

**CORE STANDARDS
FOR
DAY PROCEDURE CENTRES**

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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). It sets out the basic standards for the operation and management of day procedure centres, as defined in section I, that are essential for the safe delivery of medical services.

In December 2014 to March 2015, the Government of the Hong Kong Special Administrative Region conducted a public consultation on a proposed regulatory regime for private healthcare facilities (PHFs) based on the recommendations of the Steering Committee on Review of Regulation of Private Healthcare Facilities and its Working Groups set up under the Food and Health Bureau. Under the new regulatory regimen, there will be four types of PHFs subject to regulation, namely hospitals which are now regulated under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Chapter 165, Laws of Hong Kong), ambulatory facilities providing high-risk medical procedures (“day procedure centres”), medical clinics operated by incorporated bodies (“medical clinics”) and health services establishments. A new legislation will be introduced to provide for the regulatory regime.

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 are formed under the PSC by nomination of the HKAM and constituent Colleges, comprising members who practise 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”).

In developing the Core Standards, the PSC and the Task Forces have taken into account the legislation and regulatory standards of overseas jurisdictions with adaptation to local practice environment. The Core Standards should be read with the Procedure-specific Standards that are subsequently promulgated by the HKAM. The document is subject to review as and when necessary.

This document serves 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 organise their private practices. The Core Standards will be adopted as an essential part of the regulatory standards when the statutory licensing system is implemented.

I. Application of the Core Standards

“Day procedure centres” refer to premises where high-risk procedures are performed. High-risk medical procedures are defined by the following principles and criteria.

General Principles

1. Any procedure defined by ANY one of the following three factors will be regarded as high-risk medical procedure –
 - a) Risk of procedures
 - b) Risk of anaesthesia involved
 - c) Patient’s condition
2. Medical practitioners and dentists should take into account, in addition to the criteria for defining high-risk and hospital-only medical procedures, the age, body size and other physical conditions of the patient when deciding whether a medical procedure is high-risk and should be performed in ambulatory facility or in hospital.
3. Certain high-risk procedures should only be performed in hospital in view of their risks. Overall, high-risk medical procedures may be performed in ambulatory setting only if -
 - a) the patient is discharged in the same calendar day of admission;
 - b) the expected total duration of procedure and recovery requiring continuous confinement within the facility does not exceed 12 hours; and
 - c) patient's condition is not Class 4 or worse (i.e. Class 4 or 5) by American Society of Anaesthesiologist (ASA) Physical Status Classification System¹.

¹ ASA Physical Status Classification System :

Class 1 – normal healthy patient

Class 2 – mild systemic disease

Class 3 – severe systemic disease – stable

Class 3 – severe systemic disease – unstable (acute exacerbation)

Class 4 – severe systemic disease that is a constant threat to life

Class 5 – moribund patient who is not expected to survive without the operation

The following high-risk procedures should only be performed in hospitals:

- a) Administration of chemotherapy (cytotoxic) into body cavity or deep-seated organ
- b) Image-guided core biopsy of deep-seated organ
- c) Transarterial catheterisation or deep venous catheterisation
- d) Continuous venous-venous haemofiltration / haemodiafiltration
- e) Organ transplant [except corneal transplant] or complicated transplant procedures
- f) Bronchoscopy or pleuroscopy
- g) Therapeutic gastrointestinal endoscopy on children aged under 12 years old
- h) Injection of sclerosing / embolisation agents into vascular / lymphatic compartment of deep-seated head and neck region

Risk of Procedures

4. High-risk surgical procedures include the following procedures –

- a) Creation of surgical wound to allow access to major body cavity or viscus² (including access to central large joints) [except peripheral joints distal to knee and elbow (i.e. ankle and below, and wrist and below)]
- b) Removal of tissue and/or fluid of a total volume of 500ml or above [except suprapubic tap]
- c) Removal of tissue and/or fluid of any volume from deep seated organ in children aged under 12 years old
- d) Removal of any volume of fluid and/or tissue from thoracic cavity [except diagnostic pleural tapping]
- e) Insertion of any prosthesis [except prosthesis in ENT cavity, dental prosthesis and implants, facial implants, extra-ocular prosthesis and implants, intrauterine or vaginal prosthesis, bulking agents of urethra, prostatic urethral stent, urethral slings, testicular prosthesis]

²Not including needle injection into joint cavity, intraocular injection with fine needle by ophthalmologists and injection of Botox

- f) Any core biopsy [except core biopsy of (1) superficial tissue (such as skin, prostate, breast and uterus) but excluding thyroid or salivary glands; (2) superficial muscle; or (3) peripheral muscle]
 - g) Any biopsy of deep-seated organ
 - h) Lumbar puncture
 - i) Transplant of any cell, tissue and organ (including autograft, allograft, xenograft and processed tissue or blood products³) or skin flap (including face lift) [except skin graft less than 1% of total body surface area, conjunctival autograft and transplant procedures which primarily involve dental-alveolar region]
 - j) Termination of pregnancy*
 - k) Dilation and curettage
 - l) Circumcision with use of skin sutures in paediatric patients
5. High-risk endoscopic procedures include the following –
- a) Endoscopic procedures requiring image guidance (such as endoscopic retrograde cholangiopancreatography (ERCP))
 - b) Endoscopic procedures involving invasion of a sterile cavity (such as arthroscopy, laparoscopy and hysteroscopy) [except cystoscopy⁴] or gastrointestinal tract
 - c) Therapeutic endoscopic procedures (such as endoscopic resection) [except minor therapeutic procedures (such as removal of foreign body)]
 - d) Bronchoscopy or pleuroscopy

³ Include platelet-rich plasma (PRP)

⁴ Cystoscopy does not include therapeutic cystoscopic procedures such as cystoscopic insertion of ureteric catheter or stent, endoscopic urethral dilatation or urethrotomy, cystoscopic removal of stone or foreign body or polyp, cystoscopic injections/diathermy/cautery or haemostasis, cystoscopic lithotripsy.

* Under the section 47A of the Offences Against the Person Ordinance (Cap 212), any treatment for the termination of pregnancy must be carried out in a hospital or clinic maintained by the Government or declared by the Director of Health by notice published in the Gazette to be an approved hospital or clinic, except in the situation that two registered medical practitioners are of the opinion that the termination is immediately necessary to save the life or to prevent grave permanent injury to the physical or mental health of the pregnant woman.

6. High-risk dental procedures include the following –

Maxillofacial surgical procedures that extend beyond dento-alveolar process, including but not limited to –

- a) Maxillary osteotomies and mandibular osteotomies including angle reduction
- b) Open reduction and fixation of complex maxillofacial fracture
- c) Surgical treatment of diagnosed malignancies
- d) Surgical treatment of complex haemangioma
- e) Surgery involving major salivary glands
- f) Open surgery of temporomandibular joint except arthrocentesis and arthroscopy
- g) Harvesting of autogenous bone from outside the oral cavity
- h) Primary cleft lip and palate surgery

7. The following procedures are also classified as high-risk –

- a) Administration of chemotherapy (cytotoxic) through parenteral routes regardless of therapeutic indication
- b) Image-guided core biopsy [except (1) superficial tissue (such as skin, prostate, breast and uterus) but excluding thyroid or salivary glands; (2) superficial muscle; or (3) peripheral muscle], or image-guided biopsy of deep seated organ
- c) Haemodialysis
- d) Transarterial catheterisation or deep venous catheterisation
- e) Extracorporeal shock wave lithotripsy (ESWL) requiring image guidance
- f) Injection of sclerosing/embolisation agents into vascular/lymphatic compartment of deep-seated head and neck region

Scope of High-risk Anaesthetic Procedures⁵

8. A procedure is considered to be high-risk if it involves any of the following modes of anaesthesia or sedation:
- a) General anaesthesia
 - b) Neuroaxial blocks (spinal, epidural, caudal)
 - c) Major plexus block (brachial, lumbar, sacral)
 - d) Intravenous regional anaesthesia
 - e) Intercostal nerve block
 - f) Major nerve block:
 - Glossopharyngeal nerve, vagus nerve or their terminal branches, including superior, inferior and recurrent laryngeal nerves;
 - Sciatic and femoral nerves; or
 - Posterior tibial nerve, pudendal nerve or para-cervical block
 - g) Use of sedative or analgesic drugs with reasonable expectation that it will, in the manner used, result in deep sedation⁶ for a significant percentage of a group of patients
 - h) Tumescence anaesthesia

Patient's Condition

9. A procedure is considered high-risk if it is performed on a patient whose physical status is Class 3-unstable or worse (i.e. Class 3-unstable, Class 4 or Class 5) as classified by the American Society of Anaesthesiologists (ASA) Physical Status Classification System.

⁵ The risks of anaesthesia considered by the Working Group include risk of gross, vital physiological derangement, risk of inadvertent systemic injection (such as neurovascular bundle and intra-dural injection), loss of protective reflexes, prolonged disturbance of mobility or body balance, disturbance/loss of major functions of vital organs.

⁶ Definition of “deep sedation” should refer to the “Guidelines on Procedural Sedation” promulgated by the Hong Kong Academy of Medicine.

II. Core Standards for Day Procedure Centres (“the Facility”)

1. Management/Governance

1.1. Person-in-charge

- 1.1.1. There should be a Person-in-charge (PIC), who is a registered medical practitioner, at all times. If the Facility provides dental services, there should be a registered dentist in charge of the dental services of Facility. The Facility should appoint a registered medical practitioner or registered dentist, respectively, to deputise the PIC in the latter’s absence from duties.
- 1.1.2. The PIC is held accountable for the medical management of the Facility. He is responsible for the adoption and implementation of policies and procedures concerning healthcare services in the Facility.
- 1.1.3. The PIC ensures that the policies and procedures are consistent with the Code of Professional Conduct issued by the Medical Council of Hong Kong and/or the Code of Professional Discipline for the Guidance of Dental Practitioners in Hong Kong issued by the Dental Council of Hong Kong wherever applicable.
- 1.1.4. PIC should ensure that all healthcare professionals working in the Facility have the requisite qualifications, valid registration, training and experience related to the healthcare services they provide.

1.2. Staff training and credentialing

- 1.2.1. All staff involved in clinical care should be appropriately trained including training in the use of any medical equipment and in assisting in medical procedures. There are at all times a sufficient number of suitably qualified and trained staff in the Facility, taking into account the number and needs of patients and types of services provided.
- 1.2.2. The PIC should ensure that the staff involved in clinical care are practising within their professional scope of practice and competence and in accordance with the code of practice of relevant professions.
- 1.2.3. There is a process to recognize and regularly review employees’ and visiting healthcare professionals’ qualifications, training and competence.

- 1.2.4. The Facility should provide job orientation programme for new staff. Current operational manuals and clinical guidelines are easily accessible and available to staff for their reference.

1.3. Research

- 1.3.1. If clinical research is conducted on patients, the PIC should ensure that research ethics have been reviewed and the conduct of research is in accordance with standard that may be prescribed by relevant regulatory authorities. The PIC should also ensure that any clinical drug trial conducted is covered by a valid clinical trial certificate issued under the Pharmacy and Poisons Regulations (Cap 138A).

2. Physical Conditions

2.1. Facility management

- 2.1.1. The physical design, size, layout and condition of the Facility are appropriate for the safe and effective delivery of services and the needs of its patients.
- 2.1.2. All buildings, furniture, furnishings, fittings and equipment of the Facility should be maintained in good operational order.
- 2.1.3. The Facility should be kept clean and hygienic. Ventilation, lighting and signage should be adequate and appropriate.
- 2.1.4. The PIC should ensure that the construction and use of the clinic premises are in compliance with relevant ordinances and regulations of the Laws of Hong Kong.

2.2. Equipment and store

- 2.2.1. All equipment used in the establishment should be used as intended for its purposes, in good working order and properly maintained. Records of maintenance and servicing of medical equipment should be kept.
- 2.2.2. Staff using medical equipment should have completed training in the safe and proper use of the equipment.
- 2.2.3. The PIC should ensure that the Facility has appropriate and readily accessible medical equipment, instruments, appliances and materials that are necessary for the type and level of patient care it provides. The quantities stored should be appropriate for the safe and effective

provision of its services.

2.2.4. Equipment intended for single use should not be reused.

2.3. Back-up power supply

2.3.1. Where high-risk procedures are conducted or life-support systems are used, back-up power supply is available for the life support systems, for recovering patients, and for safe completion or cessation of high-risk procedures.

3. Service Delivery and Care Process

3.1. Patients' rights

3.1.1. The Facility should establish written policies and procedures to protect the rights of its patients.

3.1.2. Patients have the right to know the name and rank of staff providing services.

3.1.3. Patients have the right to be informed of the treatment planned for them and give informed consent to their treatment.

3.1.4. The privacy of patients should be considered and respected by all staff of the Facility.

3.1.5. Patients and their carers or representatives have the right to be informed about the procedures for making complaints and the process of managing and responding to their complaints by the Facility.

3.1.6. Patients have the right to access their own health records.

3.2. Patient identification

3.2.1. There are written policies and procedures for patient identification. There should also be appropriate verification process to ensure that the correct patient has the correct procedure performed on the correct site.

3.3. Medical records

3.3.1. There shall be a written policy in place for the creation, management, handling, storage and destruction of all healthcare records.

3.3.2. For every patient, the PIC should ensure that complete, comprehensive and accurate medical records are maintained and retained for specified

minimum period.

- 3.3.3. Medical records should include at least the following: unique identifier, patient's name, gender, date of birth, residential address, contact telephone number, drug allergy history, relevant consultation notes and investigation(s), treatment, and, where appropriate, sick leave and referral records.
- 3.3.4. All medical records should be accurate, legible and up-to-date. All entries in the record should be dated and signed where appropriate.
- 3.3.5. Patient records are confidential and should be kept secure. All stored personal data should be protected from unauthorized access, alteration or loss. The staff handling personal data should be aware of the provisions of the Personal Data (Privacy) Ordinance (Cap 486) and have due regard to their responsibilities under that Ordinance.

3.4. Drug management

- 3.4.1. The PIC should ensure that the handling and supply of medicines at the Facility are in accordance with the requirements of the legislation in Hong Kong and prevailing guidelines issued by relevant regulatory authorities including but not limited to the codes of professional conduct or discipline issued by the Medical Council of Hong Kong and the Dental Council of Hong Kong.
- 3.4.2. The Facility should provide drugs and biological products in a safe and effective manner to meet the needs of the patients and to adequately support the clinical services. The facility should ensure proper vaccine storage and handling, with reference to the Hong Kong Reference Framework for Preventive Care for Children in Primary Care Settings Module on Immunisation.
- 3.4.3. The PIC should ensure that there are written policy and procedures covering all aspects of medicine management including but not limited to:
 - ordering, procurement, receipt, storage, labelling, administration and disposal of medicines; and
 - error and adverse incident reporting and management.
- 3.4.4. The PIC should keep an up-to-date drug formulary. All medicines supplied should be registered pharmaceutical products in Hong Kong.

Drug procurement documents should be kept appropriately for future reference and inspection.

3.4.5. All medicines should be clearly labelled and stored appropriately. A system is in place to check the expiry dates of medicines. Expired medicines should not be used for dispensing or administration and should be disposed properly.

3.4.6. Medicines are dispensed under the supervision of a registered medical practitioner, dentist, or pharmacist. Staff responsible for dispensing and administering medicines should receive appropriate training. A system is in place to monitor the accuracy of dispensing and administration of medicines.

3.5. Laboratory and radiology support

3.5.1. The PIC should put in place procedures for obtaining routine and emergency laboratory and radiology services to meet the needs of patient.

3.6. Special needs of paediatric patients

3.6.1. If the Facility admits paediatric patients, the PIC should ensure that treatment is provided by persons who have appropriate qualifications, skills and experience in treating children. Resuscitation equipment and medication is made ready in accordance to the age of the patients.

3.7. Continuous quality improvement

3.7.1. The PIC should implement a system for reviewing the quality of services at appropriate intervals. Findings of the review should be followed up to assure that effective corrective actions have been taken.

3.7.2. The PIC should ensure that policies and procedures relating to safe conduct of all patient care activities are developed and implemented.

3.7.3. The PIC should ensure that there is a written incident management system outlining the procedures to follow in the case of an incident or adverse event. The PIC should review all adverse event reports, document the review and quality improvements measures taken and disseminate the lesson learnt regarding the adverse event identified to all staff.

3.7.4. The PIC should report any specified reportable events to the regulatory authority in prescribed form and manner.

3.8. Charges

- 3.8.1. Patients should be informed of the charges of service whenever practicable. An up-to-date fee schedule covering all chargeable items should be readily available for reference of patients at the admission/reception office, cashier and where appropriate. If it is not possible to provide a fixed fee for a particular chargeable item, the fee could be presented in the form of a price range or could be marked to indicate that price information will be available upon request.

3.9. Complaint handling

- 3.9.1. The PIC should implement a mechanism for handling all complaints made by patients or persons representing the patient. The mechanism consists of procedures for receiving, investigating, responding to the complainant and documentation, with a specified time frame.
- 3.9.2. The PIC should ensure that patients and/or carers of patients are provided with information about the procedure for making complaints and the process for managing and responding to any complaints.

4. Infection Control

4.1. Infection control policies and procedures

- 4.1.1. The PIC should ensure that there is a written infection control policy, procedures and guidance outlining the procedure to prevent or reduce the risk of a patient acquiring an infection while at the Facility. Reference shall be made to guidelines issued by international or local health authorities (e.g. the Centre for Health Protection of the Department of Health).
- 4.1.2. The Facility should have an active infection control programme which includes measures to prevent, identify and control infections.
- 4.1.3. Appropriate and adequate stocks of personal protective equipment are available for use by staff.
- 4.1.4. The PIC should report to the Department of Health any unusual clustering of communicable diseases, in addition to the statutorily reportable infectious diseases stipulated in the Prevention and Control of Disease Ordinance (Cap 599).

4.2. Cleaning, Disinfection and Sterilisation of Medical Equipment

- 4.2.1. Reusable equipment and supplies used in operative or invasive procedure involving sterile tissue or vascular system should be properly processed and rendered sterile by appropriate procedures of sterilisation. Sterile equipment and supplies should be stored in a clean and dry area. There should be a system for regular checking of expiry of sterile supplies.
- 4.2.2. There should be written policies and procedures on the use of disposable equipment and on method of control to assure cleaning, disinfection and sterilisation of reusable equipment.
- 4.2.3. All sterilising equipment are regularly inspected and maintained with proper documentation. Relevant staff are appropriately trained in the use of the sterilising equipment.

4.3. Waste disposal

- 4.3.1. Clinical and chemical waste should be handled properly and safely according to written policies and procedures promulgated by the Environmental Protection Department pursuant to the Waste Disposal Ordinance (Cap 354).
- 4.3.2. Radioactive waste should be handled properly and safely according to the provisions of the Radiation Ordinance and the Radioactive Substances Licence issued by the Radiation Board in respect of the handling of the waste pursuant to the Radiation Ordinance (Cap 303).

5. Resuscitation and Contingency

5.1. Risk management

- 5.1.1. The PIC should ensure that there is a written risk management policy and safety inspection procedures for the identification and assessment of risks and hazards in the Facility and its services.
- 5.1.2. The PIC should ensure that there is a written emergency response policy outlining the procedures to be followed in the event of an emergency affecting the provision of services at the Facility.

5.2. Resuscitation of patients

- 5.2.1. The PIC should ensure that there are written policies and procedures for resuscitation of patients and resuscitation facilities for emergencies.

Resuscitation equipment should be easily accessible and checked at regular interval. The PIC should ensure that there are sufficient staff who are trained for cardiopulmonary resuscitation on duty at all times. The Facility should carry out resuscitation drills regularly.

- 5.2.2. If the Facility provides services to paediatric patients, there should be resuscitation equipment and drugs appropriate for paediatric patients and staff with appropriate training and skills to perform the resuscitation.

5.3. Emergency transfer

- 5.3.1. There should be written protocol in place for emergency transfer of patients to acute care hospitals when necessary.
- 5.3.2. Clinical records of sufficient content to insure continuity of care should accompany the patient, but the preparation of records should not delay the transfer.

5.4. Fire safety and evacuation

- 5.4.1. The PIC should ensure that there are adequate precautions against the risk of fire.
- 5.4.2. The PIC should ensure that there is an internal fire and emergency response plan incorporating evacuation procedures. Fire evacuation exercise is conducted at regular intervals. Records of the drills should be documented.

**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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