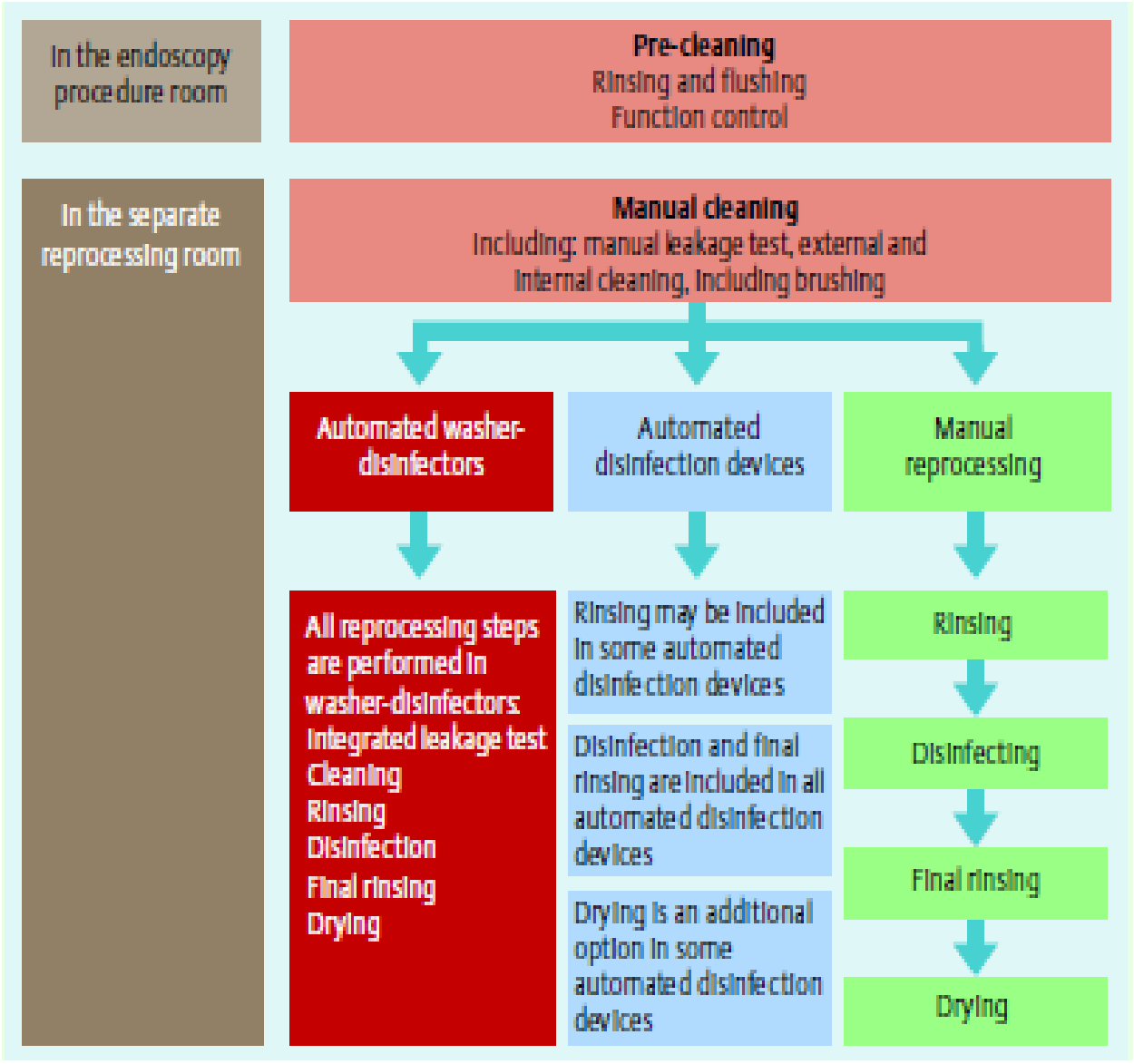
i. All healthcare personnel should be trained, understand and adhere to standard reprocessing guidelines. Always consult the endoscope manufacturer's instructions related to the unique design of a particular endoscope, which may require specific reprocessing procedures.

ii. Endoscope reprocessing should be performed as soon as possible after use, after removal of the insertion tube from the patient and prior to disconnecting from the power source.

iii. Endoscopic reprocessing comprises the following steps:
    - Pre-cleaning. Immediately after use, macroscopically visible dirt is removed from external surfaces and the interior of scope channels.
    - Leak testing.
    - Manual cleaning. This consists of the manual cleaning of external surfaces and the interior of scope channels, including brushing.
    - Rinsing. This is the removal of residual cleaning process chemicals that may interfere with the following disinfection stage.
    - Disinfection. All microorganisms are reduced to such a level that they will not harm future patients.

- Rinsing. A further rinse removes the chemical load from the instruments/scopes which have been disinfected.
- Drying. Internal and external surfaces are dried to avoid growth of waterborne microorganisms.
- Storage. Endoscopes are stored in a safe and closed cupboard.

Figure 1: Different Methods for Reprocessing Endoscopes



- Pre-cleaning in the endoscopy room.

i. Immediately after removing the endoscope from the patient, wipe the insertion tube with the wet gauze soaked in the freshly prepared detergent solution or wipes. Check for bite marks or other surface irregularities.

ii. Place the distal end of the endoscope into the detergent solution. Suction the solution through the biopsy/suction channel, alternate suctioning detergent solution and air several times until the solution is visibly clean. Finish by suctioning air.

Note that:

- Alternate suctioning of fluid and air is more effective in the removal of debris from internal lumens.
- Immediate flushing of the biopsy/suction and air/water channels precludes drying of organic and inorganic debris on lumen surfaces and may remove large numbers of microorganisms.

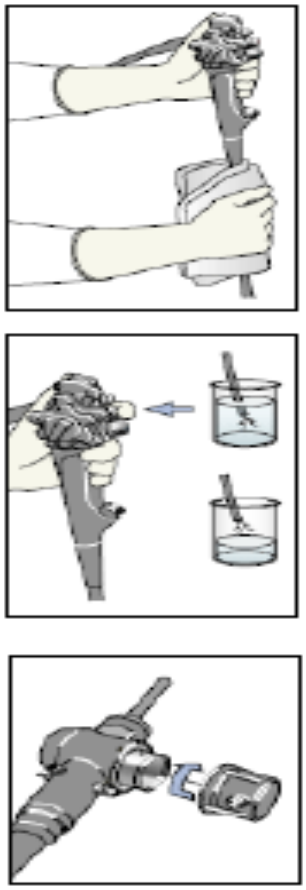
iii. Remove the air-water valve; connect the air-water channel cleaning adapter to the air-water port for continuing flushing and blowing the air and water channel in accordance with the endoscope manufacturer's instructions.

iv. Detach the endoscope from the light source and suction pump.

v. Attach water resistant cap.

vi. Transport the endoscope in a closed container to the reprocessing room.

Pre-cleaning



- <u>Leak testing in the reprocessing room.</u>

  - Perform leak testing after each use according to the manufacturer's instructions. Leak testing is performed before immersion of the endoscope in cleaning solutions in order to minimize damage to parts of the endoscope not designed for fluid exposure.

  - The leak testing procedure will detect any damage to the endoscope. If there is no leakage, continue with manual cleaning. If a leak is detected the reprocessing procedure must be interrupted immediately and repair of the endoscope initiated.

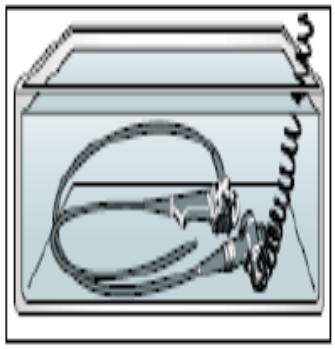
    ✓ Remove all detachable valves.

- ✓ Attach the leakage tester to the maintenance unit and check air to make sure that it is functioning well.
- ✓ Attach the end of the leakage tester flexible tube to the venting connector on the water resistant cap, turn on the air pump to pressurize the scope (expanding of the A-rubber) before submerging it in the water (refer to specific manufacturer's instructions for different brands of endoscope and leakage tester).
- ✓ With the pressurized insertion tube completely submerged, flex the distal portion of the scope in all directions, observing for bubbles. Submerge the entire endoscope and, observing the control head of the scope, depress the freeze and release buttons. Check the insertion tube and distal bending section as well as the universal cord for bubbles coming from the interior of the scope.
- ✓ If continuous bubbling is seen, this indicates a leak. Remove the endoscope from the water immediately. Turn off the maintenance unit. Send for repair.
- ✓ If no leak is detected, remove the endoscope from water, turn off the maintenance unit then disconnect the leakage tester. After the A-rubber returns to normal, disconnect the leakage tester. Continue with manual cleaning.

Note:

- ➢ Do not turn off the maintenance unit if the endoscope is still in the water especially if leakage is found.
- ➢ Do not attach or remove the leakage tester while under water.

Leak Test



- Manual cleaning in the reprocessing room.

i. Cleaning is the essential and most important step in endoscope reprocessing. Manual cleaning must always be performed before manual or automated disinfection.

ii. The purpose of cleaning is to remove all inorganic material from the internal and external surfaces of flexible endoscopes. Without proper cleaning, protein debris can harden and cause biofilm formation on the biopsy channel of the endoscope. Protein debris remaining on the endoscope surface prevents disinfection and sterilization fluids or gases reaching all parts of potentially contaminated surfaces. As a consequence, transmission of infectious organisms may occur upon reuse of the endoscope.

   - Immerse the endoscope in a sink filled with a freshly-made solution of water and a medical grade, low-foaming, neutral pH detergent formulated for endoscopes.
   - Dilute and use detergent according to the detergent manufacturer's instructions. Detergent solutions with antimicrobial activity should be freshly prepared at least on a daily basis.

Detergents without antimicrobial activity should be single use only.

Note:

- Freshly prepared detergent solution should be used for each endoscope to prevent cross-contamination.
- Low-foaming detergents are recommended such that the device can be clearly visualized during the cleaning process, preventing personnel injury and allowing for complete cleaning of luminal surfaces. Excessive foaming can inhibit good fluid contact with the device surfaces.

- Wash all debris from the exterior of the endoscope by using a piece of gauze.

- Use a channel opening brush to clean all removable parts, including inside and under the suction valve, air/water valve, and biopsy port cover and openings.

- Brush all accessible endoscope channels with a channel cleaning brush at least three times or until there is no visible debris on the brush.
- After each passage, rinse the brush in the detergent solution, removing any visible debris before retracting and reinserting it.

- Attach the endoscope manufacturer's cleaning adapters for suction, biopsy, air-water channels, and specific cleaning adapters for special

endoscope channels (e.g., elevator channel, auxiliary channel and double-channel scopes). Flush all channels with the detergent solution to remove debris.

- Flush all lumens to remove organic material. Use a 2 to 5 ml syringe to flush the elevator channel and auxiliary channel. All auxiliary water channels, wire channels and balloon inflation channels have to be cleaned according to manufacturer's instructions.

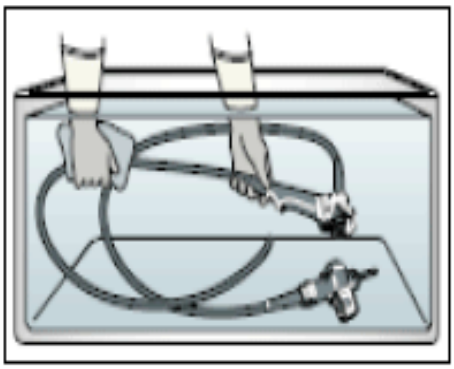
- Soak the endoscope and its internal channels for the period of time recommended by the manufacturer.

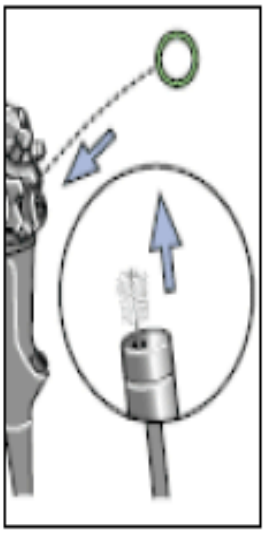
- For ultrasonic cleaning of endoscopic accessories it is recommended that the same detergent as for manual cleaning be used.

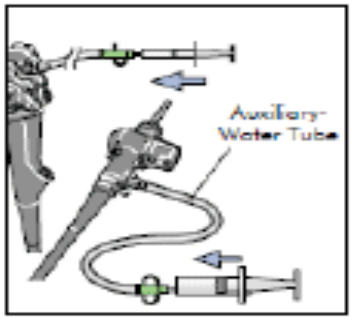
Note:

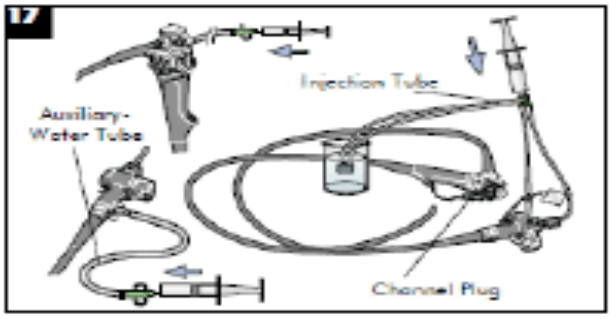
- Clean and high-level disinfect reusable brushes between cases. Note that reusable brushes should be inspected between use and replaced when worn, frayed, bent, or otherwise damaged. Worn bristles are ineffective in cleaning and damaged brushes may damage endoscope channels.

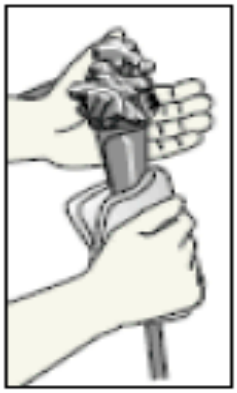
Manual Cleaning and Rinsing











- Rinsing.

i. Rinse the endoscope and valves under running tap water of drinking-water quality.
ii. Immerse the endoscope and irrigate all channels.
iii. Discard the rinsing water after each use to avoid concentration of the detergent and the risk of reduced efficacy of the disinfectant solution.
iv. Clean and rinse the container before the next procedure.

- Disinfection.

  i. Disinfection should be carried out immediately after cleaning.
  ii. Failure to adhere to disinfection guidelines is a major contributing factor in transmission of infections.
  iii. The disinfection process can eliminate most pathogenic microorganisms except bacterial spores. Its efficacy is affected by factors which include:
    - Prior cleaning of the endoscope.
    - Presence of organic and inorganic load.
    - Type and level of microbial contamination.
    - Concentration of the germicide and disinfection time.
    - Presence of biofilms.
    - Temperature and pH of the germicide used.
  iv. The disinfectant solution should be tested at least every day for efficacy using the manufacturer's test strip.
    - Immerse the endoscope and valves in a disinfectant solution of proven efficacy (e.g., the aldehyde group, i.e. glutaraldehyde (GA), orthophthalaldehyde (OPA) or the oxidizing substances including peracetic acid and its salts).
    - Irrigate all channels with a syringe until air is eliminated to avoid dead spaces. Follow the manufacturer's recommendation for the contact time with the solution.
    - Remove the disinfection solution by flushing air before rinsing.

Table 2: Advantages and Disadvantages of Glutaraldehyde

Advantages	Disadvantages
▪ In-use solution stable for 14 days (28 days for one product) (product-specific data). ▪ Excellent compatibility with materials; does not damage.	▪ Slow action against bacterial spores and mycobacteria at 25°C. ▪ Sensitizing, irritant to skin, eyes and respiratory tract; stains skin; ventilation is recommended. ▪ Adverse effects for patients after insufficient rinsing of devices. ▪ Fixative tends to create residue film; thorough cleaning is essential. ▪ Environmental health and safety measures are expensive.

Table 3: Advantages and Disadvantages of Orthophthalaldehyde (OPA)

Advantages	Disadvantages
▪ In-use solution is stable for 7-14 days. ▪ Excellent compatibility with materials; does not damage.	▪ Slow action against bacterial spores. ▪ Irritant to eyes and respiratory tract; stains skin; ventilation is recommended. ▪ Little data on hazards of long-term exposure and on safe exposure levels. ▪ “Anaphylaxis−like” reactions after repeated use have been reported in other endoscopy application areas. ▪ Little data on fixation behaviour.

Table 4: Advantages and Disadvantages of Peracetic Acid (PAA)

Advantages	Disadvantages
▪ Fast high level disinfection and sporicidal activity. ▪ Preferably single-shot use. ▪ Depending on formula, in-use solutions are stable for 1-14 days. ▪ Environmentally friendly substance. ▪ No chemical cross-linking of protein residues.	▪ Depending on pH value, irritant to skin, eyes and respiratory tract; strong odour of vinegar; ventilation is recommended. ▪ Material compatibility depends on the pH value and temperature; endorsement of compatibility with endoscopes and processor is required. ▪ Acid-related coagulation of proteins is possible, depending on pH value.

Table 5: Advantages and Disadvantages of Chlorine Dioxide

Advantages	Disadvantages
▪ Fast high level disinfection and sporicidal activity. ▪ In-use solution stable for 7-14 days.	▪ Irritant to skin, eyes, and respiratory tract; strong odour of chlorine; ventilation is recommended. ▪ Damage to endoscopes has been reported; endorsement of compatibility with endoscopes is required (an additional coating might be required with some types of endoscopes-manufacturer- specific). ▪ Waste water restriction for chlorine compounds in some countries.

Table 6: Advantages and Disadvantages of Reprocessing in Washer-Disinfectors

Advantages	Disadvantages
▪ High level of standardization in reprocessing. ▪ Low risk of either patient or staff infection. ▪ Complete documentation. ▪ Full compatibility with latest European norms. ▪ Economic use of chemicals and other resources. ▪ More user−friendly. ▪ More reliable. ▪ Regular validation of full process will increase reliability. ▪ Separation between clean/dirty areas.	▪ High cost. ▪ Dedicated user skills and knowledge still required. ▪ More complexity and more training required. ▪ Without regular maintenance there is a risk of infection.

Table 7: Advantages and Disadvantages of Reprocessing in Automated

Advantages	Disadvantages
▪ Low purchase costs compared with washer-disinfectors. ▪ Lower workload compared with full manual reprocessing.	▪ Lack of standardization of manual cleaning. ▪ In case of reuse of disinfectant, efficacy problems and cross-contamination need to be considered. ▪ Increased workload of routine testing (i.e., disinfectant efficacy testing). ▪ Traceability and documentation

	is more time-consuming. ▪ More complexity and more training required. ▪ Without regular maintenance there is a risk of infection.

Disinfection Devices

Table 8: Advantages and Disadvantages of Manual Reprocessing

Advantages	Disadvantages
▪ Easy to establish without any major investments.	▪ Validation not possible, but standardization for all reprocessing steps is possible. ▪ Staff exposure to process chemicals. ▪ Increased workload, because staff are involved in each reprocessing step. ▪ In case of reuse of disinfectant, efficacy problems can be expected. ▪ Traceability and documentation is more time consuming. ▪ Increased risk of infection and re-contamination.

- Final rinsing.

  i. Rinse the endoscope and valves under running filtered water.
  ii. Immerse the endoscope and irrigate all channels.
  iii. Discard the rinsing water after each use to avoid concentration of the disinfectant and thus damage to mucosa.

- Drying.

  i. The drying process is important to prevent growth of microorganisms during storage.
  ii. It should be performed after each processing cycle and not just before storage as to prevent bacterial transmission and nosocomial infection.
  iii. The final drying step greatly reduces the possibility of recontamination of the endoscope with waterborne microorganisms.
    - Ensure correct final drying before storage.
    - Flush the channels with 70-90% ethyl alcohol or isopropyl alcohol (at the end of the list).
    - Dry with compressed filtered air.

- Storage.

  i. Hang the endoscope vertically with the distal tip hanging freely in a clean, well-ventilated, dust-free storage cupboard.

  Note:

  - A storage cupboard with good ventilation system will encourage continued air drying of the endoscope surfaces, and prevent undue moisture

build-up, thus discouraging any microbial contamination.

- Padding the lower portion of the storage cupboard with non-porous material may prevent damage to the distal end of the scope.
- Correct storage will prevent damage to the external surfaces of the endoscope.

ii. Ensure the valves are dry and lubricate if necessary and store separately.

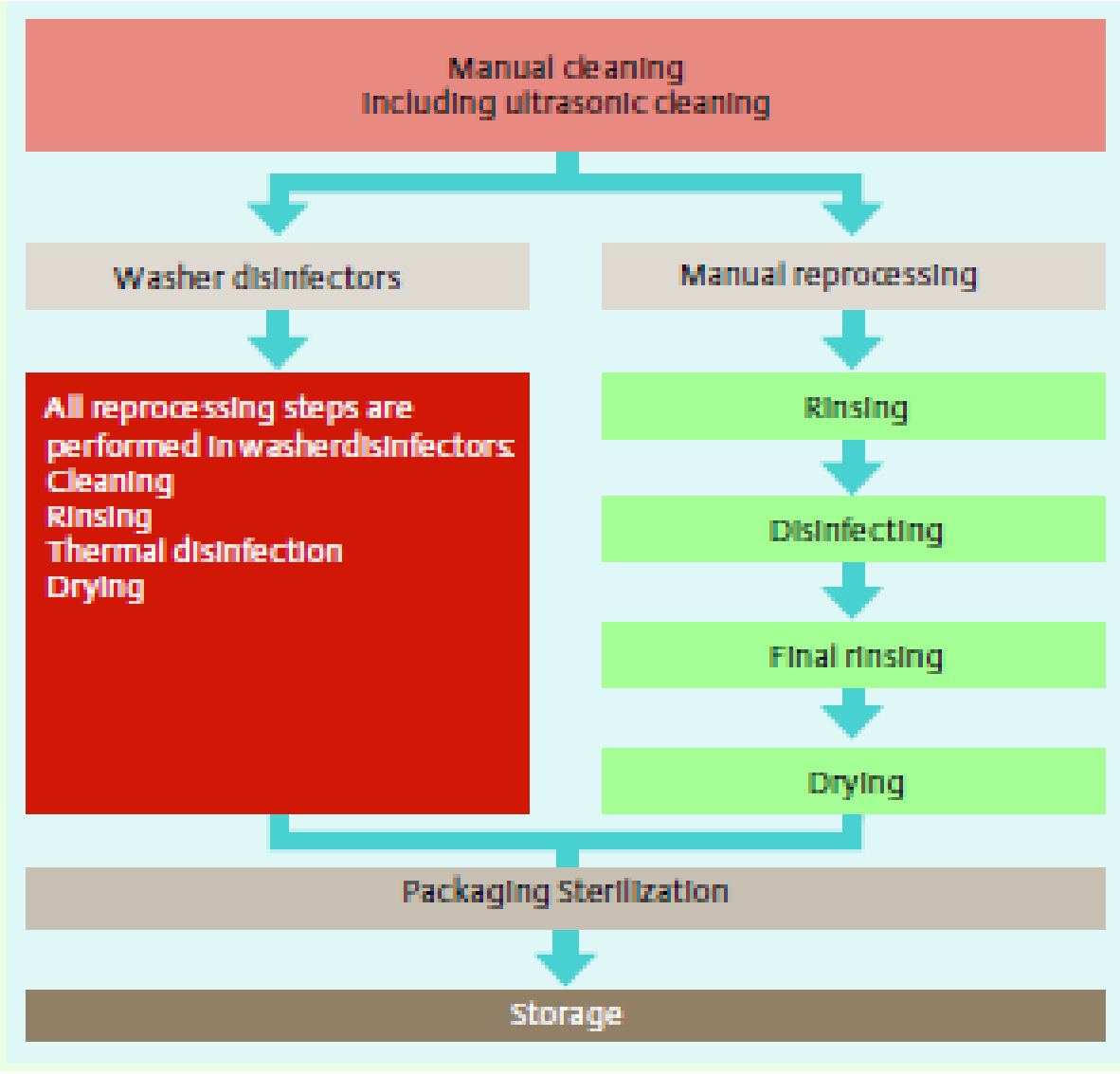
- Automated endoscope reprocessors (AERs).

i. Manual cleaning is the essential step in cleaning and disinfection of flexible endoscope before using the automated reprocessor. The AER is useful as it can standardize the endoscope reprocessing process and reduce personnel exposure to the chemical used for disinfection.
ii. When using the AER, the staff must ensure that all manufacturers' instructions are adhered to.
iii. A copy of work instruction on how to use the AER must be available for reference in the endoscopy unit. All staff involved in using the reprocessor must have easy access of the work instructions.
iv. Drying and storage are the same as described in manual disinfection.
v. They must be cleaned and maintained on a daily basis.
vi. They must have regular maintenance and regular microbiological surveillance.

- Outbreak management.

  i. If any contamination is found it is the responsibility of the clinical service provider to take the suspect piece of equipment out of service.

Figure 2: Reprocessing of Endoscopic Accessories



Appendix 1: Manual Cleaning of Flexible Endoscopes

Step 1: Pre-cleaning.

Before the endoscope is detached from the light source and/or video processor:

- Suck detergent through the working channel (minimum 250ml).
- Ensure that the working channel is not blocked.
- Flush the air/water channel with water from the water bottle.
- Use rinsing valves if available.
- Wipe down the insertion tube with a soft, disposable cloth/ sponge.
- Check the outer surface of the endoscope for any damage.
- Detach the endoscope from the light source and/or video processor.
- Transport the endoscope in a closed system to the reprocessing room.

All further reprocessing steps must be performed in the reprocessing room.

Step 2: Leakage test.

- Dismantle all detachable parts of the endoscope, e.g., suction valves and air/water valves, distal caps and water bottle inlets.
- Attach a soaking cap if necessary.
- Before starting the cleaning step, perform the leakage test according to manufacturer's instructions in order to check the inner and outer surfaces of the endoscope for any damage.

Note: If the leakage test is positive, the reprocessing procedure must be interrupted immediately and repair of the endoscope must be initiated.

Step 3: Manual cleaning.

- Immerse the endoscope completely in water with detergent.
- Fill all channels with cleaning solution. Use the endoscope-specific adapters to ensure complete filling/rinsing with detergent.
- Clean all external surfaces, valve ports, and channel openings, using a soft, disposable cloth/sponge, and brushes. The distal end is brushed with a soft toothbrush and special attention is paid to the air/water outlet nozzle and the bridge/elevator where fitted.
- Brush all accessible channels with a flexible, purpose-designed brush. Appropriately sized brushes for each channel should be used to ensure good contact with the channel walls. The brush must be passed through each channel several times until clean and the brush itself must be cleaned in detergent with a soft toothbrush each time it emerges.
- Brushing/cleaning should be done with the endoscope completely immersed in the fluid in order to avoid splashing of contaminated liquids.
- Valves and distal caps must also be cleaned according to the manufacturer's instructions (mainly in the same way as the endoscope but additionally using an ultrasonic bath).

Note: Concentrations and exposure times should be in line with the manufacturer's instructions.

Step 4: Rinsing.

- Rinse all outer surfaces and all channels by flushing with water followed by air to expel as much fluid as possible prior to disinfection. The rinsing removes detergent residues and avoids interactions between detergents and disinfectants.
- Drain, disinfect and rinse the container/basin before the next reprocessing procedure.

Appendix 2: Reprocessing of Flexible Endoscopes in Washer-Disinfectors and Automated Disinfection Devices

Thorough manual cleaning is a prerequisite for effective disinfection. Therefore, manual cleaning including brushing must always be done before automated reprocessing is performed. The standard cleaning procedure for flexible endoscopes, steps 1-4 of appendix 1: Manual cleaning of flexible endoscopes must be done before a washer-disinfectors is used.

Step 5: Loading of washer-disinfector.

- Load the basket, immersion trays or tank of the washer-disinfector in accordance with the manufacturer's recommendations.
- Attach channel connectors/separators to ensure complete and thorough irrigation of all lumens.
- Ensure that all channels are connected. The specific design of the machine must be taken into account.
- Valves and distal caps must be placed into a special basket.
- Remove gloves and close the washer-disinfectors.

Step 6: Reprocessing.

- Select and start the cycle.
- After completion of the automated cycle, ensure that all cycle stages have been completed in accordance with set parameters.
- Open the washer-disinfector and remove the endoscope.

Step 7: Drying and storage.

- Dry the endoscope externally and flush each channel with air. The drying process may be supported by flushing 70% alcohol through the endoscope channels.

- If there is to be further use, wipe the eyepiece and light guide connector as well as the plugs, before connecting the endoscope to the light source.
- Fit the disinfected and rinsed valves. The endoscope is now ready for use again.
- Before storage, the endoscope channels and outer surfaces must always be dried completely, in order to prevent the growth of microorganisms.
- Endoscopes should be stored vertically in a well ventilated storage cupboard.
- Valves should not be connected as this might block the air ventilation in the endoscope channel. Valves and distal caps should be stored separately next to the endoscope.

Appendix 3: Manual Reprocessing of Flexible Endoscopes

Thorough manual cleaning is a prerequisite for effective disinfection. Therefore manual cleaning must always be done before disinfection is performed. Steps 1-4 detailed in appendix 1: Manual cleaning of flexible endoscopes must always be done before disinfection.

Step 5: Disinfection.

- After thorough manual cleaning, including brushing of all accessible channels, the endoscope is immersed completely in disinfectant solution.
- Fill all endoscope channels completely with disinfectant. Use the endoscope-specific rinsing adapters to ensure complete contact with disinfectant and to avoid any dead spaces.
- Valves and distal caps must be disinfected with the endoscope.
- Manufacturers' recommendations must be followed with regard to concentration and contact time of the disinfectant.

Step 6: Rinsing

- Rinse all outer surfaces and all channels by flushing with water to remove all traces of disinfectant.
- Rinse all valves and distal caps under water as well.
- The water must be of at least drinking water quality and should be free of pathogens such as Pseudomonas aeruginosa. If necessary, filtered water may be used for rinsing.

Note: Always discard the rinse water after each use in order to avoid any recontamination.

Step 7: Drying and storage

- Dry the endoscope externally and flush each channel with air. The drying process may be supported by flushing 70% alcohol through the endoscope channels.
- If there is to be further use, wipe the eyepiece and light guide connector as well as the plugs, before connecting the endoscope to the light source.
- Fit the disinfected and rinsed valves. The endoscope is now ready for use again.
- Before storage, always dry the endoscope channels and outer surfaces completely in order to prevent the growth of microorganisms.
- Endoscopes should be stored vertically in a well ventilated storage cupboard.
- Valves should not be connected as this might block the air ventilation in the endoscope channel. Valves and distal caps should be stored separately next to the endoscope.

Appendix 4: Manual Reprocessing of Reusable Endoscopy Accessories

Step 1: Cleaning.

- Disconnect and dismantle accessories as far as possible.
- Immerse accessories in detergent solution immediately after use.
- Clean the single components of the devices externally using a soft cloth/sponge, and brushes.
- Brush or clean with the accessories completely immersed in the fluid, in order to avoid splashing of contaminated liquids.
- Inject detergent solution into all accessible lumina to remove secretions and debris (at least 10-20 ml solution in each lumen).
- Ensure that all lumina are flushed completely to avoid air blockages.
- Remove the instruments from the detergent solution.

Notes:

- All types of detergents recommended for reprocessing of medical devices can be used for cleaning endoscopy accessories. Compatibility of materials must be respected. Instructions from the manufacturers of the process chemicals must be complied with.
- Aldehydes cannot be used for cleaning steps because they denature and coagulate protein, thus fixing it, and this may impair cleaning.
- Cleaning must be done before disinfection.
- The water quality available in the endoscopy unit should be specified.

Step 2: Ultrasonic cleaning.

- Use a medical grade ultrasonic cleaner with a frequency range over 30 kHz (38 to 47 kHz) and a maximum operating temperature of 45°C, following the manufacturer's instructions.

- Ensure that the detergent used is a non-foaming solution, suitable for manual cleaning as well as for ultrasonic cleaning.
- Renew the cleaning solution at least daily or more frequently if the solution is contaminated.
- Ensure that the tray is large enough and deep enough to allow for complete immersion of the devices.
- Load the basket/tray of the ultrasonic cleaner with the dismantled and pre-cleaned accessories.
- Avoid any ultrasound “shadows“ or dead spaces where ultrasound waves cannot act. Do not overload the tray.
- The instrument should be coiled with a diameter of not less than 15-20 cm, in accordance with manufacturer’s instructions.
- Flush all channels and lumens completely again with at least 10 ml of detergent solution, to avoid air blockage.
- Follow the instructions of both the manufacturer of the ultrasonic cleaner and the manufacturer of the device.
- Cover the ultrasonic cleaner with a lid.
- Leave the accessories in the ultrasonic cleaner and complete the recommended contact time for ultrasonic cleaning, following the manufacturers’ instructions for the devices, the ultrasonic cleaner and the detergents.
- Remove the accessories from the ultrasonic cleaner.
- Flush all channels with air to remove excess fluid.

Notes:

During ultrasonic cleaning the temperature can range from 40°C to 60°C. Proteins can be fixed at higher temperatures. When using enzymatic detergents ensure that the temperature is not over 45°C, as compatible with detergent efficacy.
The temperature in the ultrasonic cleaner should be monitored.

Step 3: Rinsing.

- Transfer the cleaned accessories to a bowl or tray containing water of at least drinking quality and renew the water after each rinsing cycle.
- Flush all lumina completely and thoroughly in the water to remove detergent residues. Flush the lumina with at least 20 ml water.
- Rinse external surfaces thoroughly, using water of at least drinking quality, to remove chemical residues.
- Remove the devices from the water.
- Drain or aspirate all lumina with air to remove residual rinse water.

Step 4: Drying.

- Dry the external surfaces with a non-shedding cloth and compressed air.
- Dry each lumen completely with compressed air.
- Dry all coiled accessories in a hanging position to support the drying procedure.
- Assemble the accessories and check their correct functioning.

Step 5: Sterilization.

- Put the accessories into sterile packaging for special instruments.
- Select the appropriate adequate sterilization procedure for the thermostable and thermolabile instruments in accordance with manufacturers' instructions (general recommendation: steam autoclave, pre-vacuum, and national laws).
- After completion of the sterilization cycle, ensure all cycle stages have been completed in accordance with set parameters.

▪ Check the sterile packaging for any damage and check the sterilization indicators.
Step 6: Storage. ▪ Store sterilized instruments (in the sterile packaging) in a closed cupboard, protected from dust, humidity, and temperature fluctuation. ▪ Follow instructions concerning the durability of the sterile packaging.

Appendix 5: Reprocessing of Endoscopic Accessories in Washer-Disinfectors and Automated Disinfection Devices

As an additional step, washer-disinfectors may be used. Before this is done, pre-cleaning, ultrasonic cleaning and rinsing must be completed. Steps 1 to 3 of appendix 4: Manual reprocessing of reusable endoscopic accessories.

Step 4: Loading of the washer-disinfector.

- After thorough cleaning as described above, load the basket, immersion trays, or tank of the washer-disinfector in accordance with the manufacturer's recommendations.
- Attach connectors to ensure complete and thorough irrigation of all lumina.
- Ensure that all lumina are connected; the specific design of the machine must be taken into account.
- Handles, coils, or wires must be fitted into a special basket.
- Remove gloves and close the washer-disinfector.

Step 5: Reprocessing.

- Select and start the cycle.
- After completion of the cycle, ensure that all cycle stages have been completed in accordance with set parameters.
- Open the washer-disinfector and remove the accessories.
- Dry the accessories if necessary with a non-shedding cloth.
- Dry each lumen with compressed air.

To complete the cycle, follow steps 5 and 6 of Appendix 4: Manual reprocessing of reusable endoscopic accessories.

6.11 ANTIBIOTIC PROPHYLAXIS IN ENDOSCOPY

6.11.1 Introduction.

6.11.1.1 Bacteraemia is common following some forms of gastrointestinal endoscopic therapy, such as dilatation or injection sclerotherapy, and can occur with diagnostic endoscopy alone.

6.11.1.2 Fortunately complications resulting from dissemination of endogenous bacteria are uncommon, and infective endocarditis is an extremely rare complication.

6.11.1.3 Furthermore, for most diagnostic and therapeutic procedures there is scant evidence that antibiotic prophylaxis can reduce the incidence of infective complications.

6.11.2 Aims.

6.11.2.1 These guidelines aim to help clinicians in deciding which patients undergoing gastrointestinal endoscopy should receive antibiotic prophylaxis.

Scenario for prophylaxis	Rationale	Antibiotics	Dose/route	Grade of recommendation ; comments
1. Patients with valvular heart disease, valve replacement, and/or surgically constructed systemic– pulmonary shunt or conduit, or vascular graft	Prevention of infective endocarditis or conduit/graft infection	Not indicated		1C+
2. ERCP for the following patient groups: a. ongoing cholangitis or sepsis elsewhere	Prevention of procedure-related bacteraemia	Be guided by recent culture results. Patients should already have been established on antibiotics. Additional single-dose ERCP prophylaxis is not normally recommended	May need advice from clinical microbiologist	1A
b. biliary obstruction and/or common bile duct stones and/or straightforward stent change	Prevention of cholangitis	Not indicated unless biliary decompression not achieved. A full course of antibiotics becomes indicated if adequate biliary decompression is not achieved during the procedure		1C

c. ERCP when complete biliary drainage unlikely to be achieved patients with biliary disorders, such as: i) Primary sclerosing cholangitis ii) Hilar cholangiocarcinoma	Prevention of cholangitis	Ciprofloxacin* OR Gentamicin	750 mg orally 60-90 min before procedure (but not recommended in children) 1.5 mg/kg intravenously. over 2–3 min	2C *Antibiotics that cover biliary flora, such as enteric gram negative organisms and enterococci should be used
d. Communicating pancreatic cyst or pseudocyst	Reducing risk of introducing infection into cavity	As above	As above	3

e. biliary complications following liver transplant	Prevention of cholangitis	As above PLUS amoxicillin OR Vancomycin	1 g intravenously single dose 20 mg/kg intravenously infused over at least 1 h	3
3. Endoscopic ultrasound (EUS) intervention for the following patient groups: a. fine needle aspiration of solid lesions ▪ (upper-GI tract) ▪ (lower-GI tract)	Prevention of local infection	Not indicated insufficient data to make firm recommendation		1C; low rates of bacteraemia and local infection

b. fine needle aspiration of cystic lesions in or near pancreas, or drainage of cystic cavity	Prevention of cyst infection	Co-amoxiclav OR Ciprofloxacin Antibiotics may be continued for 3 to 5 days after the procedure	1.2 g intravenously single dose 750 mg one oral dose	1C 1C

4. Percutaneous endoscopic gastrostomy (PEG)	Prevention of peristomal infection AND possibly reduction in risk of other infections such as aspiration pneumonia	Co-amoxiclav OR Cefuroxime Teicoplanin can be used if past anaphylaxis or angioedema with penicillin/cephalosporin	1.2 g intravenous injection or infusion just before procedure 750mg intravenous injection or infusion just before procedure 400 mg intravenously for adults	1A; decreases risk of soft tissue infection * Patients already receiving broad-spectrum antibiotics do not require additional prophylaxis for PEG

5. Variceal bleeding (not strictly prophylaxis) for patient with decompensated liver disease	Prevention of infections such as bacterial peritonitis	Third-generation cephalosporin Cefriaxone OR Cefotaxime Alternative: Ciprofloxacin	 1g intravenously once daily for a maximum of 1 week 2 g intravenously three times daily for a maximum of 1 week 400mg intravenously twice daily for a maximum of 1 week	1B; risk for bacterial infection associated with cirrhosis and GI bleeding is well established

6. Profound immunocompromise (patients with severe neutropenia (<0.5x109/l) and/or advanced haematological malignancy)	Prevention of procedure-related bacteraemia	Only indicated in procedures with high risk of bacteraemia (e.g., sclerotherapy, dilatation, ERCP with obstructed system)	Discuss with haematologist and/or clinical microbiologist	
7. Patients receiving immunosuppressive agents	Prevention of procedure-related bacteraemia	Not recommended		3
8. Synthetic vascular graft and other non valvular cardiovascular devices.	Prevention of graft and device infection	Not recommended		1C+
9. Prosthetic joints	Prevention of septic arthritis	Not recommended		1C+; very low risk of infection

6.12 ANTIPLATELETS AND ANTITHROMBOTICS IN ENDOSCOPY

6.12.1 Introduction.

6.12.1.1 With the increasing use of antithrombotic agents (ATA), including antiplatelet agents (APA), their management during the periendoscopic period has become a more common and more difficult problem. The increase in use is due to the availability of new drugs and the widespread use of drug-eluting coronary stents. Joint management with the cardiologist is strongly advised in patients on a ntithrombotic agents undergoing endoscopy.

6.12.2 Risk assessment.

6.12.2.1 Procedure risks.

a) Low risk procedures.

- Diagnostic procedures, including biopsy (gastroscopy, colonoscopy, flexible sigmoidoscopy).
- ERCP without sphincterotomy.
- EUS without FNA.
- Enteroscopy and diagnostic deep (balloon-assisted) enteroscopy.
- Capsule endoscopy.
- Enteral stent deployment.

b) High risk procedures.

- Polypectomy.
- Biliary or pancreatic sphincterotomy.
- Pneumatic or bougie dilation.
- PEG placement.
- Therapeutic deep (balloon-assisted) enteroscopy.
- EUS with FNA.
- Endoscopic haemostasis.
- Tumour ablation by any technique.

- .Treatment of varices.

6.12.2.2 Condition risks.

a) Low risk conditions.
   - Uncomplicated or paroxysmal non-valvular atrial fibrillation.
   - Bio-prosthetic valve.
   - Mechanical valve in the aortic position.
   - Deep vein thrombosis.

b) High risk conditions.
   - Atrial fibrillation associated with valvular heart disease, prosthetic valves, active congestive heart failure, left ventricular ejection fraction <35%, a history of a thromboembolic event, hypertension, diabetes mellitus, or age >75 yrs.
   - Mechanical valve in the mitral position.
   - Mechanical valve in any position and previous thromboembolic event.
   - Recently (<1 yr) placed coronary stent.
   - Acute coronary syndrome.
   - Non stented percutaneous coronary intervention after myocardial infarction.

6.12.3 Elective procedures.

6.12.3.1 Specific procedures.

a) Diagnostic endoscopy.
   - For diagnostic endoscopic procedures without biopsy sampling, it is recommended to continue all APA treatment.
   - If biopsy sampling is indicated in patients taking single APA therapy of aspirin or clopidogrel, we recommend continuing APA therapy if indicated.

- In patients taking a combination of aspirin and thienopyridines, we recommend continuing dual antiplatelet therapy, if indicated, if mucosal biopsies without electrocautery are anticipated.

b) Colonoscopic polypectomy.
   - It is recommended that pure-cutting current is not used. It is also recommended that aspirin is not discontinued irrespective of polyp size and that thienopyridines are withheld if polyps >1 cm have to be resected, provided that the patient is not at high risk for thrombotic events.
   - When polyps must be resected in patients who cannot discontinue thienopyridines, preventive measures (preferably detachable loop ligating device for pedunculated polyps, and sub-mucosal injection of diluted adrenaline for sessile polyps) should be readily available.
   - In patients with large polyps who are receiving thienopyridines, a biopsy may be performed and polypectomy deferred.

c) Sphincterotomy.
   - For endoscopic sphincterotomy, it is recommended:
     - To continue aspirin if clinically warranted.
     - To withhold clopidogrel or prasugrel.
     - To use blended current.
   - For the extraction of large biliary stones in patients taking aspirin, mechanical lithotripsy is recommended over endoscopic sphincterotomy plus large-balloon papillary dilation (the latter technique should be performed after withholding any APA).

d) PEG placement.

- We recommend continuing aspirin in patients undergoing PEG placement.
- In the absence of appropriate studies, no recommendation can be made for patients taking clopidogrel or a combination of aspirin and thienopyridines.

e) ESD and EMR.
   - For EMR and ESD, discontinuation of all anti-thrombotic agents, including aspirin, is recommended provided the patient is not at high risk for a thrombotic event.

f) EUS FNA.
   - It is recommended that thienopyridines are discontinued before any EUS-FNA and that aspirin be withheld before EUS-FNA of pancreatic cysts in patients with a low risk of thrombotic events.

g) Endoscopic stent placement and dilatation of strictures.
   - For endoscopic dilation of digestive strictures or stent placement, we recommend that aspirin be continued (except when large-diameter pneumatic achalasia balloon dilation is performed). Thienopyridines should be discontinued.

h) Deep enteroscopy, such as double balloon and single balloon enteroscopy.
   - We recommend continuing aspirin and considering discontinuation of thienopyridines.

i) Oesophageal variceal ligation.
   - It is recommended that for EVL aspirin is continued and thienopyridines are withheld.

j) Haemostasis using APC.

- It is recommended that aspirin or clopidogrel is continued in patients undergoing APC of potentially bleeding lesions.
- In the absence of appropriate studies, no recommendation can be made for patients taking a combination of aspirin and thienopyridines.

6.12.3.2 Risk of stopping antithrombotic therapy before elective endoscopy.

a) If antithrombotic therapy is temporary, elective procedures should be delayed until anticoagulation is no longer needed.

b) Administration of vitamin K to reverse anticoagulation for elective procedures should be avoided.

c) In patients at low risk of thrombosis it is advised that warfarin simply be withheld before the procedure and that bridge therapy with heparin is usually unnecessary.

d) Role of bridge therapy in endoscopy (Refer Table 1)

Table 1: Role of bridge therapy in endoscopy

Condition	Associated diagnosis	Management
Atrial fibrillation	None	Withold warfarin 3-5 days before procedure. Restart warfarin within 24 hr.*
	Mechanical valve(s) and/or history of cerebrovascular accident, transient ischemic attack, or systemic embolism	Withold warfarin and start unfractionated heparin (UFH) when INR <2.0. Stop UFH 4-6 hr before procedure and restart after procedure. Resume warfarin on the evening of the procedure and continue both agents until INR is therapeutic. (*Therapeutic doses of SC UFH or low molecular weight heparin LMWH may be considered in lieu of IV UFH.)
	Mechanical bi-leaflet, aortic valve	Withold warfarin 48-72 hr before procedure for a target INR 1.5. Restart warfarin within 24 hr.*
Valvular heart disease	Mechanical mitral valve or mechanical aortic valve plus any of the following: atrial fibrillation, previous thromboembolic event, left ventricular dysfunction, hypercoagulable condition, mechanical tricuspid valve or >1 mechanical valve	Hold warfarin and start UFH when INR <2.0. Stop UFH 4-6 h before procedure and restart after procedure. Resume warfarin on the evening of the procedure and continue both agents until INR is therapeutic.(* Therapeutic doses of SC UFH or LMWH may be considered in lieu of IV UFH.)

* Continuation or reinitiation of anticoagulation should be adjusted according to the stability of the patient and estimated risks surrounding the specific intervention/ procedure performed.

e) Re-initiation of antithrombotic agents after elective endoscopy.
   - There is no consensus as to the optimal timing of re-initiation of anticoagulant therapy after endoscopic interventions, and decisions are likely to depend on procedure-specific circumstances as well as the indications for anticoagulation.
   - In patients with valvular heart disease and a low risk of thromboembolism, warfarin may be restarted within 24 hours of the procedure.
   - In patients with high risk of thromboembolism on UFH or LMWH, warfarin should be restarted as soon as ‘‘bleeding stability allows’’ and continued until the INR reaches an appropriate therapeutic level.

6.12.4 Endoscopic procedures in acutely bleeding patients receiving antithrombotic therapy.

6.12.4.1 Stopping or reversing antithrombotic agents.

a) High-dose (10 mg) vitamin K should not be given routinely to patients with mechanical valves because this may create a hypercoagulable condition.

b) FFP is preferable.

c) Alternatively, low-dose vitamin K (e.g., 1-2 mg) with or without FFP may be appropriate.

d) For patients taking antiplatelet agents with life-threatening or serious bleeding, options include stopping these agents and/or administration of platelets.

6.12.4.2 Restarting antithrombotic agents after endoscopic haemostasis.

a) For aspirin related peptic ulcer bleeding (PUD), resumption of aspirin + PPI is superior to switching to clopidogrel.

b) The absolute risk of rebleeding after endoscopic haemostasis in patients who must resume anticoagulation is unknown, and the timing for resumption of anticoagulation should be individualized. Joint management with the cardiologist is strongly advised.

c) We suggest that in patients with high-risk stigmata for rebleeding (e.g., a visible vessel) intravenously administered UFH be used initially (because of its relatively short half-life) if early anticoagulation is required.

6.12.5 Endoscopy in patients with vascular stent or acute coronary syndrome (ACS) taking antithrombotic agents.

6.12.5.1 Elective endoscopy.

a) We recommend that elective procedures be deferred in patients with a recently placed vascular stent or ACS until the patient has received antithrombotic therapy for the minimum recommended duration per current guidelines. Once this minimum period has elapsed, we suggest that clopidogrel or ticlopidine be withheld for approximately 7 to 10 days before endoscopy and that aspirin be continued. Clopidogrel or ticlopidine may be reinitiated as soon as deemed safe with consideration of the patient's condition and any therapy performed at the time of endoscopy.

b) Consultation with the patient's cardiologist is strongly advised to help determine the optimal management of these patients.

Recommencement of APA's may also be considered when the cardiovascular risk outweighs the GI risk.

6.12.5.2 Urgent endoscopy.

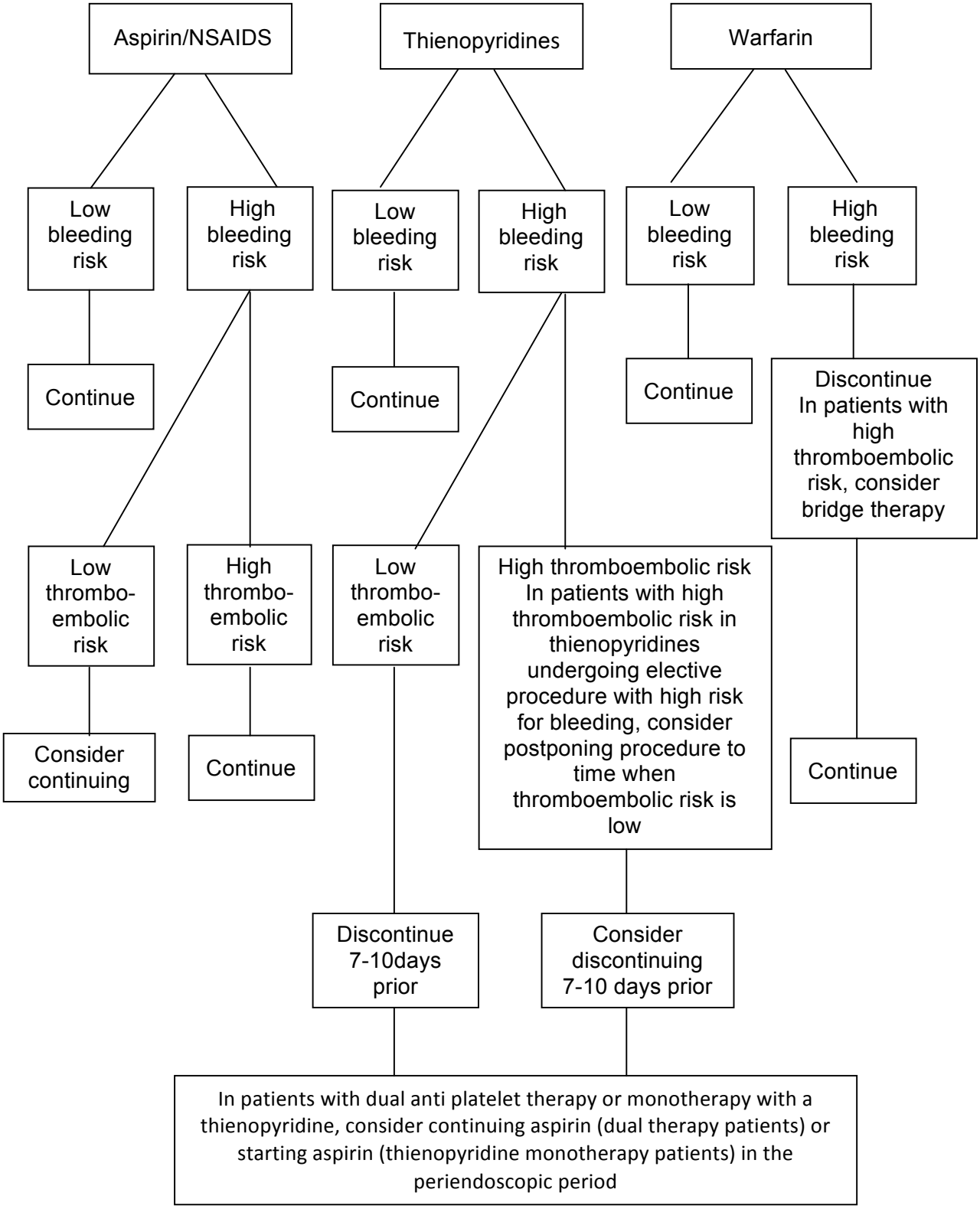
a) Administration of platelets may be appropriate for patients with life-threatening or serious bleeding. In situations of significant bleeding occurring in patients with a recently (within 1 year) placed vascular stent and/or ACS, cardiology consultation be obtained before stopping antiplatelet agents.

Bleeding risk	Endoscopic procedure	Continuation of aspirin?	Continuation of clopidogrel or prasugrel?
Low risk	OGDS and colonoscopy+/– biopsy	yes	Yes
	EUS without FNA	yes	Yes
	Colonic polypectomy <1 cm	yes	no(*)
	Dilation of digestive stenosis	yes	No
	EUS-FNA of solid masses	yes	No
	Digestive stenting	yes	No
	ERCP with stent placement or papillary balloon dilation without endoscopic sphincterotomy	yes	Yes
	Argon plasma coagulation	yes	no(**)
High risk	EMR, ESD and ampullary resection	no	No
	Endoscopic sphincterotomy	yes	No
	Endoscopic sphincterotomy + large-balloon papillary dilation	no	No
	Colonic polypectomy >1 cm	yes	no(*)
	EUS-FNA of cystic lesions	no	No
	Percutaneous endoscopic gastrostomy	yes	no evidence available
	Esophageal band ligation	yes	No

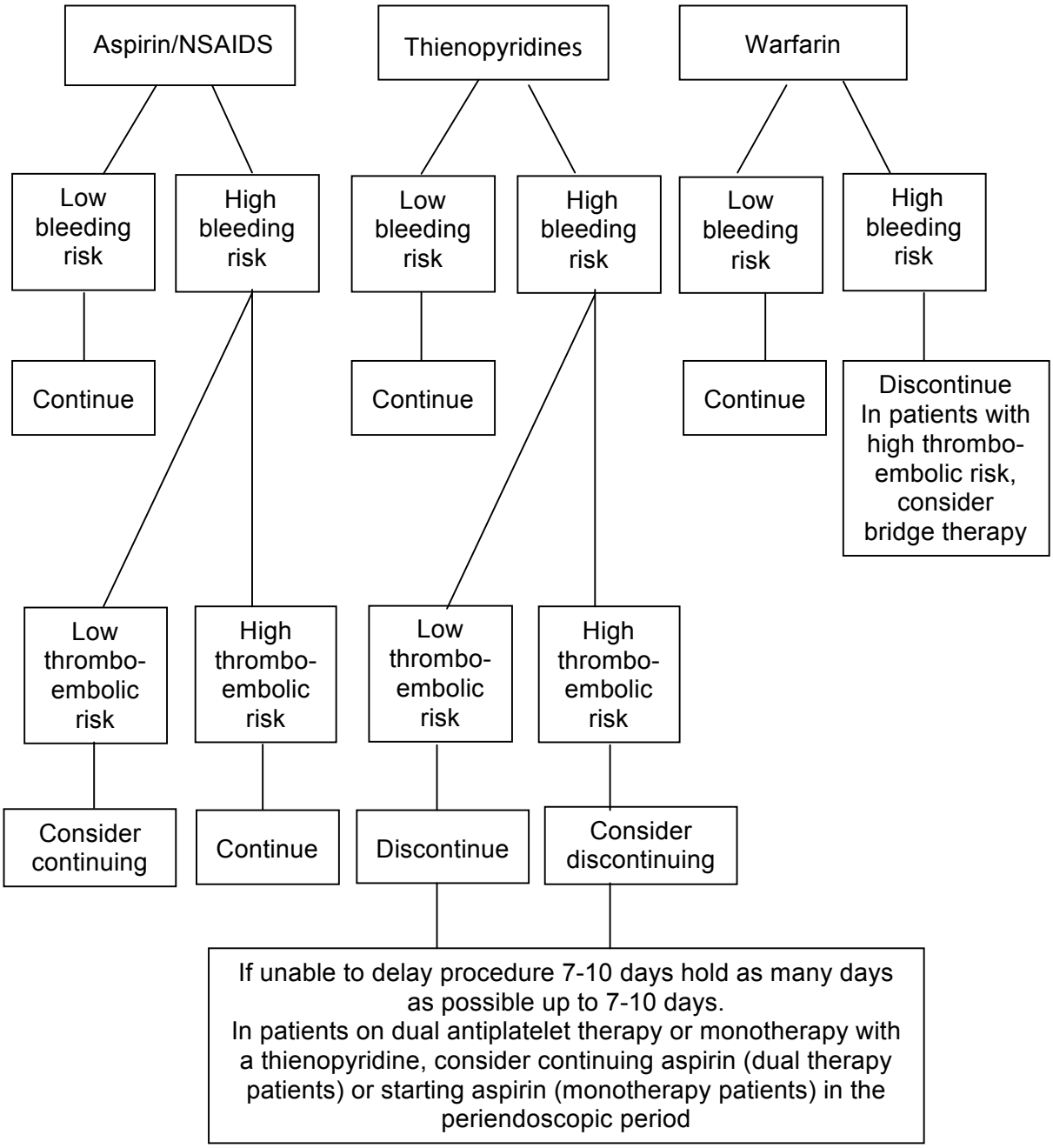
* Bleeding may be prevented by placing a detachable loop ligating device or, if not possible, by submucosal injection of diluted adrenaline. The resection of small polyps (<1 cm) is probably safe in patients taking clopidogrel (not prasugrel) with such preventive measures; insufficient data are available concerning prophylactic endoclip placement.

** Argon plasma coagulation can be safely used to treat angiodysplasias without withholding thienopyridines.

Management of Antithrombotic Agents in the Elective Endoscopic Setting



Management of Antithrombotic Agents in the Urgent Endoscopic Setting



6.13 RESEARCH AND AUDIT

6.13.1 The national gastroenterology subspecialty committee in conjunction with the clinical research centres (CRC) shall support research activities by facilitating funding, facilities and protected time for staff.

6.13.2 Gastroenterologists and GI fellows shall be encouraged to participate in investigator-initiated trials, industry-sponsored research and clinical databases.

6.13.3 Collaboration with other disciplines such as surgery, radiology, oncology, biostatistics etc. when conducting research is encouraged.

6.13.4 Collaboration with the universities and other institutions when undertaking research is encouraged.

6.13.5 The service will work closely with the clinical research centres, Clinical Research Malaysia and other research bodies in the national institutes of health to advance research activities.

6.13.6 The national gastroenterology subspecialty committee supports the setting up of national databases on specific gastroenterological disorders e.g., inflammatory bowel diseases, colonic polyps, hepatitis, liver and bowel cancers.

6.13.7 The national gastroenterology subspecialty committee encourages the individual gastroenterology units to conduct regular audits.

6.14 ENDOSCOPIC UNIT EQUIPMENT AND MEDICATION REQUIREMENT

a) Reliable oxygen source with back up tank.
b) Airway equipment; appropriate sized oral airways, endotracheal tubes, laryngoscopes and masks.
c) Positive pressure ventilation device.
d) Equipment.
e) Defibrillator.
f) Non-invasive blood pressure apparatus.
g) Pulse oximeter.
h) Capnography.
i) Electrocardiographic monitor.
j) Temperature monitoring system for procedures lasting more than 30 minutes.
k) Oxygen analyzer.
l) Suction apparatus.
m) Drugs.
    i. Epinephrine.
    ii. Atropine.
    iii. Antihistamines.
    iv. Hydrocortisone.
    v. Ephedrine.
    vi. Vasopressors (norepinephrine, isoproterenol, dopamine).
    vii. Calcium chloride or gluconate.
    viii. Glucose.
    ix. Naloxone.
    x. Flumazenil.
    xi. Antiemetic.
    xii. Sodium bicarbonate.
    xiii. Lidocaine.
    xiv. Adenosine.
    xv. Magnesium sulphate.
    xvi. Digoxin.
    xvii. Frusemide.

xviii. Potassium chloride.
xix. Heparin sodium.
xx. Aspirin.
xxi. Nitroglycerin.
xxii. Drugs for sedation and analgesia (refer section 6.9 on sedation).

6.15 OESOPHAGOGASTRODUODENOSCOPY (OGDS)

6.15.1 Introduction.

a) Oesophagogastroduodenoscopy (OGDS) refers to the endoscopic examination of the oesophagus, stomach and the first and second portions of the small intestine for the purpose of diagnosis and treatment of disorders of the upper gastrointestinal tract.

6.15.2 Mandatory equipment required.

a) Mandatory endoscopy suite equipment as per SOP.
b) Gastroscope.
c) Biopsy forceps.
d) Mouth piece/bite block.
e) Topical anaesthetic.
f) Suction equipment.
g) Sterile water bottle and sterile water.
h) Lubricant.
i) Haemoclip.
j) Cyanoacrylate
k) Band ligator.
l) Injector needles.
m) Adrenaline for injection
n) Electrocautery unit.

6.15.3 Additional equipment that may be needed.

a) Therapeutic gastroscope.
b) Bottles of formalin for biopsy specimens.
c) Argon plasma coagulators.
d) Water jet system.
e) Slide glass.
f) *Helicobacter pylori* test kit.
g) Polypectomy snare.
h) Equipment for EMR and ESD.

6.15.4 Pre-procedure.

a) Indications for the procedure must be reviewed by the endoscopist before commencement of the procedure.
b) The patient should be fasted at least 4 hours prior to the procedure.
c) Document baseline blood pressure, pulse, respirations, oxygen saturation, level of consciousness and pain level.
d) Document drug allergies and daily medications, including dose and frequency.
e) Refer section 16.0 on antiplatelets and antithrombotics in endoscopy if needed.
f) Informed consent should be obtained prior to the procedure.
g) Review discharge instructions with the patient or responsible adult before sedation is administered.

6.15.5 Intra-procedure.

a) Patient positioning.
b) Use left lateral position to facilitate drainage of pharyngeal secretions.
c) The patient's head may be flexed in a forward position to ease the introduction of the endoscope.
d) Mouth block and oxygen should be in place prior to administration of sedation.

e) Sedation should be administered by the doctor or a nurse under the direction of the doctor (refer section 13.0 on sedation in endoscopy).
f) Crash cart must be readily accessible at all times.

6.15.6 Patient monitoring.

a) Continuous pulse oximetry is mandatory. Document blood pressure and respiratory rate at least every 5 minutes during the procedure or more often if the patient's condition warrants.
b) Should oxygen saturation drop below 95% for more than 30 seconds, measures to rouse the patient should be performed.
c) Termination of procedure should be strongly considered if oxygen saturation drops below 90% for more than 1 minute.
d) Pain level should be continuously monitored during the procedure and sedation adjusted accordingly if needed.
e) All medications given must be documented during the procedure.

6.15.7 Additional comfort measures.

a) Place a pillow behind the patient's back for extra support while on his or her back.
b) Ensure the patient is comfortable with sedation. Sedation may need to be increased should patient become uncomfortable.

6.15.8 Post-procedure.

a) Keep the patient on the left side until fully awake and able to control secretions.
b) Monitor vital signs such as blood pressure, pulse, oxygen saturation, level of consciousness and pain level every 5-10 minutes until they have returned to baseline.
c) Endoscopic findings informed to patient by attending physician.

d) The patient may be discharged home with written discharge instructions which include contact numbers, possible complications specific to the procedure, dietary advice and activity restrictions.
e) The endoscopist should be notified if the patient experiences vomiting, abdominal pain, distension, haematemesis or maelena.

6.16 ENDOSCOPIC VARICEAL LIGATION (EVL)

6.16.1 Introduction

a) Endoscopic variceal ligation (EVL) is a procedure in which an enlarged varix in the oesophagus is tied off or ligated by a rubber band delivered via an endoscope and a rubber band applicator.
b) The procedure can be done electively to prevent bleeding (primary or secondary prophylaxis), or it can be done as an emergency procedure to stop active bleeding.

6.16.2 Mandatory equipment required.

a) Endoscopy system (refer section 6.0).

6.16.3 Mandatory specialized equipment needed.

a) Rubber band applicator with 3-6 rubber bands preloaded depending on the number of varices to be banded.
b) Injection needle (21G) - for rescue therapy in case of failure.
c) Cyanoacrylate glue and lipoldol (in case of failure of EVL).

6.16.4 Pre-procedure.

a) Elective EVL can be done as an outpatient and routine admission is unnecessary.
b) Indications for the procedure must be reviewed by the endoscopist before commencement of the procedure.
c) In cases of UGIB secondary to suspected varices, endoscopy should be attempted as soon as patient is stable and resuscitated, and should not be delayed for more than 12 hours if the patient is stable.

d) The patient should be fasted at least 6 hours prior to the procedure, though if an emergency scope is needed, IV erythromycin ethyl succinate 250 mg can be given to improve endoscopic views at least 30 minutes prior to the procedure.
e) A recent FBC and coagulation profile should be available.
f) Group and save of blood is advisable, but not mandatory in elective cases.
g) All emergency cases for variceal bleeding MUST have blood cross-matched.
h) Document baseline blood pressure, pulse, respirations, oxygen saturation and level of consciousness.
i) Document drug allergies and daily medications, including dose and frequency.
j) Informed consent should be obtained before the procedure is commenced.

6.16.5 Intra-procedure.

a) Patient positioning.
b) Refer section 5.1 (Roles and Responsibilities)

6.16.6 Patient monitoring

a) Refer section 5.1 (Roles and Responsibilities)
b) Emergency equipment including suction, oxygen and crash cart must be readily available.
c) Conscious sedation should be given in all patients unless there are contraindications (refer section 6.9).
d) Initial OGDS performed to delineate the varices and to determine number of rubber bands needed.
e) Endoscope is then withdrawn and the band applicator with the appropriate number of bands pre-loaded is placed onto the tip of the endoscope with the help of an assistant.
f) Endoscope with the band applicator is then reintroduced into the oesophagus and the applicator placed very closely over the varix to be banded.

g) Ensure that there an en face view of the varix before suction is applied to prolapse the targeted varix into the applicator. Then the band is applied with a clockwise motion of the firing mechanism and suction released once visual confirmation of the band placement is made.
h) This procedure is then repeated as necessary until all targeted varices are obliterated.
i) The first varix to be targeted should be the most distal followed by banding of the more proximal varices.
j) Actively bleeding varices or varices with stigmata of recent haemorrhage (e.g., red wale sign, haematocystic spot) should be preferentially banded first.

6.16.7 Post-procedure.

a) Refer section 6.0.
b) Keep NBM for at least 4 hours post-procedure.
c) The endoscopist should be notified if the patient experiences vomiting, abdominal pain, distension or haematemesis.
d) All patients should be commenced on non-selective beta blockers if there are no contraindications.
e) In patients who have the procedure done as an emergency to arrest a variceal bleed, antibiotics and vasoactive agents (e.g., octreotide, terlipressin) should be commenced at the appropriate dose.
f) Arrangements should be made for a repeat procedure at an appropriate time to verify obliteration of varices +/- re-EVL.

6.17 CYANOACRYLATE (HISTOACRYL GLUE) INJECTION

6.17.1 Introduction.

a) Histoacryl® is an acrylic resin (N-butyl-2-cyanoacrylate) which is available in 0.5 ml ampoules. It is a tissue glue and can be used to glue cut surfaces. It also rapidly polymerises in the presence of water joining the bonded surfaces together and can be used to stop

bleeding from gastric varices or as a rescue therapy to stop bleeding in oesophageal varices where endoscopic varices ligation (EVL) has failed or is not available.

6.17.2 Indications.

a) Cyanoacrylate injection is performed in the context of controlling or preventing an UGIB from gastric varices, either as an emergency procedure or electively.
b) It can also be used in uncontrolled oesophageal variceal bleeding as a rescue therapy.

6.17.3 Mandatory equipment required.

a) Endoscopy system (refer section 6.0).

6.17.4 Mandatory specialized equipment needed.

a) Water jet.
b) Injector needle 21G.
c) Histoacryl glue (cyanoacrylate).
d) Lipoldol - 2 ampoules x 10 cc each.
e) Normal saline solution for injection.
f) Industrial strength alcohol - for cleaning purposes.
g) 6 x 2 cc syringes.
h) Water for injection 10 mls.
i) Sengstaken-Blakemore tube/band ligator - for rescue therapy only.

6.17.5 Pre-procedure.

a) The patient should be fasted at least 4 hours prior to the procedure. If an emergency endoscopy is needed, IV erythromycin ethyl succinate 250 mg can be given to improve endoscopic views at least 30 minutes prior to the procedure.
b) FBC and coagulation profile (INR/PT) should be available within the last 72 hours. Coagulopathy should preferably be corrected prior to procedure commencement.
c) All emergency cases done MUST have blood cross-matched.

d) Document baseline blood pressure, pulse, respiratory rate, oxygen saturation and level of consciousness.
e) Document drug allergies and daily medications, including dose and frequency.
f) Informed consent including risk of embolism should be explained to the patient and obtained by the endoscopist.
g) Elective intubation and ventilation is recommended in unstable patients with high risk of aspiration. Joint management with the anaesthetist is strongly recommended in this situation.

6.17.6 Intra-procedure.

a) Patient positioning.
b) Use left lateral position to facilitate drainage of pharyngeal secretions.
c) The patient's head may be flexed in a forward position to ease the introduction of the endoscope.
d) Mouth block and oxygen should be in place prior to commencement of sedation.
e) Sedation should be administered by the doctor or a nurse under the direction of the doctor (refer section 6.9).
f) Crash cart must be readily accessible at all times.

6.17.7 Patient monitoring.

a) Continuous pulse oximetry. Document blood pressure and respiratory rate at least every 5 minutes during the procedure or more often if the patient's condition warrants.
b) Should oxygen saturation drop below 95% for more than 30 seconds, measures to rouse the patient should be performed.
c) Termination of the procedure should be strongly considered if there is failure to maintain oxygen saturation above 90%.
d) Pain level should be continuously monitored during the procedure and sedation adjusted accordingly if needed.
e) Adequate conscious sedation should be given in all patients unless there are contraindications.

6.17.8 Histoacryl glue preparation.

a) Draw 1 ml of lipiodol in a 2 ml syringe (lipiodol comes in 10 ml ampoule). Prepare at least 3 syringes.
b) Draw 2 ml of lipoIdol in a 2 ml syringe (this is for purposes of priming the injector). Prepare at least 2 syringes.
c) Before you snap open the tip of the cyanoacrylate ampoule holds it vertically and taps the narrowed tip so that the solution settles in the bottom.
d) Next draw the whole ampoule (0.5 ml of cyanoacrylate) of glue into the 2 cc syringe with 1 ml of lipoIdol and gently shake.
e) The glue has to be freshly made immediately before injecting into the varix.
f) If lipoIdol is unavailable, pure histoacryl glue can be used.
g) At least two 2 ml syringes containing saline should be available for flushing.

6.17.9 Histoacryl glue administration.

a) Prime the injector needle with 2 ml of lipiodol to prevent injection of air into the varices and also to prevent glue settling in the gastroscope. Saline or water for injection may be used for this purpose.
b) It is preferable to use a bigger bore injection needle (19G) but a 21G needle is sufficient as the glue mixture is very viscous and hard to inject.
c) Keep a few 2 ml syringes ready loaded with water/saline for injection and additional glue ready for further injection if needed.
d) Glue injection for gastric varices is usually done in a retroflexed view. Once the needle is in the varix, inject the glue mix. Follow immediately with 2 ml of water or saline to flush the remaining glue mix from the lumen of the needle into the varix.
e) Withdraw the needle from the varix and flush another 2 ml of water into the gastric/oesophageal lumen before withdrawing the needle back into the sheath to prevent any glue mix from being left in the needle and occluding the needle or gastroscope.

f) Do not wait for the glue to solidify in the varix and then withdraw the needle - that might cause the needle to stick - forceful removal will result in de-roofing of the varix and further bleeding.
g) Withdraw the needle from the varix while assistant keeps flushing after the whole glue mix has been injected.
h) In the event of the needle getting stuck in the varix - simply withdraw the needle into the sheath - keep the sheath attached to the varix and then withdraw.
i) After the glue is injected do not apply suction to avoid occluding the scope channel.
j) Limit each injection to 1 ml to prevent embolism but it can be repeated to completely obliterate all the tributaries.
k) Obliteration of the varix can be checked by probing with the sheath of the injection needle where an obliterated varix will feel firm to hard whereas a normal varix will feel spongy.

6.17.10 Post-procedure.

a) Refer section 6.0.
b) Appropriate antibiotics should be administered in variceal bleeding. Refer section 6.11 on antibiotic prophylaxis in endoscopy.

6.18 ENDOSCOPIC HAEMOSTASIS

6.18.1 Introduction.

a) Endoscopic haemostatic therapy has been shown to improve outcomes in upper GI bleeding (UGIB). Haemostatic devices used for UGIB have also been applied to the small bowel and colon.
b) UGIB originates proximal to the Ligament of Treitz; in practice from the oesophagus, stomach and duodenum. Lower GI bleeding (LGIB) is that originating from the small bowel and colon.
c) The diagnostic accuracy of upper endoscopy in UGIB is more than 95%. Endoscopic therapy can dramatically reduce the risk of rebleeding or continued bleeding, the need for surgery, the

number of units of packed erythrocytes required for transfusion and the length of hospital stay.

d) Around 25% of patients presenting with GI haemorrhage in hospital have bleeding that originates in the lower GI tract and colonoscopy is used for haemostasis of colonic bleeding. A large majority of these (80-85%) will stop bleeding spontaneously without any specific treatment. These patients should receive resuscitation and transfusion, if required, to restore circulatory volume.

e) Although lower GI haemorrhage is defined as bleeding that originates from a source distal to the Ligament of Trietz, approximately 10-15% of patients with haematochezia will have an upper GI source of bleeding identified on upper endoscopy. Small bowel sources account for 0.7-9.0% of cases of severe haematochezia.

f) The most common causes of acute UGIB include peptic ulcer disease (PUD), gastric and duodenal erosions, reflux oesophagitis, oesophageal and gastric varices, Dieulafoy lesion, Mallory-Weiss tears, gastric antral vascular ectasia (GAVE) and arteriovenous malformations (AVMs). Bleeding from the colon may arise from neoplasms, diverticulosis, angiodysplasia, AVMs or other causes.

g) Therapeutic modalities include contact thermal devices (multipolar electrocautery probe e.g., heater probe, bipolar electrocautery probes e.g., gold probe), noncontact thermal devices (e.g., argon plasma coagulation [APC]), adrenaline injection, and mechanical devices (e.g., band ligators, clips, and loops). Endoscopic management of variceal bleeding will be discussed separately.

6.18.2 General principles of management are:

a) Adrenaline injection should be combined with thermal therapy or mechanical clips to achieve haemostasis. Thermal therapy or haemostatic clips may be used on their own for haemostasis.

b) Haemoclips are comparable in efficacy to thermo-coagulation as monotherapy for patients with major stigmata of recent haemorrhage (SRH).
c) The use of the Forrest classification in peptic ulcer bleeding in recommended.
d) Endoscopic stigmata that predict a high risk of recurrent bleeding in PUD are active spurting, a visible vessel, and an adherent clot; these lesions should be treated.
e) Patients with PUD should be tested and treated for *Helicobacter pylori.*
f) GAVE should be treated with either thermal therapy or band ligation.
g) Angiodysplasia is treated with thermal therapy e.g., APC.
h) Dieulafoy lesions and Mallory-Weiss tears are treated with injection, thermal and/or mechanical therapy.
i) Diverticular bleeding is treated with adrenalin injection, thermal therapy and/or mechanical therapy.
j) Various combinations of adrenalin injection, thermal therapy, and clips have been used to stop polypectomy bleeding. Adrenalin injection, a detachable loop or haemoclip has been used for the prevention of post polypectomy bleeding.

6.18.3 Mandatory equipment required.

a) Standard equipment for OGDS (refer section 6.15) and colonoscopy (refer section 6.19).
b) Therapeutic or double-channel upper endoscope with biopsy channel of 3.7 mm.
c) Therapeutic colonoscope with biopsy channel of 3.7 mm.
d) Thermocoagulation.
e) Multipolar probe e.g., heater probe.
f) Bipolar probe e.g., gold probe.
g) Electrosurgical cautery unit.
h) Argon plasma coagulator (APC).

i) Clipping device.
j) Polypectomy snare.
k) Water jet system.
l) Endoloop.
m) Injector needle.

6.18.4 Additional equipment that may be needed.

a) Bottles of formalin for biopsy specimens.
b) Request forms and label container.
c) Rapid urease test kit.
d) Duodenoscope.
e) Distal attachment cap.

6.18.5 Pre-procedure.

a) Indications for the procedure must be reviewed by the endoscopist before commencement of the procedure.
b) Before the use of moderate or deep sedation, a directed pre-procedure history and physical examination should be documented. The history should focus on:
c) Indications for the procedure and on conditions that might affect the performance of the endoscopy (e.g., prior GI surgery) or safety of therapeutic procedures (e.g., implanted defibrillators/pacemakers).
d) Aspects that might affect the administration of sedation, such as:
    - Abnormalities of the major organ systems.
    - Previous adverse experience with sedation/analgesia as well as regional and general anaesthesia.
    - Drug allergies, current medications, and potential drug interactions.
    - Time and nature of last oral intake.
    - History of tobacco, alcohol, or substance use or abuse.
e) A thorough review of any medications the patient may be taking, with special attention to the use of anticoagulants, antiplatelet agents, or

medications associated with GI haemorrhage (e.g., NSAIDs) should be performed. (Refer section 6.12 on antiplatelets and antithrombotics in endoscopy).

f) Keep the patient nil by mouth

g) Document baseline blood pressure, pulse, respirations, oxygen saturation, level of consciousness, and pain level.

h) Venous access should be available. Insert two large bore intravenous lines.

i) Patients with UGIB should undergo stabilization and resuscitation before the initiation of endoscopic therapy. The initial management of UGIB is patient assessment and stabilization with volume resuscitation.

j) The initial assessment should focus on the patient's vital signs, the presence or the absence of hypovolaemia and/or shock, and other medical comorbidities.

k) Risk stratify the patient using an appropriate scoring system (e.g., Rockall or Blatchford scoring system) to identify patients at risk of a poor outcome following an UGIB. This has to be taken into account with other clinical factors in assigning patients to different levels of care.

l) High-risk patients are those with haematemesis, hemodynamic instability, coagulopathy, renal failure, older age, and multiple comorbidities; these patients require more intensive monitoring.

m) Loading dose of IV proton pump inhibitor (PPI) 80 mg should be administered in all patients with suspected non-variceal UGIB followed by continuous infusion of PPI 8 mg/hr for 72 hours.

n) Pre-procedure IV erythromycin may improves mucosal visibility.

o) Urgent investigations include full blood count, coagulation profile and group cross match (GXM)/group and hold (G&H) urgently.

p) Transfuse blood (packed cells) if needed to maintain haemoglobin 7-8 g/dl. Transfuse blood products as required.

q) For colonoscopy bowel preparation may be needed.

r) Bowel preparation is similar as for a diagnostic colonoscopy, except in emergency bleeding.

6.18.6 Intra-procedure.

a) Patient positioning and monitoring (refer section 6.0).
b) Endoscopic haemostasis is only indicated for major stigmata of recent haemorrhage (Forrest 1a, 1b, 2a, and 2b lesion).
c) Injection therapy (e.g., adrenaline injection).
d) Adrenaline may be used as an initial therapy with subsequent thermal or mechanical therapy. It should not be used as the sole modality of endoscopic haemastasis.Dilute 1 cc pure adrenaline (1:1,000) with 9 cc of water for injection to achieve final dilution of 1:10,000.
e) Use 23 G injector needle for delivery.
f) Before adrenaline injection, the endoscopy nurse should check that the injector needle properly extends out and retracts in.
g) The endoscopy nurse and endoscopist should agree on simple, unambiguous injection commands, such as 'needle out', 'inject 1 ml', and 'needle in'. In response to the 'needle out' command, the nurse should extend the needle 4 mm beyond its sheath.
h) The duration of the needle in the 'out' position should be minimized to avoid accidental mucosal trauma from the exposed needle.
i) Prime the injector catheter with diluted adrenaline.
j) The endoscopist should advance the needle tangentially into the submucosa using mild manual pressure.
k) The endoscopy nurse should provide feedback regarding resistance during injection. Moderate resistance is expected when injecting into interstitial tissue. Minimal resistance suggests that the injection is off target (for example, the injection is too superficial).
l) Thrusting the needle too deeply and too perpendicularly into the bowel wall can lead to ineffective injection into the muscularis propria or even into the peritoneum. If such a situation occurs, the needle should be withdrawn slightly.

m) A submucosal bleb (a visible circumscribed submucosal accumulation of fluid) indicates proper depth of injection.
n) Leakage of injected fluid onto the mucosal surface or into the lumen indicates that the injection was too superficial. If this situation occurs, the injection should be immediately stopped and the needle inserted deeper into the bowel wall.
o) Inject adrenaline circumferentially in four quadrants a few millimetres away from a bleeding site (about 1-3 mm from the vessel) to decrease the bleeding rate and to clear the endoscopic field before central injection of the bleeding site. Blanching of the injected mucosa from vasospasm provides a preliminary clue that the adrenaline is working.
p) Inject at the periphery of the bleeding source starting from the most distal point to achieve the blanching of the mucosa.
q) Caution should be exercised not to inject more than 20 mls of diluted adrenaline 1: 10,000. This is because adrenaline injection can potentially produce cardiovascular toxic effects including angina, tachycardia, cardiac arrhythmias, and hypertension.
r) Adrenaline typically markedly reduces or stops bleeding initially, but bleeding may recur ≥20 min after injection if a permanent clot has not already been formed as adrenaline is absorbed and flushed into the circulation and its local effect, therefore, wears off. Thus, a second haemostatic technique should be applied to provide a more durable therapy.

6.18.7 Multipolar/bipolar coagulation heater probes.

a) Use pure coagulation setting of 15-20 W.
b) 10 Fr heater probe is recommended.
c) The probe should touch the tissue to deliver ablative energy; energy is not delivered to the target when a probe is off the tissue.

d) The probe should be placed directly on the ulcer at the site of major SRH (for example, a non bleeding visible vessel) to maximize the energy delivered to the target and minimize scatter injury.
e) Endoscopist should ensure the metal part of heater probe is advanced beyond the channel in order to prevent damage to the scope.
f) Sufficient contact time between the probe and mucosa to ensure successful coagulation of bleeding surface. The probe should be applied directly onto the vessel until a 'crater' is formed.
g) Effective haemostasis is suggested by whitening of the lesion and flattening of a non bleeding visible vessel or clot remnant.
h) Repeated application of thermal energy can result in the build-up of coagulum at the catheter tip, which can impede conductivity, necessitating removal of the probe and cleaning of the tip.
i) During probe removal, mucosa that is adherent to the probe may tear and rebleed. Water irrigation during probe removal may reduce this phenomenon.
j) The risk of mucosal adherence is decreased with a heater probe because it has a teflon® coating at its tip whereas with regard to multipolar electro-coagulation probes, tissue desiccation after superficial injury limits deep energy penetration and injury.
k) By contrast, the heater probe transfers heat and thereby potentially produces deep tissue injury even after tissue desiccation because it has a ceramic tip.

6.18.8 Argon plasma coagulation.

a) Setting of APC (refer 6.30) on electrosurgery in endoscopy.
b) APC requires a tank filled with argon gas that must be periodically checked to ensure that it is properly pressurized.

c) The tank must also be securely attached to the endoscopy cart to prevent it from toppling over. The endoscopy nurse should verify that the gas tank is nearly full before use.
d) APC requires a special grounding pad, placed on the patient's thigh or shoulder, to complete a circuit that is generated by charged electrons.
e) The argon flow rate should be set at 0.8-1.0 litre per minute.
f) APC power is adjusted according to the thickness of the bowel wall that requires treatment. The thin-walled caecum is treated with energy settings of only 40-50 W to avoid perforation, whereas the thick-walled stomach is treated with energy settings of 60-75 W. It is recommended wattage settings for different GI organs or segments are posted on the APC machine for easy access.
g) The ionized gas or plasma seeks the nearest tissue, even if tangentially located or indirectly visualized, to go to ground. This feature enables lesions to be treated even if seen tangentially rather than *en face*.
h) There are two types of catheters. The straight catheter is preferred for lesions that are treated *en face* whereas the side catheter is preferred for lesions that are treated tangentially (for example, ulcers in awkward locations).
i) The APC probe is available in 1.5 mm, 2.3 mm, and 3.2 mm diameters. The apparatus includes an electrosurgical generator.
j) Before APC application, the endoscopy nurse should test the probe by applying it to a target attached to the grounding socket; this procedure purges the APC catheter to prime it with argon gas.
k) The probe is extended beyond the endoscope channel so that both the blue tip and black stripe near the probe tip are visible to prevent inadvertent burning of the endoscope tip.
l) During APC treatment for UGIB, argon gas accumulates within the GI lumen and this gas must be periodically aspirated to prevent GI distension.

m) Application of the APC probe instantly produces a visible glow at the probe tip and charring of the targeted tissue is apparent. Failure to observe these effects is most commonly due to the probe being too far from the target tissue.
n) APC tends to produce superficial (<2 mm deep) tissue injury that aims to arrest GI bleeding.
o) The probe is fired while hovering over, but not touching, the target tissue because tissue contact produces deep (>4 mm depth) tissue injury similar to the effects of monopolar electrocautery.
p) APC minimizes the risk of deep injury that can produce a GI perforation or stricture. The risk of GI perforation is about 0.5% or lower with APC.
q) The optimal distance between the APC probe and targeted tissue depends upon the machine model and wattage setting, but the probe is generally held a few millimetres above the target tissue. The optimal distance of 2 to 8 mm from the device to the target tissue must be maintained during energy delivery.
r) Repeated application of thermal energy can result in the build up of coagulum at the catheter tip, which can impede conductivity, necessitating removal of the probe and cleaning of the tip
s) APC should not be applied when a target lesion is covered by a clot or fluid, or when the probe tip is wet.
t) A wet probe tip should be purged before application.
u) APC therapy results in superficial ulcers that generally heal within several weeks.

6.18.9 Mechanical therapy.

a) Application of haemostatic clips should be done for visible vessels. It is important for the endoscopist and endoscopy nurses to familiarize themselves with the operational characteristics of the clips available in their unit.

b) Proper haemoclip deployment requires a skilled endoscopist for placement at the correct angle and precise spot.
c) Missing a target, even slightly, can render a haemoclip ineffective and interfere with the proper deployment of another haemoclip.
d) Several factors may complicate the accurate placement of a haemoclip: intestinal peristalsis, respiratory movements or transmitted cardiac pulsations and limited endoscopic visibility.
e) Haemoclips are less successful for the treatment of fibrotic lesions, such as chronic ulcers, than for the treatment of inflammatory lesions, such as acute ulcers.
f) Haemoclips can be accidentally dislodged when placing subsequent haemoclips and can spontaneously dislodge within 1 day of application and this drawback limits their efficacy.
g) Haemoclips are best deployed *en face* rather than tangentially.
h) A haemoclip device should be passed smoothly and carefully down the endoscopic channel to avoid kinks in the catheter that interfere with deployment.
i) Looping of the endoscope in the GI tract also interferes with haemoclip deployment. Looping of the endoscope is often a problem for ulcers that are located on the lesser curvature of the stomach, in the posterior duodenum, or in the gastric cardia.
j) The endoscopist should ascertain that the haemoclip is endoscopically visible beyond the endoscopic tip, but not excessively visible beyond this tip because this reduces visibility and operator control.
k) The haemoclip should be opened and fully extended directly around the bleeding lesion so that the jaws are across the target and can be embedded into adjacent intact tissue. On opening, the haemoclip is typically 11-12 mm wide from jaw to jaw.
l) The haemoclip is rotated by turning the handle of the clipping device.
m) The endoscopist should declare simple, short, unambiguous orders such as "open clip", and "close clip".

n) A reversible haemoclip is still attached to the deployment device after the clip has been closed, and the closing of the haemoclip can be undone by reversing this step.

o) If the haemoclip is properly deployed, the endoscopist then commands "release clip" and the nurse pushes the handle forward to irreversibly release the haemoclip from its deployment device.

p) Premature retraction of a deployment device without this release will rip the clipped tissue off the mucosa and potentially generate bleeding.

q) By contrast, premature release of the haemoclip without verifying its correct placement can produce irreversible, improper haemoclip placement.

r) More than one haemoclip may be required to clamp an actively bleeding artery in an ulcer.

s) Haemoclips are relatively inefficacious for arteries that are larger than 2 mm wide.

t) Haemoclips generally fall off 10-14 days after deployment - after rebleed.

u) MRI can be safely performed with most, but not all, brands of haemoclips.

6.18.10 Post-procedure.

a) Refer section 5.1 and 6.2 for post-procedure care.

b) High risk patients should be monitored in a high dependency unit (HDU).

c) The endoscopist should be notified if the patient rebleeds, develop abdominal pain, etc.

d) Resumption of usual medications and diet will be advised by the endoscopist.

e) Patient should continue with infusion of PPI (8mg/hr) for 72 hours. Patient should be discharged with single dose oral PPI for

at least 4 weeks. The duration of oral PPI therapy shall be determined by the endoscopist.

f) Patients with low-risk lesions can be considered for outpatient treatment.

g) Second-look endoscopy for patients at high risk for recurrent bleeding may be advised for selected patients but its role has yet to be defined.

h) Scheduled repeat endoscopy for gastric ulcer should be arranged in 6-8 weeks.

FORREST CLASSIFICATION

Grade	Endoscopic Picture	Risk of Rebleeding
I	**Active haemorrhage**	
	IA Spurting	85 -100%
	IB Oozing	10 – 27%
II	**Signs of recent haemorrhage**	
	IIA Visible vessel	50%
	IIB Adherent clot	30 – 35%
	IIC Haematin covered flat spot	<8%
III	**No signs of haemorrhage**	
	Clean bed of ulcer	<3%

ROCKALL NUMERICAL RISK SCORING SYSTEM

Score					
Variable	**0**	**1**	**2**	**3**	
Age	<60 years	60-79 years	≥80 years		Initial score criteria (pre-endoscopy)
Shock	'no shock', SBP* ≥100 mm Hg, pulse <100 beats per minute	'tachycardia', SBP≥100 mm Hg, pulse ≥ 100 beats per minute	'hypotension', SBP <100		
Comorbidity	no major comorbidity		cardiac failure, ischaemic heart disease, any major comorbidity	renal failure, liver failure, disseminated malignancy	
Diagnosis	mallory-weiss tear, no lesion identified and no SRH	all other diagnoses	malignancy of upper GI tract		Additional criteria for full score (post-endoscopy)
Major stigmata of recent haemorrhage (SRH)	none, or dark spot only		blood in upper GI tract, adherent clot, visible or spurting vessel		

Maximum additive score prior to diagnosis = 7

Maximum additive score after diagnosis = 11

GLASGOW-BLATCHFORD SCORE

Admission Risk Marker	Score Component Value
Blood urea	
≥6·5 <8·0	2
≥8·0 <10·0	3
≥10·0 <25·0	4
≥25	6
Haemoglobin (g/L) for men	
≥12.0 <13.0	1
≥10.0 <12.0	3
<10.0	6
Haemoglobin (g/L) for women	
≥10.0 <12.0	1
<10.0	6
Systolic blood pressure (mm Hg)	
100–109	1
90–99	2
<90	3
Other markers	
Pulse ≥100 (per min)	1
Presentation with maelena	1
Presentation with syncope	2
Hepatic disease	2
Cardiac failure	2

A score of 0 identifies low-risk patients.

Low-risk criteria of GBS

- Urea <6·5 mmol/L
- Haemoglobin □13 g/dl (men) or □12 g/dl (women)
- SBP □110 mm Hg
- Pulse <100 beats per min
- Absence of maelena, syncope, cardiac failure, or liver disease

In the validation group, scores of 6 or more were associated with a greater than 50% risk of needing an intervention.

6.19 COLONOSCOPY

6.19.1 Introduction.

Colonoscopy is the endoscopic examination of the large intestine including anus, rectum, sigmoid, descending, transverse, ascending colon and caecum. The terminal ileum may also be examined.

6.19.2 Mandatory equipment required.

a) Mandatory endoscopy suite equipment (refer section 6.2).
b) Colonoscope.
c) Endoscopic video centre.
d) Water bottle.
e) Colonic biopsy forceps.
f) Labels with patient's name.
g) Suction apparatus.
h) Snare.
i) Request forms and label containers for cytopathology/histopathology.
j) Polyp traps.
k) Retrieval forceps/baskets.
l) Injector/needles.
m) Haemoclip.
n) Thermo-coagulator.

6.19.3 Additional equipment that may be needed.

a) Dilating balloons.
b) Cytology brushes.
c) Endoloop.
d) Colonic stent.
e) Argon plasma coagulator.
f) Band ligator.

g) Equipment for endoscopic mucosal resection (EMR)/endoscopic mucosal dissection (ESD).
h) Viral and fungal tubes for culture

6.19.4 Preparation for colonoscopy.

a) Bowel preparation.
b) The patient must undergo bowel cleansing before the procedure.
c) Sodium phosphate.
d) Polyethylene glycol solution (PEG).
e) Any other agents with similar efficacy.
f) Iron preparations should be stopped 3-4 days before colonoscopy.
g) Modification of anticoagulant regimens and avoidance of antiplatelets and NSAIDs may be needed depending on the indications for colonoscopy (refer section 16.0 on antiplatelets and antithrombotic in endoscopy).
h) Patient should have no indigestible or high-residue food for 24 h before colonoscopy (refer section 6.8 on bowel preparation for colonoscopy).
i) Written instructions should be provided.

6.19.5 Pre-procedure.

a) Before the use of moderate or deep sedation, a directed pre-procedure history and physical examination should be documented.
b) The history should focus on:
    - Indications for the procedure and on conditions that might affect the performance of the endoscopy (e.g., prior GI surgery) or safety of therapeutic procedures (e.g., implanted defibrillators/pacemakers).
    - Aspects that might affect the administration of sedation or anaesthesia, such as:

- Abnormalities of the major organ systems.
- Previous adverse experience with sedation/ analgesia as well as regional and general anaesthesia.
- Drug allergies, current medications and potential drug interactions.
- Time and nature of last oral intake.
- History of tobacco, alcohol, or substance use or abuse.

c) Patients should undergo a focused physical examination including:
   - Vital signs (blood pressure, pulse rate, respiratory rate and oxygen saturation should be documented).
   - Auscultation of the heart and lungs.
   - Evaluation of the airway.

d) Informed consent should be obtained and documented for colonoscopy procedure and any sedation or analgesia provided except in emergency situations with non-competent patients**.**

e) Venous access should be available.

f) Discharge instruction should be given to the patient before sedation.

6.19.6 Intra-procedure.

6.19.6.1 Patient positioning.

a) The left lateral position facilitates insertion of the endoscope. The position of the patient may be changed during the procedure to facilitate passage of the endoscope.

6.19.6.2 Patient monitoring.

a) ECG, blood pressure and pulse oximetry should be monitored continuously during the procedure.
b) During sedated endoscopic procedures, blood pressure and pulse rate should be recorded at intervals no greater than 5 minutes.(Refer section 6.9 on sedation in endoscopy)
c) Suction should be readily available.
d) Oxygen via nasal prong/catheter shall be administered when using intravenous sedation.

6.19.7 Measures to facilitate passage of the colonoscope:

a) Nurses may be required to exert pressure on the abdomen of the patient to facilitate the passage of the endoscope.
b) All specimens should be labelled, bagged and sent to the laboratory.
c) Photo documentation. Major abnormalities are photo documented.
d) Documentation of medications. Doses and routes of administration of all medications used during the procedure are documented.

6.19.8 Post-procedure.

a) The patient should be kept on his or her side until fully awake and able to control secretions.
b) Monitor vital signs such as blood pressure, pulse rate and oxygen saturation frequently (15-30 minutes or whenever indicated) until patient recovers.
c) Immediately after the procedure a procedure report is prepared.
d) The patient should be clinically reviewed by the endoscopist and findings explained.
e) Discharge from the endoscopy unit.

f) Documentation that the patient has met predetermined discharge criteria before discharge from the endoscopy unit.
g) Patient may be discharged home accompanied by an escort with discharge instructions.
h) Discharge instructions should address:
    - Diet restrictions.
    - Resumption of usual medications.
    - Return to activities, especially driving.
    - Procedure-specific information regarding potential delayed complications.
    - Contact telephone number in the event of emergencies or should questions arise.
i) Endoscopist should be notified if the patient develops symptoms e.g., abdominal pain, bleeding, etc.

6.20 POLYPECTOMY

6.20.1 Introduction.

A polyp is an abnormal growth of tissue projecting from a mucosal membrane. If it is attached to the surface by a narrow elongated stalk, it is pedunculated. If no stalk is present, it is said to be sessile. Removal of a polyp is called a polypectomy. It can be done surgically or endoscopically. Endoscopic polypectomy refers to the removal of polyps with a scope. This is only a general guide as endoscopic removal of polyps can be extremely complex and clinical judgment and experience is extremely important.

6.20.2 Mandatory equipment required.

a) Mandatory endoscopy suite equipment (refer section 6.2).
b) Gastroscope (refer section 6.3).
c) Colonoscope (refer section 6.19).
d) Endoloop.

e) Polypectomy snare (11 mm, 13 mm, 15 mm, 20 mm, 25 mm, 30 mm, 33 mm snares, oval/hexagonal, rotatable/non-rotatable, variable stiffness).
f) Hot biopsy forceps.
g) Thermocoagulation unit.
h) Electrosurgical unit.
i) Adrenaline.
j) Lifting solution - e.g., normal saline or gelafundin.
k) Haemoclips.

6.20.3 Additional equipment that may be needed:

a) Bottles of formalin for biopsy specimens.
b) Labels with patient's name and pathology requisitions.
c) Slide glass.
d) Water jet.
e) Injector needles - at least 23 G.
f) Image enhanced and magnification scope.
g) Dyes for chromoendoscopy - e.g., methylene blue solution, indigo carmine.
h) Spot tattoo marker.

6.20.4 Pre-procedure

a) Indications for the procedure must be reviewed by the endoscopist before commencement of the procedure.
b) OGDS (refer section 6.3).
c) Colonoscopy (refer section 6.5).
d) Anticoagulation (refer section 6.12).
e) If removal of a large polyp >2 cm is planned, a recent coagulation profile and FBC is suggested.

6.20.5 Intra-procedure.

6.20.5.1 Initial endoscopy should be done to delineate the lesion to be removed

6.20.5.2 Appropriate snare or removal modality should be selected based on the lesion.

6.20.5.3 It is recommended that all polyps be assessed using a relevant classification - e.g., the Paris classification and Kudo's classification.

6.20.5.4 In general, most pedunculated lesions can be removed with a snare or a snare + endoloop.

6.20.5.5 Use of pure coagulation current is recommended in most cases.

6.20.5.6 Please refer section 6.30 for electrosurgical settings needed for polypectomy for more detailed information.

6.20.5.7 Snare selection is important and they are variable ranging from 1-3 cm.

6.20.5.7.1 Hot Snare.

- Used on larger polyps. May sometimes require lifting of the polyp to be removed in some cases. Generally if cutting with mechanical pressure, snare should be closed with constant mild-moderate pressure during coagulation.
- Electrosurgical cutting for these polyps should be done with snare closed with very light hold during blend-cut or endo-cut current.
- Beware of excessive desiccation as it will affect the cutting.

6.20.5.7.2 Hot biopsy.

- Can be used safely in the left colon and transverse colon to remove polyps <5 mm in size. It should not be used on polyps larger then 5 mm and should be used cautiously in the right colon due to the risk of perforation.

6.20.5.7.3 Cold snare.

- Can be used safely in the entire colon to remove polyps <5 mm in size. There may be some minor bleeding after polyp removal but it is self-limiting.

6.20.5.7.4 Endoloop.

- Should be applied to pedunculated polyps before polypectomy if the endsocopist judges that there is a high risk of bleeding post polyp removal.

6.20.5.8 Patient positioning.

a) For colonoscopy (refer section 6.19).
b) For OGDS (refer section 6.15).
c) Sedation should be administered by the doctor or a staff nurse under the direction of the doctor (refer section 6.9 on sedation in endoscopy).
d) The crash cart must be readily accessible at all times.

6.20.5.9 Patient monitoring.

a) Continuous pulse oximetry is mandatory. Document blood pressure and respiratory rate at least every 5

minutes during the procedure or more often if the patient's condition warrants.

b) Should oxygen saturation drop below 95% for more than 30 seconds, measures to rouse the patient should be performed.
c) Termination of procedure should be strongly considered if oxygen saturation drops below 90% for more than 1 minute.
d) Pain level should be continuously monitored during the procedure and sedation adjusted accordingly if needed.
e) Emergency equipment including suction, oxygen and crash cart must be readily available.

6.20.6 Post-procedure.

a) Keep the patient on the left side until fully awake and able to control secretions.
b) Monitor vital signs such as blood pressure, pulse, oxygen saturation, level of consciousness and pain level every 5-10 minutes until they have returned to baseline.
c) Endoscopic findings informed to patient by endoscopist.
d) The patient may be discharged home (accompanied by an adult with the discharge instructions if sedation has been given) or admitted if required.
e) The endoscopist should be notified if the patient experiences vomiting, abdominal pain, distension, haematemesis or maelena.

6.21 DEVICE ASSISTED (DEEP) ENTEROSCOPY

6.21.1 Introduction.

Enteroscopy refers to the endoscopic examination of the small bowel.

6.21.2 Mandatory equipment required.

a) Mandatory endoscopy suite equipment (refer section 6.2).
b) Video enteroscope.
c) Balloon pump controller.
d) Water bottle.
e) Plastic overtubes with either single, double balloons or overtube with raised helical element at distal end.
f) Suction apparatus.

6.21.3 Additional equipment that may be needed.

a) Argon plasma coagulator.
b) Argon plasma coagulator probes.
c) Distal cap.
d) Rubber band.
e) Enteroscope balloon.
f) Applicator.
g) Fluoroscopy.
h) Alcohol 70%.
i) Biopsy forceps.
j) Mouth piece/bite block.
k) Tattooing ink.
l) Endoloop.
m) Snares and haemoclips.

6.21.4 Pre-procedure.

a) The patient should have nothing by mouth for 8 hours prior to procedure.
b) Bowel preparation one day prior procedure (if by retrograde approach) (refer section 6.8 on bowel preparation for colonoscopy).

c) Document baseline vital signs, blood pressure, pulse, respiration, oxygen saturation, and level of consciousness.
d) Document medication allergies and daily medications, including dose and frequency.
e) The endoscopist should obtain an informed consent from the patient or substitute decision maker.
f) Venous access should be available.
g) For double-balloon-enteroscopy, the following steps are required:
    i. Prior to set up, the scope balloon channel should be flushed with air to ensure no residual water that will affect the expansion of the balloon.
    ii. With the metal applicator, a rubber band and balloon are attached on to the applicator and then slowly advanced via the distal end of the enteroscope with alcohol applied on the scope as lubricant.
    iii. A second rubber band is then attached to the distal end of the enteroscope over the balloon with care not to obscure the endoscopic view or occlude the suction channel.
    iv. The tubing attaching the overtube and balloons is attached from the balloon pump to the enteroscope and overtube according to the numbered channel.
    v. Connections of the tubing to the correct sites should be verified by inflating and deflating the balloons.
    vi. Balloon pressure is regulated at approximately 5.6 kPa (42 mmHg) by a pressure-sensing and feedback mechanism.
    vii. Attachment of the single-balloon splinting tube to the overtube is not required before the procedure and it can be attached directly to the scope.

6.21.5 Intra-procedure.

A) Double balloon enteroscopy (DBE) by the antegrade approach.

a) Patient is placed in the left lateral position to facilitate drainage of secretions.

b) Adequate sedation is to be given by either anaesthetist or assistant (refer section 6.9 on sedation in endoscopy).

c) The enteroscope (without the overtube) is initially advanced through the oropharynx and, under direct visualization, is passed into the oesophagus with the same technique used for a standard upper endoscopy.

d) After the pylorus is intubated, the enteroscope is advanced deep into the duodenum until looping is encountered (lack of forward propulsion).

e) With this position achieved, the balloon on the distal end of the enteroscope is inflated for the first time. Care should be taken not to inflate the balloon at the ampulla to prevent potential development of pancreatitis.

f) With the enteroscope balloon inflated and serving as an anchor, the overtube is gently advanced over the enteroscope to the point of maximal insertion, located at 155 cm (corresponding to a solid white line on the therapeutic enteroscope).

g) Water will be introduced intermittently to overcome friction between the enteroscope and overtube.

h) The overtube balloon will then be inflated and the enteroscope balloon is deflated.

i) In this position, the first advancement of the enteroscope can occur.

j) Once the enteroscope can no longer be advanced, the balloon on the tip of the enteroscope is inflated and the overtube balloon is deflated.

k) Next, the overtube is advanced to the point of maximal insertion so that both balloons are together. In this position, both balloons are inflated and a ‘‘pull-back’’ manoeuvre is performed where both the overtube and the enteroscope are withdrawn together until loops have been reduced or the enteroscope starts to travel in a retrograde fashion.

l) The entire advancement and reduction cycle can then be repeated.

m) During the majority of examinations, a point is obtained during the examination where forward advancement of enteroscope is no longer possible. At the point of maximal insertion, it is advisable to tattoo the area with Indian ink (SPOT tattoo), injected with a sclerotherapy needle. This tattoo can then be visualized during subsequent capsule endoscopy examination or balloon-assisted enteroscopy performed from the opposite approach as well as marking for subsequent surgical identification.

n) The endoscopist will require assistance during the DBE procedure from the nursing staff or another physician to

maintain the overtube straight while the enteroscope is being advanced.

o) Withdrawal of the enteroscope is done in an orderly fashion by repetitive alternating inflation and deflation of the enteroscope and overtube balloon.

B) Single balloon enteroscopy (SBE) by the antegrade approach.

Section 6.21 (A) applies to this procedure.

a) Angulation technique.

- The enteroscope is inserted maximally, and the tip of the enteroscope is angulated through 180 degrees to its maximum “up-angle” or “down-angle”. With this simple hook shape of the scope, the enteroscope can maintain the small intestine in the same position.
- Next, the splinting tube is inserted and advanced to the distal portion of the enteroscope. The enteroscope balloon is then inflated, and the tip of the enteroscope is returned to the neutral position.
- With the splinting tube balloon inflated, a reduction manoeuvre is then performed. This sequence of steps is then repeated until the point of maximal insertion.

b) Advancement technique.

- The enteroscope is passed into the proximal jejunum just distal to the ligament of treitz, and the splinting tube is subsequently passed over the scope into the proximal jejunum.

- Next, the splinting tube balloon is inflated, and the enteroscope is reduced by gently pulling back on the splinting tube and enteroscope together.
- After the enteroscope is reduced, the splinting tube balloon is kept inflated, and the enteroscope is advanced until the hub of the scope reaches the proximal end of the splinting tube.
- Next, the balloon is deflated, and the splinting tube is gently advanced over the enteroscope until the 150 cm mark is reached. The splinting tube balloon is reinflated, and reduction of the scope and splinting tube is repeated.
- Therapeutic manoeuvres and tattooing can be performed in a manner similar to how they are performed during DBE.

As in the case with DBE, the SBE can be visualized under direct fluoroscopic observation and is recommended during the initial learning cases.

C) Balloon-assisted enteroscopy by the retrograde approach.

a) It is recommended to start using the DBE system and reduction manoeuvres when looping is first appreciated in the colon, typically at the level of the proximal transverse colon.

b) Balloon inflation and deflation should occur as described above for the anterograde approach.

6.21.6 Post-procedure.

a) The patient should be kept on his or her side until fully awake and able to control secretions.
b) Monitor vital signs such as blood pressure, pulse and oximetry done frequently (15-30 minutes or whenever indicated) until patient recovers.
c) Administer reversal agents for over sedation if necessary.
d) Review discharge and follow-up instructions, including diet, activity, and possible untoward reactions, with the patient or carer.
e) Patient may be discharged home accompanied by an adult with discharge instructions.
f) Physician should be notified if the patient develops symptoms e.g., abdominal pain, distension or fever.

6.22 ENDOSCOPIC ULTRASONOGRAPHY

6.22.1 Introduction.

Endoscopic ultrasonography (EUS) is an imaging technique that combines endoscopy with ultrasonography. An ultrasound probe attached to the tip of the endoscope can be introduced into the upper GI tract and this allows for the detailed ultrasound examination of the walls of the oesophagus, stomach and duodenum. EUS is also used to study internal organs that lie next to the GI tract, such as the posterior mediastinum, gallbladder, biliary tract and the pancreas. Further diagnostic or therapeutic procedures like pancreatic pseudocyst drainage, celiac plexus block and fine needle aspiration of cystic or solid lesions may be performed via EUS.

6.22.2 Indication.

a) Staging of tumours of the GI tract, pancreas, bile ducts, and

mediastinum.

b) Evaluating abnormalities of the GI tract wall or adjacent structures.
c) Tissue sampling of lesions within, or adjacent to, the wall of the gastrointestinal tract.
d) Evaluation of abnormalities of the pancreas, including masses, pseudocysts, and chronic pancreatitis.
e) Evaluation of abnormalities of the biliary tree.
f) Providing endoscopic therapy under ultrasonographic guidance.

6.22.3 Mandatory equipment required.

a) Mandatory endoscopy suite equipment (refer section 6.2).
b) Ultrasound unit.
c) EUS endoscope - radial and linear scopes.
d) Needle for fine needle aspiration (FNA) (19G, 22G, 25G).
e) Glass slides.
f) Alcohol 99.98%.
g) FNA samples preservative solution (optional).
h) Coplin jar.
i) Mouth guard.

6.22.4 Additional equipment that may be needed.

a) Equipment for EUS guided trucut biopsy.
b) Trucut biopsy needle (19G, 22G, 25G).
c) Equipment for celiac plexus block/neurolysis.
d) Spray needle for celiac plexus neurolysis.
e) Alcohol 99.9% 20 cc.
f) Bupivacaine 20% 20 cc.

6.22.5 Equipment for pseudocyst drainage.

a) 19G fine needle aspiration needle.
b) Guide wire 0.035 inches.

c) Cystotome/needle knife.
d) Electrocautery unit.
e) Balloon dilator (8-15 mm).
f) Double pigtailed 7F or 10F plastic stents of various lengths.
g) Covered metal stent (optional).

6.22.6 Pre-procedure.

a) Patient should be fasted for 4 hours prior to procedure.
b) Document baseline vital signs including blood pressure, pulse, respiration, oxygen saturation and pain level.
c) Obtain past medical and surgical history.
d) Document drug allergies and current medications, including dose and frequency.
e) Modification of anticoagulant regimes and avoidance of antiplatelets and NSAIDs may be required depending on the indication for EUS (refer section 6.12 on antiplatelets and antithrombotic in endoscopy).
f) Obtain informed consent.
g) Secure intravenous access.
h) Antibiotic prophylaxis is indicated if fine needle aspiration/ therapeutic measure of cystic lesions are performed (refer section 6.11 on antibiotic prophylaxis in endoscopy).
i) Review the discharge instructions with the patient or responsible adult before sedation is administered.
j) Ensure that a responsible escort is available to accompany the patient home.
k) Check and make sure the EUS system and scopes are functioning.
l) If a balloon is used, ensure that no air is trapped inside during balloon inflation with water.
m) Enter patient's name and registration number into the ultrasound database for labelling of patient's EUS images.

6.22.7 Intra-procedure.

a) Patient positioning.
b) Use left lateral position to facilitate drainage of pharyngeal secretions.
c) The patient's head may be flexed in a forward position to ease the introduction of the endoscope.
d) outh block and oxygen should be in place prior to administration of sedation.
e) Sedation should be administered by the doctor or a nurse under the direction of the doctor (refer section 6.9 on sedation in endoscopy).
f) The crash cart must be readily accessible at all times.

6.22.8 Patient monitoring.

a) Continuous pulse oximetry is mandatory. Document blood pressure and respiratory rate at least every 5 minutes during the procedure or more often if the patient's condition warrants.
b) Should oxygen saturation drop below 95% for more than 30 seconds, measures to rouse the patient should be performed.
c) Termination of procedure should be strongly considered if oxygen saturation drops below 90% for more than 1 minute.
d) Pain level should be continuously monitored during the procedure and sedation adjusted accordingly if needed.
e) All medications given must be documented during the procedure.

6.22.9 Post-procedure.

a) Keep the patient on the left side until fully awake and able to control secretions.

b) Monitor vital signs such as blood pressure, pulse, oxygen saturation, level of consciousness and pain level every 5-10 minutes until they have returned to baseline.
c) Endoscopic findings informed to patient by attending endoscopist.
d) The patient may be discharged home with written discharge instructions which include contact numbers, possible complications specific to the procedure and diet and activity restrictions.
e) The endoscopist should be notified if the patient experiences vomiting, abdominal pain, distension, haematemesis or maelena.

6.22.10 Complications.

a) Perforation.
b) Bleeding.
c) Pancreatitis.
d) Infection.
e) Pneumothorax/pneumomediastinum.

6.22.11 Precautions.

a) Prophylactic antibiotics should be given to reduce the risk of infection before FNA of cysts.
b) Administration of adequate IV fluids prior to celiac plexus neurolysis to avoid hypotension.

6.23 ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY

6.23.1 Introduction.

Endoscopic retrograde cholangiopancreatography (ERCP) is an endoscopic procedure to visualize the biliary and pancreatic ductal systems by selective cannulation of the ampulla of vater and retrograde contrast injection using a side-viewing duodenoscope.

6.23.2 Mandatory equipment required.

a) Mandatory endoscopy suite equipment (refer section 6.2).
b) Side-viewing endoscope (duodenoscope).
c) Ionic contrast agent and 20 cc syringes.
d) Sphincterotomes.
e) ERCP catheters.
f) Guide wires.
g) Electrocautery unit.
h) Snares, Soehendra stent retriever and rat-tooth forceps for stent removal.
i) Stone retrieval balloons (8.5-20 mm balloon diameters).
j) Stone retrieval baskets.
k) Mechanical lithotripter.
l) Soehendra lithotripter.
m) Biopsy forceps.
n) Specimen bottles with formalin.
o) Plastic stents of various lengths and diameters (3F, 5F, 7F, 10F).
p) Nasobiliary/nasopancreatic catheters.
q) Injection needles.
r) Brush cytology catheters.
s) Dilating balloons (4 mm, 6 mm, 8 mm, 10mm diameters).
t) Dilating catheters (7F, 8.5F, 10F).
u) Contrast medium.
v) Lead aprons, lead goggles, thyroid shields and radiation film badge.
w) Fluoroscopy unit.

6.23.3 Additional equipment that may be needed.

a) Self expandable metallic stents of various types, sizes and diameters - uncovered SEMS (diameter 10 mm; lengths 6 cm, 8 cm, 10 cm); partially covered SEMS (diameter 10 mm; lengths 6 cm, 8 cm); fully covered SEMS (diameter 10mm, length 6 cm, 8 cm).
b) Intraductal biopsy forceps.
c) Cholangioscope with electro-hydraulic lithotripsy (EHL)/laser.

6.23.4 Pre-procedure.

a) Indication for the procedure must be reviewed by the endoscopist prior to procedure.
b) The patient should be fasting for at least 4 hours prior to the procedure.
c) Monitor baseline vital signs, including blood pressure, pulse, respiratory rate, pain level, and oxygen saturation.
d) Medication allergies and daily medications, including dose and frequency should be documented.
e) Notify the endoscopist if the patient is allergic to contrast. Depending upon the severity of allergy, steroids or antihistamines may be prescribed before the procedure. Non-ionic contrast should be recommended for use in this subgroup of patients.
f) Full blood count, prothrombin time/international normalized ratio (INR) and liver function tests (LFT) (less than 72 hours) must be available and reviewed.
g) Coagulopathy may need to be corrected.
h) Recent imaging studies should be available (US/CT scan/MRI/ EUS).
i) Antiplatelet therapy and anticoagulation should be managed accordingly (refer section 6.12 on antiplatelets and antithrombotic in endoscopy).
j) The endoscopist should obtain an informed consent.
k) Intravenous access must be secured.
l) Prophylactic antibiotics should be given when indicated (refer section 6.11 on antibiotic prophylaxis in endoscopy).

6.23.5 Intra-procedure.

a) Patient positioning.

The patient should be preferably placed in the prone position.

6.23.6 Patient monitoring.

a) Pulse oximetry and the pulse rate should be continuously monitored. The blood pressure should be performed and documented every 5 minutes.
b) Emergency equipment, including suction, oxygen and crash cart must be readily available.
c) Topical anaesthesia such as lignocaine spray 10% may be used to facilitate insertion of the endoscope.
d) Sedation is administered in accordance with guidelines (refer section 6.9 on sedation in endoscopy). An anaesthetist may need to be present in selected cases.

6.23.7 Additional measures.

i. Frequent suctioning is important to keep the patient comfortable and the airway clear.
ii. Flush a standard ERCP catheter with contrast before the procedure begins.
iii. It is important to keep the catheter free of air bubbles because they interfere with the diagnosis of stones.
iv. When the endoscopist has achieved selective cannulation of the desired duct, he or she may ask the nurse to inject the contrast.
v. Gentle injection pressure should be used when infusing contrast to decrease the risk of pancreatitis.
vi. A 10 cc syringe is commonly used because smaller size syringes generate greater force.

6.23.8 Post-procedure.

a) Keep the patients on his or her side until fully awake and able to control secretions.

b) Monitor blood pressure, pulse, respiration, oxygen saturation, level of pain, and consciousness every 5-10 minutes. The pulse and oxygen saturation are monitored continuously.

c) Recovery after ERCP may be longer depending upon the amount and type of sedation used.

d) Observe for signs and symptoms of complications such as pancreatitis and perforation which may manifest with abdominal pain, vomiting and fever. Notify the endoscopist if these complications are suspected.

e) In selected cases if the patient‘s recovery is uneventful, he or she may be released in the company of a responsible adult with discharge instructions. Some patients may require hospital admission.

f) Immediately after the procedure a procedure report is prepared.

g) The patient should be clinically reviewed by the endoscopist and findings explained.

h) Discharge from the endoscopy unit.

    1) Documentation that the patient has met predetermined discharge criteria before discharge from the endoscopy unit.

    2) Patient may be discharged home accompanied by an escort with discharge instructions.

    3) Discharge instructions should address:

        - Diet restrictions.
        - Resumption of usual medications.
        - Return to activities, especially driving.
        - Procedure-specific information regarding potential delayed complications e.g., pancreatitis, cholangitis, GI bleeding, gut perforation.
        - Contact telephone number in the event of emergencies or should questions arise.

6.24 BILIARY STENTING

6.24.1 Introduction.

During endoscopic retrograde cholangiopancreatography (ERCP), biliary stents are commonly employed in the management of bile duct obstruction and leaks. Biliary stenting can be performed either by ERCP, EUS or transhepatic approaches. Biliary stenting via ERCP will be discussed.

6.24.2 Indications.

Malignant biliary stricture.
Benign biliary stricture.
Ischaemic stricture post-cholecystectomy.
Primary sclerosing cholangitis.
Anastomotic stricture post liver transplantation.
Chronic pancreatitis.
IgG4-related autoimmune cholangitis.
Tuberculous biliary stricture.
Post operative bile leak.
Choledocholithiasis with cholangitis.
Conduct of biliary stenting via ERCP.

6.24.3 Mandatory equipment required.

i. Mandatory endoscopy suite equipment (refer section 6.2).
ii. Standard ERCP equipment (refer section 6.10).
iii. Biliary stent (plastic or metallic).
iv. Stent delivery catheter.
v. Radiopaque guide wire.
vi. Biliary dilator.

6.24.4 Pre-procedure.

i. Standard pre-procedure measures (refer section 6.10).
ii. An ultrasound (US)/CT scan/magnetic resonance cholangio-pancreatography (MRCP)/EUS of abdomen should be done and imaging films made available for review prior to the procedure.

6.24.5 Intra-procedure.

i. Plastic stent insertion.
    - Shortest possible stent length is selected that will still ensure adequate drainage.
    - Stents are usually positioned so that one end is finally 1-2 cm beyond the proximal extent of the biliary obstacle and the other end protrudes 1 cm into the duodenum.
    - Estimation of stent length.
        - Slowly withdrawing a graduated guide wire or a guiding catheter that has radiopaque graduations at 1 cm intervals and measuring the length outside the scope using a ruler.
    - Biliary sphincterotomy is not necessary for inserting a single plastic biliary stent or SEMS. It is nevertheless routinely performed before stenting by some endoscopists because they think that this will facilitate stent exchange during follow-up, or if more than one biliary stent is to be placed (e.g., because of hilar obstruction or benign biliary stricture).
    - If endoscopic biliary sphincterotomy is performed, blended rather than pure-cut current should be used as this decreases the incidence of bleeding without affecting the incidence of pancreatitis following ERCP.

- If the stricture is tight, dilation of the stricture before stenting may be useful (in case of doubt, a bougie of diameter equal to or greater than that of the intended stent may be inserted through the stricture).
- The stent is loaded the right way up onto the guiding catheter, the guiding catheter is flushed with saline, the guide wire is cleaned and moistened to reduce friction, and the whole stent insertion system (guiding catheter, stent and pusher tube) is introduced into the working channel of the endoscope.
- Once inserted beyond the biliary obstacle, the guiding catheter is disconnected from the pusher tube by the assistant and the stent is progressively inserted by repeating the following manoeuvre:
    - 1-2 cm of the stent is pushed out of the duodenoscope (elevator in “low” position).
    - The elevator is closed while the assistant tightens the guiding catheter by moving apart the ends of the guiding catheter and of the pusher tube.
- During the whole procedure, the endoscope is kept close to the papilla to avoid looping of the insertion system in the duodenum.
- If stent insertion is difficult, the duodenoscope may be placed in a “long position” and, while it is pulled back with anticlockwise rotation to straighten loops (elevator in “up” position), the guiding catheter is straightened by the assistant to advance the stent.
- Once the stent is thought to be in the correct position, the guide wire and the guiding catheter are withdrawn while the pusher tube is held in contact with the stent to prevent stent dislocation.

ii. Self-expanding metal biliary stent (SEMS).

- The required stent length is assessed in the same way as with plastic stents, except for covered SEMS in patients with the gallbladder in situ. In such cases try to avoid occluding the cystic duct ostium by inserting the stent below the ostium.
- If applicable, the SEMS delivery catheter and the constraining sheath are flushed with saline before the delivery catheter is advanced over the guide wire into the desired location.
- The SEMS is deployed under fluoroscopic control by pulling back the constraining sheath, with the elevator in the low position.
- The position of the SEMS is maintained during deployment by pulling on the delivery catheter; it can be adjusted in the distal direction by more traction on the delivery catheter or, in the proximal direction, by recapturing the SEMS inside the constraining sheath (not possible with all SEMS models) and advancing the delivery catheter again. SEMS models with a low shortening ratio may deploy with only limited traction on the constraining sheath and require careful manipulation.
- After SEMS delivery, the catheter is withdrawn, taking care to not displace the SEMS with the olive at the tip of the catheter.
- If the stent has been deployed too proximally, it may be useful to withdraw the delivery catheter while leaving the guide wire in place and to attempt stent repositioning using a balloon or a rat tooth forceps. If this fails, a second SEMS may be inserted to prolong the first one. If the SEMS is positioned too distally with a large portion protruding into the

duodenum, it may be trimmed (using argon plasma coagulation [APC] with specific settings).

6.24.6 Post-procedure.

i. Standard post-procedure measures (refer section 6.10).

ii. Antibiotic prophylaxis is recommended when incomplete biliary drainage is anticipated (refer section 6.11 on antibiotic prophylaxis in endoscopy).

iii. Post-procedure monitoring of sepsis should be emphasized. If sepsis is suspected, monitoring of temperature, total white cell count and urine output are important.

iv. Monitoring of liver function tests should be done at regular intervals to detect resolution of obstructive jaundice.

v. Plastic stent will need to be replaced /removed in 3 months depending on the indication.

6.25 ENTERAL STENTING

6.25.1 Introduction.

Enteral stenting is a minimally invasive palliative procedure that involves the placement of a large diameter self-expanding metal stent (SEMS) across an intrinsic or extrinsic gastroduodenal obstructing lesion resulting in re-establishment of the normal anatomical conduit and permitting oral feeding. It can be placed under fluoroscopic guidance. The specifics of each stent, their characteristics and also their respective deployment techniques can vary significantly.

6.25.2 Indications.

a) Unresectable or untreatable malignant disease resulting in GI obstruction i.e., Intrinsic or extrinsic tumours, which are

unresectable or untreatable resulting in GI obstruction such as stomach and duodenal cancers.

b) Extrinsic gastroduodenal obstruction due to pancreatic malignancy, cholangiocarcinoma, malignant lymphadenopathy, localised intraperitoneal metastasis or lymphoma.
c) Anastomotic recurrence in the afferent or efferent loop of the gastrojejunostomy following definitive or palliative surgery for upper GI malignancy.
d) Treatment of malignant fistulas in the stomach and duodenum to adjacent organs.
e) Benign strictures secondary to chronic ulcer disease where surgery is not an option.

6.25.3 Mandatory equipment required.

a) Endoscopy system **(**refer section 6.2 and 6.3).

6.25.4 Additional equipment that may needed.

a) Upper endoscope (diagnostic or therapeutic).
b) Ultra slim upper endoscope (depends on clinical situation).
c) Duodenoscope (depends on clinical situation).
d) Fluoroscopy.
e) Guide wires.
f) Self-expanding metal stent (SEMS).
g) Non-ionic contrast medium.
h) Dilators.
i) Guiding catheters.

6.25.5 Pre-procedure.

a) Indications for the procedure must be reviewed by the endoscopist before commencement of the procedure.

b) Endoscopist should ensure that there are no contraindications to the procedure. Particular care should be noted of the coagulation profile.
c) Admission to ward day prior to procedure.
d) FBC and coagulation profile no later than 72 hours prior to the procedure.
e) Informed consent should be obtained by the endoscopist prior to the procedure.
f) Anticoagulation and need for antiplatelet medications (refer section 6.12 on anti-antiplatelets and antithrombotic in endoscopy)
g) A large bore (16G) nasogastric tube should be inserted and left on free drainage 12-24 hours before the procedure to reduce risk of aspiration and empty the s tomach (if feasible).
h) Fasting for at least 12 hours before the procedure in addition to the above as gastric emptying may be significantly impaired.
i) Admission post procedure is mandatory.

6.25.6 Intra-procedure.

a) Patient positioning.
    i. Use left lateral position to facilitate drainage of pharyngeal secretions.
    ii. The patient's head may be flexed in a forward position to ease the introduction of the endoscope.
    iii. In certain cases a prone position may be necessary.
    iv. Should the patient be intubated, positioning in the supine position may also be possible.

b) Patient monitoring.
    i. Continuous pulse oximetry. Document blood pressure and respiratory rate at least every 5 minutes during the procedure or more often if the patient's condition warrants.

ii. Emergency equipment including suction, oxygen and crash cart must be readily available.
iii. Stent placement may be under direct vision or under fluoroscopic guidance.
iv. The distal margin of the stent must be delineated - either through contrast injection after passage of a guide wire and catheter or direct vision if passage of an endoscope is feasible.
v. Carefully select a stent correspondent to the length of the stricture with an adequate diameter.
vi. The stent should be deployed with an experienced assistant under either imaging guidance.
vii. It is important to ensure that the distal end of the stent is within the lumen of a straight segment of the duodenum.
viii. Predilatation is generally not recommended due to the risk of perforation but may in certain very select cases be necessary.

6.25.7 Post-procedure.

a) Keep the patient on the left side until fully awake and able to control secretions.
b) Monitor vital signs such as blood pressure, pulse, oxygen saturation, level of consciousness and pain level every 5-10 minutes until they have returned to baseline.
c) Keep patient in the ward for at least 24 hours and watch for signs of perforation, peritonitis or mediastinitis.
d) A radiological examination may be considered post-stenting.
e) For stents placed lower in the GI tract, a barium meal and follow through or a CT scan with oral contrast may be used to confirm stent placement.

f) If the endoscopist is confident the stent is in place, fluids can be allowed on the day itself post-procedure and then soft diet once the stent is confirmed to be in place the following day.

g) Refer section 6.12 on antiplatelets and antithrombotic management post-procedure.

h) Appropriate dietary advice and instructions should be given. High fibre and large chunks of meat should be avoided. Food should be chewed well. This is to avoid the possibility of an obstructing food bolus.

i) Dietician referral before discharge is mandatory.

j) The patient may be discharged home with written discharge instructions which include contact numbers, possible complications specific to the procedure and diet and activity restrictions.

k) The endoscopist should be notified if the patient experiences fever, vomiting, abdominal pain, distension, haematemesis or maelena.

6.26 COLONIC STENTING

6.26.1.1 Introduction.

Malignant colonic obstruction may be treated by using conventional surgery with resection or diversion procedures, but patients presenting with malignant obstruction often are poor surgical candidates. Urgent surgical intervention in this setting is associated with a mortality rate of 10% and morbidity up to 40%.

Endoscopic placement of self-expanding metallic stents (SEMS) is an effective alternative to surgical decompression for colonic obstruction. It can be used for palliative management of malignant stricture or as “bridge to surgery” for patients with malignant

obstruction or benign colonic stricture who are candidates for surgery.

6.26.2 Mandatory equipment required.

Please refer section 6.19 on colonoscopy.

6.26.3 Additional equipment that may be needed.

a) Colorectal self-expanding metallic stents (SEMS).
b) Endoscopic catheter.
c) Stiff guide wire (0.035 inch).
d) Fluoroscopy.
e) Contrast medium.

6.26.4 Preparation for colonic stenting.

a) A water-soluble contrast enema examination may be performed to evaluate the stricture location, length, and expected difficulties associated with tortuous bowel segments.
b) Bowel preparation.
c) The patient must undergo bowel cleansing before the procedure (refer section 6.8 on bowel preparation in colonoscopy).
d) Stenting of left-side colonic obstruction requires only cleansing enemas for preparation.

6.26.5 Pre-procedure.

a) Before the use of moderate or deep sedation, a directed pre-procedure history and physical examination should be documented.
b) Patients should undergo a focused physical examination including:
    i. Vital signs (blood pressure, pulse rate, respiratory rate and oxygen saturation should be documented).
    ii. Auscultation of the heart and lungs.

iii. Evaluation of the airway.

c) Informed consent should be obtained by the endoscopist.

d) Venous access should be available.

6.26.6 Intra-procedure.

a) Patient positioning.
Patient is placed in the left decubitus or supine position.

b) Patient is kept under sedation or anaesthesia (refer section 6.9 on sedation in endoscopy).

c) Technique of stent placement.

i. A therapeutic colonoscope is advanced to the site of the lesion.

ii. When the lesion is identified, a guide wire (super stiff) is passed through the stricture under colonoscopic and fluoroscopic guidance.

iii. A catheter is inserted after the guide wire is passed successfully past the lesion.

iv. Contrast medium is injected to determinate the length of the obstructive lesion.

v. The stent is then inserted along the guide wire.

vi. The correct position of the stent will be confirmed using fluoroscopy and endoscopy.

d) Patient monitoring.

i. ECG, blood pressure, and pulse oximetry should be monitored continuously during the procedure.

ii. Blood pressure and pulse rate should be recorded at intervals no greater than 5 minutes.

iii. Suction should be readily available.

iv. Oxygen via nasal prong/catheter shall be administered when using intravenous sedation.

v. Documentation of medications. Doses and routes of administration of all medications used during the procedure are documented.

6.26.7 Post-procedure.

a) The patient should be kept on his or her side until fully awake and able to control secretions.
b) Monitor vital signs such as blood pressure, pulse rate and oxygen saturation frequently (15-30 minutes or whenever indicated) until patient recovers.
c) Discharge from the endoscopy unit.
d) Documentation that the patient has met predetermined discharge criteria before discharge from the endoscopy unit.
e) Patient may be discharged with discharge instructions.
f) Discharge instructions should address:
    - Diet restrictions.
    - Resumption of usual medications.
    - Potential delayed complications.
    - Contact telephone number in the event of emergencies or should questions arise.

g) Physicians should be notified if the patient develops symptoms e.g., abdominal pain, vomiting, and rectal bleeding.
h) Immediately after the procedure a procedure report is prepared.
i) A plain radiograph of the abdomen may be taken one day after stent placement to evaluate the expansion and position of the stent and to exclude complication such as perforation.

6.27 CAPSULE ENDOSCOPY

6.27.1 Introduction.

a) Endoscopic examination of the small intestine is limited by its significant length and distance from accessible orifices. The desire to explore this relatively inaccessible area led to the development of an ingestible miniature camera.

b) Video capsule endoscopy, capturing pictures at a rate of 14 pictures per second, provides visualization of the GI tract by transmitting images wirelessly from a disposable capsule to a data recorder worn by the patient. The equipment is removed after 8 hours (the approximate battery life) by which time the capsule has reached the caecum in 85% of cases.

c) On completion of the procedure, the data from the recorder is downloaded onto a computer workstation which allows approximately 50,000 images to be viewed as a video.

6.27.2 Indications for capsule endoscopy.

a) Obscure GI bleeding including iron deficiency anaemia.
b) Suspected Crohn's disease.
c) Suspected small intestinal tumours and surveillance in patients with polyposis syndromes.
d) Suspected or refractory malabsorptive syndromes (e.g., celiac disease).
e) Evaluation of suspected Barrett's oesophagus, oesophagitis, oesophageal varices (optional).

6.27.3 Contraindications for capsule endoscopy.

a) Patients with known or suspected GI obstruction, strictures or fistulas based on the clinical picture or pre-procedure testing.
b) Patients with cardiac pacemakers or other implanted electro-medical devices.
c) Patients with swallowing disorders.
d) Pregnancy.

6.27.4 Mandatory equipment required.

p) Video capsule.
q) Data recorder with belt.
r) Battery pack.
s) Chargers.
t) 8 electrodes.
u) Sensor device.
v) Reporting and processing of images and data application and software package.
w) Glass of water.
x) Simethicone solution (optional).

6.27.5 Pre-procedure.

a) Change the battery pack the evening before the procedure according to the manufacturer's instruction.
b) Bowel preparation with polyethylene glycol solution/ oral sodium phosphate one day prior to procedure as to improve the small bowel visualisation (refer section 12.0 on bowel preparation in colonoscopy).
c) No food is allowed after taking the bowel preparation. Only clear liquids are allowed until 10 pm the night before.
d) The patient should have nothing by mouth for 8 hours prior to procedure.

e) The patient should refrain from taking medications for 2 hours before the procedure.
f) Instruct the patient to wear loose fitting clothing.
g) On the procedure day, calibrate the electrodes and download the information into the recorder according to the manufacturer's instructions.
h) Obtain the patient's height, weight and waist size.
i) Document medical and surgical history.
j) Document medication allergies and daily medications, including dose and frequency.
k) Review the list of contraindications with the patient.
l) Informed consent should be obtained. This should include mention of possible capsule retention requiring surgery, potential complications related to swallowing of the capsule, potential risk of electromagnetic interference and the possibility of an incomplete study that might necessitate its repetition.

6.27.6 Intra-procedure.

a) Attach the electrodes and data recorder to the patient as per the manufacturer's instructions.
b) Videotape the patient's name and face for identifying information.
c) Video capsule is swallowed with a small amount of water.
d) The patient should be kept nil by mouth for 4 hours or at least 2 hours after the real time view has confirmed passage past the pylorus.
e) Inform the patient not to disconnect the belt or suspenders until after the test is completed.
f) Avoid vigorous physical activity such as running or jumping, and bending over while the test is in progress.
g) Advise the patient to check the blinking light on the recorder roughly every 15 minutes. If it is not blinking, instruct them to inform the doctor or return to the unit for further instructions.

h) The patient must check all bowel movements while the test is in progress to see if the capsule has passed prematurely.
i) For inpatients, approximately 8 hours after ingesting the capsule or after confirmed passage into the caecum via the real time viewer, remove the recording device.
j) For outpatients, the patient must return to the unit after 8 hours to have the belt and recorder removed.

6.27.7 Post-procedure.

a) Resume normal diet after the test is complete.
b) Images are downloaded into a computer for evaluation.
c) If the capsule does not pass within 2 weeks, the patients should notify the physician who may perform an abdominal X-ray.
d) Physician should be notified if the patient develops symptoms of abdominal pain, nausea or vomiting, fever, dysphagia or chest pain.
e) Patient should be informed the result of the test.

6.27.8 Complications.

a) Capsule retention.
    i. Capsule retention is defined as a capsule remaining in the digestive tract and confirmed by plain radiographs at 2 weeks post digestion or one that has required directed therapy to aid its passage.

    Frequency of capsule retention:
    - Suspected crohn's disease - 1%.
    - Known crohn's disease - 5%.
    - Obscure GI bleeding - 1.5%.
    - Suspected small bowel obstruction - 21%.

    Group of patients at higher risk:

- Chronic NSAIDs use.
- Extensive crohn's enteritis.
- Abdominal radiation injury.
- Prior major abdominal surgery.
- Prior small bowel resection.

ii. May be due to asymptomatic aspiration, gastroparesis, retention in a Zenker's diverticulum, a fractured capsule and intestinal perforation.

iii. Retained capsules, usually clinically asymptomatic, may require endoscopic removal or surgery.

b) Electromagnetic interference in patient undergoing oesophageal capsule studies.

6.27.9 Precautions.

a) Patients should not undergo MRI after capsule endoscopy until they have safely passed the capsule.

6.27.10 Limitation.

a) The capsule endoscopy system is purely diagnostic and is not used to biopsy or treat any condition.

6.27.11 Imaging the oesophagus.

a) There is a capsule endoscopy system currently available for oesophageal applications.
b) The capsule dimensions, transmission wavelength, field of view, and the minimum size of the object that can be detected are similar to the small bowel capsule. However, the capsule battery life is only 20 minutes (vs 8-12 hours for small-bowel capsules), cameras are located on both ends of the capsule, and the

capsule takes 18 frames per second (vs 2-3 frames per second for small-bowel capsules).

6.27.11 Imaging the colon.

a) A capsule endoscope for the colon is available.

6.27.12 Patency capsule.

a) This patency capsule which has dissolvable plugs at both ends has been devised to improve its use as a non-invasive tool in the assessment of functional patency of intestinal strictures. Larger studies are needed before the patency capsule can be recommended for routine use in the high risk group.

6.28 UREA BREATH TEST

6.28.1 Introduction.

a) *Helicobacter pylori* (*H pylori*) infects an estimated 50% of the global population. It is a potentially curable cause of dyspepsia and peptic ulcer disease. The urea breath test (UBT) is a non-invasive test for *H pylori* infection. It remains the best test to diagnose *H pylori* infection, has a high accuracy and is easy to perform; with a sensitivity of 88-95% and specificity of 95%-100%.There is also overwhelming evidence that UBT is an excellent test for follow-up after *H pylori* eradication.

6.28.2 Preparation.

a) Decrease of the gastric *H pylori* bacterial load may arise from the use of antimicrobial agents, PPIs and ulcer bleeding. These could lead to a low bacterial load and to false negative results of the UBT.

b) PPIs should be stopped 2 weeks before performing UBT. There was a 10-40% rate of false-negative results when UBT was done with patients on PPIs.
c) Antimicrobial agents should be stopped 4 weeks prior to UBT. It is not necessary to stop H2RA before performing UBT.
d) The time for testing the success of *H pylori* eradication should be at least 4 weeks after the end of treatment.

6.28.3 Pre-procedure.

a) The patient should be fasted for at least 4 hours (only plain water allowed).
b) Write the patient's ID, date and time for baseline bag. Time for second sample bag should be written after taking the UBT tablet (20 minutes from the time after taking tablet).

6.28.4 Steps in 13C-UBT.

a) Patient is asked to breathe into the baseline bag.
b) Ask the patient to hold the sample bag against the mouth, breath in through the nose and hold his/her breathe for 5-10 seconds. If the patient has difficulty holding his/her breath, make two or three short breaths into the bag instead.
c) Ask the patient to immediately swallow one UBT tablet with 100ml of water. Do not chew, crush or dissolve the tablet.
d) The patient is then asked to lean on his/her left side for 5 minutes and subsequently to remain seated for a further 15 minutes.
e) Following that (20 minutes after swallowing the UBT tablet), patient is asked to breathe into the second sample bag. Then both sample bags will be collected for analysis.
f) The patient is then informed that the urea breath test is done and will be reviewed by the attending doctor.

6.29 OESOPHAGEAL MANOMETRY AND AMBULATORY OESOPHAGEAL pH MONITORING

6.29.1 OESOPHAGEAL MANOMETRY

6.29.1.1 Introduction.

a) Oesophageal manometry is indicated for the evaluation of dysphagia not definitely diagnosed by means of endoscopy and/or radiology.

6.29.1.2 Indications.

a) To diagnose suspected primary oesophageal motility disorders (e.g., achalasia and diffuse oesophageal spasm).
b) To diagnose suspected secondary oesophageal motility disorders occurring in association with systemic diseases (e.g., systemic sclerosis).
c) To guide the accurate placement of pH electrodes for ambulatory pH monitoring studies.
d) As part of the pre-operative assessment of some patients undergoing anti-reflux procedures.
e) To reassess oesophageal function in patients who have been treated for a primary oesophageal disorder (e.g., sub-optimal clinical response to pneumatic balloon dilatation) or undergone anti-reflux surgery (e.g., dysphagia following fundoplication).

6.29.1.3 Mandatory equipment required.

a) Pressure sensing apparatus.
b) Recording device.
c) Ink/thermal writing polygraph or computer-generated reporting using analog to digital conversion and software analysis.
d) Sensing/transducer device.

e) Water-perfused catheters coupled to volume-displacement transducers.
f) Solid-state strain gauges.

6.29.1.4 Patient preparation and technique.

a) Equipment should be checked and calibrated before commencing each study.
b) Patients should fast for a minimum of 4 hours for solids and 2 hours for liquids prior to the procedure. (A longer period of fasting may be appropriate for patients suspected to have achalasia cardia).
c) Medications known to affect oesophageal motor function should be avoided for 24 hours prior to procedures. (e.g., beta blockers, nitrates, calcium channel blockers, anticholinergic drugs, prokinetics, nicotine, caffeine, opiates).
d) Any concurrent medications should be recorded.
e) Local anaesthetic may be used and if so its use should be documented.
f) A brief history and review of the patient's case records should alert the technician to any contra-indications to performing oesophageal studies or to the existence of conditions that may hinder the performance or interpretation of the test (e.g., large hiatal hernias, previous oesophageal surgery).

6.29.1.5 Intra-procedure.

a) The catheter may be placed via either the trans-nasal or trans-oral route.
b) Once the catheter has been inserted, the patient should be placed in the recumbent position if a water-perfused catheter is used and allowed a period of 5-10 minutes to accommodate to the catheter.

c) Water-perfused systems exhibit an upward shift of pressure baseline when the subject moves into an upright position, such that studies are best performed supine.
d) At the beginning of the manometric assessment, one or more (preferably three) of the most distal recording sites should be in the stomach. This can be verified by asking the patient to take a deep breath. Intra-abdominal pressure readings go up with inspiration and down on expiration. Conversely, pressure readings taken within the thoracic cavity go down on inspiration and up on expiration.
e) The station pull-through technique allows identification of the location and length of the sphincter high pressure zone (HPZ).
f) The lower oesophageal sphincter (LOS) resting pressure (pressure of HPZ minus intra-gastric pressure) is estimated from the mean of at least three radially orientated ports/transducers.
g) A series of wet swallows (5 ml of water) are used to examine LOS relaxation.
h) Oesophageal body motility is assessed using several sensors (at least three) positioned 3-5 cm apart above the LOS.
i) Both the distal (lower) and proximal (upper) oesophageal body are assessed, using a further series of wet swallows (at least 10 for both upper and lower oesophagus).
j) At least 20-30 seconds should be allowed between swallows as rapid repetitive swallowing inhibits peristalsis.
k) If peristalsis appears absent, the function of the sensors should be checked by asking the patient to cough.

6.29.1.6 Reporting.

a) General information.
b) Patient identification details.
c) Date and timing of the test.
d) Indications for the procedure.
e) A list of current medications.

f) The catheter was placed via the mouth or nares.
g) Type of apparatus.
h) Medications used during the procedure.
i) Technical difficulties were encountered during the procedure.

6.29.1.7 Lower oesophageal sphincter.

a) The location of the upper and lower border of the HPZ measured from the nares or incisors.
b) Calculation of LOS length.
c) Baseline lower oesophageal sphincter (resting) pressure. Pressures are measured relative to gastric pressure in millimetres of mercury. It is useful to state if LOS pressures have been measured in relation to respiration (i.e., end-expiratory values) or as an average of all pressures. Information relating to swallow-induced LOS relaxation is essential, as assessed by the residual pressure during maximal LOS relaxation. The number and/or percentage of wet swallows accompanied by complete relaxation should be given.

6.29.1.8 Oesophageal body.

a) Measurements (e.g., mean values +/- range) should be provided for the amplitude of pressure waves at a number of standard locations within the distal oesophagus.
b) An oesophageal pressure wave is defined as transient elevations of intra-oesophageal pressure of >20 mmHg above the baseline.
c) Values for the percentage of wet swallows that produce normally propagated peristalsis, failed peristalsis, simultaneous pressure waves, low pressure/ feeble peristaltic waves (<30 mmHg) and repetitive waves (>3 peaks at a recording site) are noted.

6.29.1.9 Interpretation.

a) A meaningful summary and manometric diagnosis.

6.29.2 AMBULATORY OESOPHAGEAL pH MONITORING

6.29.2.1 Introduction.

The accurate placement of pH electrodes for ambulatory pH monitoring studies can be performed using oesophageal manometry.

6.29.2.2 Indications.

a) Patients with symptoms clinically suggestive of acid gastro-oesophageal reflux, who fail to respond during a high dose therapeutic trial of a PPI.
b) Patients with symptoms clinically suggestive of acid gastro-oesophageal reflux without oesophagitis or with an unsatisfactory response to a high dose PPI in whom anti-reflux surgery is contemplated.
c) Patients with extra-oesophageal reflux symptoms.

6.29.2.3 Mandatory equipment required.

a) pH electrodes or wireless pH telemetry capsule.
b) Data loggers or receiver.

6.29.2.4 Pre-procedure.

a) PPI should be withdrawn 7 days and histamine H2 antagonists 3 days before the study. Antacids should not be consumed on the day of the study.

b) Patient is instructed to wear a front-button shirt to allow change of shirt if required.
c) Prior to and following ambulatory oesophageal pH monitoring, a calibration using neutral and acidic buffers should be undertaken with appropriate temperature compensation to ensure the electrode is responsive and has not drifted during the study by more than 0.5 pH units.

6.29.2.5 Intra-procedure.

a) The pH electrode is placed 5 cm above the manometrically determined upper border of the LOS, to prevent the electrode temporarily entering the stomach during the oesophageal shortening associated with swallowing.
b) Endoscopy is required for placement of a wireless telemetry capsule.

6.29.2.6 Post-procedure.

a) Patients should be instructed to complete a diary during oesophageal pH monitoring documenting the timing of meals, symptoms and supine periods.
b) Patients are advised to carry out their routine daily activities as usual.
c) Certain foods or drinks are not recommended while the electrode or capsule is in place.
    i. Tomatoes, pickles.
    ii. All fruits and fruit juices.
    iii. Sour cream, yoghurt, cottage cheese, cream cheese, cheese slices.
    iv. Tea, coffee, milk.
    v. Soda, cola, apple cider.
    vi. Jam, jelly, honey.
    vii. Vinegar, salad dressing.
    viii. Mustard, soy sauce.

d) If a conventional pH electrode is used, while the pH electrode is in place, patient is advised not to accidentally remove it. The patient is advised to return after 24 hours to have the electrode removed and pH data extracted.
e) If a wireless telemetry capsule is used, the patient will have to return in 24-48 hours to have the pH data downloaded to specific software.

6.30 ELECTROSURGERY IN ENDOSCOPY

6.30.1 The use of electrosurgical units.

Electrosurgery is used in the majority of endoscopic therapeutic procedures. An understanding of the fundamental electrosurgical principles and various settings available on electrosurgical units is essential for the safe and effective use of electrosurgery during endoscopy.

6.30.2 Key points and recommendations.

6.30.2.1 Protection measures for the patient.

a) The electrosurgical unit (ESU) should only be used by medical personnel after appropriate training.
b) Inspect the ESU for damage, including insulation of all cables and electrodes, missing components, and working lights and sounds (set on an audible level) prior to use.
c) The ESU should stand firm; no fluids should be placed on top of the ESU.
d) Do not use worn out or defective active electrodes, forceps or scissors.
e) Do not repair active electrodes, forceps or scissors.
f) Do not use the ESU in the presence of flammable material or substances (e.g., alcohol or nitrous oxide).
g) The patient must be insulated against all electrically conductive parts. Make sure that the patient does not come into contact with

other metal parts not insulated from the ground (e.g., operating table), although this concern is greatly diminished by the use of isolated and/or balanced ESUs.

h) Place the patient on a dry, electrically insulating layer.

i) Pacemaker or defibrillator (all types): seek advice from competent authority prior to endoscopy. Permanent ECG monitoring is recommended in these patients during electrosurgery. The use of bipolar applications might minimize possible complications. If a monopolar electrosurgical system is used, position the neutral electrode as close as possible to the active electrode. Direct contact with the implanted device and the leads should be avoided.

j) The power settings should be adapted to the type of procedure, tissue structure, patient body mass index, endotherapy instrument used, and manufacturers' recommendations. Always use the lowest power setting possible that will accomplish the desired tissue effect.

k) Before activating the ESU, the power settings should be rechecked and verbally confirmed between the Endoscopist and the assistant.

l) If current is not required, keep the foot away from the pedal to prevent accidental pressing, or disconnect the electrode from the ESU.

m) If inadequate current output is observed, stop the procedure immediately. Use the power switch as emergency stop for malfunctions. Leakage of current may be the result of a malfunctioning endotherapy instrument, ESU or broken insulation of the endoscope and may cause user and/or patient burns. ESU that constantly monitor leakage of current may help to ensure user and patient safety.

6.30.2.2 Staff safety.

a) Avoid contact with the neutral electrode.

b) When applying current, always be sure to wear gloves and touch the equipment or patient body with the entire palm of the hand, not with a single finger.
c) Electrosurgical equipment needs to be grounded in order to minimize interference with video endoscopic systems.
d) Smoke generated during electrosurgical procedures can be irritating and potentially harmful to personnel; surgical masks and adequate ventilation of smoke may be useful.

6.30.3 Neutral electrode.

a) Only patient neutral electrodes (plates or grounding pads) recommended by the ESU manufacturer should be used. For example, some ESUs require split type plates to monitor the quality of contact between the plate and the patient; single-use plates should not be reused.
b) Check expiration date (if expired patient plates are used, the adhesive may fail to maintain contact with the patient's skin and burns may result).
c) Check the patient plate for any damage/modification or sharp edges.
d) The neutral electrode should not be attached over some structures, including bony protuberances, metal implants or prostheses, skin folds, scar tissue, hairy areas, any form of skin discoloration/injury, limbs with a restricted blood supply, adjacent to ECG electrodes or onto pressure areas/points.
e) The neutral electrode should be attached over well perfused muscle tissue; the skin must be clean, dry, and free of hair to avoid loss of contact between the plate and the skin. The electrode should not be completely wrapped around a limb. Overlapping needs to be avoided. Ensure that the neutral electrode has full patient-skin contact.
f) The patient plate should be of appropriate size for the patient weight and should never be cut to size.

g) Patient plates that have once been removed from the patient skin have to be replaced by new ones.

6.30.4 Special situation: polypectomy or EMR.

a) Adjust settings according to particular conditions (e.g., low power settings for small bowel and caecum).
b) If polypectomy snare sticks in a polyp, increase cutting (see text above).
c) Do not touch metal parts, such as clips, with snare when applying current.
d) Do not touch the scope with metal parts of endotherapy instruments.
e) Watch out that snare tip does not accidentally touch the bowel wall opposite to mucosectomy.
f) Avoid deep coagulation of muscle layer (risk of late perforation).
g) Before applying current, make sure that the muscularis propria is not entrapped in the snare loop.

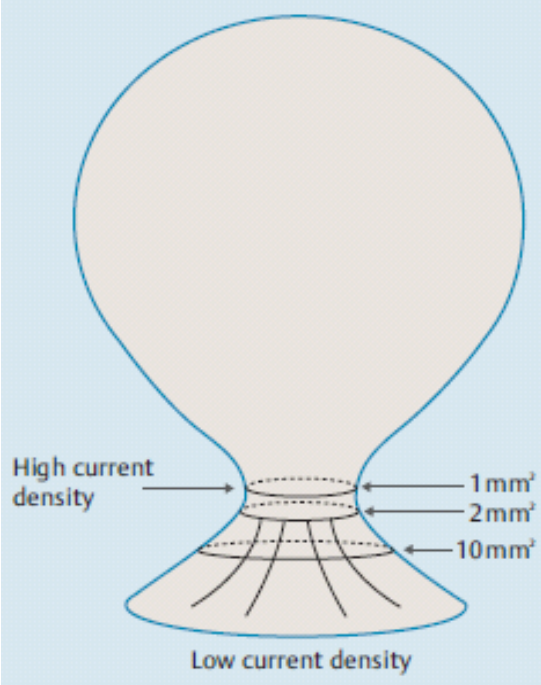
6.30.5 Interference with other electrical equipment.

a) Modern endoscopy units are equipped with several electrical devices and appliances that may potentially give rise to electrical interferences. For example, the ECG can create a false ground and skin burns can develop at points of contact with the electrodes if the electrode cables are placed close to, or entwined with, cables leading to the active electrode.
b) In a patient with a cardiac pacemaker or an implantable cardioverter-defibrillator, constant supervision must be maintained when applying high frequency current, particularly in monopolar mode, as it can result in cardiac arrest in a truly pacemaker-dependent patient. Monitoring of the patient ECG must include the possibility to detect pacemaker discharges (artefact filter should be disabled)

and peripheral pulse should be monitored using a pulse oximeter. Defibrillator equipment should be readily accessible. A pre-procedure ECG should be obtained and, if necessary, the device should be reset in ventricular asynchronous (VOO) mode. This type of adjustment should be made by the appropriate personnel (e.g., cardiologist or pacemaker technician), and once the endoscopic procedure is terminated, the device is interrogated and reset to the pre-procedure mode. During the procedure, bipolar electrosurgery is preferred, if feasible. If the monopolar mode is used, pure cut current may be preferable and the neutral electrode is positioned in a location that minimizes the current crossing the pacemaker-heart circuit. In emergent situations, placing a magnet close to the device temporarily ”reprograms” the pacer into asynchronous mode if the device has a magnet mode (most have). A magnet marketed by one pacemaker manufacturer is usually effective with other brands of pacemaker.

6.30.6 Electrosurgical settings.

a) Heat generated in the digestive mucosa is directly proportional to the square of current intensity (e.g., if current intensity is doubled, the heat generated increases by a factor of 4). Understanding this relationship between current intensity, density, and heat is essential for adequate ESU operation. As an example, the thermal effect of current application to the base of a polyp is shown.



Current densities during polypectomy at various levels of a polyp stalk. The density of the monopolar current administered through the snare (and, hence, the rise in temperature) varies according to cross-sectional areas.

b) All other things being equal, the larger the base of the polyp or the snare wire, the more energy will be required to section it.

6.30.7 Practical applications.

a) Polypectomy.

Although this section deals with colon polypectomy, the principles described here are applicable to other polypectomy sites. Bleeding is the most frequent complication of polypectomy, occurring in 1%-4% of cases, compared with a 0.5 % risk for perforation.

b) Polypectomy snares.

- Polypectomy snares of different size, shape, and wire characteristics are commercially available. A snare with a particular diameter and shape is selected according to the size of the polyp and bowel features (e. g. a small oval snare is preferable for removing a small polyp in a diverticular-laden, narrow, colonic segment). It is important to have a snare design that facilitates capture of the lesion.

6.30.8 Current application.

a) The use of blended or coagulation current, rather than pure cut waveforms, is preferred for polypectomy. In the absence of firm evidence-based data, no specific recommendation can be made regarding the selection of a particular electrosurgical current for polypectomy except for the avoidance of pure cut current.

b) Once seized with a snare, the polyp should be tented away from the colon wall in order to decrease the risk of perforation.

c) During polypectomy, tissue resistance will increase as desiccation occurs, and sectioning the central part of the polyp base is therefore slower.

d) Contact between the surface of the polyp and the bowel wall should be avoided to minimize contralateral burn. This may be difficult with a very large polyp, but wiggling the polyp during current application will minimize damage of normal tissue in contact with the polyp being resected.

e) A risk of snare entrapment in desiccated tissue exists for very large polyps. If the area of contact between the snare and the tissue is large, current density may be too low to efficiently section the polyp base. The natural tendency is to increase snare tightening around the polyp but this may section the tissue without providing enough coagulation or increase the area of contact between the snare and the tissue surrounding the metal wire, further decreasing cutting efficiency. This situation can best be avoided by not overly tightening the snare (strangulation) or attempting polypectomy on a large pedicle with too low a power setting.

6.30.9 Resection of small polyps with a hot biopsy forceps.

a) Polypectomy using a hot biopsy forceps should be avoided as this technique leaves residual neoplastic tissue in situ in 15% of cases and the pathological examination of resected specimens is severely hampered by thermal artefacts. If the technique is nevertheless used to sample a large polyp or to resect a polyp of

less than 5 mm, the forceps should be tented away from the bowel wall to allow for current concentration to a relatively small area and limit thermal damage to the submucosa. As the area of contact between the metal cups of the forceps is relatively large, the current in the tissue can be sizeable, resulting in a significant thermal effect. A deep thermal effect can cause delayed wall necrosis and perforation, particularly in areas where the digestive wall is thin, such as the caecum and ascending colon.

6.30.10 Risk of explosion during colon polypectomy.

a) Several case reports have described explosions occurring at the time of electrosurgery in the colon. The risk of explosion exists when combustible gas concentrations are elevated in the colon (methane >5%, hydrogen >4 %, and oxygen >5%). These conditions may be present in poorly prepped or unprepped colons, or when mannitol-based bowel preparations are used. With the advent of polyethylene glycol or sodium phosphate-based preparations for bowel cleansing, this concern has markedly decreased. Using carbon dioxide for gut distension during endoscopy can also minimize the explosion risk.

6.30.11 Sphincterotomy.

a) Practical issues related to sphincterotomy are as follows:
    a) If no effect is observed within one or two seconds after current application, it may be useful to reduce the length of wire in contact with the surrounding tissue.
    b) Uncontrolled rapid cutting (”zipper effect”), a potentially dangerous event, may develop as the length of wire in contact with the tissue decreases (e.g., once tissue has been cut) or if the force applied with the sphincterotome is high.
    c) As heating related to coagulation is thought to favour the development of local oedema that might obstruct pancreatic outflow, the combination of current waveforms

has been explored as a potential means to reduce post sphincterotomy pancreatitis. However, comparative studies of combined current waveforms vs. pure cut or blended current used throughout sphincterotomy have found no difference in the outcome of post sphincterotomy pancreatitis.

6.30.12 Haemostasis.

a) All ESUs offer coagulation modes that can be applied immediately during a cutting procedure using a nonspecific device (e.g., applying coagulation current at the bleeding edge of a biliary sphincterotomy using the sphincterotome wire) or to treat a spontaneously bleeding lesion with a specific device (e.g., bipolar coagulation probe).

6.30.13 Endoscopic mucosal resection and submucosal dissection.

a) Endocut and pulsecut are commonly used settings for EMR and ESD, although some endoscopists use pure cut waveforms. Compared with EMR, ESD is technically more challenging and time consuming but enables en bloc resection in most cases. The instruments (knives) used for dissection and the type of current waveforms and power settings selected are influenced by various parameters, such as lesion location, tissue characteristics, and operator preferences. As the technique of ESD is not yet standardized, endoscopists mainly rely on personal or reported experience thus far.

6.30.14 Monopolar vs. bipolar accessories.

a) All ESUs used in digestive endoscopy provide monopolar and bipolar modes; few provide bipolar cutting current. This is due to the limited availability of devices adapted for bipolar use apart from coagulation probes.

b) Bipolar mode is currently used almost exclusively with catheter probes designed for haemostasis of nonvariceal bleeding lesions. This type of probe provides treatment outcomes similar

to other effective modalities. Bipolar probes usually permit irrigation, which is particularly useful if an endoscope with a single working channel is used.

TABLE 1. Pacemakers: recommendations for managing pacemakers in the setting of electrosurgical procedures

	Pre-procedure	During procedure	Post-procedure
Universal recommendations	1. Assess the type of implanted cardiac device, its location, the reason for the patient's need for the device and dependence on the device. 2. Determine whether the patient is pacemaker dependent and attempt to predict whether prolonged electromagnetic current will be needed. a. If patient is not pacemaker dependent, then no reprogramming is necessary. b. If pacemaker dependent and prolonged electrocautery may be required, see specific recommendations below.	1. Closely monitor vital signs and heart rhythms with electrocardiography during the procedure. The patient should be monitored continuously via hard-wired monitoring. 2. Cardioverter-defibrillation equipment should readily available. 3. Use alternative methods to electrocautery whenever possible. 4. Apply bipolar or multipolar currents rather than unipolar currents whenever possible. 5. Whenever unipolar cautery is required, place the grounding pad on the patient in a location such that the applied current does not pass close to or through the leads of the cardiac device. 6. Minimize the strength of the electrosurgical current applied. 7. Apply the electrosurgical current intermittently and for the shortest amount of time possible. 8. External pacing can be effective. It can be set to the asynchronous mode and will be unaffected by cautery.	1. If the pacemaker or ICD was reprogrammed, restore baseline function of the device. 2. There is no need for further follow-up if the device is interrogated after the procedure.
AACF/AHA[4]	1. Procedure team should be responsible for determining type of implanted cardiac device, its location, the reason for the patient's need for the device and dependence on the device. 2. If pacemaker dependent and prolonged electrocautery may be required, the pacemaker should be reprogrammed to the asynchronous mode for the duration of the procedure.		1. Restore baseline settings and closely monitor the patient in the immediate postprocedural period, but no need for specific consultation or follow-up.
ASGE[1]	1. Procedure team should be responsible for determining type of implanted cardiac device, its location, the reason for the patient's need for the device and dependence on the device. 2. If pacemaker dependent and prolonged electrocautery may be required, the pacemaker should be reprogrammed to the asynchronous mode for the duration of the procedure.		1. Restore baseline settings and closely monitor the patient in the immediate postprocedural period, but no need for specific consultation or follow-up.
HRS/ASA[5]	1. A team specifically trained in cardiovascular implantable devices should be consulted to determine type of implanted cardiac device, its location, the reason for the patient's need for the device and dependence on the device. 2. If pacemaker dependent and prolonged electrocautery may be required, reprogram the pacemaker to the asynchronous mode only when electrosurgical procedures are used above the level of the umbilicus.		1. Consult cardiology or pacemaker/ICD service for restoring baseline device settings. 2. An additional evaluation of the device should be performed within 1 month after the procedure.

ACCF/AHA, American College of Cardiology Foundation/American Heart Association; *ASGE*, American Society for Gastrointestinal Endoscopy; *HRS/ASA*, Heart Rhythm Society and the American Society of Anesthesiologists; *ICD*, implantable cardioverter-defibrillator.

TABLE 2. Recommendations for managing ICDs in the setting of electrosurgical procedures

	Pre-procedure	During procedure	Post-procedure
Universal recommendations	1. Assess the type of implanted cardiac device, its location, the reason for the patient's need for the device, and dependence on the device. 2. Reprogram an ICD to inactivate tachyarrhythmia detection before procedures in which electrocautery is to be used. If unable to do so, a magnet could be used if the magnet can be secured over the pulse generator. Consult cardiology or a team specifically trained in cardiovascular implantable device management.	1. Closely monitor vital signs and heart rhythms with electrocardiography during the procedure. 2. Cardioverter-defibrillation equipment should be readily available. 3. Use alternative methods to electrocautery whenever possible. 4. Apply bipolar or multipolar currents rather than unipolar currents whenever possible. 5. Whenever unipolar cautery is required, place the grounding pad on the patient in a location such that the applied current does not pass close to or through the leads of the cardiac device. 6. Minimize the strength the electrosurgical current applied. 7. Apply electrosurgical current intermittently and for the shortest amount of time possible.	1. The ICD should be reprogrammed to its original function as soon as possible by trained personnel, including either a cardiologist or a team specifically trained in cardiovascular implantable device management.

ICD, Implantable cardioverter-defibrillator.
The American College of Cardiology Foundation/American Heart Association, American Society for Gastrointestinal Endoscopy, and Heart Rhythm Society and the American Society of Anesthesiologists all agree on these recommendations.[1,45]

APPENDICES

1.0 Procedure Forms

H**OSPITAL**
ENDOSCOPY UNIT
CLINICAL ASSESSMENT

AFFIX PATIENT LABEL

PATIENT DETAILS

NAME: IC NO/RN NO:
DATE OF BIRTH: AGE: GENDER: M / F
RACE: NATIONALITY: TEL NO:
ADDRESS:
MODE OF ADMISSION: WALKING ☐ WHEELCHAIR ☐
STRETCHER ☐ OTHERS ☐

DETAILS OF PATIENT ESCORT

NAME: TEL NO:
RELATIONSHIP: TRANSPORT:
WILL WAIT ☐ WILL RETURN ☐

NURSING ADMISSION RECORD

WARD / OUT PATIENT:
DATE OF ADMISSION:
TIME OF ADMISSION:
PROPOSED PROCEDURE:
OGDS ☐ ERCP ☐ DRE ☐
COLONOSCOPY ☐ EUS ☐
OTHERS:
CONSULTANT:
NIL ORALLY (HRS):

ALLERGIES/REACTION

*** RISK STRATIFICATION (PLEASE CIRCLE ONE)**

ASA SCORE	DESCRIPTION	EXAMPLE
CLASS 1	HEALTHY PATIENT	
CLASS 2	MILD SYSTEMIC DISEASE - NO FUNCTIONAL LIMITATION	CONTROLLED HYPERTENSION, DIABETES
CLASS 3	SEVERE SYSTEMIC DISEASE - DEFINITE FUNCTIONAL LIMITATION	BRITTLE DIABETIC, FREQUENT ANGINA, MYOCARDIAL INFARCTION
CLASS 4	SEVERE SYSTEMIC DISEASE WITH ACUTE UNSTABLE SYMPTOMS	RECENT MYOCARDIAL INFARCTION, CONGESTIVE HEART FAILURE, ACUTE RENAL FAILURE, UNCONTROLLED ACTIVE ASTHMA
CLASS 5	SEVERE SYSTEMIC DISEASE WITH IMMINENT RISK OF DEATH	

BOWEL PREPARATION

TYPE: PEG ☐ SODIUM PHOSPHATE ☐
OTHERS:

VITAL SIGNS

BP:
PULSE:
RR:
O2 SAT:

INVESTIGATIONS

HB:
PLATELET COUNT:
PTT:
PT/INR:

MEDICAL RISK ASSESSMENT

	YES	NO
DIABETES MELLITUS	☐	☐
HYPERTENSION	☐	☐
CARDIAC DISEASE	☐	☐
RESPIRATORY DISEASE	☐	☐
LIVER DISEASE	☐	☐
BLEEDING DISORDER (E.G., LOW PLATELET COUNT)	☐	☐
ANTIPLATELET (E.G., ASPIRIN/CLOPIDOGREL [PLAVIX])	☐	☐
ANTICOAGULANT (E.G., WARFARIN/HEPARIN)	☐	☐
OTHERS (E.G., OPERATION)	☐	☐

CHECKLIST

	YES	NO
INFORMED CONSENT	☐	☐
PROCEDURE INFROMATION LEAFLET READ	☐	☐
EXPLANATION (PRE/POST PROCEDURE) GIVEN	☐	☐
REFERRAL LETTER	☐	☐
PREVIOUS CLINICAL NOTES	☐	☐
X-RAY/ECG/SCAN	☐	☐
DENTURES REMOVED (WITH PATIENT)	☐	☐
JEWELLERY/NAILPOLISH (REMOVED)	☐	☐
UNDERGARMENT (REMOVED)	☐	☐

DATE: TIME:

NAME OF ADMITTING GIA: SIGNATURE:

CONSENT TAKEN BY ENDOSCOPIST

NAME: SIGNATURE:

DATE: TIME:

CURRENT MEDICATION

HOSPITAL
ENDOSCOPY UNIT
ENDOSCOPY INTRA-PROCEDURE FORM

AFFIX PATIENT LABEL

NAME: IC NO/RN NO:
DATE: TIME:
PROCEDURE ROOM:
ENDOSCOPIST:
GIA:

PROCEDURES PERFORMED

OGDS ☐ COLONOSCOPY ☐ ERCP ☐
DBE ☐ OTHERS (SPECIFY):

THERAPEUTIC PROCEDURES:

	YES	NO
LIDOCAINE SPRAY:	☐	☐
SEDATION:	☐	☐

TIME PROCEDURE COMMENCED:

TIME PROCEDURE COMPLETED:

LEVEL OF SEDATION

O - AWAKE
1 - DROWSY
2 - SEDATED, ROUSABLE WITH VERBAL COMMENTS
3 - SEDATED, ROUSABLE WITH PAIN STIMULI
4 - UNAROUSABLE

PROCEDURE CHECKLIST

	YES	NO
ALLERGIES RECORDED	☐	☐
MOUTH GUARD INSERTED	☐	☐
OXYGEN REQUIRED (___ L/MIN)	☐	☐
SUCTION REQUIRED	☐	☐

MONITORING

	YES	NO
OXYMETRY	☐	☐
BP	☐	☐
ECG	☐	☐
CAPNOGRAPHY	☐	☐
IV CANNULA SITU	☐	☐
BLOOD PRODUCTS	☐	☐
TYPE:		
AMOUNT:		
ANTIBIOTIC PROPHYLAXIS	☐	☐
DETAILS:		

SPECIMENS

RAPID UREASE TEST:	POSITIVE	☐
	NEGATIVE	☐
	NOT DONE	☐

HPE:

OTHERS:

TIME	SP02%	BP/MMHG	PULSE/MIN	RR/MIN	LEVEL OF SEDATION (0-4)	MIDAZOLAM	PETHIDINE	HYOSCINE	OTHERS

SPECIAL INSTRUCTION:

ADVERSE EVENTS:

NAME OF GIA: SIGNATURE:

HOSPITAL
ENDOSCOPY UNIT
ENDOSCOPY POST-PROCEDURE FORM

AFFIX PATIENT LABEL

DATE: TIME ADMITTED TO RECOVERY BAY:
NAME: IC NO/RN NO:

	YES	NO
ABDOMINAL PAIN		
ABDOMINAL DISTENTION		
NAUSEA/VOMITING		

LEVEL OF SEDATION

0 - AWAKE
1 - DROWSY
2 - SEDATED, ROUSABLE WITH VERBAL COMMENT
3 - SEDATED , ROUSABLE WITH PAIN STIMULI
4 - UNAROUSABLE

TIME	SP02%	BP/mmHG	PULSE/MIN	RR/MIN	LEVEL OF SEDATION (0-4)	PAIN SCORE (0-10)	MIDAZOLAM	FLUMAZENIL	NALOXONE	OTHERS

DISCHARGE CHECKLIST

	YES	NO
FINDINGS EXPLAINED BY ENDOSCOPIST		
IV CANNULA REMOVED		
PATIENT TOLERATING FLUIDS/DIETS		
PERSONAL BELONGINGS RETURNED		
DISCHARGE INSTRUCTIONS CHECKED, READ AND GIVEN TO PATIENT		
X-RAY/SCN RETURNED TO PATIENT		
MEDICATION PRESCRIBED		
MEDICAL LEAVE/TIME SLIP GIVEN		
CLINIC APPOINTMENT GIVEN		
REPEAT ENDOSCOPY APPOINTMENT GIVEN		
ENDOSCOPY DATE GIVEN:		
MOBILITY ON DISCHARGE: WALKING		
WHEELCHAIR		
STRETCHER		
OTHERS:		

DISCHARGE

DESTINATION: HOME ☐ WARD ☐ OTHERS: ☐
TRANSPORT: TAXI ☐ BUS ☐ PRIVATE VEHICLE ☐ HOSPITAL TRANSPORT ☐

ACCOMPANIED BY: Rykieuituyu4yuiueuu7re56lwgyol9w3r4uo54 DATE:

RELATIONSHIP: TIME:

DISCHARGING ENDOSCOPIST/DOCTOR: SIGNATURE:

SPECIFIC POST DISCHARGE INSTRUCTIONS (IF APPLICABLE):

DISCHARGING NURSE/GIA: SIGNATURE:

Form 1.4

HOSPITAL **ENDOSCOPY UNIT** **DISCHARGE INTRUCTIONS (TO BE GIVEN TO PATIENT)**	**AFFIX PATIENT LABEL**
DATE: TIME: NAME: IC NO/RN NO:	IF YOU EXPERIENCE ANY PROBLEMS, PLEASE CONTACT THE ENDOSCOPY UNIT, HOSPITAL_____ TEL NO: _____ OFFICE HOURS: 8.00 AM - 5.00 PM (MONDAY - FRIDAY) WEEKEND AND PUBLIC HOLIDAYS: CLOSED

	YES	NO	REMARKS
1. TO RESUME DIET UNLESS OTHERWISE INSTRUCTED BY DOCTOR	☐	☐	
2. TO RESUME NORMAL MEDICATION	☐	☐	
3. TO INFORM YOUR DOCTORS IF YOU EXPERIENCE THE FOLLOWING:			
A. SEVERE PAIN OR VOMITING	☐	☐	
B. PASSAGE OT VOMITING OF BLOOD	☐	☐	
C. TEMPERATURE OF GREATER THAN 101°F/38°C	☐	☐	
D. REDNESS , TENDERNESS AND SWELLING AT SITE OF INTRAVENOUS CANNULA THAT PERSISTS FOR MORE THAN 48 HOURS	☐	☐	
4. ESCORT TO ACCOMPANY PATIENT IF PATIENT HAD RECEIVED SEDATION	☐	☐	
5. MEDICATION ON DISCHARGE GIVEN	☐	☐	
6. FOLLOW-UP APPOINTMENT DATE GIVEN	☐	☐	
7, MEDICAL LEAVE/TIME SLIP GIVEN	☐	☐	
8. HEALTH EDUCATION GIVEN	☐	☐	
9. PERSONAL BELONGINGS RETURNED	☐	☐	
10. INFORMATION LEAFLET READ AND GIVEN	☐	☐	

NAME OF GIA: SIGNATURE:

2.0 CONSENT FORM

2.1 OESOPHAGOGASTRODUODENOSCOPY (OGDS) CONSENT FORM

Patient Consent

I acknowledge that the doctor has explained:

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic/sedation required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- Tissue samples may be removed and could be used for diagnosis or management of my condition.
  These samples will be stored and disposed sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on best medical practice.
- A doctor other than the consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following patient information form:

☐ **Oesophagogastroduodenoscopy (OGDS)**

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and my concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video/s maybe recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

Identification details
I/C / RN No.: Patient Name: Address: Date of Birth: Gender: M / F

I request to have the procedure.
Name of Patient:
Signature:
Date:

Patients who lack capacity to provide consent
Consent must be obtained from a substitute decision maker.
Name of substitute decision maker: Signature: Relationship to patient: Date: I/C No:

Doctor's statement
I have explained to the patient all the above points under the patient consent section and I am of the opinion that the patient/substitute decision maker has understood the information. Name of Doctor: Designation: Signature: Date:

Procedure

An upper gastrointestinal (GI) endoscopy is where the doctor uses an instrument called an endoscope to look at the inside lining of your oesophagus (food pipe), stomach and duodenum (first part of the small intestine). This is done for patients with swallowing problems, nausea, vomiting, reflux, bleeding, indigestion, abdominal pain or chest pain.

This procedure may or may not require a sedative injection or anaesthetic.

Risks of OGDS and sedation

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications include:

- Nausea and vomiting.
- Pain, redness or bruising at the sedation injection site (usually in the hand or arm).
- Allergy to medications given at time of the procedure.

Uncommon risks and complications include:

- About 1 person in every 1,000 will experience bleeding from the oesophagus (food pipe), stomach and duodenum where a lesion or polyp was removed. This is usually stopped through the endoscope. Rarely, surgery is needed to stop bleeding.
- Damage to your teeth, jaw or throat due to the presence of instruments in your mouth.
- An existing medical condition that you may have getting worse.

Rare risks and complications include:

- Missed abnormalities.
- About 1 person in every 10,000 will accidentally get a tear (perforation) in the oesophagus, stomach or duodenum. This can cause a leak of stomach contents into the abdomen. If a tear occurs, you will be admitted to hospital for further treatment which may include surgery or therapy through the endoscope.
- 'Dead arm' type feeling due to positioning with the procedure - usually temporary.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.

2.2 ENDOSCOPIC VARICEAL LIGATION (EVL) AND CYANOACRYLATE (HISTOACRYL) GLUE INJECTION CONSENT FORM

Patient Consent

I acknowledge that the doctor has explained:

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic/sedation required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- If immediate life-threatening events happen during the procedure, they will be treated based on best medical practice.
- A doctor other than the consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following patient information form/s:

☐ **Oesophagogastroduodenoscopy (OGDS)**

☐ **Endoscopic variceal band ligation (EVL) and injection of cyanoacrylate (histoacryl) glue**

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video/s may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

Identification details
I/C / RN No.: Patient Name: Address: Date of Birth: Gender: M / F

I request to have the procedure.
Name of Patient:
Signature:
Date:

Patients who lack capacity to provide consent
Consent must be obtained from a substitute decision maker.
Name of substitute decision maker: Signature: Relationship to patient: Date: I/C No:

Doctor's statement
I have explained to the patient all the above points under the patient consent section and I am of the opinion that the patient/substitute decision maker has understood the information. Name of Doctor: Designation: Signature: Date:

Procedure

Varices are large veins that appear in the oesophagus and stomach. These may rupture and cause significant bleeding requiring endoscopic treatment.

The doctor will use an instrument called the endoscope to look at the inside lining of your oesophagus (food pipe), stomach and duodenum (first part of the small intestine).

Banding of oesophageal varices involves placement of rubber bands over the varices at the time of endoscopy.

Gluing is usually reserved for stomach varices and involves injecting glue into them. This will cause the blood in the varices to clot and eventually the clotted vein will disappear.

This procedure may or may not require a sedative injection or anaesthetic.

Risks of EVL and histoacryl glue injection, and sedation

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications include:

- Nausea and vomiting.
- Faintness or dizziness, especially when you start to move around.
- Pain, redness or bruising at the sedation injection site (usually in the hand or arm).
- Chest pain and difficulty in swallowing for up to 2 weeks after the procedure.
- Allergy to medications given at time of the procedure.

Uncommon risks and complications include:

- Bleeding from the oesophagus (food pipe) where a varix has been banded. This can be serious just as the bleeding due to untreated varices can be. Once the course of banding is completed the risk of bleeding of any sort is greatly reduced.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.
- Bacteraemia (infection in the blood). This will need antibiotics.
- Damage to your teeth, jaw or throat due to the presence of instruments in your mouth.
- An existing medical condition that you may have getting worse.

Rare risks and complications include:

- A tear (perforation) in the oesophagus can accidentally occur. This can cause a leak of stomach contents into the chest. If a tear occurs, you will be admitted to hospital for further treatment which may include therapy through the endoscope or surgery.
- Glue, if used, can move into the blood vessels in the lungs causing breathing difficulties. The glue cannot be removed and will remain in the lungs. Glue can also spread into blood vessels in other parts of the body such as the bowel and the brain, and could cause serious damage.
- 'Dead arm' type feeling due to positioning with the procedure - usually temporary.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Death as a result of complications to this procedure is uncommon.

2.3 COLONOSCOPY CONSENT FORM

Patient Consent

I acknowledge that the doctor has explained:

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic/sedation required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- Tissue samples may be removed and could be used for diagnosis or management of my condition. These samples will be stored and disposed sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on best medical practice.
- A doctor other than the consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following patient information form/s:

☐ **Colonoscopy**

☐ **Bowel preparation for colonoscopy**

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and my concern have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video/s may be recorded during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

Identification details
I/C / RN No.: Patient Name: Address: Date of Birth: Gender: M / F

I request to have the procedure.
Name of Patient:
Signature:
Date:

Patients who lack capacity to provide consent
Consent must be obtained from a substitute decision maker.
Name of substitute decision maker: Signature: Relationship to patient: Date: I/C No:

Doctor's statement
I have explained to the patient all the above points under the patient consent section and I am of the opinion that the patient/substitute decision maker has understood the information. Name of Doctor: Designation: Signature: Date:

Procedure

A colonoscopy is where the doctor uses an instrument called a colonoscope to look at the inside lining of your large bowel. This procedure starts from your back passage (anus) and goes up to the right side of your large bowel (caecum) and part of the small bowel (ileum). This is done to see if there are any growths, polyps or disease in your bowel.

Small pieces of your bowel may need to be removed for pathology tests.

This procedure may or may not require a sedative injection or anaesthetic.

Risks of colonoscopy and sedation

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications include:

- Mild pain and discomfort in the abdomen after the procedure. This usually settles with walking and moving around to get rid of the trapped air.
- Pain, redness or bruising at the sedation injection site (usually in the hand or arm).

Uncommon risks and complications include:

- About 1 person in every 1,000 will accidentally get a tear (perforation) to the bowel causing leakage of bowel contents into the abdomen. Therapy through the colonoscope may be needed to repair the tear failing which surgery may be required.
- About 1 person in every 100 will experience a significant bleed from the bowel where a polyp is removed. Further endoscopy, a blood transfusion or an operation may be necessary.
- Occasionally we may not be able to see the entire large bowel. This can happen if your bowel is not completely clean or the colonoscope could not be passed to the end of your large bowel.
- Missed polyps, growths or bowel disease.
- Change of anaesthetic from a sedative injection to a general anaesthetic.
- Dead arm' type feeling due to positioning with the procedure - usually temporary.
- An existing medical condition that you may already have getting worse.

Rare risks and complications include:

- Missed abnormalities.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.

2.4 ENTEROSCOPY CONSENT FORM

Patient consent

I acknowledge that the doctor has explained:

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic/sedation required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- Tissues samples may be removed and could be used for diagnosis or management of my condition. These samples will be stored and disposed sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on best medical practice.
- A doctor other than the consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following patient information form:

☐ **Enteroscopy**

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video/s may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

Identification details
I/C / RN No.:
Patient Name:
Address:
Date of Birth:
Gender: M / F

I request to have the procedure.
Name of Patient:
Signature:
Date:

Patients who lack capacity to provide consent
Consent must be obtained from a substitute decision maker.
Name of substitute decision maker: Signature: Relationship to patient: Date: I/C No:

Doctor's statement
I have explained to the patient all the above points under the patient consent section and I am of the opinion that the patient/substitute decision maker has understood the information. Name of Doctor: Designation: Signature: Date:

Procedure

Enteroscopy is where the doctor uses an instrument called an endoscope to look at the oesophagus (food pipe), stomach and mainly the small bowel. It can be performed via the mouth or the back passage (anus). It is done to rule out any disease in the small bowel.

This procedure may or may not require a sedative injection or anaesthetic.

Risks of an enteroscopy and sedation

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications include:

- Nausea and vomiting.
- Faintness or dizziness, especially when you start to move around.
- Pain, redness or bruising at the sedation injection site (usually in the hand or arm).
- Allergy to medications given at time of the procedure.

Uncommon risks and complications include:

- About 1 person in every 1,000 will experience bleeding where a lesion or polyp was removed. This is usually stopped through the endoscope. Rarely, surgery is needed to stop bleeding.
- Damage to your teeth, jaw or throat due to the presence of instruments in your mouth.
- An existing medical condition that you may have getting worse.
- About 1 in 100 people will get swelling and inflammation of the pancreas (pancreatitis). This may need pain relief. This usually settles over the next 24- 48 hours. It can be severe and need further treatment, which may result in admission to hospital.

Rare risks and complications include:

- Missed polyps or growths.
- About 1 person in every 10,000 will accidentally get tear (perforation) in the oesophagus, stomach or duodenum. This can cause a leak of stomach contents into the abdomen. If a tear occurs, you will be admitted to hospital for further treatment which may include surgery or therapy through there endoscope.
- 'Dead arm' type feeling due to positioning with the procedure - usually temporary.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.

2.5 ENDOSCOPIC ULTRASOUND (EUS) CONSENT FORM

Patient consent

I acknowledge that the doctor has explained:

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic/sedation required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- Tissue samples may be removed and could be used for diagnosis or management of my condition. These samples will be stored and disposed sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on best medical practice.
- A doctor other than the consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following patient information form:

☐ **Endoscopic ultrasound (EUS)**

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video/s may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

Identification details
I/C / RN No.: Patient Name: Address: Date of Birth: Gender: M / F

I request to have the procedure.
Name of Patient:
Signature:
Date:

Patients who lack capacity to provide consent
Consent must be obtained from a substitute decision maker.
Name of substitute decision maker: Signature: Relationship to patient: Date: I/C No:

Doctor's statement
I have explained to the patient all the above points under the patient consent section and I am of the opinion that the patient/substitute decision maker has understood the information. Name of Doctor: Designation: Signature: Date:

Procedure

An endoscopic ultrasound (EUS) is where the doctor
uses an instrument called an endoscope, which has an ultrasound probe at its tip to examine the wall layers (inside and outside) of the upper and lower gastrointestinal tract. It also provides excellent pictures of your pancreas, bile ducts and organs in your chest.

The EUS allows a fine needle biopsy (sample) of tissue to be taken inside or outside the wall of the gut. Further therapy may be performed as appropriate.

This procedure may or may not require a sedative injection or anaesthetic.

Risks of EUS and sedation

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications include:

- Nausea and vomiting.
- Faintness or dizziness, especially when you start to move around.
- Pain, redness or bruising at the sedation injection site (usually in the hand or arm).
- Allergy to medications given at time of the procedure.

Uncommon risks and complications include:

- About 2 people in every 100 will get an infection from a fine needle biopsy/aspiration of a cyst. Antibiotics are given during and after the procedure to reduce the risk of this complication.
- About 1 person in every 100 will experience pancreatitis. This usually settles without specific treatment.
- About 2 people in every 1,000 will have minor bleeding from the gut where the fine needle biopsy was taken. This can usually be stopped through the endoscope. Rarely, surgery is needed to stop the bleeding.
- About 1 person in every 1,000 will experience bleeding from the oesophagus (food pipe), stomach and duodenum where a lesion or polyp was removed. This is usually stopped through the endoscope. Rarely, surgery is needed to stop bleeding.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.
- Damage to your teeth jaw or throat due to the presence of instruments in your mouth.
- An existing medical condition that you may have getting worse.

Rare risks and complications include:

- Missed abnormalities.
- About 1 person in every 10,000 will accidentally get tear (perforation) in the oesophagus, stomach or duodenum. This can cause a leak of stomach contents into the abdomen. If a tear occurs, you will be admitted to hospital for further treatment which may include surgery or therapy through the endoscope.
- 'Dead arm' type feeling due to positioning with the procedure - usually temporary.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.

2.6 ENDOSCOPIC RETROGRADE CHOLANGIO-PANCREATOGRAPHY (ERCP) CONSENT FORM

Patient Consent

I acknowledge that the doctor has explained:

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic/sedation required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues samples may be removed and could be used for diagnosis or management of my condition. These samples will be stored and disposed sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on best medical practice.
- A doctor other than the consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following patient information form:

☐ **ERCP**

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and my concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following with my doctor.
- I understand that image/s or video/s may be recorded during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

Identification details
I/C / RN No.:
Patient Name:
Address:
Date of Birth:
Gender: M / F

I request to have the procedure.
Name of Patient:
Signature:
Date:

Patients who lack capacity to provide consent
Consent must be obtained from a substitute decision maker.
Name of substitute decision maker: Signature: Relationship to patient: Date: I/C No:

Doctor's statement

I have explained to the patient all the above points under the patient consent section and I am of the opinion that the patient/substitute decision maker has understood the information.
Name of Doctor:
Designation:
Signature:
Date:

Procedure

An ERCP is where the doctor examines the tubes (ducts) that drain your liver, pancreas and gallbladder.

You will lie on the x-ray table on your tummy.

The doctor will pass the endoscope into the food pipe, stomach and the small bowel.

A fine plastic tube will be passed inside the endoscope into the liver and/or pancreas. Contrast material (dye) will be injected and x-rays taken. The doctor may then remove stones to relieve duct blockage or insert stents (plastic/metal devices) as appropriate.

This procedure may or may not require a sedative injection or anaesthetic.

Risks of ERCP and sedation

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications include:

- About 1-7 people out of every 100 people will get swelling and inflammation of the pancreas (pancreatitis). This may need pain relief. This usually settles over the next 24-48 hours. It can be severe and need further treatment, which may result in admission to hospital.
- Nausea and vomiting.
- Pain, redness or bruising at the sedation injection site (either in the hand or arm).
- Allergy to medications given at time of the procedure.

Uncommon risks and complications include:

- Less than 1 person in every 100 will have a bleed as a result of the procedure. This can happen if a cut is made in the duct to remove a stone. This is usually stopped through the endoscope.
- About 1 person in every 100 will have a tear through the bowel or duct wall. This complication may sometimes require surgery or further therapy through the endoscope.
- Bacteraemia (infection of the blood) or cholangitis (infection of the bile). This will need antibiotics.
- The procedure may not be able to be finished due to technical problems.
- Change of anaesthetic from a sedative injection to a general anaesthetic.
- Dead arm' type feeling due to positioning with the procedure - usually temporary.
- An existing medical condition that you may have getting worse.

Rare risks and complications include:

- Missed abnormalities.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.
- Death as a result of complications to this procedure is rare.

2.7 CAPSULE ENDOSCOPY CONSENT FORM

Patient Consent

I acknowledge that the doctor has explained:

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- If immediate life-threatening events happen during the procedure, they will be treated based on best medical practice.
- A doctor other than the consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following patient information form:

☐ **Capsule endoscopy**

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and my concern have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following with my doctor.
- I understand that image/s or video/s may be recorded during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

Identification details
I/C / RN No.: Patient Name: Address: Date of Birth: Gender: M / F

I request to have the procedure.
Name of Patient:
Signature:
Date:

Patients who lack capacity to provide consent
Consent must be obtained from a substitute decision maker.
Name of substitute decision maker: Signature: Relationship to patient: Date: I/C No:

Doctor's statement
I have explained to the patient all the above points under the patient consent section and I am of the opinion that the patient/substitute decision maker has understood the information. Name of Doctor: Designation: Signature: Date:

Procedure

A capsule endoscopy is where a pill-sized video capsule is swallowed. The capsule slowly travels through your digestive system, the same as food would normally travel. This capsule is disposable and usually passed within 24-48 hours.

The capsule has its own built-in light source and camera to take pictures of the inside of your small bowel. 2-4 images are taken per second for up to 8 hours. The images are transmitted to a radio recorder that is worn around your waist. You should NOT remove the belt at any time during the procedure.

This procedure is safe, easy to do, and permits examination of the entire small bowel.

It does not require sedation as the procedure is usually painless.

The capsule procedure does have some limitations. It does not allow any treatment such as removing a polyp. A further endoscopy procedure or surgery will be required for this.

Risks of complication of capsule endoscopy

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications include:

- About 1 person in every 100 will have difficulty passing the capsule. This can be due to a narrowing (stricture) due to a tumour, inflammation or scarring from previous surgery. This is not usually serious in the short term, but surgery or another endoscopic procedure may sometimes be needed to remove it.

Uncommon risks and complications include:

- Missed abnormalities.
- Incomplete study of the small bowel due to slow bowel function.

3.0 PATIENT INFORMATION LEAFLET

3.1 OESOPHAGODUODENOSCOPY (OGDS) PATIENT INFORMATION FORM

1. What is an upper gastrointestinal endoscopy? (OGDS: Oesophagoduodenoscopy)

An upper gastrointestinal (GI) endoscopy is where the doctor uses an instrument called an endoscope to look at the inside lining of your oesophagus (food pipe), stomach and duodenum (first part of the small intestine). This is done to look at reasons as to why you may have swallowing problems, nausea, vomiting, reflux, bleeding, indigestion, abdominal pain or chest pain.

An endoscope is a long, thin, flexible tube with a small camera and light attached which allows the doctor to see the pictures of the inside of your gut on a video screen. The scope bends, so that the doctor can move it around the curves of your gut. The scope also blows air into your stomach; this expands the folds of tissue in your stomach so that the doctor sees the stomach lining better. As a result, you might feel some pressure, bloating or cramping during the procedure.

This instrument can also be used to remove or burn growths or to take tissue biopsies.

You will then lie on your left side, and the doctor will pass the endoscope into your mouth and down your oesophagus (food pipe), stomach and duodenum (first part of the small intestine). Your doctor will examine the lining again as the endoscope is taken out.

The endoscope does not cause problems with your breathing.

You should plan on 2 to 3 hours for waiting, preparation and recovery. The procedure itself usually takes anywhere from 10 to 15 minutes.

If the doctor sees anything unusual or wants to test for bacteria in the stomach a biopsy (small pieces of tissue) for testing at pathology may be taken.

This procedure may or may not require sedation.

2. Will there be any discomfort? Is any anaesthetic needed?

To make the procedure more comfortable a sedative injection or a light anaesthetic can be given.

Before the procedure begins the doctor will put a line into a vein in your hand or forearm. This is where the sedation or anaesthetic is injected and may spray your throat with a numbing agent that will help prevent gagging.

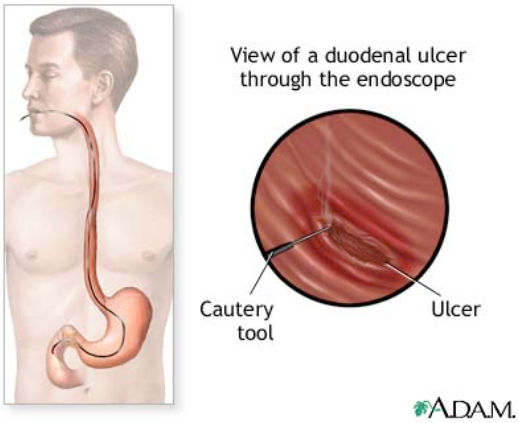
3. What is sedation?

Sedation is the use of drugs that give you a ‘sleepylike’ feeling. It makes you feel very relaxed during a procedure.

You may remember some or little about what has occurred during the procedure.

Sedation is generally very safe but every anaesthetic has a risk of side effects and complications. The risk to you will depend on:

- Personal factors, such as whether you smoke or are overweight.
- Whether you have any other illness such as asthma, diabetes, heart disease, kidney disease, high blood pressure or other serious medical conditions.



4. What are the risks of this specific procedure and sedation?

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications include:

- Nausea and vomiting.
- Faintness or dizziness, especially when you start to move around.
- Pain, redness or bruising at the sedation injection site (usually in the hand or arm).
- Allergy to medications given at time of the procedure.
- Not being able to find out where the bleeding is coming from.
- Not being able to stop the bleeding.

Uncommon risks and complications include:

- About 1 person in every 1,000 will experience bleeding from the oesophagus (food pipe), stomach and duodenum where a lesion or polyp was removed. This is usually stopped through the endoscope. Rarely, surgery is needed to stop bleeding.
- Bacteraemia (infection in the blood). This will need antibiotics.
- Damage to your teeth, jaw or throat due to the presence of instruments in your mouth.
- An existing medical condition that you may have getting worse.

Rare risks and complications include:

- Missed abnormalities.
- About 1 person in every 10,000 will accidentally get a tear (perforation) in the oesophagus, stomach or duodenum. This can cause a leak of stomach contents into the abdomen. If a tear occurs, you will be admitted to hospital for further treatment which may include surgery or therapy through the endoscope.
- Your procedure may not be able to be finished due to problems inside your body or because of technical problems.
- 'Dead arm' type feeling due to positioning with the procedure - usually temporary.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.
- Death as a result of complications to this procedure is rare.

5. Your responsibilities before having this procedure.

You are less at risk of problems if you do the following:

- Bring all your prescribed drugs, those drugs you buy over the counter, herbal remedies, and supplements and show your doctor what you are taking. Tell your doctor about any allergies or side effects you may have.
- If you take warfarin, clopidogrel (plavix), dipyridamole or any other drug that is used to thin your blood ask the doctor ordering the test if you should stop taking it before the procedure as it may affect your blood clotting. Do not stop taking them without asking your doctor.
- Tell your doctor if you have:
  - ✓ Had heart valve replacement surgery including implantable devices.
  - ✓ Received previous advice about taking antibiotics before a dental treatment or a surgical procedure.

  If so, you may also need antibiotics before the procedure.

6. Preparation for the procedure.

Your stomach must be empty for the procedure to be safe and thorough, so you will not be able to eat or drink anything for at least 4 hours before the procedure.

7. What if the doctor finds something wrong?

Your doctor may take a biopsy (a very small piece of the stomach lining) to be examined at pathology.

Biopsies are used to identify many conditions.

8. What if I don't have the procedure?

Your symptoms may become worse and the doctor will not be able to give you the correct treatment without knowing the cause of your problems. Gastrointestinal bleeding is potentially life-threatening.

9. Are there any other tests I can have instead?

Yes. Your doctor could discuss with you other ways of managing your condition. In bleeding from the upper gastrointestinal tract surgery may be an option. Another option is angiography where the bleeding vessel is occluded after an X-ray of the vessels. A video capsule endoscopy may be another option to view the gastrointestinal tract.

10. What can I expect after this procedure?

Your throat may feel sore and you might have some cramping pain or bloating because of the air entering the stomach during the procedure.

You will be told what was found during the examination or you may need to come back to discuss the results, and to find out the results of any biopsies that may have been taken.

In cases of gastrointestinal bleeding you may be hospitalized after the procedure.

There is a possibility of rebleeding and you may need to undergo another endoscopy procedure or surgery.

11. What are the safety issues following endoscopy?

Sedation will affect your judgment for about 24 hours. For your own safety and in some cases legally:

- Do NOT drive any type of car, bike or other vehicle. You must be taken home by a responsible adult person.
- Do NOT operate machinery including cooking implements.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, take other mind-altering substances, or smoke. They may react with the sedation drugs.

If you are discharged home, notify the hospital emergency department straight away if you have:

- Bloody vomitus, blackish or reddish stool.
- Unexplained giddiness or feel faint.
- Severe ongoing abdominal pain.
- Trouble swallowing.
- Fever.
- Sharp chest or throat pain.
- Have redness, tenderness or swelling for more than 48 hours where you had the injection for sedation (either in the hand or arm).

Notes to talk to my doctor about:

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3.2 ENDOSCOPIC VARICEAL BAND LIGATION AND INJECTION OF CYANOACRYLATE (HISTOACRYL) GLUE PATIENT INFORMATION FORM

1. What is an upper gastrointestinal endoscopy and variceal banding/injection of cyanoacrylate (histoacryl) glue?

An upper gastrointestinal (GI) endoscopy is where the doctor uses an instrument called an endoscope to look at the inside lining of your oesophagus (food pipe), stomach and duodenum (first part of the small intestine).

Varices are large veins that appear in the oesophagus and stomach. These may rupture and cause significant bleeding requiring endoscopic treatment. Banding of oesophageal varices involves placement of rubber bands over the varices at the time of endoscopy. Gluing is usually reserved for stomach varices and involves injecting glue into them. This will cause the blood in the varices to clot and eventually the clotted vein will disappear. It is not possible to know which treatment is necessary until the endoscopy is performed.

This procedure is usually repeated every 2 to 3 weeks to see if other bands are needed. After about 3 sessions the varices are usually sufficiently treated.

An endoscope is a long, thin, flexible tube with a small camera and light attached which allows the doctor to see the pictures of the inside of your gut on a video screen. The scope bends, so that the doctor can move it around the curves of your gut. The scope also blows air into your stomach; this expands the folds of tissue in your stomach so that the doctor can see the stomach lining better. As a result, you might feel some pressure, bloating or cramping during the procedure.

You will lie on your left side, and the doctor will pass the endoscope into your mouth and down your oesophagus (food pipe) stomach and duodenum (first part of the small intestine). Your doctor will examine the lining again as the endoscope is taken out. The endoscope does not cause problems with your breathing.

You should plan on 2 to 3 hours for waiting, preparation and recovery. The procedure itself usually takes anywhere from 10 to 30 minutes.

If the doctor sees anything unusual or wants to test for bacteria in the stomach he may need to take a biopsy (small pieces of tissue) for testing at pathology.

2. Will there be any discomfort? Is any anaesthetic needed?

To make the procedure more comfortable a sedative injection or a light anaesthetic can be given.

Before the procedure begins a line will be put into a vein in your hand or forearm. This is where the sedation or anaesthetic is injected. Your throat may be sprayed with a numbing agent that will help prevent gagging.

3. What is sedation?

Sedation is the use of drugs that give you a ‘sleepy-like’ feeling. It makes you feel relaxed during a procedure that may be otherwise unpleasant or painful.

You may remember some or little about what has occurred during the procedure.

Sedation is generally very safe but every anaesthetic has a risk of side effects and complications most of it are temporary.

The risk to you will depend on:

- Personal factors, such as whether you smoke or are overweight.
- Whether you have any other illness such as asthma, diabetes, heart disease, kidney disease, high blood pressure or other serious medical conditions.

4. What are the risks of this specific procedure and sedation?

There are risks and complications with this procedure.
They include but are not limited to the following.

Common risks and complications include:

- Nausea and vomiting.
- Faintness or dizziness, especially when you start to move around.
- Pain, redness or bruising at the sedation injection site (usually in the hand or arm).
- Chest pain and difficulty in swallowing for up to 2 weeks after the procedure.
- Allergy to medications given at the time of procedure.

Uncommon risks and complications include:

- Bleeding from the oesophagus (food pipe) where a varix has been banded. This can be serious just as the bleeding due to untreated varices can be. Once the course of banding is completed the risk of bleeding of any sort is greatly reduced.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.
- Bacteraemia (infection in the blood). This will need antibiotics.
- Damage to your teeth, jaw or throat due to the presence of instruments in your mouth.
- An existing medical condition that you may have getting worse.

Rare risks and complications include:

- A tear (perforation) in the oesophagus can accidentally occur. This can cause a leak of stomach contents into the chest. If a tear is made, you will be admitted to hospital for further treatment which may include treatment through the endoscope or surgery.
- Glue, if used, can move into the blood vessels in the lungs causing breathing difficulties. The glue cannot be removed and will remain in the lungs. Glue can also spread into blood vessels in other parts of the body such as the bowel and the brain and could cause serious damage.
- Your procedure may not be able to be finished due to problems inside your body or because of technical problems.
- 'Dead arm' type feeling due to positioning with the procedure - usually temporary.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Death as a result of complications to this procedure is uncommon.

5. Your responsibilities before having this procedure.

You are less at risk of problems if you do the following:

- Bring all your prescribed drugs, those drugs you buy over the counter, herbal remedies and supplements and show your doctor what you are taking. Tell your doctor about any allergies or side effects you may have.
- Do not drink any alcohol and stop recreational drugs 24 hours before the procedure. If you have a drug habit please tell your doctor.
- If you take warfarin, clopidogrel (plavix), dipyridamole or any other drug that is used to thin your blood ask the doctor ordering the test if you should stop taking it before the procedure as it may affect your blood clotting.
- Do not stop taking them without asking your doctor.
- Tell your doctor if you have:
  - ✓ Had heart valve replacement surgery.
  - ✓ Received previous advice about taking antibiotics before a dental treatment or a surgical procedure.

  If so, you may also need antibiotics before the endoscopic variceal band ligation.

6. Preparation for the procedure.

Your stomach must be empty for the procedure to be safe and thorough, so you will not be able to eat or drink anything for at least 4 hours before the procedure.

7. What if the doctor finds something wrong?

Your doctor may take a biopsy (a very small piece of the stomach lining) to be examined at pathology.

Biopsies are used to identify many conditions.

8. What if I don't have the procedure?

Your symptoms may become worse and the doctor will not be able to give you the correct treatment without knowing the cause of your problems. Bleeding from oesophageal varices may be life threatening

9. Are there any other tests I can have instead?

Your doctor could discuss with you ways of managing your condition. Usually treatments are reserved for situations where banding fails.

10. What can I expect after this procedure?

You will remain in the recovery area for about 2 hours until the effect of the sedation wears off.

Your doctor will tell you when you can eat and drink. Most times this is straight after the procedure**.**

Your throat may feel sore and you might have some cramping pain or bloating because of the air entering the stomach during the procedure.

You will be told what was found during the examination or you may need to come back to discuss the results, and to find out the results of any biopsies that may have been taken.

11. What are the safety issues following endoscopy?

Sedation will affect your judgment for about 24 hours.
For your own safety and in some cases legally:

- Do NOT drive any type of car, bike or other vehicle. You must be taken home by a responsible adult person.
- Do NOT operate machinery including cooking implements.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, take other mind-altering substances, or smoke. They may react with the sedation drugs.

If you are discharged home, notify the hospital emergency department straight away if you have:

- Severe ongoing abdominal pain.
- Trouble swallowing.
- Fever.
- Sharp chest or throat pain.
- Have redness, tenderness or swelling for more than 48 hours where you had the injection for sedation (either in the hand or arm).

Notes to talk to my doctor about:

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3.3 ENDOSCOPIC HAEMOSTASIS PATIENT INFORMATION FORM

1. What is endoscopic haemostasis?

An upper gastrointestinal (GI) endoscopy is where the doctor uses an instrument called an endoscope to look at the inside lining of your oesophagus (food pipe), stomach and duodenum (first part of the small intestine).

This is being done to look for the reason for the bleeding you are having and to try to perform some treatment to stop the bleeding.

The treatment depends on the cause of the bleeding and could include:

- An injection of adrenaline and
- The burning of a bleeding blood vessel with a special type of probe or
- The placement of a metal clip on a bleeding blood vessel or
- Placing rubber bands on a bleeding vein or
- Injecting glue into a bleeding vein.

An endoscope is a long, thin, flexible tube with a small camera and light attached which allows the doctor to see the pictures of the inside of your gut on a video screen. The scope bends, so that the doctor can move it around the curves of your gut. The scope also blows air into your stomach; this expands the folds of tissue in your stomach so that the doctor sees the stomach lining better. As a result, you might feel some pressure, bloating or cramping during the procedure.

This instrument can also be used to remove or burn growths or to take tissue biopsies.

You will then lie on your left side, and the doctor will pass the endoscope into your mouth and down your oesophagus (food pipe), stomach and duodenum (first part of the small intestine). Your doctor will examine the lining again as the endoscope is taken out.

The endoscope does not cause problems with your breathing.

You should plan on 2 to 3 hours for waiting, preparation and recovery. The procedure itself usually takes anywhere from 10 to 15 minutes.

If the doctor sees anything unusual or want to test for bacteria in the stomach they may need to take a biopsy (small pieces of tissue) for testing at pathology.
This procedure may or may not require a sedation anaesthetic.

2. Will there be any discomfort? Is any anaesthetic needed?

To make the procedure more comfortable a sedative injection or a light anaesthetic can be given.

Before the procedure begins a line will be put into a vein in your hand or forearm. This is where the sedation or anaesthetic is injected and may spray your throat with a numbing agent that will help prevent gagging.

3. What is sedation?

Sedation is the use of drugs that give you a ‘sleepy-like’ feeling. It makes you feel relaxed during a procedure that may be otherwise unpleasant or painful.

You may remember some or little about what has occurred during the procedure.

Sedation is generally very safe but every anaesthetic has a risk of side effects and complications. The risk to you will depend on:

- Personal factors, such as whether you smoke or are overweight.
- Whether you have any other illness such as asthma, diabetes, heart disease, kidney disease, high blood pressure or other serious medical conditions.

4. What are the risks of this specific procedure and sedation?

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications include:

- Nausea and vomiting.
- Faintness or dizziness, especially when you start to move around.
- Pain, redness or bruising at the sedation injection site (usually in the hand or arm).
- Allergy to medications given at time of the procedure.
- Not being able to find out where the bleeding is coming from.
- Not being able to stop the bleeding.

Uncommon risks and complications include:

- About 1 person in every 10,000 will accidentally get a tear (perforation) in the oesophagus, stomach or duodenum. This can cause a leak of stomach contents into the abdomen. If a tear occurs, you will be admitted to hospital for further treatment which may include surgery or therapy through the endoscope.
- Bacteraemia (infection in the blood). This will need antibiotics.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.
- Damage to your teeth, jaw or throat due to the presence of instruments in your mouth.
- An existing medical condition that you may have getting worse.

Rare risks and complications include:

- Your procedure may not be able to be finished due to problems inside your body or because of technical problems.
- 'Dead arm' type feeling due to positioning with the procedure - usually temporary.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Death as a result of complications to this procedure is rare.

5. Your responsibilities before having this procedure.

You are less at risk of problems if you do the following:

- Bring all your prescribed drugs, those drugs you buy over the counter, herbal remedies and supplements and show your doctor what you are taking. Tell your doctor about any allergies or side effects you may have.
- If you take warfarin, clopidogrel (plavix), dipyridamole or any other drug that is used to thin your blood ask the doctor ordering the test if you should stop taking it before the procedure as it may affect your blood clotting.
- Do not stop taking them without asking your doctor.
- Tell your doctor if you have:
  - ✓ Had heart valve replacement surgery including implantable devices.
  - ✓ Received previous advice about taking antibiotics before a dental treatment or a surgical procedure.

  If so, you may also need antibiotics before the procedure.

6. Preparation for the procedure.

Your stomach must be empty for the procedure to be safe and thorough, so you will not be able to eat or drink anything for at least 4 hours before the procedure.

7. What if the doctor finds something wrong?

Your doctor may take a biopsy (a very small piece of the stomach lining) to be examined at pathology.

Biopsies are used to identify many conditions.

8. What if I don't have the procedure?

Your symptoms may become worse and the doctor will not be able to give you the correct treatment without knowing the cause of your problems. Gastrointestinal bleeding is potentially life-threatening.

9. Are there any other tests I can have instead?

Yes. Your doctor could discuss with you other ways of managing your condition. Surgery may be an option. Another option is angiography where the bleeding vessel is occluded after an X-ray of the vessels.

10. What can I expect after this procedure?

You may be hospitalized after the procedure.

There is a possibility of rebleeding and you may need to undergo another endoscopy procedure or surgery.

Your throat may feel sore and you might have some cramping pain or bloating because of the air entering the stomach during the procedure.

You will be told what was found during the examination or you may need to come back to discuss the results, and to find out the results of any biopsies that may have been taken.

11. What are the safety issues following endoscopy?

Sedation will affect your judgment for about 24 hours. For your own safety and in some cases legally:

- Do NOT drive any type of car, bike or other vehicle. You must be taken home by a responsible adult person.
- Do NOT operate machinery including cooking implements.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, take other mind-altering substances, or smoke. They may react with the sedation drugs.

If you are discharged home, notify the hospital emergency department straight away if you have:

- Bloody vomitus, blackish or reddish stool.
- Unexplained giddiness or feel faint.
- Severe ongoing abdominal pain.
- Trouble swallowing.
- Fever.
- Sharp chest or throat pain.
- Have redness, tenderness or swelling for more than 48 hours where you had the injection for sedation (either in the hand or arm).

Notes to talk to my doctor about:

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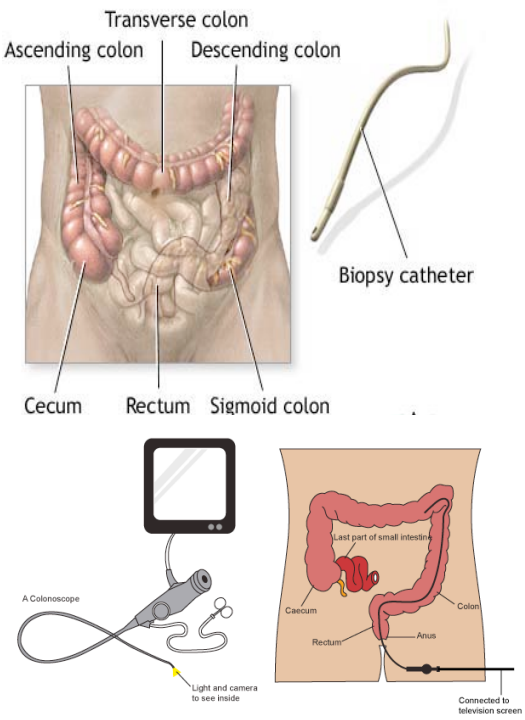
3.4 COLONOSCOPY PATIENT INFORMATION FORM

1. What is a colonoscopy?

Colonoscopy is a procedure where the doctor looks inside your large bowel (rectum and colon) using a colonoscope.

A colonoscope is a long, thin and flexible tube with a video camera attached to one end which the doctor is able to guide into your anus, safely advance to the areas in the large bowel that need to be examined and view the images on a video monitor.



2. What is this procedure for?

Colonoscopy helps your doctor assess diseases of the anus, rectum and colon. The large bowel is the site of many diseases including polyps, cancer and inflammation. Colonoscopy is often done because you have had problems such as bleeding from the rectum, ongoing diarrhoea or constipation, blood or pus in the stool or ongoing lower belly pain. It may sometimes be done without symptoms. This is known as screening colonoscopy.

Tissue samples (biopsy) can be collected and treatment can be performed through the colonoscope if required, for example polyps (small growth of tissue on the lining of the colon or rectum that may sometimes become cancerous) can be taken out or bleeding can be controlled using electrocautery (electrical heat) or small clips.

3. How do I prepare for this procedure?

Before the procedure tell your doctor if you:

- Are allergic to any medicine.
- Are taking any medicines including herbal remedies.
- Have bleeding problems or are taking blood thinners such as warfarin, heparin, aspirin, dipyridamole (persantin®), clopidogrel (plavix®) or ticlopidine (ticlid®).
- Are taking arthritis medicines.
- Have heart or lung disease.
- Have diabetes.
- Are pregnant or suspect you might be pregnant.
- Have had surgery or radiation in the past.
- Have had a barium test in the last 4 days.
- Have a pacemaker, joint replacement or heart valve replacement.
- Have a drug habit or consume alcohol excessively.

If you take aspirin, dipyridamole (persantin®), clopidogrel (plavix®) or ticlopidine (ticlid®) you may be told to stop them several days before the test. If you take warfarin you must discuss with your doctor how to manage your medicine. If you are on insulin or other medicines for diabetes the dose may need to be adjusted or even withheld before the procedure. Discuss with your doctor.

You will usually be required to cleanse your bowels 1 day prior to the procedure (bowel preparation). This is explained below.

You will be asked to sign a consent form before the procedure.

Talk to the doctor about any questions or concerns you have regarding the procedure.

On the day of the colonoscopy, if you are wearing jewellery, spectacles or dentures you will be asked to remove them before the procedure. If you have been given sedation during the procedure, your memory, reflexes and judgment may be temporarily affected, therefore you should have a responsible adult to accompany you home after the procedure.

Bowel Preparation

- It is crucial that you follow advice regarding bowel preparation (cleansing of the bowels) so that the doctor can have clear views during colonoscopy.
- A low fibre diet is necessary one day prior to the procedure. Stop taking milk and other dairy products such as butter and cheese as well as meats and leafy vegetables. Iron supplements should be stopped 5- 7 days before the procedure as iron can alter the colour of your colon lining.
- 1 day prior to the procedure you may take a light early breakfast such as white bread and soup (usually by 8 am). Avoid red coloured liquids and food as they may be mistaken for blood in the colon. Avoid dairy products and Milo™. Avoid opaque liquids after breakfast. A clear liquid diet may be taken for dinner.
- Your doctor will prescribe an oral laxative to take the evening before the colonoscopy and on the day of colonoscopy, if the procedure is planned for the following morning. Examples of some commonly prescribed laxatives are fleet phospho-soda® and fortrans®.
- Oral fleet phospho-soda® is available as a solution in small bottles and is usually taken in 2 doses. 45 cc of fleet® solution is mixed with half a glass of plain water to be drunk over ½ hour starting at 8 pm followed by at least 4-6 glasses of plain water thereafter. This process is repeated the next day 4 hours before the scheduled morning procedure. This applies for procedures performed early the following morning.
- It is important that you drink water as advised to keep yourself adequately hydrated and ensure proper bowel cleansing. There is a slight risk of developing kidney damage or electrolyte (salt) imbalance in the blood with fleet phospho-soda® especially in ill or elderly patients.
- During the cleansing period, you should remain near a toilet as you will spend a significant amount of time there. You may find this process unpleasant but it is important for the doctor to have clear views of your colon. This is so that abnormalities in the colon will not be missed.
- Alternative to fleet phospho-soda® is fortrans® which is available as powder form in sachets. Fortrans® is preferred if you have kidney or heart disease. Mix 2 sachets in 1 litre of water each and drink each litre over 1 hour beginning from about 6pm. You can continue to consume clear liquids after that till midnight. The next morning, 5 hours before the scheduled colonoscopy, mix 2 sachets in 1 litre of water each and drink each litre over 1 hour.
- If colonoscopy is planned for the afternoon, the total dose (i.e. 3-4 litres) may be taken in the morning beginning 6am. Also, depending on your medical condition, your doctor may alter the dose or timing of the laxatives, or may prescribe laxative enemas. You will be advised accordingly.

4. How is this procedure done?

You will be made as comfortable as possible during this procedure. You may be given a sedation anaesthetic and pain reliever. An intravenous (IV) line will be inserted into a vein of your arm or hand for giving medications. Your pulse and oxygen levels will be monitored throughout the procedure.

Colonoscopy is usually done with you lying on your left side. Lubricant is applied to your anus and the doctor will perform a gentle

examination of your anal canal using a gloved finger. The colonoscope is then gently introduced into your anus and advanced through the entire large bowel.
Air is gently passed into the bowel to facilitate passage of the colonoscope. The doctor's assistant may on occasions have to place gentle pressure on your abdomen to facilitate passage of the colonoscope. There are some naturally occurring bends in the large bowel and going around them may sometimes be uncomfortable for short periods but sedation and pain relievers will minimise the discomfort. The entire procedure usually takes between 15 and 30 minutes (excluding preparation time).

5. What are polyps and why are they removed?

Polyps are fleshy growths in the bowel lining, and they can be as small as a tiny dot or up to several centimetres in size.

They are not usually cancer but can grow into cancer over time. Taking polyps out is an important way of preventing bowel cancer.

The doctor usually removes a polyp along the endoscope by using a wire loop. An electric current is sometimes also used. This is not painful.

6. What is sedation? What are the possible risks from sedation?

Sedation is the use of drugs to give you a sleepy feeling and make you feel relaxed. You may remember some or little about what has occurred during the procedure.

Sedation is generally very safe but has risks which may depend on whether you are a smoker, are overweight or have illness such as asthma or other lung diseases, diabetes, heart disease, kidney disease, high blood pressure or other serious medical conditions.

Possible risks include pain during the administration of medications, and soreness or swelling at the site of administration.

Rarely cardiac or respiratory arrest (slowing down or stopping of heart beat or breathing) and severe allergic reactions can occur which may be fatal.

7. What are the possible risks from a colonoscopy?

This is a safe procedure and every care will be taken to minimise discomfort and risks.

The risks that may happen include:

- Perforation (tear in the lining of the bowel) causing leakage of bowel contents into the abdomen in approximately 1 in 1000 cases due to manipulation of the colonoscope. The risk is higher with polyp removal. This will require hospitalization and even surgery.
- Heavy bleeding after polyp removal or biopsy occurs in less than 1 in 1000 cases. The risk may be higher with larger polyps. Bleeding may occur even several days after. It may sometimes require further colonoscopy to stop the bleeding, blood transfusion or even surgery.
- Risk of missing a polyp or cancer. The risk is higher if the bowel is not cleaned properly.
- The procedure may not be able to be completed due to bowel disease or other problems.
- Mild pain and discomfort in the abdomen. This usually settles with walking and moving around to get rid of the trapped air.
- Pain, redness or bruising at the sedation injection site (usually in the hand or arm).
- An existing medical condition that you may already have getting worse.
- 'Dead arm' type feeling due to positioning with the procedure - usually temporary.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Heart and lung problems such as heart attack or vomit in the lungs causing

pneumonia. Emergency treatment may be necessary.
- Death due to colonoscopy is very rare.

8. What if I don't want to have the procedure?

Your symptoms may get worse. The doctor may not be able to give you the appropriate treatment without knowing the cause.

9. What can I expect after colonoscopy?

After the procedure, you will be taken to the recovery room for monitoring and observation.

You may have some cramping or bloating because of air entering the colon during the procedure. This should go away once you pass gas. You will be able to start eating after leaving the department, unless you have been instructed otherwise.

The doctor will discuss the findings and any medications or further investigations required before you leave. You will be informed if you require further appointments. Do not hesitate to clarify any doubts you may have.

If you have received sedation, you should have a responsible adult with you when you are given this information and who can accompany you home**.** Do NOT operate machinery including cooking appliances, drive any vehicle, consume alcohol and other mind altering drugs or make important decisions including signing of legal documents on the same day if you have received sedation.

10. Seek medical attention if you:
- Begin to have bright red bleeding from your anus.
- Generally feel ill, have chills muscle aches or fever.
- Begin to get sharp pains in your belly or begin vomiting.
- Feel dizzy, short of breath or faint.

You are advised to call the endoscopy unit or seek attention at the nearest emergency department.

11. What is the alternative to colonoscopy?

The alternatives are:

- Flexible sigmoidoscopy - A thin flexible tube with a camera at one end is used to visualise only the lower third of the colon. Biopsies can be taken and treatment can be applied through the sigmoidoscope.

- Double contrast barium enema - X-rays of the colon and rectum are taken after a liquid containing barium is put into the rectum. Air is also put into the rectum and colon to further outline the bowel.

- CT colonography - Also known as 'virtual colonoscopy', this is a medical imaging technique that uses X rays and computers to produce 2 and 3 dimensional views of the bowel.

- Capsule endoscopy of the colon - Involves swallowing a small video capsule about the size of a large vitamin pill which then examines the lining of the bowel for polyps or other abnormalities and images can be viewed by the doctor on a computer screen.

All the above alternatives require bowel preparation for optimum views. With the exception of flexible sigmoidoscopy, the doctor cannot take biopsies or perform treatment if required. Therefore, a colonoscopy may still be required if an abnormality is found on any of these alternative investigations.

Notes to talk to my doctor about:

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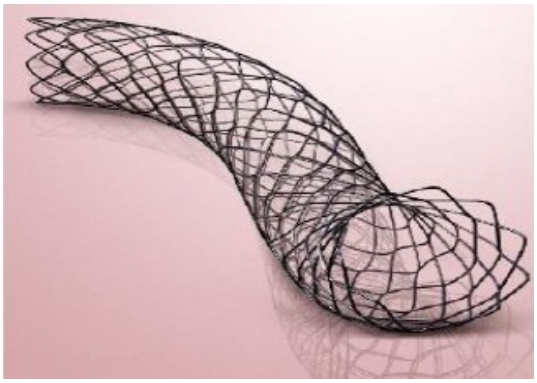
3.5 COLONIC STENT PLACEMENT PATIENT INFORMATION FORM

1. What is a colonic stent?

A stent is a flexible, metallic tube specially designed to hold open a part of your bowel that is either partially or totally blocked. Stents can be rolled up tightly to the size of a pencil to allow them to be inserted through the blockage or tumour in the bowel. Once in place, stents are allowed to expand and therefore keep open the passage through the tumour.



2. Why are stents used?

Stents can be used for the following reasons:

- Stents are suitable for patients who have complete or partial bowel obstruction (blockage). The aim of a stent in these patients is to relieve the obstruction, especially if the patient is not considered suitable for surgery.
- In patients who have potentially curative cancers, where the bowel is obstructed, a stent is used prior to surgery. Placing a stent allows the bowel to empty and return to its normal size and this can make eventual surgery safer.
- Stenting can be used as an alternative to surgery in patients who are medically unfit or have metastases (spread of cancer). These patients can avoid major surgery and the need for a stoma.

3. What does the procedure involve?

Your doctor will gently introduce a colonoscope (a flexible fiberoptic tube with a video camera attached to one end) into your anus and advance through the colon to the site of blockage. A small guide wire is placed into your back passage, beyond the blockage, using X-ray guidance. A small catheter (a thin flexible tube) will be positioned over the wire. X-rays are then taken with contrast medium (a special dye that allows the body tissues to be seen more clearly) which is injected in to the bowel to show the exact position of the blockage. The first catheter is removed and a catheter with the stent on it will be placed in the exact position. The catheter is then removed and the stent left in place.

4. Are there any risks?

Perforation

The procedure may cause perforation (a tear) leading to leakage from the bowel into the abdomen. If this happens, you may require further treatment including an operation. Perforation is rare (less than 5 in a 100 cases) but it can be serious and life threatening.

Malpositioning

Positioning the stent may be difficult due to the growth and position of your tumour. If positioning is unsuccessful then the procedure will be abandoned. If this happens, the procedure may be repeated at a later date or your doctor will discuss an alternative plan with you.

Migration

Loosening of the stent could cause it to move. Treatment may include removal of the stent, replacement, surgery or simple observation. Symptoms of migration may include:

- Pain and urgency in the back passage.
- Recurrence of your previous symptoms of obstruction.

These symptoms should be reported promptly to your doctor or nurse.

Bleeding

A small amount of bleeding may occur. This may come from the tumour or the stent rubbing against the tumour.

Pain

- Some abdominal pain may be experienced as the bowel returns to normal function.
- The majority of patients who experience discomfort (in the back passage) are patients with stents in the rectum. This is usually tolerated, after an initial period of discomfort.
- If your pain is severe this may indicate obstruction, perforation or migration. If this is the case, you should seek medical advice.

Re-obstruction

This can be caused by over growth of the tumour through the stent, blocking the bowel. If this occurs, you may experience symptoms of obstruction.

- Your bowels may stop working.
- Your abdomen may become bloated.
- You might start vomiting or have abdominal discomfort.

If this happens you should seek medical advice. This may require insertion of another stent.

Most people will not experience any serious complications from this intervention. Your doctor will discuss these risks with you.

5. What happens before the procedure?

You need to inform your doctor if you are taking any medications, especially blood thinner such as warfarin, clopidrogel, aspirin, ticlopidine or dipyridamole.

You will not be allowed to eat anything or drink for 6 hours before procedure.

A cannula will be placed into a vein in your hand so that during the procedure you can be given sedation to help you relax and pain killers to relieve any discomfort.

6. What will happen prior to and during the procedure?

- You will be asked to sign a consent form.
- A cleansing solution (enema) will be put into your back passage to empty your lower bowel.
- You will be asked to lie on your left side or back on a treatment trolley.
- You will be offered a sedative and analgesia before and during the procedure.
- Oxygen will be given via a mask before the sedation.
- The procedure will take approximately 30-90 minutes to complete, depending on your individual circumstances.
- Sometimes it may take more than one attempt to position the stent. Occasionally it is not possible to do the procedure, in which case, your doctor will discuss an alternative plan with you.

7. What happens after the procedure?

- You will feel rather sleepy for a couple of hours.
- You may require an x-ray to assess the position of the stent and to rule out perforation
- Your doctor will advise when you can start to drink and eat.
- You may experience some bleeding from your bowel in the first two days after insertion but this should stop. The bowel may feel uncomfortable and possibly painful for up to 3 days.
- If you continue to experience pain or bleeding persists, please contact your hospital.

8. General advice after colonic stent placement.

- Eat a light diet for 48 hours after the procedure.

- Drink plenty of fluids with your meals to get enough nutrition.
- You may be prescribed stool softener to help you go to toilet.
- If you need to have any X-rays, scans or MRI scans, you should tell the doctors that you have a stent.
- You must inform any doctor who may need to perform a rectal examination that you have a stent in place.
- The stent should not interfere with any of your normal activities.

9. What are the alternatives to having a stent?

- Doing nothing will very likely lead to complete blockage of the bowel.
- Major surgery may be an option but has increased risks involved.

Notes to talk to my doctor about:

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3.6 ENTEROSCOPY PATIENT INFORMATION FORM

1. What is an enteroscopy?

An enteroscopy is a procedure where the doctor uses an instrument called an endoscope to look at the oesophagus (food pipe), stomach and the small bowel. This is common if bleeding, inflammation, ulceration or other abnormalities of the small bowel are suspected.

An endoscope is a long, thin, flexible tube with a small camera and light attached which allows the doctor to see the pictures of the inside of your gut on a video screen. The scope bends, so that the doctor can move it around the curves of your gut. The scope also blows air and this expands the folds of tissues so that the doctor can see the linings better. As a result, you might feel some pressure, bloating or cramping during the procedure.

This instrument can also be used to remove or burn growths or to take tissue biopsies.

Before the procedure, the doctor may spray your throat with a numbing agent that will help prevent gagging. Most patients have some sedation.

You will then lie on your left side, and the doctor will pass the endoscope into your mouth and down to your small intestine. Your doctor will examine the lining again as the endoscope is taken out.

Sometimes the endoscope is inserted into the small bowel via the rectum. Bowel preparation is required for this.

If the doctor sees anything unusual he may need to take a biopsy (small pieces of tissue) for testing. Polyps and tumours encountered may need to be removed.

You should plan on two to three hours for waiting, preparation and recovery. In experience hand the procedure itself usually takes anywhere from 30 min to 2 hours.

2. Will there be any discomfort? Is any anaesthetic needed?

The procedure can be uncomfortable and to make the procedure more comfortable a sedative injection or a light anaesthetic will be given.

Before the procedure begins, a line will be set in your hand or forearm. This is where the sedation or anaesthetic is injected.

3. What is sedation?

Sedation is the use of drugs that give you a ‘sleepy-like’ feeling. It makes you feel relaxed during a procedure that may be otherwise unpleasant or painful.

You may remember some or little about what has occurred during the procedure.
Sedation is generally very safe but every anaesthetic has a risk of side effects and complications most of it are usually temporary. Whilst these are usually temporary, some of them may cause long-term problems.

The risk to you will depend on:

- Personal factors, such as whether you smoke or are overweight.
- Whether you have any other illness such as asthma, diabetes, heart disease, kidney disease, high blood pressure or other serious medical conditions.

4. What are the risks of this specific procedure?

There are risks and complications with this procedure.
They include but are not limited to the following.

Common risks and complications include:

- Nausea and vomiting.
- Faintness or dizziness, especially when you start to move around.

- Headache.
- Pain, redness or bruising at the sedation injection site (usually in the hand or arm).
- Muscle aches and pains.
- Allergy to medications given at time of the procedure.

Uncommon risks and complications include:

- About 1 person in 100 will experience bleeding from the oesophagus (food pipe), stomach or small bowel where a lesion or polyp was removed. This is usually minor and can usually be stopped through the endoscope. Rarely, surgery is needed to stop bleeding.
- Damage to your teeth or jaw due to the presence of instruments in your mouth.
- Your procedure may not be able to be finished due to technical problems.
- An existing medical condition that you have getting worse.
- About 1 out of every 100 people will get swelling and inflammation of the pancreas (pancreatitis). This may need pain relief. This usually settles over the next 24-48 hours. It can be severe and need further treatment, which may result in admission to hospital.

Rare risks and complications include:

- Missed polyps or growths.
- About 1 person in 1,000 will accidentally get a tear (perforation) through the wall of the gut. It can cause a leak of gut contents into the abdomen. If a tear is made, you will be admitted to hospital for further treatment which may include surgery or therapy through the endoscope.
- Bacteraemia (infection in the blood). This will need antibiotics.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- 'Dead arm' type feeling due to positioning with the procedure - usually temporary.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.
- Death as a result of complications to this procedure is rare.

5. What are you responsibilities before having this procedure?

You are less at risk of problems if you do the following:

- Bring all your prescribed drugs, those drugs you buy over the counter, herbal remedies and supplements and show your doctor what you are taking. Tell your doctor about any allergies or side effects you may have.
- Do not drink any alcohol and stop recreational drugs 24 hours before the procedure. If you have a drug habit please tells your doctor.
- If you take warfarin, clopidogrel (plavix), dipyridamole or any other drug that is used to thin your blood ask your doctor if you should stop taking it before the procedure as it may affect your blood clotting. Do not stop taking them without asking your doctor.
- Tell your doctor if you have:
  - ✓ Had heart valve replacement surgery.
  - ✓ Received previous advice about taking antibiotics before a dental treatment or a surgical procedure.

  If so, you may also need antibiotics before the enteroscopy.

6. Preparation for the procedure.

Your stomach must be empty for the procedure to be safe and thorough, so you will not be able to eat or drink anything for at least six hours before the procedure.

A bowel preparation will be needed if it is performed via the back passage (anus).

7. What if the doctor finds something wrong?

Your doctor may take a biopsy (a very small piece of the stomach lining) to be examined at Pathology.

Biopsies are used to identify many conditions.

8. What if I don't have the procedure?

Your symptoms may become worse and the doctor will not be able to give you the correct treatment without knowing the cause of your problems.

9. Are there other tests I can have instead?

X-rays and CT or MRI scans can be used to look at the small bowel. Capsule endoscopy is another alternative to visualise the small bowel. They are not as accurate and treatment cannot be performed. Surgery may sometimes be an alternative option.

Your doctor will discuss with you other ways of managing your condition.

10. What can I expect after the enteroscopy?

You will remain in the recovery area for about 2 hours until the effect of the sedation wears off.

Your doctor will tell you when you can eat and drink.
Most times this is straight after the procedure.
Your throat may feel sore and you might have some cramping pain or bloating because of the air entering the stomach during the procedure.

You will be told what was found during the examination or you may need to come back to discuss the results, and to find out the results of any biopsies that may have been taken.

12. What is the safety issues following endoscopy?

Sedation will affect your judgment for about 24 hours. For your own safety and in some cases legally:

- Do NOT drive any type of car, bike or other vehicle. You must be taken home by a responsible adult person.
- Do NOT operate machinery including cooking implements.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, take other mind-altering substances, or smoke. They may react with the sedation drugs.

If you are discharged home, notify the hospital emergency department straight away if you have:

- Severe ongoing abdominal pain.
- Trouble swallowing.
- Fever.
- Sharp chest or throat pain.
- Have redness, tenderness or swelling for more than 48 hours where you had the injection for sedation (either in the hand or arm).

Notes to talk to my doctor about:

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3.7 ENDOSCOPIC ULTRASOUND (EUS) PATIENT INFORMATION FORM

1. What is an endoscopic ultrasound (EUS) and fine needle biopsy?

An endoscopic ultrasound (EUS) is where the doctor uses an instrument called an endoscope, which has an ultrasound probe at its tip to examine the wall layers (inside and outside) of the upper and lower gastrointestinal tract. It also provides excellent pictures of your pancreas, bile ducts and organs in your chest.

An endoscope is a long, thin, flexible tube with a small camera and light attached which allows the doctor to see the pictures of your gut on a video screen. The scope bends, so that the doctor can move it around the curves of your gut. The scope also blows air and this expands the folds of tissues so that the doctor can see the linings better. As a result, you might feel some pressure, bloating or cramping during the procedure.

The EUS allows a fine needle biopsy/aspiration (sample) of tissue to be taken inside or outside the wall of the gut. This needle is passed through the scope, and using the ultrasound as a guide, it is passed into the tissue of concern.

The EUS procedure is mostly used to:

- Diagnose tumours of the oesophagus, stomach, duodenum, pancreas and bile ducts.
- Diagnose some tumours of the lung.
- Diagnoses diseases of internal organs including pancreatitis or cysts of the pancreas.
- Detect bile duct stones including gall stones.
- Assess abnormalities of the walls (inside and outside) of the gut.
- Collect fluid samples from the lungs or abdominal cavity.

This procedure has 2 possible points of body entry, through a patient's mouth or anus, depending on the disease under investigation.

You should plan on 2 to 3 hours for waiting, preparation and recovery. The procedure itself usually takes anywhere from 30 to 60 minutes.

This procedure may or may not require a sedative injection.

2. Will there be any discomfort? Is any anaesthetic needed?

To make the procedure more comfortable a sedative injection or a light anaesthetic will be given.

Before the procedure begins, a line will be put into a vein in your hand or forearm. This is where the sedation or anaesthetic is injected.

3. What is sedation?

Sedation is the use of drugs that give you a 'sleepy-like' feeling. It makes you feel relaxed during a procedure.

You may remember some or little about what has occurred during the procedure.

Sedation is generally very safe but every anaesthetic has a risk of side effects and complications. The risk to you will depend on:

- Personal factors, such as whether you smoke or are overweight.
- Whether you have any other illness such as asthma, diabetes, heart disease, kidney disease, high blood pressure or other serious medical conditions.

4. What are the risks of this specific procedure?

There are risks and complications with this procedure.
They include but are not limited to the following.

Common risks and complications include:

- Nausea and vomiting.
- Faintness or dizziness, especially when you start to move around.
- Pain, redness or bruising at the sedation injection site (usually in the hand or arm).
- Allergy to medications given at time of the procedure.

Uncommon risks and complications include:

- About 2 people in every 100 will get an infection from a fine needle biopsy/aspiration of a cyst. Antibiotics are given during and after the procedure to reduce the risk of this complication.
- About 1 person in every 100 will experience pancreatitis. This usually settles without specific treatment.
- About 2 people in every 1,000 will have minor bleeding from the gut where the fine needle biopsy was taken. This can usually be stopped through the endoscope. Rarely, surgery is needed to stop the bleeding.
- About 1 person in every 1,000 will accidentally get a tear or tear (perforation) through the wall of the gut. This can cause a leak of stomach contents into the abdomen. Surgery of further therapy through the endoscope may be needed to repair the tear.
- Missed growths in and around the gastrointestinal tract.
- Your procedure may not be able to be completed.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.
- Damage to your teeth, jaw or throat due to the presence of instruments in your mouth.
- 'Dead arm' type feeling due to positioning with the procedure - usually temporary.
- An existing medical condition that you may have getting worse.

Rare risks and complications include:

- Bacteraemia (infection in the blood). This will need antibiotics.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Death as a result of complications to this procedure is rare.

5. Your responsibilities before having this procedure.

You are less at risk of problems if you do the following:

- Bring all your prescribed drugs, those drugs you buy over the counter, herbal remedies and supplements and show your doctor what you are taking. Tell your doctor about any allergies or side effects you may have.
- Do not drink any alcohol and stop recreational drugs 24 hours before the procedure. If you have a drug habit please tells your doctor.
- If you take warfarin,clopidogrel (plavix), dipyridamole or any other drug that is used to thin your blood ask the doctor ordering the test if you should stop taking it before the procedure as it may affect your blood clotting. Do not stop taking them without asking your doctor.
- Tell your doctor if you have:
  - ✓ Had heart valve replacement surgery.
  - ✓ Received previous advice about taking antibiotics before a dental treatment or a surgical procedure.

If so, you may also need antibiotics before the EUS.

6. Preparation for the procedure.

Your stomach must be empty for the procedure to be safe and thorough, so you will not be able to eat or drink anything for at least 4 hours before the procedure.

7. What if the doctor finds something wrong?

Your doctor may take an aspiration or biopsy (a very small piece of tissue) to be examined at pathology.

Biopsies are used to identify many conditions.

8. What if I don't have the procedure?

Your symptoms may become worse and the doctor will not be able to give you the correct treatment without knowing the cause of your problems.

9. Are there other tests I can have instead?

Yes. A computer tomography scans (CT), magnetic resonance imaging (MRI) or surgery may sometimes be an option. Your doctor will discuss these options with you.

10. What can I expect after the endoscopic ultrasound?

You will be in the recovery area for about 2 hours until the effect of the sedation wears off.

Your doctor will tell you when you can eat and drink. Most times this is straight after the procedure.

You might have some cramping pain or bloating because of the air entering the bowel during the procedure. This should go away when you pass wind.

You will be told what was found during the examination or you may need to come back to discuss the results, and to find out the results of any biopsies /samples that may have been taken.

11. What are the safety issues following endoscopy?

Sedation will affect your judgment for about 24 hours. For your own safety and in some cases legally:

- Do NOT drive any type of car, bike or other vehicle. You must be taken home by a responsible adult person.
- Do NOT operate machinery including cooking implements.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, take other mind-altering substances, or smoke. They may react with the sedation drugs.

If you are discharged home, notify the hospital emergency department straight away if you have:

- Severe ongoing abdominal pain.
- Trouble swallowing.
- Fever.
- Sharp chest or throat pain.
- Have redness, tenderness or swelling for more than 48 hours where you had the injection for sedation (either in the hand or arm).

Notes to talk to my doctor about:

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3.8 ENDOSCOPIC RETROGRADE CHOLANGIO-PANCREATOGRAPHY (ERCP) PATIENT INFORMATION FORM

1. What is an ERCP?

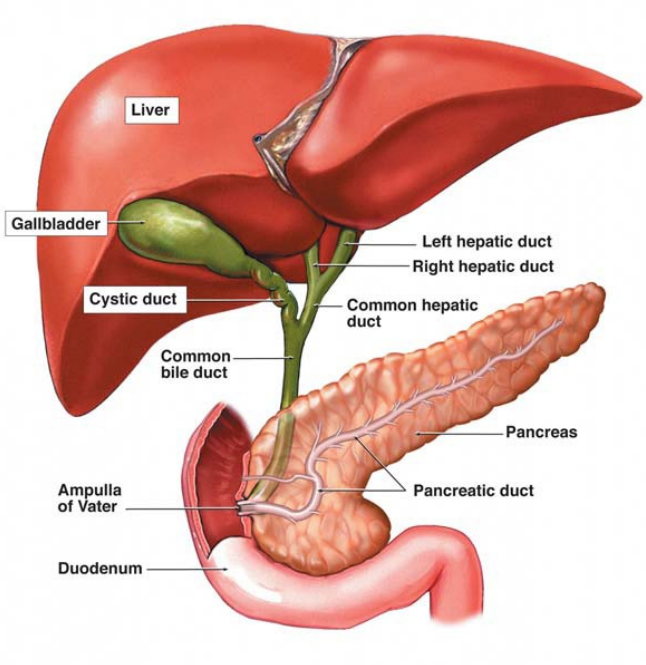
An ERCP is where the doctor examines the ducts of your liver, pancreas and gallbladder.

This is done by giving you medication to help you relax. You will lie on the x-ray table on your tummy. The doctor will pass the endoscope, which is a flexible tube with a camera attached which allows the doctor to see the food pipe, stomach and the small bowel.

A fine plastic tube will be passed inside the endoscope into the liver and/or pancreas. Contrast material (dye) will be injected and x-rays taken.

The doctor may then remove stones and relieve duct blockage.

This procedure may or may not require a sedative injection anaesthetic.



2. Will there be any discomfort? Is any anaesthetic needed?

The procedure can be uncomfortable and to make the procedure more comfortable a sedative injection or a light anaesthetic may be given.

Before all endoscopy procedures begin, the doctor will insert a line into a vein in your hand or forearm. This is where the sedative injection or anaesthetic is injected.

3. What is sedation?

Sedation is the use of drugs that give you a 'sleepy-like' feeling. It makes you feel relaxed during a procedure that may be otherwise unpleasant or painful.

You may remember some or little about what has occurred during the procedure.

Sedation is generally very safe but every anaesthetic has a risk of side effects and complications. The risk to you will depend on:

- Personal factors, such as whether you smoke or are overweight.
- Whether you have any other illness such as asthma, diabetes, heart disease, kidney disease, high blood pressure or other serious medical conditions.

4. What are the risks of this specific procedure?

There are risks and complications with this procedure.

They include but are not limited to the following.

Common risks and complications include:

- Up to 10 people out of every 100 people will get swelling and inflammation of the pancreas (pancreatitis). This may need pain relief. This usually settles over the next 24 to 48 hours. It can be severe and need further treatment, which may include treatment in ICU and/or surgery. A drug may be inserted through the anus to help the risk of this complication.
- Nausea and vomiting.

- Faintness or dizziness, especially when you start to move around.
- Pain, redness or bruising at the sedation injection site (either in the hand or arm).
- Allergy to medications given at time of the procedure.

Uncommon risks and complications include:

- Less than 1 person in every 100 will have a bleed as a result of the procedure. This can happen if a cut is made in the duct to remove a stone. This may be stopped through the endoscope.
- About 1 person in every 100 will have a tear through the bowel or duct wall. This may require a drainage tube in your nose to remove the bile. This complication may sometimes require surgery.
- Bacteraemia (infection of the blood) or cholangitis (infection of the bile). This will need antibiotics.
- The procedure may not be able to be finished due to technical problems.
- Change of anaesthetic from a sedative injection to a general anaesthetic.
- 'Dead arm' type feeling due to positioning with the procedure - usually temporary.
- An existing medical condition that you may have getting worse.

Rare risks and complications include:

- Missed abnormalities.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.
- Death as a result of complications to this procedure is very rare.

5. What are your responsibilities before having this procedure?

- Tell your doctor if you could be pregnant as X-rays are used as part of the procedure.
- Bring all your prescribed drugs, those drugs you buy over the counter, herbal remedies and supplements and show your doctor what you are taking. Tell your doctor about any allergies or side effects you may have.
- If you take warfarin, clopidogrel (plavix), dipyridamole or any other drug that is used to thin your blood ask your doctor if you should stop taking it before the procedure as it may affect your blood clotting. Do not stop taking them without asking your doctor.
- Tell your doctor if you have:
  - ✓ Had heart valve replacement surgery.
  - ✓ Received previous advice about taking antibiotics before a dental treatment or a surgical procedure.

  If so, you may also need antibiotics before the ERCP.

6. Preparation for the procedure.

You should not eat or drink anything for at least 4 hours before the procedure to make sure you have an empty stomach, which is necessary for a safe examination.

7. What if the doctor finds something wrong?

Your doctor may take a biopsy (a very small piece of the bowel lining) to be examined at pathology.

Biopsies are used to identify many conditions.

8. What if I don't have the procedure?

Your symptoms may become worse and the doctor will not be able to give you the correct treatment without knowing the cause of your problems.

9. Are there other tests I can have instead?

An MRI scan can be used to gather some information but cannot be used for treatment. Other treatment options include drainage under X-ray control, endoscopic ultrasound and surgery.

10. What can I expect after this procedure?

- Usually you remain in the recovery area for about 2 hours until the effect of the sedation wears off.
- You may need to be admitted after the procedure.
- Your doctor will tell you when you can eat and drink.
- You may experience bloating or pass wind because of the air introduced during the procedure.
- You will be told what was found during the examination.
- Your doctor may recommend dietary restrictions for 1 to 2 days after the procedure.

11. What are the safety issues?

Sedation will affect your judgment for about 24 hours. For your own safety and in some cases legally:

- Do NOT drive any type of car, bike or other vehicle. You must be taken home by a responsible adult person.
- Do NOT operate machinery including cooking implements.
- Do NOT make important decisions or sign a legal document on the same day.
- Do NOT drink alcohol, take other mind-altering substances, or smoke. They may react with the sedation drugs.

If you are discharged home, notify the hospital emergency department straight away if you have;

- Severe ongoing abdominal pain.
- Fever.
- Sharp chest or throat pain.
- Have redness, tenderness or swelling for more than 48 hours where you had the injection for sedation (either in the hand or arm).
- Bleeding which can occur up to 3 weeks after the procedure. Symptoms of bleeding include dizziness, fainting or passing blood or black bowel movements.

Notes to talk to my doctor about:

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3.9 CAPSULE ENDOSCOPY PATIENT INFORMATION FORM

1. What is capsule endoscopy?

Capsule endoscopy is where a pill-sized video capsule is swallowed. The capsule slowly travels through your digestive system, the same as food would normally travel. This capsule is disposable and usually passed within 24 to 48 hours.

The capsule has its own built-in light and camera to take pictures of the inside of your small bowel. 2 to 4 images are taken per second for up to 8 hours. The images are transmitted to a radio recorder that is worn around your waist. You should NOT remove the belt at any time during the procedure.

2. When is capsule endoscopy required?

Capsule endoscopy may be advised for the assessment of:

- Bleeding from your digestive system of unknown cause.
- Crohn's disease involving the small intestine.
- Coeliac disease.
- Small bowel tumours or polyps.

3. Will there be any discomfort? Is any anaesthetic needed?

No. The capsule is approximately the size of a large antibiotic capsule, so this is similar to swallowing a mouthful of food.

4. What are the risks of this specific procedure?

There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications include:

- About 1 person in every 100 will have difficulty passing the capsule. This can be due to a narrowing (stricture) due to a tumour, inflammation or scarring from previous surgery. This is not usually serious in the short term, but surgery or another endoscopic procedure may be needed to remove it.

Uncommon risks and complications include:

- Missed abnormalities.
- Incomplete study of the small bowel due to slow bowel function.

5. Preparation for the procedure.

Iron tablets needed to be stopped at least 7 days before your procedure.

It is vital that your stomach is empty during the procedure to ensure a clear view.

No food for 10 - 12 hours and no fluids are to be taken at least 4 hours before you swallow the capsule.

No food for a further 4 hours after swallowing the capsule. Clear fluids may be allowed after 2 hours.

6. What if the doctor finds something wrong?

Your doctor will discuss with you any findings after the images from the capsule are downloaded and looked at on a computer.

7. What if I don't have the procedure?

Your symptoms may become worse and the doctor will not be able to give the correct treatment without knowing the cause of your problems.

8. Are there other tests I can have instead?

There are other tests that can be done, such as X-rays, scans or small bowel endoscopy (enteroscopy). Capsule endoscopy generally provides an accurate view of the entire small bowel not always possible with these other

tests. Your doctor will discuss options with you.

9. What can I expect after capsule endoscopy?

The capsule passes naturally with your bowel movement. You should not feel any pain or discomfort.

10. What are the safety issues?

You should not have an MRI scan whilst the capsule is inside you. Normally the capsule passes in 24-48 hours.

If you are discharged home, notify the hospital emergency department straight away if you have:

- Any abdominal pain.
- Nausea and vomiting.
- Black tarry motions or bleeding from the back passage.
- Fever.
- Dysphagia or chest pain.

Notes to talk to my doctor about:

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ABBREVIATIONS

ACEI: Angiotensin Converting Enzyme Inhibitors
AER: Automated Endoscope Reprocessor
AMO: Assistant Medical Officer
APA: Antiplatelet Agents
APC: Argon Plasma Coagulator
ARB: Angiotensin-II Receptor Blockers
ASA: American Society of Anaesthesiology
ATA: Antithrombotic Agents
AVMs: Arteriovenous Malformations
BP: Blood Pressure
CC: Cubic Centimetre
CE: Capsule Endoscopy
CKD: Chronic Kidney Disease
CME: Continuous Medical Education
CNE: Continuous Nursing Education
CPC: Clinical Pathology Conference
CPD: Continuous Professional Development
CPG: Clinical Practice Guidelines
CPR: Cardio-Pulmonary Resuscitation
CT: Computed Tomography
DBE: Double Balloon Enteroscopy
ECG: Electrocardiography
ED: Emergency Department
EHL: Electro-Hydraulic Lithotripsy
EMR: Electronic Medical Record
EMR: Endoscopic Mucosal Resection
ERCP: Endoscopic Retrograde Cholangiopancreatography
ESD : Endoscopic submucosal dissection
ESU: Electrosurgical Unit
EUS: Endoscopic Ultrasonography
EVL: Endoscopic Variceal Ligation
F: Female

FBC: Full Blood Count

FDA: Food and Drug Administration

FFP: fresh Frozen Plasma

FNA: Fine Needle Aspiration

Fr: French

G: Gauge

GA: Glutaraldehyde

GAVE: Gastric Antral Vascular Ectasia

GFR: Glomerular Filtration Rate

GI: Gastrointestinal

GIA: Gastrointestinal Assistant

GP: General Practitioner

GXM: Group Cross Match

G&H: Group and Hold

Hb: Haemoglobin

HDU: High Dependency Unit

HDW: High Dependency Ward

HLD: High-Level Disinfectant or High-Level Disinfection

HPZ: High Pressure Zone

Hr: Hour/s

IC NO: Identification Card Number

INR: International Normalized Ratio

IV: Intravenous

kPa: Kilopascals

KPI: Key Performance Indicator

LFT: Liver Function Tests

LGIB: Lower Gastrointestinal Bleeding

L/MIN: Litre/s per Minute

LMWH: Low Molecular Weight Heparin

LOS: Lower Oesophageal Sphincter

M: Male

MAG: Magnesium Salt Preparations

MDT: Multidisciplinary Team

MEC: Minimum Effective Concentration

Min(s): Minute(s)

ml(s): Milliliter(s)

mm: Millimeter

mmHg: Millimetre(s) of Mercury

MO: Medical Officer

MRI: Magnetic Resonance Imaging

MSDS: Material Safety Data Sheet

NBM: Nil by Mouth

NSAIDs: Non-steroidal Anti-Inflammatory Drugs

NYHA: New York Heart Association

OGDS: Oesophagogastroduodenoscopy

OPA: Orthophthalaldehyde

OSP: Oral Sodium Phosphate

02 Sat: Oxygen Saturation

PAA: Peracetic Acid

PEG: Percutaneous Endoscopic Gastrostomy

PEG: Polyethylene Glycols

PICO: Sodium Picophosphate

PPI: Proton Pump Inhibitor

PR: Pulse Rate

PT: Prothrombin Time

PTT: Partial Thromboplastin Time

PUD: Peptic Ulcer Disease

QA: Quality Assurance

RN: Registered Nurse

RN NO: Registration Number

RR: Respiratory Rate

SBE: Single Balloon Enteroscopy

SBP: Systolic Blood Pressure

SC: Subcutaneous

SEMS: Self-Expanding Metal Stent

SIADH: Syndrome Of Inappropriate Anti-Diuretic Hormone Secretion

SOP: Standard Operating Procedure

SpO2: Oxygen Saturation

SRH: Stigmata of Recent Haemorrhage

TBSP: Table Spoon

TEL NO: Telephone Number

UBT: Urea Breath Test

UFH: Unfractionated Heparin

UGI: Upper Gastrointestinal

UGIB: Upper Gastrointestinal Bleeding

US: Ultrasound

W: Watt

+/-: With or Without

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