Working draft of WFAS standard

**General requirement for the risk control in the safe use of acupuncture**

The World Federation of Acupuncture-Moxibustion Societies

**世界针灸学会联合会**

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# Foreword

The World Federation of Acupuncture-moxibustion Societies (WFAS) is responsible for the publishing of this standard.

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# Introduction

Being a traditional medical method, acupuncture has very few damage to human body. At present, acupuncture has been used in over 180 countries in the world and over 20 countries and regions have covered acupuncture into the national medical insurance. But, being a kind of invasive therapy, acupuncture has a certain risk, especially when practitioners don't receive adequate training. In recent years, there are the reports on the acupuncture adverse events in different countries which results in a certain question on the safe use of acupuncture. Some practitioners of acupuncture don't manipulate according to acupuncture technical specifications, which leads to some doubts about the safety of acupuncture. Therefore, in the consideration of all relevant stakeholders, it is necessary to specify the safe use of acupuncture so as to reduce the risk or control the risk to the acceptable level. This standard was developed in response to worldwide demand in the acupuncture procedure.

There are many kinds of acupuncture needles. Before developing the standards for specific acupuncture needles, it’s necessary to extract the common problems encountered in acupuncture with different kinds of needles, for example the definition, grade, source and control measures of acupuncture risks, and then develop a general requirement in the safe use of acupuncture. The purpose of this standard is intended to build a framework for the establishment of subsequent related specific standards on acupuncture safe use, and avoid the repetition of the common issues during the development of individual standard on acupuncture safe use with different kinds of needles.

As a general requirement in the safe use of acupuncture, this project proposal is not for a specific acupuncture needle, but for dealing with the common problems encountered in acupuncture with different kinds of needles and specifying the procedure to prevent from the risks of acupuncture.

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

# 1 Scope

This standard specifies the risks in the acupuncture procedure and the general requirement for its safe use, including the definition of risk, grade of risk and source of risk, control flow and control measures of acupuncture risk for the different acupuncture needles and the procedure for their use.

This standard is applicable to the issues on acupuncture safe use. It does not apply to the specifications of acupuncture needles, but to those for dealing with the common problems encountered in acupuncture with different kinds of needles and the procedure to prevent from the risks of acupuncture.

This standard excludes the specific criteria for the training of acupuncture practitioners and the clinical treatment or efficacy of acupuncture.

# 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 17218: 2014 Sterile acupuncture needles for single use

WHO Guidelines on Basic Training and Safety in Acupuncture. [online]. 1999. Available at https://apps.who.int/iris/handle/10665/66007

# 3 Terms and definitions

## 3.1 Acupuncture risks

possibility of loss, injury, or other adverse circumstance due to acupuncture

## 3.2 Adverse reactions to acupuncture

adverse medical events not related to the treatment goal intended by acupuncture therapy itself during or after the normative acupuncture treatment,, including normative diagnosis, normative needle manipulations and normative using of acupuncture instruments.

## 3.3 Adverse events of acupuncture

adverse medical events no causal relationship with acupuncture therapy during or after the normative acupuncture treatment.

## 3.4 Adverse accidents

adverse events that are contrary to the treatment goal of acupuncture and cause severe physical or mental injury to the receiver of acupuncture during or after the normative acupuncture treatment.

## 3.5 Acupuncture contraindications

any condition which renders acupuncture inappropriate or undesirable

[Source: WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region: 2007, 5.1.201]

# 4 Scope of acupuncture risks

## 4.1 Risks to acupuncture receiver

The risk of occurrence of serious adverse events related to acupuncture is very low, lower than many common western treatments. Generally speaking, acupuncture performed by a well-trained provider using normative techniques is safe, and receivers have very low risks. Serious adverse events are possibly happened under the condition of abnormal manipulation or unnomartive manipulation.4.1.1 Adverse reactions to acupuncture

Common: fainting during acupuncture, pain, allergy, stasis of blood, hematoma, fatigue

Uncommon: agitation, panic, hypoesthesia

### 4.1.2 Infection and diseases transmission

There are skin infection affecting either local area where needled or extensive area over body, transmission of infectious diseases such as hepatitis B, hepatitis C, AIDS, syphilis.

### 4.1.3 Nerve injury

Injury of peripheral nerves may occur due to mechanical action of acupuncture device and have the sensory disturbance at the nerve distribution area, including numbness, feverish sensation, pain, decreasing of tactile sense, sensation of warmth and pain. Additionally, dysfunction in various degrees can be detected such as injury of the median nerve, ulnar nerve, radial nerve, brachial plexus, sciatic nerve, tibial nerve and peroneal nerve.

### 4.1.4 Injury of important viscera

The mechanical action of acupuncture device may destroy the anatomic integrity of organic tissues or viscera, leading to mechanical injury. Perhaps it could be resumed to: traumatic pneumothorax, subarachnoid hemorrhage, injury of the brain tissue, spinal cord, blood vessels, and internal organs. The most grievous injuries (i.e. among the above mentioned injuries, injury of the brain and the heart) can be counted as the most grievous injuries which may lead to death.

## 4.2 Risks to acupuncture providers

Acupuncture providers are threatened by multiple occupational hazards. Pricking wounds and infection are held as two major issues. Pricking by various contaminated acupuncture apparatus may cause blood transmission diseases.

*NOTE: Local or general infection which may lead to fatal result can be caused by pathogens which enter into the body through pricking wound. AIDS, hepatitis B and hepatitis C are held as the major types biological professional hazards, which taking AIDS as the extremely harmful one.*

## 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 Grade of acupuncture risks

## 5.1 High grade risks of acupuncture

Traumatic pneumothorax, subarachnoid hemorrhage, injury of the brain tissue, the spinal cord, the heart, blood vessels, the liver, the spleen, the kidney, the gallbladder, the stomach, intestines, hepatitis B, hepatitis C, AIDS, syphilis, infection affecting extensive area over body, sever nerve injury, etc.

## 5.2 Moderate grade risks of acupuncture

Skin infection affecting either local area where needled, slight nerve injury, hematoma, etc.

## 5.3 Low grade risks of acupuncture

Receivers' adverse reactions to acupuncture and providers' pricking wounds.

# 6 Control flow of acupuncture risks

The risk sources shall be analyzed according to the interrelated documents and opinions of the experts. Needling procedure is classified into the primary flow and the secondary flow. A flow-process diagram is made.



 **Chart 1 Flow chart of acupuncture risk control**

# 7 Primary causes of acupuncture risks and control measures

## 7.1 Origin of risks for acupuncture provider and control measures

### 7.1.1 Insufficient professional skills and control measures

Acupuncture provider is unable to avoid risks because of lack of awareness of the severity of acupuncture injury and insufficient professional skills of manipulation.

Control measures are required for the insufficient professional skills.

1. Improve the awareness on acupuncture risk

EXAMPLE: Acupuncture practitioner should be familiar with risky points, especially those close to important tissues and organs. Anatomic structure and adjacent structures of those points should be clarified especially under pathological conditions of tumefaction. The relevant information is in the onging standard ISO/ NP 21312 *Traditional Chinese Medicine—Safe use of acupuncture needles* in the acupoints requiring special caution.

1. Improve the special techniques of acupuncture or for the use of specific needles to minimize the risks.

EXAMPLE1: Special acupuncture techniques such as ophthalmic acupuncture, lingua acupuncture, nasal acupuncture and abdominal acupuncture.

EXAMPLE2: Specific needles such as elongated needle, fire needle, round-sharp needle and Fu's subcutaneous needle.

### 7.1.2 Lack of responsibility and control measures

It refers to insufficient responsibility of the practitioner, insufficient understanding of receivers’ condition, insufficient communication with receivers and lack of concentration during treatment.

Control measures are required for the insufficiency of responsibility.

1. Obtain detailed data about the physical condition of the patients

NOTE: More cautious manipulations than usual should be applied when pathological tumefaction are detected.

1. Conduct an effective communication with receivers.

EXAMPLE: Potential sensations should be clearly explained to the receiver and clear instructions should be given (i.e. not to change the position, to keep an even breathing, not to suddenly breathe deeply, avoid coughing or sneezing) so as to relieve nervousness and apprehension for acupuncture.

1. Concentrate the treatment process to observe the reaction of the receivers at all times.
2. A check up after the removal of needles should be followed to avoid omissions.
3. Provide information to the receivers on possible reactions of the body to the acupuncture treatment.

EXAMPLE1: The post-treatment cautions should be provided to receivers when some special techniques such as eye acupuncture, tongue acupuncture, nose acupuncture, abdominal acupuncture, auricular acupuncture and scalp acupuncture are involved.

EXAMPLE2: The receivers should get aware of the body reactions after the use of specific needles such as intradermal needle, skin needle, fire needle, three-edge needle and Fu's subcutaneous needle.

### 7.1.3 Violent manipulations and control measures

Violent manipulations including lifting and thrusting with large amplitude, deep, forceful and repeated insertion by practitioner for a more obvious needling sensation and better therapeutic effects may lead to untoward effect such as pain, hematoma, swelling and stuck needle, and even severe injuries of nerves and viscera.

Control measures are required for the violent manipulations.

1. Providing a proper use of needling manipulation should be considered.
2. Regarding risky points, the needle should be slowly and gently pushed to a proper depth needed after insertion.

### 7.1.4 Using of inappropriate needles and control measures

Using of inappropriate needles is the source of untoward effects such as infection, disease transmission, broken needle, pain and hematoma.

Control measures for inappropriate selection of needles.

* to adopt disposable needles which are conform to the existing standard;
* to apply to reusable needles using a strict sterilization procedure if condition may not be available;.
* to have a careful examination on acupuncture needles (i.e, avoiding a dull tip, hooked tip, bent body and corroded root), and
* to choose appropriate needle according to receiver’s condition and acupuncture site.

### 7.1.5 Failed sterilization and infection control and control measures

Nosocomial infection is caused by lack of awareness of aseptic operation and infection control.

Control measures for aseptic operation by thorough sterilization should be on:

* acupuncture needles;
* local skin, and
* operating hands.

*NOTE:* *An ongoing standard ISO/ CD 20520 Traditional Chinese Medicine -Infection control for acupuncture treatment is specified the relevant information.*

### 7.1.6 Lack of safety awareness by acupuncture provider and control measures

Lack of safety awareness by acupuncture provider causes accidental injury or infection.

The control measures should be as follows.

* using gloves if the receivers have open wounds, skin diseases and infectious diseases;
* avoiding transmission of unpackaged acupuncture apparatus by bare hands;
* arrange waste container for sharp needles and devices at appropriate area, and
* sealing the container when 2/3 of the capacity is occupied.

## 7.2 Origin of risks for receivers and control measures

### 7.2.1 Receiver-related risks and control measures

**7.2.1.1** Disorder of physiological functions including fainting, severe pain, allergy and hysteria reactions may be caused by certain adverse conditions such as overstress, overstrain, weakness, being starving, being very thirsty, having overeaten, being drunk and allergic constitution. Hemorrhage is easily to be induced by pricking the blood vessels of the receivers with blood diseases or disturbances of blood coagulation.

Control measures for prevention should be: Prohibiting acupuncture in these conditions.

**7.2.1.2** Injury may be caused by conventional acupuncture methods under certain pathological conditions.

A conventional needle insertion with conventional angle or depth may lead to viscera damage when tumefaction of viscera in thoracic and abdominal cavities occurs, such as irregularities of the peritoneum (roughness /looseness) occur.

Control measures for prevention should be:

* inquiring thoroughly the disease history;
* having a physical examination, and
* providing acupuncture cautiously.

**7.2.1.3** Infectious Diseases such as hepatitis B, hepatitis C, AIDS, TB can be transmitted through acupuncture.

Control measures for prevention should be paying attention to prevention and control of infectious diseases, and providing acupuncture cautiously.

NOTE: An ongoing standard ISO/ CD 20520 *Traditional Chinese Medicine - Infection control for acupuncture treatment* is specified the relevant information.

**7.2.1.4** 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 for the risk minimization should be avoiding acupuncture if not applicable in pregnancy or avoiding acupuncture at the above mentioned regions if acupuncture is a necessity for treatment.

### 7.2.2 Failed cooperation between provider and receiver and control measures

Sudden movement of receiver’s body or sudden changes of physical rhythm (referring to the breathing rhythm of acupuncture receiver) may cause injuries to receivers.

Control measures should be enhanced to improve the cooperation between provider and receiver and prevention from the injury.

1. The instructions should be given to receiver on selecting a comfortable pose before treatment.
2. An adjustment on the depth of needling or a removal of the needles should be applied in time, immediately after the changing of the position.

### 7.2.3 Improper protection of the acupuncture site by the receiver

Contact with contaminant substances such as water may lead to infection caused by generation of pathogenic microorganism at the pinhole.

The specific instruction should be given to receiver.

## 7.3 Environmental risk and control measures

### 7.3.1 Poor sanitation environment

Increasing of infection rate during acupuncture may be caused by poor sanitation environment.

Acupuncture for treatment or for healthcare should be given in medical clinics or the places which are conform to the sanitation requirements of different countries.

### 7.3.2 Medical waste littering and control measures

Environmental pollution, disease transmission, injury by sharp wastes and littering of medical wastes may be caused by duty negligence of medical organizations and medical management units.

The following control measures should be considered.

The littering of waste produced by pricking injuries is strictly forbidden because of disease transmission and environmental contamination.

* Special containers which are not easy to be penetrated and permeated should be available for collection of sharp and dull acupuncture devices respectively.
* Used needles should be collected in special containers.
* Infectious medical wastes and used needles must not be disposed with the household garbage.
* Collection and destroying of medical wastes should be done in a certain area under the regulation of medical management unit.

# 8 Bibliography

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