For discussion on
16 February 2014

Legislative Council Panel on Health Services

The Administration's response to the Research Study on Regulation of Aesthetic Practices in Selected Places

PURPOSE

This paper sets out the Administration's response to the research study on Regulation of aesthetic practices in selected places.

BACKGROUND

2. The Research Report entitled "Regulation of aesthetic practices in selected places" (the Report) prepared by the Research Office of the Information Services Division of the Legislative Council (LegCo) Secretariat examines the regulatory framework of aesthetic practices in Hong Kong, Florida of the United States (US), South Korea, Singapore and the United Kingdom (UK) in terms of (a) classification of and competency requirements for performing aesthetic procedures, (b) regulation of the beauty sector in performing aesthetic procedures, (c) regulation of the use of cosmetic-related medical devices, (d) regulation of ambulatory facilities in which aesthetic procedures are performed and (e) protection of persons undergoing aesthetic procedures. The Administration's response to the findings on each of the above five areas are set out in the ensuring paragraphs.

A. Classification of and competency requirements for performing aesthetic procedures

3. The Working Group on Differentiation between Medical Procedures and Beauty Services (WG1) under the Steering Committee on Review of Regulation of Private Healthcare Facilities (the Steering Committee) made recommendations on aesthetic procedures that should only be performed by registered medical practitioners / registered dentists

because of their inherent risks, namely, those that involve injections, mechanical / chemical exfoliation of the skin below the epidermis, hyperbaric oxygen therapy [1] and dental bleaching. These recommendations were endorsed by the Steering Committee in November 2013.

4. In view of the recommendation of the Steering Committee, the Government advised non-medical practitioners in the beauty sector in November 2013 to refrain from performing aesthetic procedures that are classified as medical procedures. Failure to follow the advice may render oneself liable for offences under the Medical Registration Ordinance (Cap. 161) or the Dentists Registration Ordinance (Cap. 156).

5. Medical practitioners and dentists in Hong Kong are required by law to comply with the Code of Professional Conduct issued by their respective councils at all time, including when they are involved in aesthetic procedures. Participation in continuous medical education is mandatory for medical and dental specialists. While voluntary for general practitioners, doctors and dentists may undertake continuous education in various ways to keep up with the latest development in medical practices, including enrolling in practical and up-to-date courses on aesthetic procedures organised periodically by institutes and associations of the medical and dental professions.

6. For medical practitioners performing aesthetic procedures, their professional conduct is regulated by the Medical Council of Hong Kong (the MCHK). They shall comply with the Code of Professional Conduct for the Guidance of Registered Medical Practitioners issued by the MCHK. In general, medical practitioners must act in patients' best interests and take the patients' needs into consideration when performing clinical treatment. They must also possess the relevant knowledge and skills. Before any treatment is offered, the medical practitioner should explain clearly to the patient the treatment procedures and risks involved, and seek the consent of the patient. If a patient is dissatisfied with the professional conduct of a medical practitioner, he may lodge a complaint to the MCHK.

[1] WG1 recommended that this procedure should only be performed by registered medical practitioners on patients with clinical need and not as a form of beauty procedure.

7. Members may wish to note that the Hong Kong Academy of Medicine (the Academy) is in the process of establishing a credentialing system. Credentialing is a process used to verify the qualifications, professional training, clinical experience and other relevant professional attributes of healthcare professionals for the purpose of forming a view about their competency, performance and professional suitability to provide safe, high quality health care services within specific organisational environment. The Academy is now working on a policy document on credentialing.

B. Regulation of the beauty sector in performing aesthetic procedures

8. Beauty industry in Hong Kong, like most other industries and businesses, runs and evolves in a free-market environment subject to laws and regulations of a general nature. Most of the practices of the beauty industry are non-invasive and pose low health risks to customers. Instead of regulating the beauty industry indiscriminately, the Government has adopted a risk-based approach to focus on the high risk procedures which may cause unnecessary harm or complications to customers if performed by a person without proper training or qualification. Against this backdrop, WG1 recommended and the Steering Committee endorsed that certain aesthetic procedures, in view of their inherent risks, should only be performed by registered medical practitioners or registered dentists.

9. As regards training and standard of practice, we understand that with the support of the Education Bureau (EDB), the Beauty and Hairdressing Industry Training Advisory Committee[2] (ITAC) was set up under the Qualifications Framework (QF) to assist the industry in implementing the QF and promote lifelong learning of its practitioners. The former Beauty ITAC developed the first version of Specification of Competency Standards (SCS) in November 2010, which sets out the competency requirements and outcome standards of the industry at various QF levels and provides a foundation for the development of education and training programmes (including in-house training programmes) that meet the practical needs of the industry.

[2] Starting from 1 January 2015, the Beauty ITAC and Hairdressing ITAC have merged to become the Beauty and Hairdressing ITAC.

10. The Recognition of Prior Learning mechanism based on the SCS for the beauty industry has been implemented. The EDB and the QF Secretariat will continue to assist the beauty industry in sustaining its development riding on the QF platform.

C. Regulation of the use of cosmetic-related medical devices

11. Currently, there is no specific law to regulate the import, distribution, sale or use of medical devices in Hong Kong except for those devices which contain pharmaceutical products or emit ionizing radiation. In 2003, the Government proposed to develop a risk-based regulatory framework on medical devices so as to protect public health while ensuring continued access to new technologies. The scope of regulation broadly includes pre-market control, post market control and use control. A voluntary Medical Device Administrative Control System (MDACS) has been established by the Department of Health (DH) since 2004 to raise public awareness of the importance of medical device safety and pave the way for implementing the long-term statutory control. Subsequently, a Regulatory Impact Assessment (RIA) was conducted from 2007 to 2008 and a Business Impact Assessment (BIA) was conducted from April 2011 to January 2013. The Administration has been working on the details of the proposed legislation, taking into account the findings of the RIA and BIA, and submitted a paper to the Legislative Panel on Health Services (the Panel) on the "Proposed Regulatory Framework for Medical Devices" (LC Paper No. CB(2)1754/13-14(04)) for discussion on 16 June 2014.

12. As mentioned in the above paper, WG1 has examined the safety and health risks of devices commonly used in beauty procedures e.g. high-power medical lasers, intense pulsed light (IPL) equipment, radiofrequency devices, etc. WG1 considers that given the heterogeneity of the devices involved, a more detailed study should be conducted to examine overseas experience and practices and the scope of control on the use of these medical devices.

13. Taking into consideration the views and recommendations of WG1, the DH is now in the process of engaging an external consultant to conduct a detailed study to examine overseas experience and practices and the scope of control on the use of the selected medical devices. Upon completion of the study in 2015, the Administration will report to the Panel on the outcome of the consultancy study and the details of the legislative proposal.

D. Regulation of ambulatory facilities in which aesthetic procedures are performed

14. The Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting (WG2) set up under the Steering Committee has completed its review on the regulation of ambulatory facilities where high-risk medical procedures/practices were performed and made recommendations on the scope and framework of regulation.

15. WG2 recommended that ambulatory facilities providing medical procedures defined to be high-risk should be regulated by statutory registration. Medical procedures are classified to be high-risk based on the risk of the procedure, risk of anaesthesia involved and the patient's condition. Regulated ambulatory facilities should be subject to a set of core standards as well as procedure-specific standards. The regulatory authority should have a mechanism to devise, review and update the scope of regulation and regulatory standards, with regard to the expert advice of the Academy. The detailed recommendations of WG2 are at **Annex**. Facilities in which high-risk medical procedures are performed for aesthetic purposes would be regulated under this proposal.

16. Taking into account the consolidated recommendations of the Steering Committee, the Government commenced a three-month public consultation on Regulation of Private Healthcare Facilities on 15 December 2014. We propose that, among others, facilities providing high-risk medical procedures in ambulatory setting should be regulated under a new regulatory regime for private healthcare facilities. Subject to the outcome of the consultation, we will implement it by legislation.

17. Before the introduction of a new regulatory regime, a territory wide-survey will be conducted to assess the number and types of private ambulatory facilities that may be affected by the new regulatory regime. An administrative listing system will also be introduced before the statutory registration comes into effect.

E. Protection of persons undergoing aesthetic procedures

18. Consumers of beauty services, like consumers of other services, are protected by general consumer protection laws including Trade Descriptions Ordinance (Cap. 362), Consumer Goods Safety Ordinance (Cap. 456), Unconscionable Contracts Ordinance (Cap. 458), Supply of

Services (Implied Terms) Ordinance (Cap. 457) and Sale of Goods Ordinance (Cap. 26). The Trade Descriptions (Unfair Trade Practices) (Amendment) Ordinance 2012, which came into effect in July 2013, prohibits certain unfair trade practices such as false trade descriptions in respect of services, misleading omissions, aggressive commercial practices and wrongly accepting payment.

19. In addition, the Undesirable Medical Advertisements Ordinance (Cap. 231) prohibits any person from publishing any advertisement that is likely to lead to the use of any medicine, surgical appliance or treatment for the purpose of treating or preventing from contracting any disease or condition specified in the Ordinance. Since October 2012, a total of 575 warning letters (as at 26 January 2015) had been issued by DH in relation to advertisements of beauty centres that have contravened the Undesirable Medical Advertisements Ordinance. During the same period, DH had taken out prosecution for four offence cases related to beauty centres which were all convicted. The penalty ranged from $3,500 to $20,000.

20. Moreover, through enhanced screening of beauty service advertisements, follow up of enquiries on beauty services and information provided by the Consumer Council on complaints related to adverse effects of aesthetic procedures since October 2012, DH had identified a total of 11 cases (as at 26 January 2015) of suspected illegal practice of medicine or dentistry, which were referred to the Police for further investigation. One of the cases had pleaded guilty and the convict was sentenced to jail for 4 weeks (suspended for 3 years) for practising medicine without licence and fined $15,000 in total for illegal possession of antibiotics, Part I poison and unregistered pharmaceutical products.

ADVICE SOUGHT

21. Members are invited to note the content of this paper.

Food and Health Bureau
Department of Health
February 2015

Annex

Recommendations of the Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting

The Working Group puts forward the following recommendations for the consideration of the Steering Committee.

Recommendation (1)

High-risk procedures/practices should be performed only in regulated ambulatory facilities or hospitals by qualified health professionals.

Recommendation (2)

A procedure is high-risk if it is so classified by ANY of the following three factors –

(a) the procedures is classified to be high-risk; or
(b) the anaesthesia involved is classified to be high-risk; or
(c) patient's condition is classified as Class 3 (severe systemic disease) – unstable (acute exacerbation) or worse according to the American Society of Anaesthesiologists (ASA) Physical Status Classification System[1].

When deciding whether a procedure is high-risk and whether a patient should undergo the procedure in ambulatory - or hospital-setting, medical practitioners and dentists should take into account the age, body size and other physical conditions of the patient, in addition to the criteria for defining high-risk and hospital-only procedures.

[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

Recommendation (3)

Certain high-risk procedures should only be performed in hospital in view of its risk. Overall, high-risk procedures may be performed in ambulatory setting only if -

(a) the patient is discharged in the same calendar day of admission;
(b) the total duration of procedure and recovery 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 Anaesthesiologists (ASA) Physical Status Classification System.

Recommendation (4)

It is recommended to adopt the scope of high-risk and hospital-only procedures as set out in the **Appendix**.

Recommendation (5)

A statutory registration system should be introduced for ambulatory facilities where high-risk procedures are performed. An administrative listing system may be implemented before the mandatory registration system takes effect.

Recommendation (6)

Regulated ambulatory facilities should be subject to a set of core facility standards and requirements that cover –

(a) management of the facility;
(b) physical conditions;
(c) service delivery and care process;
(d) infection control; and
(e) resuscitation and contingency.

Regulated facilities will also be imposed further facility standards that are specific to the procedures being performed in the facilities, e.g. haemodialysis, cytotoxic chemotherapy and anaesthesia[2].

[2] The "Guidelines on Procedural Sedation" promulgated by the Hong Kong Academy of Medicine is recommended to be the regulatory standards on anaesthetic safety.

Recommendation (7)

It is recommended that the regulatory authority will have a mechanism to devise, and review and update as required, the scope of regulation and standards with regard to the expert advice of the Hong Kong Academy of Medicine on -

(a) the range of high-risk procedures; and
(b) the relevant procedure-specific facility standards.

Recommendation (8)

Regulated ambulatory facilities should be subject to general requirements that are applicable to other comparable regulated healthcare facilities.

Appendix - Recommended Scope of High-risk and Hospital-only Procedures

General Principles

1. A procedure is high-risk if it is so classified by ANY of the following three factors -

   (a) the procedures is classified to be high-risk; or

   (b) the anaesthesia involved is classified to be high-risk; or

   (c) patient's condition is classified as Class 3 (severe systemic disease) – unstable (acute exacerbation) or worse according to the American Society of Anaesthesiologists (ASA) Physical Status Classification System.

2. Medical practitioners and dentists should take into account, in addition to the criteria for defining high-risk and hospital-only procedures, the age, body size and other physical conditions of the patient when deciding whether the procedure is high-risk and if a patient should undergo the procedure in ambulatory facility or in hospital.

A) Risk of Procedures

3. High-risk surgical procedures include the following procedures -

   (a) Creation of surgical wound to allow access to major body cavity or viscus[3] (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]

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

(e) Insertion of any prosthesis (including tissue filler) [except prosthesis in ENT cavity, dental prosthesis and implants, extra-ocular prosthesis and implants, intrauterine or vaginal prosthesis, bulking agents of urethra, prostatic urethral stent, urethral slings, testicular prosthesis]

(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 organ or tissue requiring image guidance

(h) Fine needle biopsy of deep-seated organ

(i) Lumbar puncture

(j) Transplant of any cell, tissue and organ (including autograft, allograft and processed tissue or blood products[4]) or skin flap (including face lift) [except small skin graft less than 3 cm in any dimension, conjunctival autograft and transplant procedures which primarily involve dental-alveolar region]

(k) Termination of pregnancy

(l) Dilation and curettage

(m) Circumcision with use of skin sutures in paediatric patients

4. 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 cystoscopy[5]] or gastrointestinal tract

(c) Therapeutic endoscopic procedures (such as endoscopic resection), [except minor therapeutic procedures (such as removal of foreign body)]

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[4] Include platelet-rich plasma (PRP)

[5] Cystoscopy does not include cystoscopic procedures such as cystoscopic biopsy, cystoscopic insertion or removal of ureteric catheter or stent, endoscopic urethral dilatation or urethrotomy, cystoscopic removal of stone or polyp, cystoscopic injections/diathermy/cautery or haemostasis, cystoscopic lithotripsy, etc.

(d) Bronchoscopy or pleuroscopy

5. 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

6. 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 breast and superficial lymph node], 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

B) Scope of High-risk Anaesthetic Procedures[6]

7. 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 sedation[7] for a significant percentage of a group of patients

(h) Tumescent anaesthesia

C) Patient's condition

8. 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.

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[6] 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, etc.

[7] Definition of "deep sedation" should refer to the "Guidelines on Procedural Sedation" promulgated by the Hong Kong Academy of Medicine.

D) Hospital-only procedures

9. 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