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针刺安全使用风险控制通则

General requirements for the risk control in the safe use of acupuncture

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Foreword

This document is developed in accordance with the technical procedures and rules established by the Standardization Working Committee of the World Federation of Acupuncture-Moxibustion Societies.

This document is endorsed and published by the World Federation of Acupuncture-Moxibustion Societies.

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Introduction

As a traditional medical therapy, acupuncture has minimal potential bodily harm used properly. At present, acupuncture is being used in over 190 countries in the world and over 20 of those have incorporated acupuncture in their national health coverage. However, as a kind of invasive procedure, acupuncture does carry certain risks, especially when practitioners fail to receive adequate training or do not perform the procedure according to specifications. In the medical literatures, there are reports on acupuncture adverse events from different countries. Some acupuncture practitioners do not operate according to acupuncture technical specifications, raising concerns about the safety of acupuncture. Therefore, it is necessary to specify the basic requirements for the safe use of acupuncture to minimize risks from the point of view of benefiting all. This document has been developed to address worldwide demand for safe acupuncture practices.

There are various kinds of acupuncture needles. Before developing the standards for the safe use of specific acupuncture needles, it is necessary to first extract the common problems encountered by various needles in the acupuncture process, e.g. the definitions, degree, sources, control measures, and other relevant questions of acupuncture risks, and then to develop a general rule for the safe use of acupuncture to build a framework for the establishment of subsequent related specific standards, so as to avoid the repetition of the common issues of the safe use of acupuncture in different specific standards.

As general requirements for the safe use of acupuncture, this document is not for a specific acupuncture needle, but to address the common problems encountered in acupuncture with different kinds of needles in specific procedure to prevent the risks of acupuncture.

General requirements for the risk control in the safe use of acupuncture

1 Scope

This document specifies the risks in the acupuncture application and the general requirements for its safe use, including the definitions, degree, sources, control processes, and control measures of risks and other relevant questions of different acupuncture needles and their using procedures.

This document is applicable to questions about the safe use of acupuncture. It does not apply to specific acupuncture needles, but deal with the common problems encountered in acupuncture practice using of different kinds needles and their procedures to prevent the risks of acupuncture.

This document excludes the specific criteria for the training of acupuncture practitioners, the clinical treatment plans or efficacy of acupuncture.

2 Normative references

The content of following documents constitutes an essential provision of this document by means of normative references in the text. For dated references, only the edition corresponding to that date applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 17218:2014, *Sterile acupuncture needles for single use*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
acupuncture risks

The possibility of physical or psychological damages, injuries, or other adverse conditions associated with acupuncture.

3.2
adverse events of acupuncture

All adverse medical events that occur during or after acupuncture treatments, such adverse medical events may not necessarily have a causal relationship with the acupuncture treatment itself.

3.3
adverse reactions to acupuncture

The adverse medical events that occur during or after a normative acupuncture treatment are caused by the acupuncture treatment itself and are not related to the purpose of the treatment.

NOTE Normative acupuncture treatment includes normative diagnosis, needle manipulations, and using of acupuncture instruments and devices.

3.4
acupuncture accidents

Unpredictable and hard to prevent adverse medical events that occur during or after a normative acupuncture treatment. Such adverse medical events are caused by unpredictable and irresistible reasons, and are not related to the intended purpose of the acupuncture treatment itself.

3.5
acupuncture negligence

The adverse medical events that causing personal injuries to acupuncture receivers, and are caused by acupuncture practitioners' negligent violations of health laws, administrative regulations, departmental rules, and/or diagnosis and treatment norms and routines in the process of acupuncture treatments.

3.6
acupuncture contraindications

Conditions in which acupuncture is inappropriate.

4 Scope of acupuncture risks

4.1 Risks to acupuncture receiver

In general, acupuncture performed by a well-trained acupuncturist using normative techniques is safe, and the risk to the receiver is very low. The probability of serious adverse events associated with acupuncture is also very low. Some acupuncture adverse events are acupuncture negligence, mostly related to abnormal or non-normative operations, and some are acupuncture accidents, none of which are in the category of adverse reactions to acupuncture. Risks to acupuncture receivers mainly include the following categories.

a) Adverse reactions to acupuncture: pain, allergy, stasis of blood, hematoma, fatigue, agitation, panic, hypoesthesia, etc..

b) Adverse accidents: needle shock, bent needle, broken needle, stuck needle for non-therapeutic purposes, etc..

c) Infections and diseases transmission: local or systemic skin infection by acupuncture, transmission of infectious diseases such as hepatitis B, hepatitis C, AIDS, syphilis, etc..

d) Nerve injuries: peripheral nerve injuries may occur due to the mechanical action of acupuncture devices, and sensory disturbance and varying degrees of dysfunction may be detected in the distribution area of the nerve. For example, the median nerve injury, ulnar nerve injury, radial nerve injury, brachial plexus nerve injury, sciatic nerve injury, tibial nerve injury, and peroneal nerve injury.

e) Vascular trauma, vital organ damages, disability, or death: the mechanical action of the acupuncture device may destruct the anatomical integrity of human tissues or viscera, causing mechanical injuries, disability, or death, such as traumatic pneumothorax, subarachnoid hemorrhage, and injuries to brain tissue, spinal cord, blood vessels, and internal organs, especially brain and heart injuries are the most severe consequences which can be fatal.

4.2 Risks to acupuncture providers

Acupuncture providers are exposed to multiple occupational hazards in practice,maily needlestick injuries and infections. Pricking by various types of contaminated acupuncture needles can lead to blood-borne infections for the providers.

NOTE Local or systemic infections, which may lead to fatal results, can be caused by pathogens enter into the body through puncture wounds. AIDS, hepatitis B, and hepatitis C remain the main types of occupational biological hazards.

4.3 Environmental risks

Acupuncture devices and other medical wastes contaminated by blood and tissue of the receiver are belonging to the category of special and highly contagious waste with a long incubation period.

5 Degree of acupuncture risks

5.1 High degree risks of acupuncture

Commonly include: traumatic pneumothorax, subarachnoid hemorrhage, injuries of brain tissue, spinal cord, heart, blood vessels, liver, spleen, kidneys, and gallbladder, hepatitis B, hepatitis C, AIDS, syphilis, and other severe local or systemic infections, and severe nerve or vascular injuries, disabilities, and death.

5.2 Moderate degree risks of acupuncture

Commonly include: mild local skin infections from needling, mild to moderate nerve injuries, large hematoma, and broken needles.

5.3 Low degree risks of acupuncture

Commonly include：receivers' adverse reactions to acupuncture，bent needles，stuck needles for non-therapeutic purposes，and providers' pricking needlestick injuries as mentioned above.

6 Flow chart of acupuncture risk control

The process of acupuncture risk control is classified into primary process and secondary process. The flow chart of acupuncture risk control is shown in Figure 1.

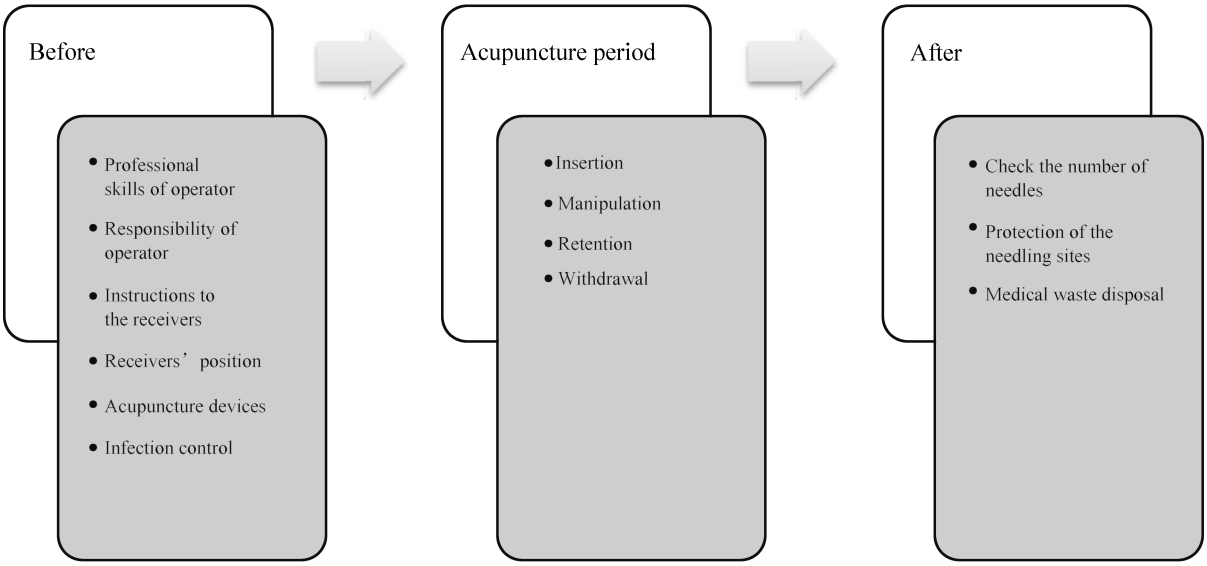

Figure 1—Flow chart of acupuncture risk control

7 Primary causes of acupuncture risks and control measures

7.1 Risks caused by acupuncture providers and their corresponding control measures

7.1.1 Insufficient professional skills：Acupuncture provider is unable to avoid risks due to the lack of awareness of the severity of acupuncture injuries and insufficient professional manipulation skills.

Control measures：

a) Improve the awareness on acupuncture risks：for potentially risky acupoints，especially those close to important tissues and organs，acupuncture practitioners should be familiar with the anatomical structures and adjacent structures of those acupoints，especially in the case of pathological tumefaction of organs.

b) Improve the professional skills on special techniques of acupuncture or the use of specific needles. Special acupuncture techniques include eye acupuncture，tongue acupuncture，nose acupuncture, abdominal acupuncture, etc.. Specific needles include elongated needle, fire needle and round-sharp needle, etc..

7.1.2 Lack of accountability: It refers to insufficient accountability of the practitioner, insufficient understanding of receivers' conditions, insufficient communication with receivers, and lack of concentration during treatment.

Control measures:

a) Obtain detailed data about the physical conditions of the patients. More cautious manipulations than usual should be applied when pathological tumefaction is detected.

b) Conduct an effective communication with receivers. Potential sensations and precautions shall be clarified to the receivers (i.e. not to change the position arbitrarily, to keep an even breathing, not to suddenly breathe deeply, avoid sudden movements such as coughing or sneezing) to relieve their nervousness and apprehension about acupuncture. Provide information to the receivers about possible reactions of the body to the acupuncture treatment as well as post-treatment cautions when some special techniques, such as eye acupuncture, tongue acupuncture, nose acupuncture, abdominal acupuncture, auricular acupuncture, and scalp acupuncture, and specific needles, such as intradermal needles, skin needles, fire needles, three-edge needles, and Fu's subcutaneous needles, are involved.

c) Concentrate on the treatment process to observe the reactions of the receivers at all times.

d) A check up after the removal of needles should be conducted to avoid omissions.

7.1.3 Excessive intensity of manipulations: To pursue a stronger needling sensation and better therapeutic effect, the needling provider adopts excessive large-scale lifting, thrusting, twirling, repeated insertion and other needling techniques, which may cause severe pain, hematoma, swelling, and stuck needle in the local area, and even severe injuries to nerves, viscera, etc..

Control measures:

a) Proper use of appropriate acupuncture techniques.

b) Regarding risky acupoints, the needle should be slowly and gently pushed at recommended angle to a proper depth after insertion.

7.1.4 Use of inappropriate needles: Using inappropriate needles is the source of untoward effects such as infections, disease transmission, broken needles, pain, hematoma, etc..

Control measures：

a） To adopt disposable sterile needles which conform to ISO 17218：2014.

b） When non-disposable needles have to be used，the repeatedly used needles must be strictly sterilized.

c） Carefully inspect the needles before the needling operation. Needles shall be prohibited if they are tip-blunt，hooked，body-bent，creased or root-rusted.

d） To choose appropriate needles according to the receiver's conditions and acupuncture sites.

7.1.5 Failed sterilization and infection control：Nosocomial infection is caused by lack of awareness of aseptic operation and infection control.

Control measures：Practitioners shall strictly carry out aseptic operation，and disinfect acupuncture needles，skin around the acupuncture sites，and operating hands to prevent nosocomial infections.

7.1.6 Lack of safety awareness by the acupuncture provide：Accidental injuries or infections result from the acupuncture provide's lack of safety awareness precautions.

Control measures：

a） Wear gloves when needling the receivers with open wounds，skin diseases，and infectious diseases.

b） Avoid transmission of unpackaged acupuncture needles by bare hands.

c） Arrange the waste container for sharp needles and devices at appropriate area.

d） Seal the container when 2/3 of its capacity is occupied.

7.2 Risks caused by receivers and their corresponding control measures

7.2.1 Disorder of physiological functions including fainting，severe pain，allergy，hysteria reactions，etc. can be caused by certain adverse conditions such as excessive stress，overstrain，fatigue，weak，hunger，dehydration，overeating，drunk，and allergic constitution. Hemorrhage can be easily induced by pricking the blood vessels of receivers with blood diseases or coagulation disorders.

Control measures：Prohibiting acupuncture under these conditions.

7.2.2 Injury may be caused by conventional acupuncture methods under certain pathological conditions. A conventional needle insertion at a conventional angle or depth may lead to viscera damage when the recipient's organs, especially the internal organs in the thoracic and abdominal cavities, have pathologically enlargements, rough surfaces, loose tissue structures, etc..

Control measures: Thoroughly inquiring the medical history, having a careful physical examination, and providing acupuncture cautiously.

7.2.3 Infectious diseases such as hepatitis B, hepatitis C, AIDS, TB, etc. can be transmitted through acupuncture.

Control measures: Pay attention to prevention and control of infectious diseases, and provide acupuncture cautiously.

7.2.4 Miscarriage may occur when acupuncture is applied to some specific acupoints as well as at certain parts of the human body such as the low back region and abdominal region.

Control measures: Women shall avoid acupuncture during pregnancy if there is no specific need. If acupuncture is a necessity for treatment, the above-mentioned areas shall be avoided.

7.2.5 During the process of acupuncture or needle retention, sudden movements of the receiver's body or sudden changes in physical rhythm (referring to the respiratory rate of the acupuncture receiver), or sudden movements such as coughing or sneezing can often cause change positions of needles, causing injuries to receivers.

Control measures:

a) Provide necessary instructions to the receiver and select a comfortable posture before treatment.

b) An adjustment of the depth of the puncture or a removal of the needles should be applied immediately after the sudden change of the position.

7.2.6 Improper protection of the acupuncture site by the receiver. Contact with contaminating substances, sewage, etc., may lead to infection caused by entering and reproduction of pathogenic microorganism vis the pinhole.

Control measures: Necessary instructions should be given to the receiver.

7.3 Environmental risks and their corresponding control measures

7.3.1 Poor hygienic conditions：The increased rate of infection during acupuncture may be caused by the poor hygienic conditions during the needling process.

Control measures：Acupuncture therapy should be administered in medical clinics or places that meet the sanitary requirements of the local healthcare facility's outpatient environment in different countries.

7.3.2 Random disposal of healthcare waste：Improper management of healthcare waste by medical institutions and health authorities has led to the random disposal of healthcare waste，which injuries people with sharps，transmits diseases，and pollutes the environmen.

Control measures：

a） Strengthen the management of medical waste and prohibit random disposal to prevent sharps from injuring people，spreading diseases，and polluting the environment.

b） Special containers that are not easy to be penetrated and permeated shall be available for the collection of sharp and dull acupuncture devices，respectively.

c） Discarded needles and other sharp acupuncture devices shall be collected in special containers for sharps.

d） Healthcare waste and used needles shall not be mixed with the household garbage.

e） Collection and destruction of healthcare waste must be carried out in a certain area under the regulation of local medical authority.

Bibliography

[1] ISO 11135：2014，*Sterilization of health-care products—Ethylene oxide—Requirements for the development，validation and routine control of a sterilization process for medical devices*

[2] ISO 14971：2019，*Medical devices—Application of risk management to medical devices*

[3] ISO/IEC Guide 51：2014，*Safety aspects—Guidelines for their inclusion in standards*

[4] ISO/IEC Guide 63：2019，*Guide to the development and inclusion of aspects of safety in International Standards for medical devices*

[5] ISO/IEC Guide 76：2020，*Development of service standards—Recommendations for addressing consumer issues*

[6] ISO/IEC Directives，Part 2，2018，*Principles and rules for the structure and drafting of ISO and IEC documents*

前　言

本文件依据世界针灸学会联合会标准工作委员会制定的技术流程和规则研制。

本文件由世界针灸学会联合会(World Federation of Acupuncture-Moxibustion Societies，WFAS)归口并发布。

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本文件的制定得到了中华人民共和国科技部-国家重点研发计划中医药现代化研究重点专项项目国际针灸临床实践指南、技术操作规范和服务标准的研制(项目编号：2019YFC1712200)中国际针灸技术操作规范编写通则(课题编号：2019YFC1712202)的基金支持。

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引 言

针刺作为一种传统医疗方法，如果使用得当，对人体的潜在伤害非常小。目前，针刺已在世界上190多个国家使用，其中20多个国家和地区已将针刺纳入国民健康保险范畴。然而，作为一种侵入性的操作，尤其是当从业者未能接受充分的培训或不按规范进行操作时，针刺确实会存在一定的风险。在医学文献中，有来自不同国家的针刺不良事件的报道，有些针刺从业者未按规范进行操作，引发了人们对针刺安全性的质疑。因此，从各利益相关方的角度考虑，有必要明确针刺安全使用的基本要求，以降低风险。本文件的研制即为满足全球对针刺安全操作的需求。

针具的种类繁多，在制定各具体针具安全使用标准之前，有必要先将各种不同针具在针刺过程中遇到的共性问题提炼出来，如针刺风险的定义、等级、来源及控制措施等相关问题，然后制定一个针刺安全使用的通则，为后续相关标准的制定打下一个框架基础，以避免针刺安全使用的共性问题在一个个具体的针具安全使用标准中大量重复出现。

作为针刺安全使用的通则，本文件并不针对某一特定的针灸针，而是通过规范各种不同针具在针刺过程中遇到的共性问题，来预防针刺风险。

针刺安全使用风险控制通则

1 范围

本文件规定了针刺应用时存在的风险及其安全使用的基本要求，内容包括不同种类的针灸针及其使用过程中的风险定义、风险等级、风险来源、控制流程及控制措施等相关问题。

本文件适用于安全应用针刺的相关问题，但不涉及针灸针的技术参数，而是用于解决应用不同种类的针灸针在针刺过程中遇到的共性问题，以避免针刺风险的出现。

本文件不包括针刺从业者培训以及针刺临床治疗和疗效方面的内容。

2 规范性引用文件

下列文件中的内容通过文中的规范性引用而构成本文件必不可少的条款。其中，注日期的引用文件，仅该日期对应的版本适用于本文件；不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

ISO 17218：2014　一次性使用无菌针灸针

3 术语和定义

下列术语和定义适用于本文件。

3.1

针刺风险　acupuncture risks

针刺相关的身心损失、伤害或其他不利状况出现的可能性。

3.2

针刺不良事件　adverse events of acupuncture

针刺治疗过程中或治疗后发生的一切不良医疗事件，这类不良医疗事件不一定与针刺治疗本身有因果关系。

3.3

针刺不良反应　adverse reactions to acupuncture

规范的针刺治疗过程中或治疗后发生的，由针刺治疗本身引起的，与治疗目的无关的不良医疗事件。

注：规范的针刺治疗包括诊断规范、操作规范、针刺用具规范。

3.4

针刺意外　acupuncture accidents

规范的针刺治疗过程中或治疗后发生的，由于不可预知和不可抗拒的原因，导致受用者出现的与治疗目的无关的、难以预料和防范的不良医疗事件。

3.5

针刺事故　acupuncture negligence

针刺施术者在针刺治疗过程中，违反医疗卫生管理法律、行政法规、部门规章和诊疗规范、常规，过失造成受用者人身损害的不良医疗事件。

3.6

针刺禁忌症　acupuncture contraindications

不应当施行针刺的情况。

4　针刺风险范围

4.1　针刺受用者风险

一般而言，由经过专业培训的针灸师使用规范的技术操作实施的针刺是安全的，受用者风险很低，与针刺相关的严重不良事件的发生概率也非常低。针刺不良事件有些属于针刺事故，多与非正常或不规范操作有关，有些属于针刺意外，均不属于针刺不良反应范畴。针刺受用者风险主要包括以下几类。

a）　针刺不良反应：疼痛、过敏、瘀血、血肿、疲劳、激动、恐慌、感觉减退等。

b）　针刺意外：晕针、弯针、断针、非治疗目的的滞针等。

c）　感染及疾病传播：针刺皮肤局部或全身感染，乙肝、丙肝、艾滋病、梅毒等传染病的传播。

d）　神经损伤：因针具的机械作用而造成外周神经损伤，在该神经分布区可能出现感觉障碍及程度不同的功能障碍，常见的有正中神经损伤、尺神经损伤、桡神经损伤、臂丛神经损伤、坐骨神经损伤、胫神经损伤、腓神经损伤。

e）　血管损伤、重要脏器损伤、残疾或死亡：因针具的机械作用而造成人体组织或器官解剖完整性的破坏出现的机械性损伤、残疾或死亡，如创伤性气胸，蛛网膜下腔出血，脑组织、脊髓、血管及内脏损伤，其中尤以脑和心脏损伤的后果最为严重，严重者可致死。

4.2　针刺施术者风险

针刺施术者在针刺过程中面临着多种职业危害，主要为针刺伤和感染。被各种污染的针具刺伤可导致针刺施术者感染经血液传播的疾病。

注：病菌通过针刺伤口进入机体，引起的局部或全身性感染可能产生致命后果，艾滋病、乙肝、丙肝感染是生物性职业危害的主要种类。

4.3　环境风险

针具及其他接触过受用者的血液或组织后具有污染性质的医疗垃圾，属于特殊的高污染垃圾，对环境造成的污染潜伏期很长。

5　针刺风险等级

5.1　严重针刺风险

常见包括：创伤性气胸，蛛网膜下腔出血，脑组织、脊髓、心脏、血管、肝脏、脾脏、肾脏、胆囊损伤，乙肝、丙肝、艾滋病、梅毒等严重的局部感染或全身感染，严重的神经损伤或脏器损伤，残疾，死亡。

5.2　中度针刺风险

常见包括：针刺局部皮肤轻度感染、轻到中度神经损伤、较大血肿、断针。

5.3　轻度针刺风险

常见包括：受用者的针刺不良反应、弯针、非治疗目的的滞针及施术者针刺伤。

6 针刺风险控制流程

针刺风险控制流程分为主流程、子流程。针刺风险控制流程见图1。

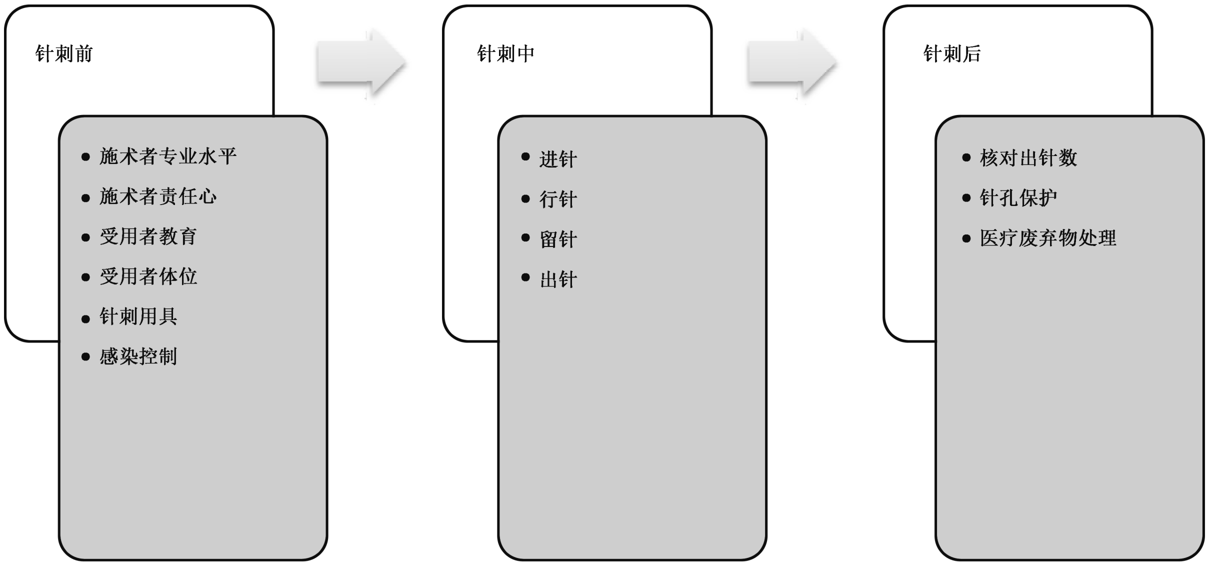

图1 针刺风险控制流程

7 针刺风险来源及控制措施

7.1 来源于施术者的风险及其控制措施

7.1.1 专业技术水平不足：针刺施术者对针刺损伤的严重性认识不够，专业技术操作水平不足，不能有意识地规避风险。

控制措施：

a) 提高针刺风险意识：对存在潜在风险的穴位，尤其是位于人体重要组织、器官部位的危险穴，针刺施术者应熟悉这些穴位的解剖结构和毗邻关系，特别是在脏器病理性肿大的情况下尤应注意。

b) 提高应用特殊针刺技术（如眼针、舌针、鼻针、腹针等）或特殊针具（如芒针、火针、长圆针等）的专业技能。

7.1.2 缺乏责任心：针刺施术者缺乏责任心，对受用者机体状况了解不足，与受用者沟通不足，施术过程中注意力不集中。

控制措施：

a) 详细了解受用者的机能状况。特别是脏器病理性体积增大时，操作应比平时更谨慎。

b) 与受用者进行有效的沟通。向受用者明确解释可能出现的感觉及注意事项（如不能随意变更体位；呼吸宜平稳，不要骤然深呼吸；不要骤作剧咳、喷嚏等动作），以消除其紧张、畏惧心理。当使用一些特殊针刺技术（如眼针、舌针、鼻针、腹针、耳针、头针）或应用特殊针具（如皮内针、皮肤针、火针、三棱针、浮针）时，针刺施术者应提前向受用者解释这些技术可能的反应，并提醒受用者针刺后的注意事项。

c) 集中注意力，随时观察受用者反应。

d） 起针后须仔细检查，以免遗漏。

7.1.3 操作强度过大：针刺施术者为追求明显的针感及更好的疗效，采用过于猛烈的大幅度提插捻转、捣刺等针刺手法，引起针刺局部剧烈疼痛、瘀血、肿胀、滞针，甚至神经、脏器损伤等严重损伤。

控制措施：

a） 正确运用适宜的针刺手法。

b） 对位于危险部位的腧穴，应进针后缓慢轻柔进针到需要的深度。

7.1.4 使用不当针具：使用不当针具引起感染、疾病传播、折针、疼痛及血肿等。

控制措施：

a） 应使用符合 ISO 17218：2014 要求的一次性使用无菌针灸针。

b） 当不得不使用非一次性针具时，应对反复使用的针具进行严格的消毒灭菌。

c） 针刺操作前，仔细检查针具，如针尖钝或有钩、针体弯曲或有折痕、针根锈蚀的针具，应禁用。

d） 根据受用者状态及针刺部位，选择适宜的针具。

7.1.5 消毒、感染控制措施不力：无菌操作和感染控制意识不足导致的医源性感染。

控制措施：针刺施术者应严格进行无菌操作，对针具、穴区皮肤、术手消毒，以防医源性感染。

7.1.6 施术者缺乏安全防护意识：施术者缺乏安全防护意识导致的意外损伤及感染。

控制措施：

a） 为皮肤有开放伤口、皮肤病、传染病受用者针刺时佩戴手套操作。

b） 避免徒手传递裸露针具。

c） 利器桶应放置于可靠的区域。

d） 利器桶 2/3 满时即停止使用，封盖。

7.2 来源于受用者的风险及其控制措施

7.2.1 受用者过度紧张或畏惧情绪较重，过度疲劳、过于虚弱、过饥、过饱、大渴、醉酒、过敏体质者，针刺容易引发其机体生理机能紊乱，出现晕针、过度疼痛、过敏反应、癔症反应等意外情况。有血液病或凝血机制障碍的受用者，针刺时若刺伤血管，易引起血出不止。

控制措施：禁针。

7.2.2 受用者处于某些病理状态时，按常规方法针刺可造成损伤。受用者脏器特别是胸腹腔内脏出现病理性体积长大、表面粗糙、组织结构疏松等，仍按常规角度或深度针刺，易误伤脏器。

控制措施：详细了解病史、仔细查体，谨慎针刺。

7.2.3 受用者患某些传染性疾病，如乙肝、丙肝、艾滋病、结核病等，可通过针刺传播。

控制措施：做好传染病防控，谨慎针刺。

7.2.4 在某些特定部位（如腰部、腹部）或特定穴位针刺时可诱发流产。

控制措施：女性孕期如无特殊需要，尽量不针刺。如确有必要进行针刺，应避开上述区域。

7.2.5 受用者在针刺或留针过程中，突然改变体位或生理节律骤变（主要指呼吸），或出现剧咳、喷嚏等突发性动作，常可导致针具改变位置，引起机体损伤。

控制措施：

a） 针刺前对受用者进行必要的指导，选择舒适的体位。

b） 如出现突发性动作，及时起针或调整针刺深度。

7.2.6 受用者未能很好地保护针孔，接触污物、污水等，有可能使病原微生物从针孔进入体内繁殖，引起感染。

控制措施:对受用者进行必要的指导。

7.3 来源于环境的风险及其控制措施

7.3.1 施术环境卫生条件差:由于施术环境卫生条件差,导致受用者在针刺过程中增加感染几率。

控制措施:根据各国具体情况,针刺治疗应在符合当地医疗机构门诊环境卫生要求的室内进行操作。

7.3.2 医疗废弃物随意丢弃:由于医疗机构及卫生主管部门对医疗废弃物管理不当,导致医疗废弃物随意丢弃、锐器伤人、传播疾病、污染环境。

控制措施:

a) 加强医疗废弃物管理,禁止随意丢弃,以防锐器伤人、传播疾病、污染环境。

b) 应区分锐器、非锐器,分别放置于专门的回收器皿中。

c) 废弃针具等锐器放入利器桶中。

d) 医疗废弃物禁止与生活垃圾混放。

e) 在卫生主管部门统一规定下,在固定的场所回收、销毁医疗废弃物。

参 考 文 献

[1] ISO 11135：2014 卫生保健品灭菌 环氧乙烷 医疗设备灭菌过程开发、确认和常规控制要求

[2] ISO 14971:2019 医疗器械 风险管理在医疗器械中的应用

[3] ISO/IEC Guide 51:2014 安全方面 在标准中引入安全条款的指南

[4] ISO/IEC Guide 63：2019 在医疗器械国际标准中开发和纳入安全条款的指南

[5] ISO/IEC Guide 76:2020 服务标准制定导则 考虑消费者需求

[6] ISO/IEC Directives，Part 2，2018 ISO 和 IEC 文件的结构和起草的原则与规则