

Safety Guidelines for Japanese Acupuncture and Moxibustion Practice 2020 Ver.1.1

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On Publication of this Safety Guidelines for Japanese Acupuncture and Moxibustion Practice 2020

Discussion around the safety of acupuncture and moxibustion in Japan began with the Guidelines of Infection Control for the Acupuncture–Moxibustion Treatment (KOBAYASHI Hiroyoshi, Supervising Editor) published in 1993 and has since been pursued principally by the Committee on Safety Guidelines for Acupuncture and Moxibustion Treatment. Although the Committee was subsequently somewhat inactive, the late Dr. OZAKI Akihiro led formation of the Acupuncture & Moxibustion Safety Committee with members from, once again, the All Nippon Acupuncture & Moxibustion Massage Association, the Japan Acupuncture & Moxibustion Association, the Japan Association of Massage & Acupuncture Teachers, the Japan College Association of Oriental Medicine, as well as the Japan Society of Acupuncture and Moxibustion (JSAM). The committee pursued various discussions which resulted in publication of the Guideline for the treatment by Acupuncture & Moxibustion in 2007 (Ishiyaku Publishers, Inc.). Dr. Ozaki's conception of the project was that by describing in detail the human and the systemic factors involved in accidents, acupuncture and moxibustion practitioners might acquire proper knowledge, which might consequently lead to greater approval by the wider population of acupuncture and moxibustion. He therefore selected senior doctors with deep knowledge of safety and infection control to be the members of the editorial committee, he was at the center of the writing work, and his editing of the Guideline was founded on the most up-to-date information at the time.

More than ten years have already passed since publication of the Guideline for the treatment by Acupuncture & Moxibustion and calls have come from all quarters regarding the need for its revision. I therefore consider that publication of this new edition, Safety Guidelines for Japanese Acupuncture and Moxibustion Practice 2020, is quite timely. The Committee for Safe Acupuncture in the Academic & Research Department of JSAM kindly led preparation of this Guideline, spending an enormous amount of time on its preparation. I would like to take this opportunity to pay my respects and to express my deep gratitude to the Committee for their unstinting efforts, to the benefit of continued safety in acupuncture and moxibustion therapy.

This Guideline has been written in itemized format and comprehensively covers a wide variety of events so as to have as many stakeholders as possible read them. This format replicates the format used in various medical guidelines. I also believe the reliability of this Guideline is unsurpassed at this point, as its preparation involved thorough and minute examination of information on the safety of acupuncture and moxibustion. On the other hand, a review of the enormous amount of information is required to set out the scientific basis for the safety of acupuncture and moxibustion, but I believe that will be the subject of future work. I look forward to the Committee for Safe Acupuncture further working on this.

Last, I would like to close by expressing my sincere hope that this Guideline is put into practice by the large majority of people involved in acupuncture and moxibustion and that it contributes to making acupuncture and moxibustion safe, reassuring, and pleasant.

January 2020

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*In September 2020, the Committee for Safe Acupuncture in Academic & Research Department was transferred to the Safety Committee in Clinical Information Department.

Foreword

It was in 1993 that the first guideline on the safety of acupuncture and moxibustion treatments was published under the title Guidelines of Infection Control for the Acupuncture–Moxibustion Treatment, which focused on measures against infection. The Committee on Safety Guidelines for Acupuncture and Moxibustion Treatment at the time edited the Guidelines under the supervision of the late Dr. KOBAYASHI Hiroyoshi (former Professor, Department of Infection Control Science, Faculty of Medicine, University of Tokyo). There was much rumor among the public at that time about the spread of blood-borne infectious diseases including hepatitis B and C, and AIDS. Concern around preventing infection heightened and in 1987 the Ministry of Health and Welfare issued to acupuncture and moxibustion practitioner organizations a directive titled Prevention of AIDS Infection in Acupuncture and Moxibustion, which prompted preparation of the Guidelines.

The World Health Organization (WHO) subsequently released their Guidelines on Basic Training and Safety in Acupuncture in 1999, and in response, the Guideline for the treatment by Acupuncture & Moxibustion were published in Japan in 2007. It was the Acupuncture & Moxibustion Safety Committee, led by the late Dr. OZAKI Akihiro (Professor Emeritus, Meiji University of Oriental Medicine [present day Meiji University of Integrative Medicine]) and Dr. SAKAMOTO Ayumi (Chair, Kuretake Gakuen [Educational Corporation]), who edited the Guidelines. The predecessor of the Acupuncture & Moxibustion Safety Committee was the aforementioned Committee on Safety Guidelines for Acupuncture and Moxibustion Treatment, and was formed with committee members from five organizations: the All Nippon Acupuncture & Moxibustion Massage Association (Public Corporation), the Japan Acupuncture & Moxibustion Association (Public Corporation), the Japan College Association of Oriental Medicine (Public Corporation), the Japan Association of Massage & Acupuncture Teachers, as well as the Japan Society of Acupuncture and Moxibustion (JSAM) (Public Corporation).

The Acupuncture & Moxibustion Safety Committee also published the Risk Management Manual for the Treatment by Acupuncture & Moxibustion in 2010, as a supplement to the Guideline for the treatment by Acupuncture & Moxibustion. It provided readily comprehensible explanations using past examples of medical accidents involving acupuncture and moxibustion, including countermeasures and legal interpretations.

Some 10 years after publication of the Guideline for the treatment by Acupuncture & Moxibustion an update was due, yet no revision had been undertaken since the first edition. Then, the Liaison Council on Acupuncture and Moxibustion Safety (previously the Acupuncture & Moxibustion Safety Committee) was established as the next generation organization comprising the aforementioned five organizations. With the agreement of all the organization heads, the Committee for Safe Acupuncture in the Academic & Research Department of JSAM (Public Interest Incorporated Association) took the lead and progressed preparation of the Guidelines, resulting in publication of the Safety Guidelines for Japanese Acupuncture and Moxibustion Practice 2020 (“this Guideline”). For a manual, the aforementioned Guideline for the treatment by Acupuncture & Moxibustion contained a large number of pages as it included a great deal of content, yet its name did not necessarily reflect that fact. This Guideline has simplified the content into itemized form and is not a revised edition but a completely new publication. In addition, as well as publishing this Guideline as a book, it was decided that it would also be made publicly available for download at no charge on the website of JSAM, so that anyone may read it.

Public comment on the draft of this Guideline was sought by making it available on the website of JSAM. Comments were subsequently posted by a total of 39 contributors and the final version was completed after revisions based on those comments. I would like to sincerely thank all the contributors who posted comments.

Last, I would like to pay my respects to all the members of the Acupuncture & Moxibustion Safety Committee involved in editing the Guideline for the treatment by Acupuncture & Moxibustion, the predecessor of this Guideline, and express my gratitude to all the people involved in the working groups for their guidance in preparing this Guideline.

It is my sincere hope that the large majority of acupuncture and moxibustion practitioners practice in accordance with this Guideline, thereby bringing acupuncture and moxibustion in Japan to a higher level of safety, and that acupuncture and moxibustion be held in high regard, both in Japan and overseas.

January 2020

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*In September 2020, the Committee for Safe Acupuncture in the Academic & Research Department was transferred to the Safety Committee in the Clinical Information Department.

Features and Usage of this Guideline

This Guideline was prepared on the premise that acupuncture and moxibustion are performed as a part of medical treatment. It therefore comprehensively describes what acupuncture and moxibustion practitioners should observe and practice from a medical safety viewpoint in their practice. The content of this Guideline was reviewed on the basis of adverse event surveys in Japan and overseas. There is at present, however, little literature that can establish scientific evidence on the safety of acupuncture and moxibustion, and it is not possible to reach any conclusions that are based on an adequate literature review. We considered it was therefore difficult to clearly specify evidence levels, as in clinical practice guidelines for specific diseases, and instead defined the wordings for each matter as follows.

First, “must,” which carries a high level of compulsion, is the wording used for matters prescribed in the Act on Practitioners of Massage, Finger Pressure, Acupuncture and Moxacauterization, etc. (“Ahaki Act”) and other laws, matters that should be observed from a medical ethics viewpoint, as well as matters with a clear scientific basis and that seek to ensure safety or patient rights. Second, “must not” carries a relatively high level of compulsion, although not obligation, and restricts matters that should be observed from a medical ethics viewpoint and matters that have a clear scientific basis but are not mentioned in the Ahaki Act and are actions that are extremely dangerous or highly likely to violate patient rights.

At the next level, “should” is used when strongly recommending actions to ensure safety or patient rights in regard to matters that have a clear scientific basis and are common knowledge in medical practice, while “should not” is used when strongly restricting actions that are highly dangerous or may violate patient rights.

Then at the third level, “it is recommended,” or the wording “it is hoped” (“it is desirable”), is used when there is a clear scientific basis in the medical field and putting those actions into practice should increase safety, while the wording “it is not recommended” is used when restricting actions that may decrease safety.

Last, at the lowest level, the wording “need to beware” (“it is necessary to exercise caution”) is used in when caution is prompted by existing guidelines that suggest the possibility of an adverse event, even though there is currently little scientific evidence.

The editors hope that keeping these in mind when adopting the Guideline into practice is of benefit to patients’ informed consent and to mutual understanding with other medical practitioners. Moreover, this Guideline is not intended for use in trials or lawsuits in the event of a medical accident, or the like.

Wordings in this Guideline Indicating Levels of Compulsion

Wording	Level of compulsion on the practitioner	Description
must	Obligation	Imposes obligation to ensure safety or patient rights
must not	Relatively strong	Strongly restricts actions that are extremely dangerous or highly likely to violate patient rights
should	Strong	Strongly recommends actions to ensure safety or patient rights
should not	Strong	Strongly restricts actions that are highly dangerous or may violate patient rights
it is recommended (it is hoped, it is desirable)	Somewhat strong	Recommends actions that are expected to increase safety
it is not recommended	Somewhat strong	Restricts actions that may decrease safety
need to beware (it is necessary to exercise caution)	Weak	Prompts caution because an adverse event may occur, even though there is currently little scientific basis.

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I. Definitions of Safety Terms and Classification

Definitions of Terms

The following are definitions of safety terms.

1. A medical accident is any personal injury that occurs at any point in the process of medical care at a place where medical care is undertaken, regardless of whether error or negligence by a medical practitioner is involved. This includes injuries that cause either physical or mental harm, and also includes medical practitioners, not only patients. “*Akushidento*” [Japanese term] is synonymous with “medical accident.” [1]
2. A medical error is a type of medical accident and is an act by a medical practitioner in the performance of medical care that causes harm to the patient in violation of the medical rules. [1]
3. An incident is an unforeseen event that causes the individuals concerned to experience a fright or surprise, “*Hiyari-Hatto*” [Japanese term], even if it does not cause personal or economic loss to the patient. “*Hiyari-Hatto*” and “*Nia-Misu*” [Japanese term] refer to “Close call” and “near miss”, respectively. These are synonymous with “incident.” [1]
4. An adverse effect (adverse reaction) is an undesirable biological reaction in treatment that occurs inevitably at a certain frequency. Adverse effects in acupuncture and moxibustion are categorized into systemic adverse effects and local adverse effects, as follows. [2]
(1) Systemic adverse effects: Severe fatigue, severe malaise, excessive drowsiness, poor mood, etc.
(2) Local adverse effects: Pain during acupuncture, microhemorrhage, itching at acupuncture site, pain at acupuncture site after treatment, etc.
5. An adverse event is an undesirable medical event that occurs during or after treatment regardless of causality. Sufferers include not only patients but also medical practitioners. Although this term is similar to medical accident, a third party retroactively investigates and records this type of event. [3, 4]
6. Risk management means actions or activities to prevent medical accidents or to promptly deal with accidents that have occurred and to minimize harm. “*Risuku kanri*” [Japanese term] and “medical safety management” are synonymous with “risk management.” [1]
7. Informed consent means the practitioner fully explaining to the patient his/her condition, the treatment policy, etc. in easy-to-understand terms, and the patient understanding and accepting the treatment, then making a choice and giving consent. [1, 5]

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Adverse Event Classification

1. The severity of adverse events is classified into Grades 1 to 5, as follows. Grades 3 to 5 are considered "serious adverse events." [1]
Grade 1 (Mild): "Presents no subjective symptoms," "Presents mild symptoms," "Has only clinical findings or laboratory results," "Does not require treatment"
Grade 2 (Moderate): "Requires minimal treatment," "Requires local or noninvasive treatment," "Instrumental activities of daily living appropriate for age are restricted" *1
Grade 3 (Severe): "Has severe or medically critical symptoms, but they do not immediately threaten life," "Requires hospitalization or extension of hospitalization period," "Self care activities of daily living are restricted" *2
Grade 4 (Life-threatening): "Requires emergency treatment"
Grade 5 (Death): "Died"

*1 "Instrumental activities of daily living" means preparation of meals, shopping for daily necessities and clothes, using a phone, managing money, etc.
*2 "Self care activities of daily living" means the individual is not bed-ridden and can bathe, dress and undress, take meals, use the toilet, and take medicine.
2. Adverse events involving acupuncture are classified as follows. [2]
 - (1) Infection
 - (2) Organ Injury (including pneumothorax and vascular injuries)
 - (3) Nerve Injury
 - (4) Skin Disorders
 - (5) Needle breakage, retained needles, foreign bodies (including embedded needles)
 - (6) Other
3. Adverse events involving moxibustion are classified as follows. [2]
 - (1) Burn Injury
 - (2) Canceration at moxibustion site
 - (3) Other
4. Adverse event causes are classified into four types based on causality. [3]
 - (1) Adverse effect (adverse reaction): Undesirable biological reaction that occurs unintentionally
 - (2) Error: Event caused through negligence, ignorance, intent, etc. on the part of the practitioner or the treatment center
 - (3) Inevitable accident: Natural disaster, etc.
 - (4) An event that has no causal relationship with the treatment or the practitioner's actions

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II. General Requirements and Precautions for Safety

Observing Laws and Regulations

1. Practitioners must observe the relevant laws and regulations, including the Act on Practitioners of Massage, Finger Pressure, Acupuncture and Moxacauterization, etc., and strive for safe treatment. They must also promptly obey instructions from governmental authorities. [1]
2. Persons who establish a treatment center (business owners) must observe the Ordinance for Enforcement of the Act on Practitioners of Massage, Finger Pressure, Acupuncture and Moxacauterization, etc., the Industrial Safety and Health Act, and other related laws and regulations and must take steps to manage safety and hygiene in the clinic and the health of employees. [1-3]

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(8.13.2019)

Risk Management

Risk management aims to prevent medical accidents or to promptly deal with accidents that have occurred and minimize damage.

1. Practitioners must understand the patient's pathological condition through inquiry and testing and must strive to make appropriate decisions on indication or non-indication. [1, 2]
2. In the course of treatment, practitioners must provide to the patient, or the guardian if there is a guardian, full and appropriate explanations of the risks that may arise through treatment (adverse events), in addition to the benefits of treatment (therapeutic effects), and must strive to obtain the patient's understanding of and consent to the treatment (informed consent). [1, 2]
3. Practitioners must seek to reduce the risks with regard to treatment and must strive to prevent adverse events and medical accidents. [2]
4. It is recommended that persons who establish a treatment center (business owners) or the managers prepare in advance a response manual in the event of a medical accident, and also make the staff at the treatment center aware of this manual. [2]
5. In the event that a patient suffers an adverse event, practitioners should tell the patient him/herself, or the guardian, if there is a guardian, that an adverse event has occurred, and should explain the cause of and treatment for the adverse event. [2]
6. In the event of a serious adverse event, practitioners should advise the patient to seek medical attention. In addition, it is recommended that when the patient receives medical attention, the practitioner concerned accompany the patient and explain to the physician the details of the incident/accident. [3]
7. In the event of an accident or incident, it is recommended that the practitioner concerned strive to prevent recurrence by analyzing the causes of the accident or incident and compiling an accident/incident report, sharing that information with the staff of the treatment center, and investigating precautions. [3, 4]
8. Practitioners should be prepared for any medical accident by subscribing to liability insurance. [5]
9. It is hoped that practitioners have completed lifesaving training and are prepared for emergencies either in the treatment center or when on out-of-clinic visits.

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Treatment Record Keeping and Protection of Personal Information

Treatment records (synonymous with medical records or clinical records) are not simply to record the details of treatment and the course of symptoms but to show that appropriate treatment has been performed and that accountability has been fulfilled. Practitioners therefore need to beware of the fact that these are public documents subject to request for disclosure in court trials, medical benefit payments, etc., and also the fact that they contain personal information. [1]

1. In the course of entering details into treatment records, it is recommended that practitioners first enter the details of treatment, and record the various important information obtained before, during, and after treatment so that they are accurate and easy-to-understand. [1, 2]
2. Practitioners and staff must take organizational, human, physical, and technical security control measures, etc. to prevent leakage, loss, or impairment of personal information, and to manage the security of other personal information. [3]
3. It is recommended that practitioners keep treatment records for five years from the date of completion of the treatment. [1, 4]
4. When handling personal information, practitioners must clearly present the purpose for using that information in advance to the patient him/herself, or the guardian if the patient is a minor or does not have the ability to make judgments, and it must not be used for any other purpose. [3]
5. When a request for disclosure of the individual's personal information is received, it must be disclosed without delay. It may be possible not to disclose all or part of that information, however, if disclosure falls under Article 28-2 (i) to (iii) of the Act on the Protection of Personal Information. [5]

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Contraindicated Treatments

It is prohibited by law for practitioners of acupuncture and moxibustion to perform surgery or prescribe drugs. [1] Practitioners must not perform treatments that are at high risk of triggering adverse events or that interfere with other medical treatments.

1. Practitioners must not perform Embedded needling therapy, where a needle is intentionally embedded inside the body, because needles that remain inside the body can injury nerves, organs, or blood vessels, or cause symptoms such as chronic pain, and may have a major impact on surgical treatments and magnetic resonance imaging (MRI). [2, 3]
2. Practitioners must not needle internal organs and nerves because it risks impairment of function. [2, 3]
3. Practitioners must not apply mercury to needles to facilitate needling (application of mercury on insertion) because there is no adequate assurance of its safety. [4, 5]

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Contraindicated Cases

Practitioners must not perform acupuncture and moxibustion treatment if doing so causes the loss of opportunity for the patient to receive appropriate medical care and there is the risk of the patient lapsing into a serious pathological condition.

1. Practitioners must give the highest priority to first aid and treatment at a medical institution in emergency cases such as cardiac arrest, respiratory arrest, impaired consciousness, heavy bleeding, extensive burn injury, and poisoning. In addition, practitioners must not perform acupuncture and moxibustion treatment as first aid. [1]
2. Practitioners should not perform treatment in cases where an abnormal vital sign (consciousness, body temperature, pulse, blood pressure, respiratory condition) is observed. Practitioners should advise such patients to promptly seek treatment at a medical institution. [2]

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Cases in Which Caution Should be Exercised

The effectiveness and safety of acupuncture and moxibustion treatment is unclear for certain pathological conditions. In addition, there are many questions about the safety of treatment for pregnant women. In the following cases, practitioners must perform treatment with extreme caution after providing especially thorough explanation as well as obtaining consent.

1. Practitioners should not perform treatment intended to heal malignant tumors because there is currently no scientific basis. This does not apply, however, to symptoms associated with malignant tumors (e.g. pain) and adverse effects of drug therapy (e.g. nausea), but it is desirable that practitioners perform such treatment under the guidance of a physician. [1, 2]
2. In the treatment of pregnant women, practitioners should exercise extreme caution so that it does not cause miscarriage or premature birth and should avoid strong stimulation at any site. It is necessary to exercise caution particularly with treatment in the abdominal region. [3]
3. In the event that localized sensation of heat or swelling is severe, practitioners should avoid localized treatment because the patient may be suffering trauma or some kind of infection. In addition, if the patient's course is unsatisfactory, practitioners should discontinue treatment and advise the patient to undergo testing at a hospital. [4, 5]
4. There have been reports of cases in which immuno-compromised patients (diabetic patients, steroid users, etc.) have developed an infection after treatment. If a patient's pathological condition has not stabilized, practitioners should abide by the physician's decision on the suitability of treatment. [4, 5]
5. Practitioners must be aware of the risk of bleeding when treating patients suffering hemorrhagic disease, undergoing anticoagulant treatment, or using anticoagulants. [4, 5]
6. Practitioners should give priority to identifying and treating the primary disease in patients showing signs of fever. It is desirable for practitioners to refrain from treatment and advise such patients to visit a hospital for a consultation. [3]

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Contraindicated Sites

Practitioners must not perform treatment at sites where it may injury organs or essential tissues or there is an extremely high risk of doing so, or where it may worsen a condition.

1. Practitioners must not needle the anterior or posterior fontanel of newborn babies, external genital organs, nipples, umbilical region, eyeballs, suppurating parts, parts affected by acute inflammation, large blood vessels, organs within the body cavity, central nervous system, and malignant tumor sites. [1-3]
2. Practitioners must not perform direct moxibustion (scarring moxibustion) on the face, external genital organs, nipples, umbilical region, suppurating parts, malignant tumors, parts affected by acute inflammation, and parts affected by skin disease. [1-3]
3. Practitioners should exercise particular caution if performing treatment in the vicinity of the above sites.

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Sites Where Caution Should be Exercised

Practitioners must exercise particular caution in treatment at sites where there is a risk of injuring organs or essential tissues, or there is the danger of marring appearance. In the course of treatment, practitioners should have a thorough knowledge of anatomy and take patients' physique into account before deciding on the stimulation requirements (needling angle, needling depth, etc.).

[1-4]

1. Face: Beware of injuring the eyeballs. Beware not to mar appearance with burn injury or internal bleeding.
2. Neck (anterior): Beware of injuring the common carotid artery, internal carotid artery, vagus nerve, and trachea.
3. Supraclavicular fossa: Beware of injuring the subclavian artery and lungs.
4. Neck (posterior): Beware of injuring the medulla oblongata, spinal cord, greater occipital nerve, and vertebral artery
5. Upper limbs: Beware of injuring the median nerve, ulnar nerve, radial nerve, and radial artery
6. Thoracic region: Beware of injuring the intrathoracic organs such as the lungs and heart. Beware of the presence of a sternal foramen.
7. Spinal region: Beware of injuring the spinal cord and nerves
8. Epigastric region: Beware of injuring the intra-abdominal organs such as the liver and stomach.
9. Hypogastric region: Beware of injuring the pelvic viscera such as the large intestine and bladder.
10. Lumbar region : Beware of injuring the intra-abdominal organs and retro-peritoneal organs (kidneys, ureter, etc.)
11. Inguinal region: Beware of injuring the femoral artery and femoral nerve.
12. Lower limbs: Beware of injuring the sciatic nerve, peroneal nerve, tibial nerve, popliteal artery, posterior tibial artery, and dorsal artery of the foot.
13. Practitioners should avoid directly needling sites where artificial devices are implanted (artificial joints, artificial blood vessels, pacemakers, etc.). Practitioners should also pay close attention when performing treatment in those areas. [5]

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Out-of-clinic Visits – Treatment Outside the Treatment Center, Outdoor Treatment, Treatment at Sports Competitions and Disaster Sites –

In the course of treatment outside the treatment center, that is, during out-of-clinic visits, practitioners must exercise particular caution with hygiene and accident prevention since treatment environments vary greatly depending on the location. Thorough preparation and safety measures are therefore required.

1. If practitioners perform treatment exclusively on out-of-clinic visits, they must notify the prefectural governor [in Japan]. [1]
2. Practitioners should not perform treatment in places where safety and hygiene are not ensured. [2]
3. It is recommended that practitioners carry out standard precautions on out-of-clinic visits. Practitioners must exercise particular caution with hygiene when performing treatment outside the treatment center, especially treatment outdoors. [2]
4. It is necessary for practitioners to exercise greater caution than in the treatment center because accidents that are difficult to predict may occur. [2]
5. Practitioners should be prepared for any medical accident by subscribing to liability insurance. [3]
6. If practitioners perform treatment at a sports competition, disaster site, etc., they should obtain permission from the organizer or the person in charge at the site in advance. When applying for permission, it is recommended that practitioners check the surroundings where treatment will be performed and also make advance arrangements with the relevant personnel, prepare a treatment plan, and submit it. [2]
7. If practitioners perform treatment at a sports competition, disaster site, etc., it is desirable that they make appropriate judgements about contraindications and indications, and cooperate with other medical personnel, such as rescue parties, etc., as necessary. [2]

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III. Infection Control

Basics of Infection Control

Infection control in Japanese medical institutions is based on guidelines by the US Centers for Disease Control and Prevention (CDC) and revolves around two kinds of precautions: standard precautions and transmission-based precautions. It is recommended that acupuncture and moxibustion practitioners also use infection control equivalent to these precautions in their practice.

For an infection to occur, (1) a source of infection (bacteria, virus, etc.), (2) a mode of transmission (droplet transmission, airborne transmission, contact transmission, etc.), and (3) a susceptible host (elderly individual, immuno-compromised patient, etc.) are required. These are called “the three elements for infection to take place.” Connection of these three elements is thus called the “chain of infection,” and the infection spreads by the chain extending. The important questions in infection control are, therefore, how, and between which elements, to break the chain of infection. [1, 2]

The basics for breaking this chain of infection in medical settings are the standard precautions and transmission-based precautions, which are described in detail in the CDC’s Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings. [1, 2]

The standard precautions are the most basic precautions in infection control and equate to the concept of carrying out patient care from the approach that all body fluids except sweat (blood, secretions, excretions, damaged skin, mucous membranes) are substances possessing transmissibility. [1, 2]

Transmission-based precautions are precautions used in addition to the standard precautions for infection that demonstrate a specific mode of transmission and comprise three kinds of precautions: droplet transmission precautions, airborne transmission precautions, and contact transmission precautions. [1, 2]

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Hygiene in Treatment Centers

1. Treatment center managers must strive to maintain hygiene in treatment centers. [1-3]
2. Surfaces in treatment center environments, such as treatment beds and trolleys, must always be maintained in a clean state by regularly cleaning them with an appropriate disinfectant. It is recommended, however, that if contamination by blood is visible, it is cleaned immediately with an appropriate disinfectant. [3-5]
3. It is not recommended that surfaces in treatment center environments be disinfected by spraying disinfectant. [4, 5]
4. It is recommended that curtains and blinds in treatment centers be cleaned if there is visible dirt. [4, 5]
5. It is recommended that the floors in treatment centers be made of materials that are easy to clean and that they be cleaned regularly. It is recommended, however, that if contamination by blood is visible, it is cleaned immediately with an appropriate disinfectant. [4, 5]

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Standard Precautions – Hand Hygiene –

1. Practitioners must perform proper hand hygiene when performing treatment. [1]
2. It is recommended that practitioners remove any rings or other accessories from their fingers when performing treatment. [2-5]
3. In order to perform proper hand hygiene, it is recommended that a place to wash hands (with water supply) be provided in treatment rooms solely for practitioners to use, and that soap be provided beside it. It is also recommended that a quick-drying alcohol-based hand rub be provided on top of treatment trolleys. [2-5]
4. It is recommended that practitioners wash their hands with running water and soap after using the toilet, when the practitioner's hands are visibly soiled, and when they have come in contact, or may have come in contact, with microorganisms for which alcohol does not achieve adequate results. [2-5]
5. It is recommended that practitioners use single-use towels such as paper towels to dry their hands after hand washing. [2-5]
6. It is recommended that practitioners disinfect their hands with a quick-drying alcohol-based hand-rub if they are not visibly soiled. [2-5] It is recommended that practitioners wash their hands with running water and soap if it is not possible to determine whether their hands are soiled due to visual problems.
7. It is recommended that the above hand hygiene be performed in the following situations. (Reference: The Five Moments for Hand Hygiene recommended by WHO) [4, 5]
 - (1) Before touching a patient
 - (2) Before aseptic procedures, such as needling
 - (3) After body fluid exposure (including situations where there is the possibility of exposure)
 - (4) After touching a patient, and
 - (5) After touching patient surroundings (bed, sheets, bath towel, etc.)
8. So as to prevent hand roughness, it is not recommended that practitioners frequent use of a quick-drying alcohol-based hand rub immediately after hand washing. [2, 3, 6, 7]
9. It is recommended that practitioners strive to prevent hand roughness on a daily basis. [4, 5]

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Standard Precautions – Personal Protective Equipment –

1. It is desirable that practitioners use proper hand hygiene to prevent infection from exposure to blood or body fluids, as well as invasion by pathogens at needling sites, and in addition, that practitioners pay close attention to avoid touching the needle body while needling and when removing needles. [1, 2]
When practitioners cannot avoid touching the needle, however, for example when using thin needles or long needles, it is recommended that they use personal protective equipment such as medical gloves or fingerstalls. [3]
2. Practitioners should always use personal protective equipment such as medical gloves or fingerstalls, particularly if there is any wound on the practitioner's hands. [3]
3. Practitioners must replace such personal protective equipment after each treatment. [1, 2, 4]
4. In Shiraku acupuncture therapy, it is recommended that practitioners use aprons or gowns, surgical masks, goggles, etc. as necessary. [1, 2]

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Standard Precautions – Respiratory Hygiene and Cough Etiquette –

Cough etiquette means the measures taken by a person with symptoms of respiratory infection (cough, sneezing, runny nose, etc.) to interrupt droplet transmission. Specific measures include wearing a surgical mask, and immediately discarding tissues containing respiratory secretions in a waste receptacle.

1. It is recommended that practitioners avoid performing treatment if they have symptoms of respiratory infection, but if they cannot avoid performing treatment, they should wear a surgical mask. In addition, practitioners must perform hand hygiene if they come in contact with respiratory secretions. [1-3]
2. It is recommended that practitioners have the patient wear a surgical mask if the patient has symptoms of respiratory infection. [1-3]

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Standard Precautions – Bed and Surrounding Environment Hygiene –

1. When disinfecting surfaces in the proximity of treatment beds, it is recommended that they be cleaned with an intermediate-level disinfectant (alcohol-based disinfectant, sodium hypochlorite, etc.) or a low-level disinfectant. It is not recommended that surfaces in the proximity be disinfected by spraying disinfectant. [1, 2]
2. Practitioners must use clean linen for treatment. If the linen is contaminated by blood or body fluids, it is recommended that it be washed for 10 minutes with hot water at 80 degrees Celsius, or that it be washed with appropriate use of a chlorine bleach (sodium hypochlorite). [3]
3. The area in the proximity of beds where treatment is performed must be cleaned so it is free of contaminants and dust. It is recommended that frequently touched surfaces such as doorknobs and handrails be cleaned more frequently and with greater intensity than other surfaces. [3, 4]

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Standard Precautions – Waste Handling –

1. When discarding absorbent cotton or guide tubes, etc. that may include needles or the patient's blood or body fluids, they must be handled as infectious waste. [1]
2. Infectious waste should be stored in containers designated for infectious waste that can be sealed, are easy to store, and cannot be easily damaged. In particular, used needles should be discarded in designated containers that are robust and puncture-resistant, to prevent needlestick accidents. [1]
3. The containers used must display the biohazard mark so that the contents of the container can be identified as infectious waste, they must be sealed at the time of collection and transport, and a specialized waste disposal service must be used for processing, in accordance with laws and regulations. [1]

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Standard Precautions – Disposal of Excreta –

1. When disposing of excreta such as vomit and excrement, it is recommended that disposable gloves, surgical masks, and plastic aprons be worn, and that contaminated areas and surroundings be disinfected by cleaning with sodium hypochlorite. When disposing of such waste, it is recommended that the area be thoroughly ventilated by opening windows, etc. [1, 2]
2. It is recommended that persons who have disposed of excreta thoroughly wash and disinfect their hands afterward. [1, 2]

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Hygienic Needling – Disinfection of the Treatment Field –

1. Practitioners must disinfect the treatment field in the course of treatment. [1]
2. To disinfect the treatment field, it is recommended that ethanol for disinfection defined by the Japanese Pharmacopoeia (76.9 to 81.4%) or 70% isopropyl alcohol be used. [2] Lower concentration alcohol-based disinfectants should not be used, as they may reduce the effectiveness of disinfection. [3, 4]
3. Low-level disinfectants (e.g., chlorhexidine gluconate, benzalkonium chloride) may be used if alcohol-based disinfectants cannot be used due to allergies or other problems. [5, 6]
4. When disinfecting the treatment field, it is recommended that the area be cleaned with a cotton pad or other material moistened with disinfectant. In the following cases, it is recommended that the antiseptic swab be replaced with a new swab before continuing to clean. [7, 8]
 - (1) If the antiseptic swab dries out during cleaning
 - (2) If contamination is visible on the antiseptic swab
 - (3) If the antiseptic swab comes into contact with damaged skin

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Hygienic Needling – Needling Technique –

Needling must be performed hygienically in order to control infection. The following should be observed when needling.

1. Practitioners must perform hand hygiene before needling.
2. It is recommended that practitioners wear medical gloves or fingerstalls.
3. When performing more hygienic needling, it is recommended that practitioners practice the aseptic technique of inserting needles without touching the body, or Clean Needle Technique (CNT). It is also recommended that if practitioners hold the needle body, they use sterilized gauze or a cotton pad to support the needle. [1]

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Equipment Cleaning, Disinfection, and Sterilization

1. It is recommended that in the course of treatment practitioners use sterile single-use needles regardless of whether they penetrate the skin or not. It is particularly recommended that when practitioners use needles whose purpose is to penetrate the skin, such as filiform, subcutaneous, or three-edged needles, they be sterile single-use needles. [1]
2. If using acupuncture needles that penetrate the skin and are intended for reuse, the needles must be cleaned and sterilized using appropriate methods. [2]
3. If using needles whose purposes are not to penetrate the skin but are intended for reuse, such as spoon needles, non-invasive dermal needles, practitioners must clean and disinfect the needles using appropriate methods. [3, 4]
4. It is recommended that any equipment that comes in direct contact with needles, such as guide tubes and needle trays, be sterile and disposable. [1]
5. If guide tubes are to be reused, they must be cleaned and sterilized using appropriate methods. In the case of needle trays, it is recommended that they be cleaned and disinfected. [3, 4]

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Occupational Infection Control – Needlestick and Other Accidents–

1. Practitioners must take steps to prevent treatment-related infection in order to protect the patient and themselves from infection and to avoid becoming a carrier.
2. It is recommended that practitioners use appropriate personal protective equipment, such as medical gloves and fingerstalls to control infection from exposure to blood and body fluids, and surgical masks to control droplet transmission. When removing needles, it is also recommended that practitioners avoid direct contact with blood and body fluids by using antiseptic swabs or sterile cotton pads. [1-3]
3. It is recommended that after removing used needles, practitioners immediately discard them in designated containers that are robust and puncture-resistant, to prevent needlestick accidents. [3, 4]
4. It is recommended that practitioners be vaccinated against hepatitis B because the hepatitis B virus is the most contagious blood-borne pathogen. [5] In addition, it is recommended that practitioners take appropriate post-exposure measures in the event they are exposed to blood or body fluids by needlestick accident involving an unvaccinated individual or a vaccine non-responder. [3]
5. It is recommended that practitioners check in advance whether they have antibodies to measles, rubella, mumps, and chickenpox pathogens and check their antibody titers, and if necessary, receive vaccinations against them because they are diseases with which susceptible individuals are likely to be infected. [5]

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IV. Preventing Adverse Events

While acupuncture and moxibustion include numerous therapies such as filiform needle therapy, low-frequency electro-acupuncture (electro-acupuncture) therapy, Kyutoshin therapy (Moxa needling therapy), Shiraku acupuncture therapy, Teishin therapy, Dermal needle therapy, Hinaishin & Empishin therapy (Intradermal needling therapy), direct moxibustion therapy, and indirect moxibustion therapy, this section mainly describes safety measures in filiform needle acupuncture and direct moxibustion. Safety measures for the other therapies, from electro-acupuncture and others, are described in the section on Safety in Related Therapies.

Infection

1. Practitioners must observe the Standard Precautions and must strive to prevent infection in the course of treatment. [1]
2. There have been reports of cases of infection after treatment of immuno-compromised patients (diabetic patients, long-term steroid users, etc.). If a patient's pathological condition has not stabilized, practitioners should abide by his/her physician's decision on the suitability of treatment. [2, 3]
3. There have been reports of suppurative arthritis after treatment. In order to prevent infection, practitioners should not perform intraarticular needling. [2, 4]
4. In order to prevent infection, practitioners should avoid directly needling sites where artificial devices are implanted (artificial joints, artificial blood vessels, pacemakers, etc.). Practitioners should also pay close attention when performing treatment in those areas. [5]

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Organ and Nerve Injury

Practitioners must fully understand local anatomy and safe depths and must avoid unnecessarily deep needling and careless technique. Practitioners need to beware when needling because pressure from the pressing hand supporting the needle, so-called pressing hand, reduces the safe depth. [1-8]

1. Practitioners must not put towels or blankets over the top of needles while they are retained because the needles may penetrate into deeper regions. [5]
2. In order to prevent pneumothorax, practitioners must use caution when needling the shoulder/upper back region and thoracic region. [1-5]
3. In order to prevent heart injury (e.g. cardiac tamponade), practitioners must exercise caution with deep needling in the precordia region and be aware of the presence of any sternal foramen in the region of chest center acupuncture point (CV17). [1-3, 6]
4. There have been reports of vascular injury (e.g. bleeding, hematoma, aneurysm) occurring in the vertebral artery, subclavian artery, inferior abdominal wall artery, popliteal artery, etc. after treatment. Practitioners should avoid careless technique and deep needling at sites where large blood vessels are present because they may cause vascular injury. [1-3, 6, 7]
5. Practitioners should avoid careless technique and deep needling and also ensure thorough hygiene is used in treatment for patients with a bleeding tendency such as hemophilia, because they are at higher risk of infection and bleeding (internal hemorrhage, hematoma) than healthy patients. [1-3, 6]
6. Practitioners should avoid careless technique and deep needling at sites where the nerves that run through the site are relatively large in anatomical terms. [1-3, 7]
7. Careless technique and deep needling especially in the posterior region of the neck carries the risk of the needle penetrating a cervical intervertebral foramen, between a vertebral arch and a cervical vertebra, or between the occipital bone and a cervical vertebra, and injuring the central nervous system (brain and spinal cord), therefore practitioners must exercise caution. [1-3, 7]

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Skin Disorders

There have been reports of cases in which skin disease (e.g., nodules, erythema, contact dermatitis) has developed when acupuncture and constitutional factors (e.g., underlying diseases and metal allergies) have combined.

1. In the course of treatment, it is desirable that practitioners ask patients beforehand whether they have any history of skin disease or any allergies to alcohol or metal, for example. [1-3]
2. Practitioners should abide by his/her physician's decision on the suitability of treatment if the patient has a history of skin disease or allergy to metal, and there is any risk that treatment may be a cause of skin disease or an aggravating factor. [1-3]
3. Practitioners should discontinue treatment and advise the patient to seek medical attention if a skin lesion coinciding with a needling site is found either during or after treatment. [1-3]
4. Practitioners need to beware of needling at parts affected by skin lesion and to beware of repeated needling over a long period at the same site, because they risk inducing an adverse event. [4, 5]

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Needle Breakage, Retained needles, and Foreign Bodies

Needle breakage is unintentional breakage of the needle body and a retained needle is part of a needle body that remains in the body due to needle breakage. "Foreign body" is the general term for anything present in the body that is not a normal cell and includes retained needles and calculus around a retained needle as well as embedded needles by Embedded needling therapy.

1. Practitioners must beware of retained needles because there are the risks that a needle remaining in the body may cause chronic pain and that it will move within the body and injure organs, nerves, or blood vessels. [1-4]
2. Practitioners must not practice Embedded needling therapy, where a needle is intentionally embedded in the body. [1-6]
3. It is recommended that practitioners use single-use filiform needles so as to prevent needle breakage. If using filiform needles intended for reuse, it is recommended that practitioners check beforehand for any defects in the needle body, needle handle, and the join between the two. [1-3]
4. If it is difficult to remove a needle because it is completely buried, it is recommended that practitioners inform the patient and also advise him/her to seek medical advice about the appropriateness of removing the retained needle. [1-4]
5. Since retained needles may cause chronic pain, for example, it is hoped that in the ordinary course of treatment practitioners ask patients, and especially the elderly, about any history of Embedded needling therapy. [1-3]

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Adverse Effects (Adverse Reactions)

General

1. It is difficult to completely prevent adverse effects (e.g., microhemorrhage, poor mood, pain accompanying needling, aggravation of symptoms, and difficulty removing needles [stuck needles]) in treatment given that it involves inserting metal into, or bringing it in contact with, the body. Practitioners must therefore strive to give full and appropriate explanations to the patient regarding any adverse effects that may accompany his/her treatment, so as to avoid unnecessary problems. [1-5]
2. Practitioners should only perform treatment once the patient has fully understood and accepted the risks of that treatment. When needling the face, it is hoped that practitioners provide careful explanation because the patient's appearance may be easily marred. [1-5]

Specific Adverse Effects

(1) Bleeding

1. Practitioners should refrain from careless technique and from using unnecessarily thick needles and should also apply adequate pressure to the needling site after removing the needle to prevent bleeding.
2. Practitioners should avoid direct contact with the needle body and the needling site by using cotton wool to hold the needle body to prevent blood-borne infection from the patient to the practitioner.

(2) Poor mood – Autonomic nervous system symptoms

1. Excessive stimulation carries the risk of inducing poor mood or autonomic nervous system symptoms such as nausea, vomiting, dizziness, or cerebral anemia (fainting). It is desirable that practitioners check the patient's sensitivity to stimulation and adjust it to an appropriate level so as to avoid excessive stimulation.
2. Practitioners need to beware that certain patients are particularly susceptible to cerebral anemia (fainting), including patients receiving treatment for the first time, patients suffering anxiety or severe tension such as nervousness or fear of needles, or who are in poor condition due to lack of sleep, etc., and patients who are frail such as the elderly. For such patients, it is desirable that practitioners start with weaker stimulation.
3. Practitioners need to beware when needling a patient who is sitting up because he/she (especially an elderly patient) is susceptible to cerebral anemia (fainting). It is desirable that practitioners avoid treating patients sitting up, or take steps beforehand to prevent falls, because it carries the risk of injury due to falling.

(3) Difficulty removing needles (stuck needles)

1. Practitioners should not insert needles any deeper than necessary because it carries the risk of difficulty removing the needle (stuck needle).
2. Practitioners should instruct patients before treatment to refrain from moving during treatment (especially while needles are retained), except for specialized treatments such as movement acupuncture therapy, to avoid difficulty removing needles (stuck needles).
3. Practitioners should avoid removing needles forcefully because it carries the risk of needle breakage and tissue injury. If there is any risk from a needle breakage, explain the situation to

the patient and recommend that he/she seek medical attention at a hospital (consultation with a physician). It is hoped that when the patient receives medical attention, the practitioner concerned accompany the patient and explain the situation to the physician the details of the incident/accident.

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Forgotten Needles

Forgetting to remove needles may cause organ injury, difficulty removing a needle (stuck needle), needle breakage, needlestick accidents, etc.

1. Practitioners should check the number of needles used before the patient changes position and before the end of treatment as a precaution against forgotten needles. It is recommended that the number of needles be checked by two or more practitioners double checking or by a single practitioner cross checking. [1]

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Adverse Events Due to Moxibustion

Adverse events due to moxibustion include burn injury, moxibustion scar suppuration, and canceration at the moxibustion site.

1. Practitioners must strive to practice moxibustion site hygiene. [1-3]
2. Practitioners should avoid moxibustion at sites where inflammation, infection, wound, circulatory impairment, etc. are present because treatment carries the risk of causing suppuration, ulceration, or symptom aggravation. [1-3]
3. Practitioners need to beware of treating parts affected by disturbance of the senses (e.g. sense of pain and sense of heat) because it is difficult for such patients to give feedback about pain and heat. Practitioners should ask the patient adequate questions about any history of disease (e.g., diabetes) that may cause sensory disturbance, and should also abide by his/her physician's decision on the suitability of treatment if his/her pathological condition has not stabilized. [1-3]
4. Practitioners should avoid excessive stimulation for immuno-compromised patients (diabetic patients, long-term steroid users, etc.) because there is a higher risk of causing suppuration and ulceration of moxibustion scars than in healthy individuals, and practitioners should also abide by their physician's decision on the suitability of treatment if his/her pathological condition has not stabilized. [1-3]
5. Practitioners should stay by the patient's side during moxibustion treatment, so that he / she is able to deal with any unforeseen situations. [1]
6. In the event of unintended slight burn injury (first degree), promptly cool the affected part under running water. If the burn injury is moderate (second degree) or worse and carries the risk of infection, practitioners should advise the patient to see a specialist. [1-3]
7. Practitioners should pay close attention performing moxibustion with excessive stimulation over a long period at the same site because it may induce an adverse event. [2-5]

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V. Safety in Related Therapies

The safety measures in therapies related to acupuncture and moxibustion (related therapies) assume the measures to prevent adverse events for each specific therapy. In all related therapies, practitioners should only commence therapy after fully explaining the expected effects and risks of the therapy to the patient and obtaining his/her consent.

Low-frequency Electro-acupuncture Therapy

Low-frequency electro-acupuncture (EA) therapy is a therapy that introduces into the body low-frequency electric stimulation via two acupuncture needles (filiform needles) inserted into the body. In the course of electro-acupuncture, practitioners must check beforehand in writing or verbally whether there is anything that may contraindicate the therapy. Practitioners must also note the outcomes of such checks in the medical record.

(1) Acupuncture needles

1. The needles used in electro-acupuncture must be needles that can withstand external forces such as muscle contraction and corrosion due to electrolysis (electrolytic corrosion), which can cause needle breakage.
2. It is strongly recommended that practitioners use sterile stainless steel filiform needles for single-use in order to prevent adverse events such as needle breakage. [1, 2]
3. Practitioners should not use silver needles as they are susceptible to electrolytic corrosion.
4. It is recommended that practitioners use needles of at least size 20 (0.20 mm needle body diameter) in order to prevent needle breakage due to electrolytic corrosion etc. Needles with a needle body length of at least 30 mm are recommended. [1]

(2) Electro-acupuncture stimulator

1. Practitioners must use a medical-grade certified electro-acupuncture stimulator as the device (energizing device) for electro-acupuncture. [1, 2]
2. Practitioners should inspect energizing devices and electrical cords before using them. It is desirable that they be regularly maintained and inspected.
3. Practitioners should not use DC pulse current because it makes needles susceptible to electrolytic corrosion. [2, 3]
4. Practitioners should not use energizing devices in proximity to VHF therapy equipment or microwave therapeutic devices because they affect the output of the energizing device. [1]

(3) Contraindicated Cases

1. Practitioners must not perform electro-acupuncture on patients who are using implanted medical devices such as pacemakers or defibrillators because it carries the risk of causing oversensing or another malfunction.
[4-6]
2. Practitioners should not use electro-acupuncture in conjunction with wearable medical devices (e.g. electro-cardiogram) because it carries the risk of malfunction.

3. It is desirable that practitioners refrain from performing electro-acupuncture on patients with whom it is not possible to adequately communicate since it is difficult to determine the right level of stimulation.

(4) Additional Precaution

1. It is hoped that practitioners keep watch during electro-acupuncture because it carries the risk of muscle contraction altering the depth of needle insertion. [7]

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Kyutoshin Therapy (Moxa Needling Therapy)

Kyutoshin therapy, also referred to as Moxa needling therapy, is a therapy that provides invasive mechanical stimulation and non-invasive heat stimulation to the body by applying moxa on the handle of the inserted acupuncture needle (filiform needle) and burning it. The types of moxa applied on the needle handle include moxa balls, cut moxa wrapped in cylinders with Japanese paper, or carbonized moxa made from charcoal. Practitioners need to beware of the risk of unintentional burn injury, such as falling off of the moxa balls.

(1) Acupuncture needles and Moxa

1. Practitioners must use filiform needles for Kyutoshin, with both metal and heat-resistant handles and bodies.
2. It is recommended that practitioners use sterile single-used filiform needles with metal handles. [1]
3. It is recommended that practitioners use needles of at least size 20 (0.20 mm needle body diameter) with a needle body length of at least 50 mm. [1]
4. Practitioners should ensure that the weight of the moxa ball, cut moxa, or carbonized moxa, including the moxa needle cap, does not cause the needle body to sag. [1]
5. Practitioners should use moxa for moxa balls that is of sufficient quality that the ball does not disintegrate during treatment. [1]

(2) Preventing Burn injury

1. Practitioners must beware of unintentional burn injury. In particular, practitioners must beware of hot needles falling over, moxa falling, and excessive radiant heat from multiple moxa needles or the needle body sagging. Practitioners must also take measures to prevent these from happening, as necessary. [1]
2. Practitioners must give the patient instructions not to move during treatment, to prevent any needle from falling over. [1]
3. Practitioners must keep watch over the patient while burning moxa. [2]
4. Practitioners should have the patient check the intensity of the heat felt and should also check the intensity of the heat with their own hands while burning moxa, because sensitivity to heat differs among individuals. [2]
5. Practitioners should not use Kyutoshin in combination with other thermotherapies, especially infrared therapy, because the radiant heat is excessive. [2]
6. Practitioners need to beware when removing needles because the temperature of the needle handle will be raised immediately after burning the moxa. [3]

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Shiraku Acupuncture Therapy

Shiraku acupuncture therapy is a therapy that releases a small amount of blood by puncturing the skin using a three-edged needle or a filiform needle. [1]

1. It is recommended that practitioners ensure all acupuncture implements and personal protective equipment that either will be contaminated or may be contaminated with blood be single-use. [2]
2. If using implements that are intended for reuse (e.g. three-edged needles), practitioners must use implements that have been cleaned, disinfected, and stored, or cleaned, sterilized, and stored, using appropriate methods. [3, 4]
3. Practitioners must wear medical gloves as protection against exposure to blood. It is also recommended that practitioners use a plastic apron or gown, surgical mask, goggles, and similar equipment, as necessary. [5]

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Teishin Therapy and Shonishin Acupuncture (Japanese pediatric acupuncture)

Teishin therapy and Shonishin acupuncture (Japanese pediatric acupuncture) are therapies that provide non-invasive mechanical stimulation to the skin, the former using Teishin, and the latter using non-invasive dermal needles.

1. It is recommended that all needles that practitioners use in Teishin therapy and Shonishin acupuncture be single-use. [1, 2]
2. If using needles intended for reuse, practitioners must use needles that have been cleaned and disinfected or sterilized using appropriate methods. [1, 2]
3. In regard to the appropriate methods mentioned in 2), it is recommended that practitioners clean and disinfect needles (cleaning only is allowable) if the needles come into contact with normal skin, while practitioners must clean and sterilize needles if they come into contact with damaged skin (e.g. skin affected by atopic dermatitis).

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Hinaishin Therapy and Empishin Therapy (Intradermal Needling Therapy) Including Ear Acupuncture Therapy

Intradermal needle is the general term for Hinaishin and Empishin in both of which have short needle body. Intradermal needling therapy is performed using Hinaishin or Empishin for the purpose of providing invasive mechanical stimulation continuously to the skin and to the subcutaneous tissue.

1. It is recommended that practitioners use sterile single-use intradermal needles. Practitioners must not reuse intradermal needles. Once they have been applied, practitioners must also not reapply intradermal needles. Practitioners must instruct patients not to reapply them. [1]
2. Practitioners should not perform treatment at sites where there is any skin abnormality, e.g. inflammation sites, injury sites, infection sites, and open wounds. [1]
3. Practitioners must instruct patients in the appropriate and safe methods of peeling off and discarding needles, to prevent needlestick accidents. Practitioners should peel off and discard intradermal needles if these are difficult for the patient to do. [1, 2]
4. There have been reports of minor cases of itching, pain, discomfort, etc. as adverse events due to intradermal needles. When performing treatment, practitioners should explain these adverse events to the patient and the ways to deal with them, and obtain their consent before proceeding. [1, 3]
5. Practitioners should avoid applying intradermal needles for long periods because it carries the risk of causing breakage and embedding in the skin due to breakage. [4]
6. Practitioners should advise the patient to promptly seek medical help if an intradermal needle or part thereof is completely embedded within the skin and cannot be removed. It is desirable that practitioners accompany the patient whenever possible and assist procedures by explaining the details of the treatment to the physician, for example.
7. Practitioners need to beware that the risk of an intradermal needle adverse event increases with the time the needle is applied. Practitioners should instruct the patient to promptly remove an intradermal needle if he/she experiences pain or discomfort at the site. [3]
8. Intradermal needles are susceptible to peeling off when they become wet with a large volume of water, such as when bathing, showering, swimming, or sweating. It is recommended that intradermal needles be removed beforehand, to prevent any accident due to them peeling off.
9. It is hoped that steps be taken to prevent intradermal needles from peeling off after they have been applied, such as covering them with adhesive tape, to prevent them from peeling off due to exercise and to prevent any consequent accident.

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Ryushin Therapy (Press-sphere Therapy) Including Ear Acupuncture Therapy

Ryushin therapy, also referred to as Press-sphere therapy, is a therapy that provides continuous, non-invasive, mechanical stimulation to the skin by applying spheres onto the acupoints or other target points on the body surface. Spheres are applied not for puncturing the skin but for pressing those points. The types of press-spheres include herbal substances, seeds, stainless steel, and granule coated by gold or silver.

1. In the course of treatment, practitioners need to beware of the patient's history because the retained spheres and adhesive tape may cause allergic reaction. [1]
2. Practitioners must fix spheres with adhesive tape to prevent the spheres from falling off.
3. There have been reports of adverse events where spheres have made their way into the inner ear via a perforation in the eardrum. In Ear acupuncture, practitioners should check whether the patient has a perforated eardrum and refrain from applying spheres if the patient has a perforation. [2-4]

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Appendix – Explanation of Terms

Accident report

A written report on the details of a medical accident. These reports help to identify accident trends and conditions, and they identify the issues and the points that require systematic prevention measures to prevent accidents from recurring.

Airborne transmission

Infection by germs that spread by floating in the air for long periods of time on droplet nuclei of 5 microns or less. It may be prevented by using filtration masks and air-conditioning, such as rooms with negative pressure.

Alcohol-based disinfectant

Alcohol is the main component of such disinfectants, of which there are two types: ethyl alcohol (ethanol) and isopropyl alcohol (isopropanol).

Benzalkonium chloride

A cationic surfactant (invert soap) and a low-level disinfectant mainly used for disinfection of environmental surfaces (beds, floors, etc.). It is sometimes added to quick-drying alcohol-based hand rub.

Biohazard marks

Marks affixed to containers holding infectious waste so as to be able to identify them as such. If the contents are liquid or sludge (e.g., blood), the mark is red, if solid (e.g., blood-stained gauze) the mark is orange, and if sharp (e.g., syringe needles, acupuncture needles) the mark is yellow.

Cardiac tamponade

A condition in which a large amount of fluid (pericardial fluid or blood) or gas accumulates in the pericardium (pericardial sac) around the heart, preventing the heart from fully expanding. This can be caused by needling to the heart.

Chlorhexidine gluconate

A low-level disinfectant for use on the body and causes little skin irritation and has almost no odor. Not only does it demonstrate sterilizing properties when used, but it also remains on the skin and demonstrates a lasting antimicrobial effect. It is sometimes added to quick-drying alcohol-based hand rubs.

Cleaning

The physical removal of organic matter from the body or equipment.

Contact transmission

Infection caused by microorganisms that spread through direct contact via the patient or indirect contact via the surrounding objects and environmental surfaces. It can be prevented by isolation in an individual room, using gloves, and hand disinfection using a disinfectant.

Dangerous needling depth (dangerous depth)

A needling depth that exceeds the safe depth and that carries the risk of injuring organs or major blood vessels or nerves.

Dermal needles

A general term for needles intended for stimulating body surface. They are divided into non-invasive needles and invasive needles.

Disinfection

Reducing the number of germs. It does not kill germs completely and the extent of effectiveness depends on the disinfectant.

Droplet transmission

Infection by germs that spread on droplet nuclei larger than 5 microns. It may be prevented by maintaining distance from the patient, by having the patient wear a mask, and so on.

Electro-acupuncture stimulators

Therapeutic devices specifically for electro-acupuncture therapy. They are classified as Class II (controlled medical devices) medical devices.

Empishin

A type of subcutaneous needle of which the shape is like a pushpin. This type of needle is inserted perpendicularly to acupoints to stimulate subcutaneous tissue. Empishin are also called as intradermal thumbtack type needles.

Ethanol for disinfection

A medium-level disinfectant widely used on the body and environmental surfaces. It is effective for almost all microorganisms, except spores. In the Japanese Pharmacopoeia, ethanol for disinfection is defined as 76.9 to 81.4 vol% ethanol.

Ethanol for disinfection defined by the Japanese Pharmacopoeia

See Ethanol for disinfection.

Filiform needle

A type of needle for insertion. It consists of a needle body (the part that is inserted) and a needle handle (the part for manipulating the needle). Usually acupuncture needles refers to filiform needles.

Fingerstalls

These are used to prevent transmission to both the patient and the practitioner. They are made of latex rubber and are available sterilized or unsterilized.

First aid

Treatment performed by trained paramedics at the scene of the injury/illness incident, or while being transported to a hospital, prior to comprehensive or decisive treatment at a medical facility, etc.

Foreign body

The general term for anything present in the body that is not a "normal cell." Specifically, this includes retained needles and calculus around a retained needle. Embedded needles that intentionally embedded inside the body are also foreign bodies.

Hemophilia

A disease caused by an inherent deficiency of blood coagulation factor, resulting in a tendency to bleed. Needling may cause bleeding into deep tissues (internal bleeding, hematoma).

Hinaishin

Type of intradermal needles. The needles are inserted sideways into the skin for stimulation to the subcutaneous tissue. Hinaishin also called as intradermal granule type needles.

Incident report

A written report on the details of an incident. These reports help to identify incident trends and conditions, and they identify the issues and the points that require systematic prevention measures to prevent accidents from recurring. An incident is an unforeseen event that causes the individuals

concerned to experience a fright or surprise, even if it does not cause personal or economic loss to the patient.

Infectious waste

Waste from medical institutions, etc. that contains infectious (or potentially infectious) pathogens that can be transmitted to humans.

Intermediate-level disinfection (disinfectants)

These kill all germs except spores, although some demonstrate sporicidal performance. They include sodium hypochlorite, povidone iodine, alcohols, etc.

Intradermal needles

The general term for an Hinaishin and Empishin in both of which have short needle body. Their needles are inserted sideways into the skin for stimulation to the subcutaneous tissue.

Isopropyl alcohol (isopropanol)

A medium-level disinfectant widely used on the human body and environmental surfaces. It is effective against virtually all microorganisms, except spores. It is a more powerful degreaser than ethyl alcohol and has a distinct odor.

Low-frequency electro-acupuncture (electro-acupuncture)

An acupuncture therapy that provides low-frequency electrical stimulation to the body via filiform needles inserted into the body.

Low-level disinfection (disinfectants)

Disinfection that is effective against most bacteria, certain types of viruses, and fungi, but ineffective against *Mycobacterium tuberculosis* and spores. Disinfectants include chlorhexidine gluconate, quaternary ammonium compounds (benzalkonium chloride and benzethonium chloride), and amphoteric surfactants.

Embedded needling therapy

These terms refer to the therapy whereby a needle is intentionally embedded inside the body.

Medical gloves

Single-use gloves used to prevent infections in both patients and health care providers, including gloves made of latex rubber, nitrile rubber, and plastic. These include unsterilized gloves for medical examination and sterile gloves used during surgery and aseptic operations.

Nerve injury

Neurological symptoms originating in injury to the nerve itself or damage to nervous tissue (such as hemorrhage and hematoma) caused by needling.

Organ injury

Injury to internal organs or blood vessels caused by needling or a retained needle.

Oversensing

Misrecognition by cardiac pacemakers of muscle potential or noise as heartbeat.

Personal protective equipment

The items used if there is a possibility of contamination of clothing by blood or body fluids, including gowns or aprons, masks, goggles, gloves and so on. These are all single-use items and are replaced after every use.

Quick-drying alcohol-based hand rub

A disinfectant based on alcohol used to make germs inactive and/or to temporarily control their proliferation on the hands.

Retained needles

Needles that remain in the body due to needle breakage. Retained needles include needles that remain inside the body by Embedded needling therapy.

Safe needling depth (safe depth)

The needling depth that does not carry the risk of injuring organs, major blood vessels, or nerves.

Shonishin acupuncture therapy (Japanese pediatric acupuncture)

Acupuncture treatment applied to babies and children. Treatment is mainly performed with non-invasive dermal needles.

Single-use filiform needles

Filiform needles intended for single-use. The type of needle is classified as a Class II medical device (controlled medical device) and the requirements is stipulated by Japan Industrial Standard (JIS T9301: 2016: Acupuncture needle for single use).

Sodium hypochlorite

A medium-level disinfectant that demonstrates immediate sterilizing properties against most microorganisms, including spores. Its use in medical devices is limited to plastic products because it corrodes metals. It is also used to bleach clothing and linen.

Stuck needles (Difficulty removing needles)

A circumstance in which an inserted needle cannot be removed.

Sterilization

Sterilizing by killing all germs, including spores.

Teishin

The stick-shaped needles with round tips intended for pressing acupoints or rubbing meridians. Types of needles that do not penetrate the skin.

Three-edged needle

A type of needle for insertion of which the tip is like a triangular awl and is used in Shiraku acupuncture therapy.

Vaccine non-responder

A person who has been vaccinated but does not have the antibody titers needed for prevention. In hepatitis B vaccination, it refers to individuals who have not become positive for antibodies even after two series of vaccinations (three vaccinations per series).

Note: When translating acupuncture and moxibustion terms this time, please note that some of them are not officially recognized translations.

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