TECHNICAL REPORT

ISO/TR 20520

Traditional Chinese medicine — Infection control for acupuncture treatment

Médecine traditionnelle chinoise — Prévention des infections en acuponcture

iTeh STANDARD PREVIEW
(standards.iteh.ai)

COPYRIGHT PROTECTED DOCUMENT

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine.*

Traditional Chinese medicine — Infection control for acupuncture treatment

1 Scope

This document specifies aspects to be considered for infection control for acupuncture treatment. Clinical practice in acupuncture treatment is outside the scope of this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
infection
invasion of bodily tissue by pathogenic microorganisms that proliferate, resulting in tissue injury that can progress to disease

3.2
infection control
policies and procedures used to minimize the risk of spreading infections

3.3
sterilization
validated process used to render product free from viable microorganisms

[SOURCE: ISO/TS 11139:2006, 2.47, modified]

3.4
disinfection
removal of all pathogenic microorganisms, except pores of germs on the surface of inanimate objects

[SOURCE: ISO 13408-1:2008, 3.18, modified]

3.5
germicide
agent that kills microorganisms

[SOURCE: ISO 13958:2014, 3.21]

3.6
acupuncture
insertion of needles into humans or animals for remedial purposes or its methods

[SOURCE: WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region, 5.1.0]

3.7
acupuncture needle
thin metal needles used in acupuncture treatment

3.8
sterile acupuncture needle
acupuncture needle that has been sterilized

[SOURCE: ISO 17218:2014, 3.6]

3.9
guide tube
assistant tool in the shape of a slender, long tube into which the acupuncture needle is placed and used to ease insertion

[SOURCE: ISO 17218:2014, 3.7, modified]

3.10
tip of the needle
sharp apex at the end of the acupuncture needle body that is inserted into the human body

[SOURCE: ISO 17218:2014, 3.3]

3.11
handle of the needle
part of the acupuncture needle that is not inserted into the human body

[SOURCE: ISO 17218:2014, 3.2]

3.12
needling hand
practitioner's hand that holds and inserts the acupuncture needle

[SOURCE: WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region, 5.1.108]

3.13
pressing hand
practitioner's hand that presses the puncturing area with one or two fingers to facilitate acupuncture needle insertion

[SOURCE: WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region, 5.1.109]

3.14
acupuncture treatment
insertion of acupuncture needles into humans or animals for remedial purposes or its methods

3.15
acupoint
specific spot on the body where an acupuncture needle may be inserted to control pain and other symptoms

4 Infection control in acupuncture treatment

4.1 Prerequisite for infection control in acupuncture treatment

4.1.1 Hand washing and hand sanitizing

After having direct contact with patients (e.g. pulse-taking, blood pressure measurement, or hand-shaking), acupuncture practitioners should wash their hands before initiating acupuncture treatment.

If hands are contaminated again after they are washed, finger tips should be washed again before conducting the following process.

In place of the above process of hand washing, hand sanitizers containing more than 60 % alcohol should be used. Among hand cleanser products, some do not require water to clean hands as liquid disinfectant evaporates while rubbing the hands together while others are similar to foam soap and require hands be rinsed with water. Such products should also be used for cleansing hands.

4.1.2 Use of protective medical gloves and covering lesions

The use of protective medical gloves should be used in the following circumstances:

— where contact with blood or body fluid is likely;

— where the practitioner has any skin lesion on the hands.

4.2 Cleaning skin at acupuncture area

Acupuncture practitioners ensure that skin areas receiving acupuncture treatments are clean. If necessary, these areas may be cleaned with an alcohol swab to remove any dirt or grease.

4.3 Use of acupuncture needles and guide tubes

— The body of the acupuncture needle should be kept in a sterilized condition before being inserted into the skin.

— After taking out an acupuncture needle from the package and until inserting it into the skin, the practitioner should be cautious so that no unsterilized things touch the body of the acupuncture needle.

— If the body of the acupuncture needle is contaminated before being inserted into the skin, the needle should be discarded.

— The practitioner should check the needles first to see whether there are abnormal changes of the needle or needle rust.

— When inserting an acupuncture needle or administering manual stimulation, the practitioner should be careful not to contaminate other parts of the needle which will be inserted into the body.

— When administering manual stimulation or inserting a needle without using a guide tube, bare hands may touch the body of the needle, but contact on the part to be inserted into the skin should be avoided as far as possible. If the body of the needle needs to be touched, the practitioner should sanitize his/her hand or should use a sterilized gauze, a cotton ball or medical gloves.

— After taking out a needle from the package, if the needle needs to be put down temporarily before use, the practitioner should place the needle on a surface that is sterilized, such as on a sterilized gauze. When placing a sterilized object on a sterilized gauze, the practitioner should place the handle of the needle, which is touched by the hands of a practitioner, on a clean area and the sterilized part (e.g. the body of the needle or the tip of a tweezers) on sterilized gauze, respectively.

5 Infection control for acupuncture needles and related medical devices

5.1 Acupuncture needle

Acupuncture needles should be sterile at the time of insertion. It is recommended to use the sterile acupuncture needle for single use.

5.2 Guide tube

If using a guide tube, single-use pre-sterilized guide tubes should be used.

5.3 Related medical devices

All equipment having contact with sterile acupuncture needles and ancillary devices should be sterile.

5.4 Disposal

Used needles should be disposed of in a suitable medical sharps container in accordance with national/local regulations.

Potentially infectious waste, such as used alcohol swabs and protective gloves should be disposed of in accordance with national/local waste disposal regulations.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Bibliography

[1]   ISO/TS 11139:2006, *Sterilization of health care products — Vocabulary*

[2]   ISO 13408-1:2008, *Aseptic processing of health care products — Part 1: General requirements*

[3]   ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[4]   ISO 13958:2014, *Concentrates for haemodialysis and related therapies*

[5]   ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

[6]   ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

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

[8]   ISO 20857, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

[9]   ISO/IEC Guide 51, *Safety aspects – Guidelines for their inclusion in standards*

[10]   ISO/IEC Guide 63, *Development and inclusion of safety aspects in International Standards for medical devices*

[11]   WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region.

[12]   WHO Guidelines on Hand Hygiene in Health Care.

[13]   Clean Needle Technique. CCAOM