

PROCEDURE-SPECIFIC STANDARDS FOR DAY PROCEDURE CENTRES

ENDOSCOPY

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Department of Health



Hong Kong Academy of Medicine

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Preface

This document is developed by the Project Steering Committee on Standards for Ambulatory Facilities (PSC), set up by the Department of Health and the Hong Kong Academy of Medicine (HKAM), and the Task Force on Endoscopy formed under the PSC.

In preparation for the new regulatory regime, the PSC was formed in April 2015 to develop regulatory standards for ambulatory facilities, co-opting members from the medical faculties of local universities, private hospitals and practitioners' associations. Seven Task Forces were formed under the PSC by nomination from the HKAM and its constituent Colleges, comprising members practising in hospital and/or ambulatory settings and from both the public and private sectors. The PSC is tasked to develop a set of basic standards for all day procedure centres ("Core Standards") and additional standards for specific classes of medical procedures ("Procedure-specific Standards").

This document sets out the basic standards for the operation and management of day procedure centres where endoscopy is performed. The Procedure-specific Standards should be read with the Core Standards promulgated by the HKAM.

The Core Standards and Procedure-specific Standards serve to provide guidance to the operators of the day procedure centres in anticipation of a new licensing system and to provide a framework for the medical and dental professionals within which they plan and organize their private practices. The Standards are subject to review as and when necessary and will be adopted as part of the regulatory standards when the statutory licensing system is implemented.

Procedure-specific Standards for Day Procedure Centres **(Endoscopy)**

Application

This set of Standards applies to day procedure centres solely conducting endoscopic procedures that do not require an aseptic surgical field. Operators of day procedure centres where endoscopic procedures are performed in an operating room, as defined by the *Guidance Notes on Use of Operating Room for Surgical Procedures in Day Procedure Centres*, should also observe the *Procedure-specific Standards for Day Procedure Centres (Surgery and Anaesthesia & Sedation)* for requirements relating to operating room.

1. Management/Governance

1.1. Staff requirement and training

- 1.1.1. An appropriate number of suitably qualified and experienced staff are in attendance during each endoscopic procedure.
- 1.1.2. Staff have received adequate training before assisting in endoscopic procedures.
- 1.1.3. Person-in-charge develops and implements a policy to determine the scope of endoscopic procedures that may be performed in the facility with reference to the guidelines promulgated by the Hong Kong Academy of Medicine and/or its Colleges and taking into account of the following factors:
 - (a) risk of surgical infections;
 - (b) necessity to quickly and safely convert to an open surgical procedure due to complications or technical difficulties; and
 - (c) physical design, staffing and equipment resources of the facility.

2. Physical Conditions

2.1. Facility management

- 2.1.1. Doors and corridors enable transfer of patients on wheelchair or stretchers.
- 2.1.2. The following functional areas in a facility are separate:
 - (a) reception and waiting area;
 - (b) perioperative or procedural area;
 - (c) area for equipment reprocessing; and
 - (d) dirty utility room.
- 2.1.3. There is access control to procedural area and recovery area, if applicable.
- 2.1.4. In a facility where procedures under deep sedation, general anaesthesia or major regional anaesthesia are performed, doors within the relevant peri-operative/procedure area permit transfer of patient on trolleys or stretchers with attachment.
- 2.1.5. The clinical areas have immediate access to hand-washing facilities.

2.2. Procedural area

- 2.2.1. The procedure room shall be spacious enough to accommodate all personnel, fittings and equipment and to allow all procedures and resuscitation to be carried out effectively.
- 2.2.2. The lighting is adequate for the procedure undertaken.
- 2.2.3. The procedure room is suitably designed, equipped and maintained for the purpose it is to be used. The procedure room is maintained at acceptable level of cleanliness. The ceiling, walls and floors are made from materials that can be easily cleaned and disinfected as needed to meet infection control requirements.
- 2.2.4. Where gaseous anaesthetic agents are used, appropriate gas administration devices and exhaust systems are in place, and relevant requirements on occupational safety are observed.

- 2.2.5. Adequate area for scrub and gowning is provided in procedural area where applicable.

2.3. Equipment reprocessing area and sterile stores

- 2.3.1. A one-way dirty to clean traffic flow is designated in the equipment reprocessing area to prevent contamination.

2.4. Equipment and store

- 2.4.1. The facility has the necessary facilities for supporting its scope of endoscopic services, including but not limited to:
- (a) tilting table, trolley or chair that accommodates the procedures performed and provides for adequate range of movement for anaesthetic procedures;
 - (b) suitable devices for administering anaesthesia;
 - (c) endoscopic instruments;
 - (d) monitoring and resuscitation equipment; and
 - (e) any other special equipment required for a particular endoscopic procedure to be performed.
- 2.4.2. There are adequate facilities and space for the collection and storage of specimens.
- 2.4.3. The facility is equipped with devices for monitoring vital signs of patients, such as blood pressure, oxygen saturation.
- 2.4.4. In a facility where procedures under sedation are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Procedural Sedation*, published by the Hong Kong Academy of Medicine.
- 2.4.5. In a facility where procedures under general anaesthesia or major regional anaesthesia are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Monitoring in Anaesthesia*, published by the Hong Kong College of Anaesthesiologists.

3. Service Delivery and Care Process

3.1. General

- 3.1.1. The PIC develops and implements written policies and procedures relating to the safe conduct of endoscopic procedures and anaesthesia in the facility, including but not limited to the following:
- (a) staffing arrangements for surgical procedures and anaesthesia;
 - (b) informed consent;
 - (c) pre-procedural assessment;
 - (d) pre-procedural instructions (e.g. fasting, medication) and care;
 - (e) documentation of procedures;
 - (f) patient discharge and care after discharge; and
 - (g) arrangement for post-procedural complications (e.g. arrangement for inpatient care).
- 3.1.2. In developing policies and procedures in relation to high-risk anaesthetic procedures, reference is taken from relevant guidelines promulgated by the Hong Kong Academy of Medicine and the Hong Kong College of Anaesthesiologists.

3.2. Pre-procedure

- 3.2.1. Patients receiving endoscopic procedures are provided with information on the procedure and anaesthesia, including but not limited to the indication of the procedure, treatment alternative(s), the likely outcomes and risk of complications, before giving consent. Informed consent is documented in the medical record and/or in signed consent form.
- 3.2.2. Pre-procedural assessment is conducted by a medical practitioner. For patient undergoing procedure under sedation, there is a pre-anaesthetic assessment in accordance with the *Guidelines on Procedural Sedation* published by the Hong Kong Academy of Medicine. For patient undergoing general anaesthesia or major regional anaesthesia, the pre-anaesthetic assessment is in accordance with the *Guidelines on the Pre-anaesthetic Consultation* published by the Hong Kong College of Anaesthesiologists. When this is not possible, there is an adequate documented mechanism for conveying findings of the consultation to the

anaesthesiologist performing the anaesthesia. The final assessment by the anaesthesiologist for performing the anaesthesia is documented.

- 3.2.3. Pre-procedural assessment includes, but is not limited to:
 - (a) history and physical examination;
 - (b) all current medications;
 - (c) allergies;
 - (d) relevant investigations and consultation(s) with other specialty if any;
and
 - (e) fitness for the procedure and the sedation or anaesthesia to be performed.
- 3.2.4. Patients are given adequate instructions for pre-procedural preparation (e.g. fasting), and post-procedural care and discharge (e.g. a responsible adult to escort and care for patient after sedation).
- 3.2.5. PIC ensures that there are written policies and procedures on the following processes before endoscopic procedures:
 - (a) checking of consent forms;
 - (b) verification processes, including time-out, to ensure correct patient, endoscopic procedure and site if applicable; and
 - (c) accomplishment of pre-procedural preparation (e.g. bowel preparation, pre-medication).

3.3. Intra-procedure

- 3.3.1. All general anaesthesia and major regional anaesthesia are administered only by an anaesthesiologist or by a trained medical practitioner under the supervision of an anaesthesiologist.
- 3.3.2. Staffing arrangements and monitoring of patients undergoing procedural sedation are in accordance with the *Guidelines on Procedural Sedation*, published by the Hong Kong Academy of Medicine.
- 3.3.3. In addition to 3.3.1, care process, staffing arrangement and monitoring of patients undergoing general anaesthesia or major regional anaesthesia and the documentation of the anaesthetic care are in accordance with the *Guidelines on Monitoring in Anaesthesia*, published by the Hong Kong College of Anaesthesiologists.

- 3.3.4. For endoscopic procedures not involving any sedation and anaesthesia (except local anaesthesia), there is at least one personnel with relevant training or experience, and who is fully conversant with the equipment used, in each procedure room to assist in the endoscopic procedures.
- 3.3.5. There are written policies and procedures on the counting of items used during the procedures and what to do if items cannot be accounted for.

3.4. Post-procedure

- 3.4.1. All patients after endoscopic procedures are observed for an adequate length of time commensurate with the endoscopic procedure performed and the sedation or anaesthesia given, if any, and their fitness for discharge are determined by the doctor-in-charge of the patient, subject to 3.4.2.
- 3.4.2. Recovery of patients who have received sedation should be in accordance with *Guidelines on Procedural Sedation* published by the Hong Kong Academy of Medicine or relevant guidelines published by the Hong Kong College of Anaesthesiologists. Recovery of patients who have received major regional or general anaesthesia takes place in an area that is adequately equipped and staffed for post-anaesthetic care, in accordance with *Guidelines on Postanaesthetic Recovery Care* published by the Hong Kong College of Anaesthesiologists.
- 3.4.3. A medical practitioner or registered nurse trained in post-anaesthetic care is in-charge of the operation of the recovery area. Staff working in the recovery area must be trained for their roles.
- 3.4.4. The anaesthesiologist or the medical practitioner administering the sedation or anaesthesia, unless he/she has delegated another medical practitioner to take up the role, is responsible for supervising the post-anaesthetic recovery of the patient until he or she can be safely discharged. Medical or nursing staff trained in the post-anaesthetic care must be present at all times when a patient is in recovery and is/are able to promptly reach the supervising medical staff when need arises.
- 3.4.5. Monitoring of patients recovering from procedural sedation is in accordance with the *Guidelines on Procedural Sedation*, published by the Hong Kong Academy of Medicine.

- 3.4.6. Monitoring of patients recovering from general or major regional anaesthesia is in accordance with the *Guidelines on Postanaesthetic Recovery Care*, published by the Hong Kong College of Anaesthesiologists.
- 3.4.7. There are written policies and procedures for discharge of patients after procedures under sedation or anaesthesia, including but not limited to:
 - (a) discharge criteria;
 - (b) discharge instructions and advice (e.g. medication, post-procedural care, complications, refraining from certain activities); and
 - (c) arrangements for enquiries or assistance outside operating hours.
- 3.4.8. For a patient who has received general anaesthesia, major regional anaesthesia or deep sedation, there is a responsible adult to escort him/her home.
- 3.4.9. There is written protocol on transfer of patients to hospital for those who are not fit to be discharged home after the procedure or anaesthesia.

3.5. Medical records

- 3.5.1. The following records are kept:
 - (a) detailed procedure or operation records of all procedures performed;
 - (b) investigation reports;
 - (c) consent forms;
 - (d) anaesthetic records;
 - (e) records of post-procedural care and pre-discharge evaluation;
 - (f) pathology report, if specimen of body tissue or fluid was taken; and
 - (g) outcome of the procedure.
- 3.5.2. Procedure records include, but are not limited to:
 - (a) name(s) of the medical practitioner(s) performing the procedure and the assistant(s), if any;
 - (b) date, time, operation diagnosis, start time and end time of the procedure, anaesthesia and sedation method, name, details of the procedure, surgical findings, and any tissue removed and/or sent for pathology;
 - (c) record of the name, dose, time and route of administration of all medications and fluids given for the procedure; and
 - (d) blood and other fluid losses of the patient at the conclusion of the

procedure, if applicable.

- 3.5.3. Without limiting 3.5.4 and 3.5.5, anaesthetic records include but are not limited to:
- (a) name(s) of the medical practitioner(s) administering the anaesthesia; and
 - (b) the name, dose, route of administration of all anaesthetic drugs given.
- 3.5.4. For procedures under general anaesthesia or major regional anaesthesia, records of anaesthetic care are in accordance with the *Guidelines on Minimum Requirements for an Anaesthetic Record*, published by the Hong Kong College of Anaesthesiologists.
- 3.5.5. For procedures under sedation, records of anaesthetic care are in accordance with the *Guidelines on Procedural Sedation*, published by the Hong Kong Academy of Medicine.

3.6. Continuous quality improvement

- 3.6.1. The PIC develops and implements policies and procedures to review the appropriateness of patient care and monitoring of clinical performance and outcomes (e.g. complication, emergency transfer, unanticipated hospital admission).

4. Infection Control

4.1. Infection control policies and procedures

- 4.1.1. There are written infection control policies, procedures and guidelines for prevention of surgical infection, including but not limited to:
- (a) standard precautions;
 - (b) use of aseptic techniques;
 - (c) environmental cleansing and disinfection;
 - (d) cleaning, disinfection and sterilisation and storage of endoscopic and/ or anaesthetic equipment; and
 - (e) monitoring of effectiveness of infection control measures.

Reference is taken from guidelines issued by relevant health and professional authorities (e.g. *Recommendations on Prevention of*

Surgical Site Infection, published by the Centre for Health Protection of the Department of Health; *Guidelines on Infection Control in Anaesthesia*, published by the Hong Kong College of Anaesthesiologists).

4.2. Reprocessing of endoscopes

- 4.2.1. Disinfection or sterilisation of endoscopes is performed according to manufacturer's instructions.
- 4.2.2. Endoscopes and accessories (including all channels and valves) are thoroughly cleaned.
- 4.2.3. Endoscopes, accessories and goggles are disinfected by a high level disinfectant. Where applicable, endoscopes and accessories are sterilised according to manufacturer's instructions.
- 4.2.4. Endoscopes are rinsed thoroughly until it is free from disinfectant and according to manufacturer's instructions. Rinsing is performed prior to forced air drying or storage.
- 4.2.5. There is a system to regularly monitor the effectiveness of disinfection of endoscopes and accessories with documentation.
- 4.2.6. Endoscopes are stored hanging in a dry and well-ventilated area with valve and channel caps removed. If endoscopes are stored horizontally, there is alarm-monitored continuous air flow through each channel. Reprocessing is performed once the maximum allowable storage time has passed.
- 4.2.7. In reprocessing of endoscopes, reference is taken from occupational safety and health guidelines issued by the Labour Department (e.g. *Chemical Safety in the Workplace - Guidance Notes on Safe Use of Chemical Disinfectants*).

5. Resuscitation and Contingency

5.1. Risk management

- 5.1.1. There are staff-to-staff communication systems for emergency in the procedure room and recovery area.
- 5.1.2. There are patient-to-staff call systems or devices (e.g. call bells) where a patient may be left alone temporarily (e.g. patient changing room in the facility).

5.2. Resuscitation of patients

- 5.2.1. There are adequate and appropriate resuscitation equipment including but not limited to:
 - (a) device that can ventilate the lungs;
 - (b) oxygen supply;
 - (c) suction;
 - (d) basic intravenous setup; and
 - (e) defibrillator.
- 5.2.2. In a facility where procedural sedation is conducted, resuscitation equipment and emergency medications as required in the *Guidelines on Procedural Sedation*, published by the Hong Kong Academy of Medicine, are in place. Regular checks on their viability are conducted and documented.
- 5.2.3. In a facility where general anaesthesia or major regional anaesthesia is performed, resuscitation equipment as required in the *Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites*, published by the Hong Kong College of Anaesthesiologists, are in place. Selection of medications to deal with emergency arising from anaesthesia shall be in consultation with an anaesthesiologist. Regular checks on their viability are conducted and documented.
- 5.2.4. Emergency medications are stored in a designated and easily accessible area in the facility.

5.3. Emergency transfer

- 5.3.1. If the patient requires emergency transfer to a hospital, the endoscopist and/or the anaesthesiologist is/are responsible for the care of the patient until the patient has been transferred to another appropriate medical staff.
- 5.3.2. There are policies and procedures in place for emergency transfer of patient to hospital for management of urgent adverse outcome.
- 5.3.3. Drills for emergency transfer are conducted at regular intervals and documented.

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Project Steering Committee on Standards for Ambulatory Facilities

Terms of reference

The terms of reference of the Project Steering Committee on Standards for Ambulatory Facilities are:

- to steer the development and promulgation of standards for ambulatory facilities providing high-risk medical procedures;
- to make recommendations on the procedure-specific standards and, where appropriate, on the essential core standards for ambulatory facilities for the legislative review; and
- to steer the conduct of impact assessment survey for regulatory control of ambulatory facilities.

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