

**PROCEDURE-SPECIFIC STANDARDS FOR
DAY PROCEDURE CENTRES**

**SURGERY
AND
ANAESTHESIA & SEDATION**

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Department of Health



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Table of contents

Preface	1
1. Management/Governance	2
1.1. Staff requirement and training	2
2. Physical Conditions.....	3
2.1. Facility management.....	3
2.2. Operative / procedure area.....	3
2.3. Equipment reprocessing area and sterile stores	4
2.4. Equipment and store	4
3. Service Delivery and Care Process.....	5
3.1. General.....	5
3.2. Pre-procedure.....	6
3.3. Intra-procedure.....	7
3.4. Post-procedure	8
3.5. Medical records.....	9
3.6. Continuous quality improvement.....	10
4. Infection Control	10
4.1. Infection control policies and procedures	10
5. Resuscitation and Contingency	11
5.1. Risk management.....	11
5.2. Resuscitation of patients	11
5.3. Emergency transfer	12
Reference	13
Annex I	15
Annex II.....	16
Annex III.....	17
Task Force on Anaesthesia and Sedation.....	17
Task Force on Surgery	18
Annex IV	19

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 Surgery and Task Force on Anaesthesia & Sedation 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 surgery, and/or anaesthesia and sedation, are performed. The Procedure-specific Standards should be read with the Core Standards promulgated by the HKAM. The Guidance Notes on Use of Operating Room for Surgical Procedures in Day Procedure Centres ("Guidance Notes") aims to provide a general guidance on the use of an operating room in a day procedure centre for surgery. The Guidance Notes is enclosed with this document at **Annex IV** as reference.

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. They 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 (Surgery and Anaesthesia & Sedation)

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 surgical procedure.
- 1.1.2. Staff have received adequate training before assisting in new surgical procedures.
- 1.1.3. Person-in-charge develops and implements a policy to determine the scope of surgical 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.
- 1.1.4. For a facility equipped with operating room, a registered nurse who has relevant experience or training is assigned to oversee the day-to-day operation of the operating room.¹ A registered specialist may assume the role of overseeing the day-to-day operation of the operating room if he/she has the relevant experience or training.

¹ As a transitional arrangement, an experienced enrolled nurse overseeing the day-to-day operation of the operating room of an existing DPC may continue to assume such role under the supervision of a registered medical practitioner or a registered dentist. The DPC seeking to obtain a full license under a statutory licensing system shall fully meet clause 1.1.4.

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 pre-operative area, areas for conducting procedure and postoperative care area.
- 2.1.4. In a facility where procedures under deep sedation, general anaesthesia or major regional anaesthesia are performed, doors within the relevant perioperative or 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. Operative / procedure area

- 2.2.1. Surgical procedures are performed in a location that is spacious enough to accommodate all personnel, fittings and equipment required for the procedure without contamination and to allow the procedure and resuscitation to be carried out effectively.
- 2.2.2. The lighting is adequate for the procedure undertaken.
- 2.2.3. For a facility equipped with operating room, each operating room is suitably designed, equipped and maintained for the purpose it is to be used. The operating room is maintained at acceptable level of

sterility. 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. The operating room is equipped with specialised ventilation system of internationally acceptable standards of air quality, including but not limited to adequate number of fresh air exchange per hour, to prevent the spread of airborne infectious disease and to minimise surgical site infection.
- 2.2.5. The ventilation system of the operating room is regularly inspected and maintained to ensure effective functioning for patient and staff safety. Documentation of repair and maintenance of the systems is kept.
- 2.2.6. Where gaseous anaesthetic agents are used, appropriate gas administration devices and exhaust systems are in place, and relevant requirements on occupational safety should be observed.
- 2.2.7. Adequate area for scrub and gowning is provided for operating room.

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 surgical 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) surgical instruments;

- (d) monitoring and resuscitation equipment; and
 - (e) any other special equipment required for a particular surgery 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 surgical 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-operative 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 surgical 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, general anaesthesia or major regional anaesthesia, there is a pre-anaesthetic assessment of the patient by the medical practitioner who performs the sedation or anaesthesia, 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-operative 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 surgical procedures:
 - (a) checking of consent forms;
 - (b) verification processes, including time-out, to ensure correct patient, surgical site and procedure; and
 - (c) accomplishment of pre-operative preparation (e.g. fasting, 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. There are written policies and procedures on the counting of items used during the procedures, such as swabs, needles, blades and other operative instruments and supplies, and what to do if items cannot be accounted for.

3.4. Post-procedure

- 3.4.1. 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.
- 3.4.2. All patients after surgical procedures are observed for an adequate length of time commensurate with the anaesthesia given and the surgical procedure performed, and their fitness for discharge are determined by the doctor-in-charge of the patient, subject to 3.4.3.
- 3.4.3. Recovery of patients who have received sedation or 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.
- 3.4.4. 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, care of post-operative site, 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-operative 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 or operation 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 operation; and
- (d) blood and other fluid losses of the patient at the conclusion of the surgery.

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. surgical site infection, 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 sterilization and storage of surgical 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).

5. Resuscitation and Contingency

5.1. Risk management

- 5.1.1. There are staff-to-staff communication systems for emergency in the operating / 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 anaesthesiologist and/or the surgeon is 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.

Reference

Hong Kong

1. Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes. Department of Health
2. Recommendations on Prevention of Surgical Site Infection. Scientific Committee on Infection Control , and Infection Control Branch, Centre for Health Protection, Department of Health
3. Guidelines on Procedural Sedation. Hong Kong Academy of Medicine
4. Guidelines on Minimum Requirements for an Anaesthetic Record. Hong Kong College of Anaesthesiologists
5. Guidelines on Monitoring in Anaesthesia. Hong Kong College of Anaesthesiologists
6. Guidelines on Postanaesthetic Recovery Care. Hong Kong College of Anaesthesiologists
7. Recommendations for the Perioperative Care of Patients Selected for Day Care Surgery. Hong Kong College of Anaesthesiologists
8. Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites. Hong Kong College of Anaesthesiologists

Australia

9. The Clinical Services Capability Framework for Public and Licensed Private Health Facilities – Perioperative. Queensland Department of Health
10. Australasian Health Facility Guidelines Part B - Health Facility Briefing and Planning - Day Surgery Procedure Unit. Australasian Health Infrastructure Alliance

Canada – Ontario

11. Out of Hospital Premises Inspection Program-Program Standards. College of Physicians and Surgeons of Ontario

Singapore

12. Directives for Private Ambulatory Surgical Centres providing Ambulatory Surgery. Ministry of Health
13. Guidelines on safe sedation practice for non-anaesthesiologists. Ministry of Health

UK

14. Day Surgery Operational Guide. Department of Health
15. Health building note 10-02: Day surgery facilities. Department of Health

USA – Pennsylvania

16. The Pennsylvania Code Chapter 551. The Commonwealth of Pennsylvania, the Government of Pennsylvania

**Project Steering Committee on
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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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Guidance Notes on Use of Operating Room for Surgical Procedures in Day Procedure Centres

This document aims to provide a general guidance on the use of an operating room, as defined below and based on prevailing international standards in respect of specialised ventilation for infection control, for day surgery in ambulatory setting.¹

Medical practitioners and dentists must exercise professional judgment in deciding whether a procedure should be performed in or outside an operating room in ambulatory setting taking into account, among others, the nature of the procedure, patient's condition, the risks and consequences of infection, and the possibility of converting to open surgery.

Operating room is a room that meets the requirements of a restricted area and is designated and equipped with specialised ventilation, among others, for performing surgical or other invasive procedures that require aseptic surgical field. These procedures usually carry a high risk of infection (either by exposure of a usually sterile body cavity to the external environment or by implantation of a foreign object into a normally sterile site) or the consequences of infection can be devastating. In this context, procedures performed through orifices normally colonised with bacteria are not included. Any form of anaesthesia may be administered in an operating room. When gaseous anaesthetic agents are used, appropriate gas administration devices and exhaust systems are in place and requirements on occupational safety should be observed.

Restricted area is a designated space that can only be accessed through a semi-restricted area. The restricted access is primarily intended to support a high level of asepsis control. Traffic in the restricted area is limited to authorized personnel and patients. Personnel in restricted areas are required to wear surgical attire and cover head and facial hair. Masks are required where open sterile supplies or scrubbed persons may be located.

Examples of high-risk surgical and dental procedures that should be performed in an operating room:

- Implantation of intraocular lens
- Arthroscopy
- Suction and evacuation
- Dilatation and curettage
- Maxillofacial surgery

¹The prevailing international standards for ventilation of day-case operating room include, among others, a minimum of 15 air changes (ACH) per hour (HTM, UK), or 20 ACH per hour with at least 4 ACH should be fresh air (FGI, US).

Examples of high-risk surgical and dental procedures that may be performed outside an operating room:

- Endoscopic procedures through natural orifices (e.g. GI endoscopy, cystoscopy, hysteroscopy) not involving insertion of implant/prosthesis into a sterile site
- Therapeutic pleural/abdominal tap
- Percutaneous biopsy of liver, kidney
- Colposcopy with loop electrosurgical excision procedure

The examples are provided for reference and not exhaustive.

Reference

Burlingame B. Operating Room Requirements for 2014 and Beyond. *FGI Guidelines Update Series #3*. The Facility Guidelines Institute, USA. 2014 Sep.

Estates and Facilities Division. Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises. Part A - Design and installation. Department of Health, UK. 2007 Nov.

Skues M, ed. *BADS Directory of Procedures*. 4th ed. The British Association of Day Surgery. 2012.

Humphreys H, et al. Guidelines on the Facilities Required for Minor Surgical Procedures and Minimal Access Interventions. *Journal of Hospital Infection*. 2012; 80: 103-109.