PROCEDURE-SPECIFIC STANDARDS FOR DAY PROCEDURE CENTRES

INTERVENTIONAL RADIOLOGY AND LITHOTRIPSY

April 2019

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 Interventional Radiology and Lithotripsy 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. Eight 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 interventional radiology and/or lithotripsy 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 (Interventional Radiology and Lithotripsy)

Application

This set of Standards applies to day procedure centres (DPC) providing scheduled medical procedures[1] in the class of interventional radiology and lithotripsy, with the exception of certain procedures that may only be performed in hospitals.[2] For those DPCs that are equipped with operating room(s), the operators should also refer to the relevant requirements in the *Procedure-specific Standards for Day Procedure Centres (Surgery and Anaesthesia & Sedation)* and the *Guidance Notes on Use of Operating Room for Surgical Procedures in Day Procedure Centres* at its Annex IV. Where other classes of scheduled medical procedures are provided (e.g. chemotherapy), relevant Procedure-specific Standards for Day Procedure Centres should also be observed.

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 interventional procedure.

1.1.2. Staff have received adequate training before assisting in new interventional procedures.

1.1.3. Person-in-charge develops and implements a policy to determine the scope of interventional 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

[1] Scheduled medical procedure is defined in Section 2 of the Private Healthcare Facilities Ordinance as "a medical procedure - (a) that is described in column 2 of Schedule 3; (b) that is not a medical procedure described in column 3 of Schedule 3; and (c) that is carried out in an ambulatory setting."

[2] Procedures that may only be performed in hospitals include image-guided core biopsy of deep seated organ, transarterial catheterisation or deep venous catheterisation, and injection of sclerosing or embolisation agents into vascular or lymphatic compartment of deep-seated head and neck region.

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.[3] 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.

2. Physical Conditions

2.1. Facility management

2.1.1. Doorways 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 the procedural and/or peri-operative areas.

2.1.4. In a facility where procedures under deep sedation, general anaesthesia or major regional anaesthesia are performed, doorways within the relevant perioperative or procedural area permit transfer of patient on trolleys or stretchers with attachment.

2.1.5. The clinical areas have immediate access to hand-washing facilities.

2.1.6. The provision and use of irradiating apparatus should conform to the Radiation Ordinance (Cap. 303).

[3] 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.

2.2. Operative/procedural area

2.2.1. Interventional 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, -

(a) each operating room is suitably designed, equipped and maintained for the purpose it is to be used;
(b) the operating room is maintained at an acceptable level of sterility;
(c) the ceiling, walls and floors are made from materials that can be easily cleaned and disinfected as needed to meet infection control requirements;
(d) the operating room is equipped with specialized 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;
(e) 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 system is kept; and
(f) adequate area for scrub and gowning is provided for operating room.

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 should be observed.

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 interventional 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) devices for specific imaging and/or interventional procedures;
(d) monitoring and resuscitation equipment; and
(e) appropriate radiation protective equipment for staff, patient and accompanying person.

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 person-in-charge develops and implements written policies and procedures relating to the safe conduct of interventional procedures and anaesthesia in the facility, including but not limited to the following:
(a) staffing arrangements for interventional procedures and anaesthesia, where applicable;
(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) management of complications (e.g. severe allergic reaction, 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.

3.1.3. Where irradiating apparatus is used, license under Radiation Ordinance (Cap. 303) is obtained.

3.2. Pre-procedure

3.2.1. Patients receiving interventional procedures are provided with information on the procedure and, where applicable, 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-sedation 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 it is not possible for the pre-sedation or pre-anaesthetic assessment to be done by the same medical practitioner who is responsible for the sedation or anaesthesia, there is an adequate documented mechanism for conveying findings of the consultation to the medical practitioner performing the sedation or anaesthesia. The final assessment by the medical practitioner for performing the sedation or 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) implants (e.g. pacemakers) and possible contraindications to specific imaging procedures, where appropriate;
(e) relevant investigations and consultation(s) with other specialty if any; and
(f) 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. Person-in-charge ensures that there are written policies and procedures on the following processes before interventional procedures:
(a) checking of consent forms;
(b) verification processes, including time-out, to ensure correct patient, procedural 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, neuroaxial block or major plexus block 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. Where applicable, there are written policies and procedures on the counting of items used during the procedures, such as guide wires, 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. All patients after interventional procedures are observed for an adequate length of time commensurate with the interventional procedure performed and any sedation or anaesthesia given, 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. 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.

3.4.3. 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/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.

3.4.4. Monitoring of patients recovering from procedural sedation is in accordance with the *Guidelines on Procedural Sedation* published by the Hong Kong Academy of Medicine.

3.4.5. 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.

3.4.6. 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.

3.4.7. For a patient who has received general anaesthesia, major regional anaesthesia or deep sedation, there is a responsible adult to escort him/her home.

3.4.8. There is written protocol on transfer of patients to hospital for those patients 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 records of all procedures and operations 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 sent for pathology; 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 procedure.

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 person-in-charge 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 sterilisation, and storage of interventional 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. R*ecommendations 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 or 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 proceduralist and/or the anaesthesiologist 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.

References

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Annex I

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.

Annex II

Project Steering Committee on Standards for Ambulatory Facilities

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Annex III

Project Steering Committee on Standards for Ambulatory Facilities

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