Clean Needle Technique

Manual

Best Practices for Acupuncture Needle Safety and Related Procedures

7th Edition

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CCAOM Clean Needle Technique Manual 7th Edition

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The Clean Needle Technique (CNT) Manual is intended for use primarily by state-licensed acupuncturists and students enrolled in a formal course of instruction at a school approved by the Accreditation Commission for Acupuncture and Oriental Medicine. As a statement of best practices concerning acupuncture needling and related techniques, the manual may also be beneficially used by state-licensed healthcare professionals in other disciplines who have acupuncture and related modalities within their lawful scope of practice and by acupuncturists outside the United States who are appropriately authorized to practice acupuncture within their respective national jurisdictions. The manual is not intended for use by persons without formal training and regulatory authorization to practice acupuncture. The manual focuses on safety and is not a guide to appropriate treatment for particular health conditions. While the manual is intended to reflect best practices as of the date of publication, opinions as to best practices may differ and change over time. Ongoing study and debate concerning best practices within the academic and practitioner communities is encouraged. The Council assumes no liability for any injury that may occur as a result of a practitioner's use of, or reliance upon, any safety protocol contained in this manual.

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Preface

The profession of acupuncture and Oriental medicine (AOM) in the United States continues to grow and evolve. As part of this evolution, practitioners are providing acupuncture services in hospitals, integrated medical centers, and teaching clinics. As more acupuncturists provide care in this complex array of integrated settings, the need for evidenced-based best practices in safety is essential. Acupuncture education in the U.S. has evolved to meet this challenge. Accordingly, AOM institutions that have achieved accreditation or accreditation candidacy status with the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM) continue to expand their curriculum to meet the changing needs of the profession, including coursework in bioscience, evidence-based practice, risk management, and safe clinical practices.

The information available from the Centers for Disease Control and Prevention (CDC), the Occupational Safety and Health Administration (OSHA), as well as state and local health departments, has also evolved since the release of previous editions of the *Clean Needle Technique Manual*. Changing epidemiological patterns, changes in what is considered best practices in clean and aseptic technique, and changes in technology have all contributed to improving clinical safety. What has not changed is the need for acupuncturists to apply Clean Needle Technique scrupulously as safety remains a critical aspect of clinical practice.

The purpose of the *Clean Needle Technique Manual* has also evolved. The first edition of the manual was one of the few English language sources covering safe practice standards for acupuncturists. AOM educational institutions now have a range of resources and an accreditation mandate to cover bloodborne pathogens, safe practice, emergency procedures, risk management, and safety protocols in their curricula. Information provided in the *Clean Needle Technique Manual* has also spread globally, promoting better safety standards worldwide.

Needling and other related acupuncture procedures are carried out in a unique manner where needles may be placed into tissue and removed, or may be placed into tissue and reside for a period of time before their removal. Other modalities may also be applied onto the surface of the skin and likewise be immediately removed or retained for a period of time. As such, the application of evidenced-based best safety practices takes into account the manner and timing of treatment. In developing the *Clean Needle Technique Manual*, experts from OSHA and the CDC were consulted to ensure that the recommendations in the manual meet current OSHA and CDC standards.

The *Clean Needle Technique Manual* plays an important role in preparing acupuncture students for safe practice and providing basic information required for national certification in

acupuncture by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) and for state licensure. This manual summarizes important principles that govern safe practice suited to support the work done in introductory acupuncture technique courses in acupuncture colleges and the Clean Needle Technique course offered by the Council of Colleges of Acupuncture and Oriental Medicine (CCAOM). The information in this manual supports and contributes to the educational curricula in the areas of AOM office procedure safety, bloodborne pathogens, and risk reduction concerning acupuncture and other adjunctive therapies as practiced in private practice, conventional and CAM integrated clinical settings, and in the teaching clinics in accredited AOM programs.

This latest edition of the *Clean Needle Technique Manual* has been expanded, updated, and exhaustively reviewed. While every effort has been made to ensure that up-to-date statistics were included with respect to adverse events arising in AOM office practices, including the small risk of spreading infectious diseases, it is important to remember that these statistics are constantly changing. Acupuncture practitioners can find updated information regarding healthcare associated illnesses on U.S. government websites, a number of which are listed in Appendix B.

Acknowledgements

The seven editions of the *Clean Needle Technique (CNT) Manual* represent the collective thinking and energy of National Acupuncture Foundation Board Members, NCCAOM Commissioners, Council of Colleges of Acupuncture and Oriental Medicine Clean Needle Technique Committee Members, and CNT Instructors and colleagues across the United States.

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Introduction

In 1984, at the request of the acupuncture profession, the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) developed guidelines and recommendations for the safe and clean practice of acupuncture. The guidelines were based on the theory and practice of safety commonly used in healthcare. Conscientious use of the procedures recommended and described in this manual will reduce the risk of spreading infection and accidents in the practice of acupuncture.

Increasing knowledge, along with the application of Standard Precautions, safe clinical practices, and risk management techniques, reduces the risk of a number of potential adverse events related to acupuncture practice, reduces the spread of infection, and help ensure public safety. Furthermore, from the medical, legal, and ethical perspectives, it is the practitioner's responsibility to ensure that Clean Needle Technique has been followed correctly.

In addition to general public health sources, such as the CDC, OSHA's Bloodborne Pathogens Standards, and the U.S. Public Health Service, the information in this manual has been drawn from acupuncture research throughout the world and adapted to the unique requirements and the practice of acupuncture. Thus, many of the recommendations in this manual are modifications of techniques currently in use throughout the United States in many healthcare professions. The guidelines and standards that have been developed are the result of the synthesis of East Asian and Western resources from academic, research, and clinical arenas.

This manual reflects the current understanding of best practices in the field of acupuncture clinical techniques. Best practices are defined as "activities, disciplines and methods that are available to identify, implement and monitor the available evidence in healthcare…These activities gain input mainly through four disciplines: clinical research, clinical epidemiology, health economics and health services research." (1) In this application, best practice principles are being used to limit risks associated with acupuncture clinical practices.

These practices are the basis of both the written and practical training and exam portions of the CNT course and exam offered by the Council of Colleges of Acupuncture and Oriental Medicine. Acupuncture schools and practitioners need to maintain an awareness of informational updates concerning safety in many areas of practice (including healthcare associated infections and OSHA bloodborne pathogens standards), and continually update their understanding of the best clinical practices in the field.

This manual is not meant to define standard practices or standard of care in acupuncture techniques. The term standard of care is often used synonymously with customary practice. It is

a legal term that is commonly defined as “what a minimally competent physician in the same field would do in the same situation, with the same resources.” (2)

Standards of care in medicine may also be defined as the customary practice of a particular area or locality. Acupuncture clinical practices vary by school, region, and training. Given the historically wide variety of valid, documented acupuncture clinical practices, this manual cannot be utilized to define acupuncture standard practices.

For the purposes of this manual, the following terms will be utilized to help acupuncture practitioners apply best practices to their personal practices:

***Critical**:* This addresses the area of highest clinical risk. The protocol is considered essential for the safety of the patient and practitioner, and scientific data demonstrates that omission could constitute a serious public health risk.

***Strongly Recommended**:* These measures are strongly supported by clinical studies that show effectiveness of the measures in reducing risk or are viewed as important by healthcare practitioners. They are considered essential measures and frequently address areas of high clinical risk.

***Recommended**:* These measures include two types of recommendations: (1) those that are supported by highly suggestive, but perhaps less easily generalized, clinical studies in a related field, and (2) those that have not been adequately researched, but have a strong theoretical rationale indicating that they are effective for clean and safe practice. Both types of recommendations are judged to be practical to implement, but are not considered essential practice for every practitioner in every situation. Practitioners should, however, consider these recommendations for implementation into their practices.

Acupuncture procedures are performed as part of the authorized scope of practice of some other healthcare professions. Moreover, some healthcare practitioners use terminology from their own profession for therapeutic needling techniques that is indistinguishable from therapeutic needling technique in the practice of acupuncture. Trigger point dry needling, dry needling, functional dry needling, and intramuscular manual therapy fall into this category. Other healthcare providers who may use needling techniques in their practice, whether or not the providers describe these techniques as acupuncture, are subject to the same safety guidelines since the safety guidelines apply according to what tool the practitioner is using and how that tool is applied in the course of treatment. Accordingly, throughout this manual the general term “practitioner” is used inasmuch as the safety standards contained in the manual represent best practices applicable to any healthcare practitioner who uses a filiform needle or related techniques as described herein.

Practitioners, instructors, patients, and others often contact the CCAOM national office for clarification concerning the best safety techniques for acupuncture procedures.

Overview of the Sections:

- In Part I of the manual, the literature identifying the potential for infections and other adverse events and therefore the need for specific techniques and skills is reviewed as a rationale for best practices.
- In Part II, safety considerations for needling are described in detail and the precautions from Part I are repeated. The repetition is intentional as both a teaching tool and to reinforce the fact that best practices, including Clean Needle Technique basics, apply in all situations.
- In Part III, sample best practices for other AOM office procedures are discussed and the precautions from Part I repeated specifically for these practices. The procedures to limit burns associated with moxibustion apply even when different forms of moxa are utilized. Room, table and practitioner preparation are the same no matter what types of treatments are being rendered. If used as a teaching tool, this manual makes such repetition necessary and beneficial.
- Part IV details the healthcare associated infections concerning which acupuncture practitioners need to be aware, both bloodborne and contact associated infections.
- Part V discusses personnel safety practices.
- Part VI discusses cleaning of the office, equipment and laundry.
- Part VII reviews some of the important federal regulations and nationwide standards for risk reduction that apply to acupuncture practitioners.
- Part VIII contains appendices for practitioner information.

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Part I: AOM Clinical Procedures, Safety, Adverse Events (AEs) and Recommendations to Reduce AEs

Safety remains the most important consideration for all clinicians, including acupuncturists. Any clinical efficacy is potentially endangered when a clinician is not cognizant of the potential risks of a clinical procedure to the patient, patient's family, or the clinician and clinical staff. The field of acupuncture has flourished in the United States in part because acupuncturists are perceived by members of the public, state regulators, and other providers to be well trained and the practice of acupuncture to be relatively safe. In this section, commonly used acupuncture and related clinical techniques will be reviewed for their safety history along with an overview of the best practices for limiting adverse events (AEs). Details of safety protocols for acupuncture and AOM-associated clinical procedures will be given in Part II and Part III.

According to the World Health Organization (WHO): (1)

> In competent hands, acupuncture is generally a safe procedure with few contraindications or complications. Its most commonly used form involves needle penetration of the skin and may be compared to a subcutaneous or intramuscular injection. Nevertheless, there is always a potential risk, however slight, of transmitting infection from one patient to another (e.g., HIV or hepatitis) or of introducing pathogenic organisms. Safety in acupuncture therefore requires constant vigilance in maintaining high standards of cleanliness, sterilization and aseptic technique.
>
> There are, in addition, other risks which may not be foreseen or prevented but for which the acupuncturist must be prepared. These include: broken needles, untoward reactions, pain or discomfort, inadvertent injury to important organs and, of course, certain risks associated with the other forms of therapy classified under the heading of "acupuncture." Acupuncture treatment is not limited to needling, but may also include: acupressure, electroacupuncture, laser acupuncture, moxibustion, cupping, scraping and magnetotherapy.
>
> Finally, there are the risks due to inadequate training of the acupuncturist. These include inappropriate selection of patients, errors of technique, and failure to recognize contraindications and complications, or to deal with emergencies when they arise.

[Licensed acupuncturists in the U.S. are well-trained. As noted in the introduction to this manual, there are a number of healthcare practitioners, however, who utilize acupuncture with minimal and inadequate training.—Ed.]

This first part of the manual is a review of the medical literature detailing the safety of various acupuncture and related AOM practices along with the uncommon risks or complications that may arise from these practices. Please note that this publication does not cover the safety issues that may arise when utilizing *materia medica*, which is beyond the scope of this manual.

There are a number of acupuncture procedures for which there are very few or no studies of adverse events (AEs). Some of the studies that include AEs in their reporting are limited in their application. Using the principles of evidence-informed practices, the information presented here is the best information available at the time of publication. While there are a number of well devised and reported studies of the minimal AEs associated with acupuncture needling, better, larger studies of AEs associated with moxibustion, gua sha, tui na and other procedures are needed. When these become available recommendations for best practices in these procedures may change.

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1. Acupuncture

Safety/Adverse Events – A Review of the Literature

Acupuncture is the insertion of needles into the skin where the therapeutic effect is expected to come primarily from the act of inserting, manipulating and/or retaining the needles in specific locations. While acupuncture points may be stimulated by a variety of methods by acupuncture practitioners (needling, moxibustion, cupping, manual pressure, electrical stimulation, laser stimulation, magnets, plum blossom, bleeding, and injection therapies among others), when the primary effect is expected from the act of inserting the needle itself, this is acupuncture.

Early reviews of the literature include those by Ernst and White, and Lao who conclude: "The risk of serious events occurring in association with acupuncture is very low, below that of many common medical treatments." (1) "Acupuncture performed by trained practitioners using Clean Needle Technique is a generally safe procedure." (2)

Lao et al. reviewed literature covering the years 1965-1999. "Over the 35 years, 202 incidents were identified in 98 relevant papers reported from 22 countries…Types of complications included infections (primarily hepatitis from a few practitioners), and organ, tissue, and nerve injury. Adverse effects included cutaneous disorders, hypotension, fainting, and vomiting. There is a trend toward fewer reported serious complications after 1988." (2)

It should be noted that single-use disposable sterile needles were becoming more frequent in use in the latter half of the 1980s.

White reviewed a significant body of published evidence regarding AEs associated with acupuncture offering a numerical value of AEs associated with acupuncture treatments. "According to the evidence from 12 prospective studies which surveyed more than a million treatments, the risk of a serious adverse event with acupuncture is estimated to be 0.05 per 10,000 treatments, and 0.55 per 10,000 individual patients. . . .The risk of serious events occurring in association with acupuncture is very low, below that of many common medical treatments." (3)

Later prospective studies conclude similarly that the vast majority of adverse events are minor and require little or no treatment. Park et al. (4) studied 2226 patients over 5 weeks of acupuncture treatments and found only 99 adverse events during that time (4.5%). The most common were bleeding/bruising (2.7%) and needle site pain (2.7%).The most likely moderately severe side effect was nerve injury (0.31%) described as temporary paresthesia which disappeared within 1 week. No serious adverse events were experienced by any patients during this study.

Witt et al. (5) observed 229,230 patients receiving, on average, ten treatments for common complaints such as pain and allergies. Of these, 19,726 reported adverse events (8.6%). Common events again included bleeding/bruising (6.14%), fatigue (1.15%), headache (0.52 %), pain including pain at the site of needle insertion (1.7%), and aggravation of symptoms (0.31%). Serious adverse events included 2 cases of pneumothorax and 31 cases of nerve injury (0.014%). 31 instances of local infections at the acupuncture insertion points were reported (0.014%) and 5 systemic infections were reported. [In the Witt study, 85% of the acupuncture practitioners received only 140 hours of acupuncture-specific training and only 15% had more than 350 hours of acupuncture training.—Ed.]

In the most recent comprehensive review of adverse events associated with acupuncture, moxibustion and cupping, Xu et al. found that between 2000 and 2011 (12 years), "117 reports of 308 AEs from 25 countries and regions were associated with acupuncture (294 cases), moxibustion (4 cases), or cupping (10 cases)." (6) Serious organ and tissue injury continue to be reported but the majority of the acupuncture-associated AEs are infections. Clusters of hepatitis had been reported in the past but not a single case is reported in this period (2000-2011). Notably, the infections had changed from the past association of acupuncture with hepatitis to skin and soft tissue infections such as *Mycobacterium* including *M. abcessus* and *Staphylococcus spp*. This is a significant reduction in the number of infections compared to earlier reports. The authors suggested this reduction in AEs in the U.S. is likely due to the introduction of CNT course. (See page 11 of the paper.) (6)

Preventing Acupuncture Needling Adverse Events

Although rare in terms of frequency, the most common adverse events associated with acupuncture are needle site bleeding, superficial hematoma and needle site pain. Less frequently, fainting due to acupuncture, tiredness, aggravation of symptoms and broken needle are reported. Other practice issues discussed here are stuck needle and forgotten needle.

Bruising and Bleeding

Given the nature of acupuncture needling, it is difficult to prevent all bleeding and bruising. In some cases, some minimal bleeding may be expected and even beneficial. It is possible to prevent severe bleeding and hematomas. Acupuncture practitioners must be aware of the vascular anatomy of their patients. Needling should be performed such that arteries and the larger veins are avoided. Mild pressure applied after needle removal will limit most minor bleeding.

Special consideration must be given to needling of the scalp and the pinna/auricle of the ear. Due to the vascular anatomy of these structures, bleeding is more common. Acupuncturists should apply clean cotton or gauze to prevent bleeding when removing the needles in these

areas and hold that cotton against the scalp or pinna a few seconds longer than when removing needles from other body parts. Additionally, the scalp and/or pinna should be checked a second time after all needles have been removed as bleeding can become apparent after a delay due to the microcirculation in these structures.

Anticoagulant medications may increase the tendency for bruising and bleeding. Some supplements may also have this effect. Obtaining a complete medication and supplement history, and any noted side effects from their use is important information to assess the potentials for bruising or bleeding.

Safety Guidelines to Prevent Bruising, Bleeding, and Vascular Injury

Critical	• Avoid needling directly into arteries and major veins through anatomical knowledge.
	• Identify those acupuncture points which lie over or next to major vessels:
	  ○ LU 9 Taiyuan (radial artery)
	  ○ HT 7 Shenmen (ulnar artery)
	  ○ ST 9 Renying (carotid artery)
	  ○ ST 12 Quepen (supraclavicular artery and vein)
	  ○ ST 13 Qihu (subclavian artery)
	  ○ ST 42 Chongyang (dorsalis pedis artery)
	  ○ SP 11 Jimen (femoral artery)
	  ○ HT 1 Jiquan (axillary artery)
	  ○ LR 12 Jimai (femoral artery and vein)
	  ○ BL 40 Weizhong (popliteal artery)

Strongly Recommended	• Palpate subcutaneous structures, including major vessels, before preparing the site for insertion. • Apply caution in patients on medications or supplements that thin the blood, especially elderly patients. • To avoid superficial bleeding or hematoma, apply pressure to points after removing needles. Reexamine needled sites a second time for signs of bleeding or hematoma and if necessary, apply pressure.
Recommended	• Visualize surface vessels and palpate those vessels immediately adjacent to acupuncture points being needled during needle insertion.

Needle Site Pain/Sensation

Needle pain may occur as a result of a number of factors. Practitioner-related issues that may increase needling sensation include poor technique, needling sites where alcohol remains on the skin, needling into dense connective tissue such as tendons, periosteum and perimysium,

excessive needle manipulation, or needling into a nerve. Patient-related conditions that may increase needling sensation include anxiety, nervousness, and moving body parts during needle insertion. Some needle site sensation, including “heavy,” “tight,” “tingling,” or other discomfort, may be expected or desired (*de qi* response). Acupuncture practitioners should learn which sensations are expected in a *de qi* response so they can differentiate that from nerve pain. Student practitioners need to hone their skills prior to working on patients in order to limit the pain associated with poor technique. Adequate anatomical knowledge and attention to the sensations of the tissues through which a needle is proceeding is needed to avoid needling into structures that stimulate nerve pain. Practitioners should limit the amount of needle manipulation performed with a single-direction twirling motion so as to prevent subcutaneous tissue fibers and fascia from being twisted around a needle shaft beyond that needed for desired therapeutic results.

It is also common that a patient with chronic pain may develop allodynia (a painful response to a normally innocuous stimulus) or hyperalgesia (an increased response to a painful stimulus). When a patient presents with a chronic pain condition such as fibromyalgia, that patient may have an increased sense of pain from either hyperalgesia or allodynia. (7,8)

Caffeine consumption may also affect patients’ pain perceptions. Studies have found that caffeine may attenuate the individual's perception of pain during exercise (9,10) and enhance muscular strength performance. (9) Caffeine consumption may also heighten anxiety and heightened anxiety is associated with increased perception of pain. (11) An early study found that caffeine could block the electroacupuncture-induced elevation of the nociceptive thresholds. (12) Some practitioners have also reported that when patients consume caffeine before acupuncture, they may report an increase in the sensation of needle insertion, particularly in anxious patients.

Safety Guidelines to Prevent Needle Site Pain

Strongly Recommended	• If alcohol is used to clean the acupuncture sites, allow alcohol to dry before needling.
Recommended	• Visualize anatomical structures while inserting the needle and during all needle manipulation. • Palpate subcutaneous structures, including tendons, muscles and bones, before preparing the site for insertion. • Manipulate needle to *de qi* response expected of a specific point, if desired; avoid non-therapeutic pain response.

Fainting

While feeling faint or lightheaded is a possible AE of acupuncture, most studies report that more people report a sensation of faintness or lightheadedness than actually faint after needle insertion. The study by Witt et al. found that while 0.72% of patients have some sort of vegetative symptoms only 0.027% actually faint. (5) White et al. in the Survey of Adverse Events Following Acupuncture (SAFA) study reported presyncope in 93 patients but fainting of only 6 patients. (13) In the report by McPherson et al. 8 patients had symptoms of faintness but only 4 actually fainted. (14)

Many sources report that patients may experience lightheadedness or faintness more commonly during the first time they receive acupuncture, if they are nervous, if there is excessive needle manipulation, or if the patient is particularly hungry or tired prior to needle insertion. (15)

Fainting as a result of acupuncture is reported more frequently in a review of the Chinese literature (16) when compared to outcomes from studies of other countries of origin. This might be associated with strong needling stimulation of patients in a sitting position, which can cause a marked vasodilatation leading to a decrease of blood pressure. (2) Feeling faint can also be associated with more intense needle manipulation. (17)

Safety Guidelines to Prevent Fainting

Strongly Recommended	• Place a first-time patient in the supine position with the knees slightly elevated for the first acupuncture treatment.
Recommended	• Explain acupuncture procedure in detail and answer all questions before acupuncture needle insertion to allay concerns and nervousness. • Inform patients that they should eat 1-2 hours before acupuncture treatments. • Limit needle manipulation during the first acupuncture treatment or until clinical assessment of the patient's response to acupuncture has been established.

Stuck Needle

After a needle has been inserted, practitioners may find it difficult to rotate, lift or withdraw the needle. This is more common if a patient moves after the needle insertion, if the practitioner uses excessive manipulation or twirling of the needle in a single direction, or if the needle is inserted to the depth that it enters into the muscle layer. To manage a situation where the needle is stuck, reassure the patient if he or she is nervous and ask him or her to relax his or her muscles; then massage or lightly tap the skin around the point after which the needle should

more easily be removed. If the needle is still difficult to withdraw, ask the patient to lie calmly for a few minutes or perform another needle insertion nearby so as to relax the muscles in the area of the stuck needle. If the needle is entangled in fibrous tissue, turn it in the opposite direction from the initial needle stimulation, twirling until it becomes loosened, then withdraw the needle.

Safety Guidelines to Avoid and/or Respond to Stuck Needle

Strongly Recommended	• Identify the recommended depth of the needle insertion for a particular point and utilize proper stimulation techniques for needles inserted below the subcutaneous level.
Recommended	• Situate patients in an initial position where they are relaxed and not likely to need to move. Remind patients to remain still during acupuncture treatment. • If a needle that was rotated in one direction becomes stuck, rotate the needle back in the opposite direction. • Stimulate the area near a stuck needle with simple finger manipulation, tapping or another needle insertion; then try again to remove a stuck needle. • Leave a stuck needle in place for a few minutes; then try again to remove the needle.

Failure to Remove Needles

Since 1999, prospective studies identify a small but persistent number of patients in which needles are not removed from the patient before they leave the treatment room or clinic. (5,18)

This error by practitioners may be related to distractions from patient care. Some very basic steps can dramatically decrease the occurrence of this practitioner mistake. Retained needles may be more common within the hairline, on the chest or back if there is significant hair present, on the dorsum of the scalp or neck in a patient lying supine, or in the ear due to the decreased visibility of the small needle handle when partially or fully covered by hair. Palpating areas looking for forgotten needles may increase the risk of needlestick injuries. Documenting the number of needles inserted at the time of insertion and then counting and documenting the number of needles removed at the end of a treatment will help prevent this AE. Use counting and proper documentation to check for missing needles. However, if needle counts do not match, palpation may be necessary but should be done with extreme caution.

Safety Guidelines for Needle Removal

Strongly Recommended	• Count and write down the number of needles used, including those discarded due to improper needle placement. Count the number of needles withdrawn from the patient. Confirm that the same number of needles inserted has been withdrawn and discarded.
Recommended	• Document needle counts in the patient chart. • Keep used/empty needle packets in the treatment room until the end of the patient's treatment; confirm all needles removed from packaging are accounted for either by removal from the patient, discarded unused or discarded after contamination.

Aggravation of Symptoms

Aggravation of symptoms occurs as a result of acupuncture on an infrequent but consistent basis.(6,13,14,18) Aggravation of symptoms is reported both as a potential adverse event and as an intended response to treatment, known as "Menken or Mengen phenomenon," or "healing crisis." (19) Many traditional medicine techniques include deliberate aggravation of symptoms (using a hot bath to bring about diaphoresis in the case of fever, purging as a treatment for gastric distress, etc.). Practitioners need to be clear about expected outcomes when speaking with patients prior to treatments. When aggravation of symptoms includes immediate fatigue and drowsiness, patients should be warned about driving immediately after treatment. (19)

Inflammation may be an expected response to a treatment. Inflammation, including cellular responses to stimuli, may increase the inflammatory response that then brings about improvement of health. (20-23)

The role of transient inflammatory response as a healing, restorative process is widely recognized. Within the tissues, inflammatory proteins transduce intracellular signals to define cellular responses essential to carrying out the healing processes. By manipulating the inflammatory phases of the healing process, it may be possible to accelerate tissue repair functions. (22-26) Aggravation of symptoms from acupuncture may be signaling this healing response.

If an aggravation of symptoms is not the expected outcome of an acupuncture treatment, the acupuncturist should evaluate the diagnosis and treatment plan for the patient and assess whether consultation with or referral to another practitioner would be beneficial.

Safety Guidelines for Aggravation of Symptoms

Recommended	• Inform the patient of the likely effects of acupuncture treatment. • Advise a patient that aggravation of symptoms may be a transient outcome of treatment. • If unexpected aggravation of symptoms occurs as a result of acupuncture treatment, consider consultation with or referral to another practitioner for further evaluation prior to performing additional acupuncture treatments. • Provide patients with information on acupuncture therapies including practitioner contact information in the event they have questions or concerns following treatment.

Preventing Rare but Serious Adverse Events (SAEs) Associated with Acupuncture Needling

Pneumothorax

Pneumothorax is defined as the abnormal presence of air in the space between the lung and the wall of the chest (pleural cavity), which prevents lung expansion. Primary spontaneous pneumothorax (PSP) occurs in healthy people without a precipitating event such as lung illness or puncture. A small area on the surface of the lung that is filled with air ("bleb") ruptures allowing air to pass into the thoracic cavity. Young men who are tall but otherwise healthy are classic presenters of primary spontaneous pneumothorax. In general the rate of PSP is 7.4/100,000 men per year in the U.S. and less for women at 1.2/100,000 per year. (27)

Secondary spontaneous pneumothorax (SPS) is defined as pneumothorax that occurs as a complication of underlying lung disease like chronic obstructive pulmonary disease (COPD), cystic fibrosis, sarcoidosis or lung cancer and so on. (28) 50 to 70% of SSP is associated with COPD in the literature case series. (29)

Traumatic pneumothorax is caused by penetrating or blunt trauma to the chest such as a stabbing, gunshot wound or severe blow. Iatrogenic pneumothorax results from a complication of a diagnostic or therapeutic intervention. (30) Pneumothorax from acupuncture is an example of iatrogenic pneumothorax.

Pneumothorax is a risk of acupuncture needling occurring only twice in nearly a quarter of a million treatments according to Ernst & White: "Those responsible for establishing competence in acupuncture should consider how to reduce these risks." (30) Yamashita et al. found 25 cases of pneumothorax in Japanese literature as of 2001. (18) Reviewing the Chinese literature, Zhang et al. found 201 cases of thoracic organ and tissue AEs with pneumothorax being the most

frequent. (31) Most recently a Xu et al. review of pneumothoraxes reported a total of 13 acupuncture-related pneumothoraxes published from 2000 to 2010 in from China, Japan, UK, New Zealand, Singapore and the U.S. (6) However, additional cases were reported in this time period (32-37) and reports of cases since the Xu et al. review (38-43) indicate pneumothorax continues to be a risk of AE in acupuncture practice.

Symptoms of acupuncture-related pneumothorax can present immediately upon penetrating the lung or hours later. Symptoms may include dyspnea (shortness of breath) on exertion, tachypnea (increased respiratory rate), chest pain, dry cough, cyanosis, and diaphoresis/sweating. (44) Acupuncture practitioners can be unaware of having created a pneumothorax or what point or points were implicated because patients, by necessity, report to an emergency department, and the information regarding practitioner or points used is not recorded.

Patients at increased risk for pneumothorax from acupuncture include cigarette smokers and marijuana smokers and those suffering from lung disease such as chronic asthma, emphysema and COPD as well as patients with lung cancer or who are on corticosteroids. (35) Patients with Marfan syndrome, homocystinuria, and thoracic endometriosis are also more predisposed to PSP than others. (30)

Patients with chronic lung disease will have loss of muscle mass; their musculature thins and “barrels” because ventilatory muscles are chronically overloaded and overworked from airflow obstruction and hyperinflation.

Pneumothorax is also a complication of dry needling. This can be seen with the patient who suffers a pneumothorax during a demonstration of deep dry needling (DDN) to treat the iliocostalis muscle. (45)

The primary areas associated with acupuncture or dry needling-induced pneumothorax are the regions of the thorax including the upper trapezius, thoracic paraspinal, medial scapular, and subclavicular areas. (44)

It is critical that a medical history establishes or rules out increased acupuncture-pneumothorax risk factors such as smoking, including marijuana smoking, and/or history or presence of lung disease such as chronic asthma, emphysema, COPD, lung cancer and/or taking corticosteroids. It is also critical to assess the physique of a patient. A very tall, thin patient or one with atrophy or muscle mass loss from hyperinflation will have a shallow surface to lung depth, increasing the risk of penetrating the lung resulting in pneumothorax. Needling should be limited to superficial penetration over the chest, back, shoulder and lateral thoracic region, no deeper than the subcutaneous tissue. It is also strongly recommended to use needles that are not

longer than safe needling depth at any thoracic region area including the Huatuojiaji points, bladder channel, and any intercostal space.

Safe needling depth is recommended at 10-20 mm; less than the face width of a U.S. nickel, 20-cent Euro coin, Canadian 25-cent piece or English 20 pence. Rather than needling at a perpendicular angle, it is strongly recommended to needle at an oblique angle. This also ensures that needles will not travel deeper into the body. Placing a blanket over needles in the thoracic area caused needles to be inserted deep enough to cause a pneumothorax in one reported case. (46) Oblique needle placement would prevent this complication.

Care should be taken when needling the GB 21 (Jianjing) and the upper trapezius muscle since the apex of the lung extends 2–3 cm above the clavicular line. (44) Incorrect needling of this area has been associated with pneumothorax.

Points most frequently associated with pneumothorax events in the Chinese literature (31) are: Jianjing (GB 21; 30%), Feishu (BL 13; 15%), Quepen (ST 12; 10%), and Tiantu (Ren 22; 10%); infrequent events occurred at Ganshu (BL 18), Jiuwei (Ren 15), Juque (Ren 14), Jianzhen (SI9), Quyuan (SI 13), and Dingchuan (EX-B1).

Peuker & Grönemeyer identify risk points ST 11 (Qishe) and ST 12 (Quepen), LU 2 (Yunmen), ST 13 (Qihu), KI 27 (KI 22-27), and ST 12-18. (47) However, any points needled in the thoracic body region risk penetrating the lung, including the front, back, or lateral body, the lower neck, shoulder and scapular region as well as the chest, ribs and just below the ribs depending on the position of the patient.

Safety Guidelines to Avoid Pneumothorax

Critical	• Obtain a medical history from a patient regarding lung function, lung diseases and smoking history before needling on the chest or back. • Assess physique of a patient. A very tall, thin patient or one with atrophy or muscle mass loss from hyperinflation will have a shorter depth of surface to lung, increasing the risk of penetrating the lung resulting in pneumothorax. • Safe needling depth to avoid pneumothorax on most patients can be as little as 10-20 mm. • Limit the depth of acupuncture needle insertion to the subcutaneous layer and initial perimysium of the intercostal muscles.
Strongly Recommended	• Needle at an oblique angle rather than at a perpendicular angle in the thoracic body (from the top of the shoulders to the T-10 area on the back, or from the top of the shoulders to the xiphoid level on the chest). This also ensures that needles will not travel deeper into the body from the weight of a sheet or gown used to cover the patient. • Limit vertical manipulation of needles on the chest or back.

	• Do not cup over needles on the thorax in the area of the lungs to avoid tissue compression that can cause needle penetration to internal organs. • If there are indications or suspicions that an organ may have been punctured, emergency transport should be called to take the patient to an emergency medical facility.
Recommended	• Avoid using needles that are longer than the safe needling depth for a particular body area. • One method to reduce risk at GB 21 (Jianjing): While isolating and lifting the trapezius muscle with a pincer grip using the opposite hand, needle across the muscle at GB 21 (Jianjing), taking care to direct the needle obliquely and not inferiorly toward the lung.

Injury to Other Organs

Injury to internal organs is a reported serious adverse event of acupuncture. (1,6,31) Heart injury is an extremely rare complication of acupuncture; however, fatalities have been reported. Xu et al. (6) report five cases of heart injury including two of cardiac tamponade and three other heart injuries during a 12 year period. Ernst and Zhang report 26 cases of cardiac tamponade with 14 fatalities since 1956; however cases of self-injury and accidental injury are included along with cardiac injury during acupuncture. (48) As an example, a case that is still sometimes cited as an "acupuncture fatality" resulted from a self-inflicted sewing needle and not from actual acupuncture practice. (49) Of the cases reported by Ernst and Zhang, only one is of a needle penetrating a sternal foramen, three were self-treatment when the goal of treatment was unclear. The majority of cases involved migration of needles or parts of needles broken off in the body. (48) Such embedded needles are not part of modern acupuncture. Excessive needle length (60 mm) is described as contributing to another case report and must be avoided. (50)

Although rare, the risk of sternal foramen must be considered. Insertion through a congenital defect in the sternum appears to be the mechanism of injury in two of the cases reported by Ernst and Zhang. (48,51,52) In a case reported from Austria in 2000, an emaciated 83-year-old woman was needled at Ren 17 (Shanzhong). The needle was inserted by an experienced acupuncturist through a sternal foramen. Symptoms appeared within 20 minutes. The report describes that the 30 mm needle may have been inserted perpendicularly in an emaciated patient. (52) Peuker and Grönemeyer (53) report that the incidence of a sternal foramen at the level of the fourth intercostal space exists in 5-8% of the population. This demographic is confirmed in recent CT studies. (54) Palpation cannot reveal the defect (53) and there is no correlation between the depth of subcutaneous fat and distance to a vital organ. (54) While the placement of internal organs directly under a sternal foramen and the depth from skin to organ

varied, CT scans suggest that 25 mm is the maximum safe insertion depth to avoid injury to the heart. (54)

In addition to depth, angle of insertion when needling the chest must be considered. Oblique or transverse needling on points located on the chest and avoiding an upward direction at Ren 15 (Jiuwei) is critical to prevent heart injury.

Symptoms of cardiac tamponade include anxiety, restlessness, low blood pressure and weakness, chest pain radiating to the neck, shoulder, back or abdomen, chest pain that gets worse with deep breathing or coughing, problems breathing or rapid breathing, discomfort that is relieved by sitting or leaning forward, fainting or light-headedness, palpitations, drowsiness, and/or weak or absent peripheral pulses.

There are reports in the Western literature of injury to other internal organs but most are not recent. Zhang et al. (31) review serious AEs from the Chinese literature and report 16 cases of abdominal organ and tissue injury including perforations of the gallbladder, bowels, and stomach with peritonitis. Injury was attributed to needling too deeply; the points cited are ST 25 (Tian Shu), Ren 12 (Zhongwan), and LR 14 (Qi Men) in the treatment of abdominal pain, appendicitis or cholecystitis.

Reporting on an acupuncture needle that remained in a lung for 14 years, Lewek et al. reviewed 25 cases of migration of needle fragments and they include to the liver, pancreas, stomach, colon, breast, kidney, and muscles and spinal cord. (55) Additionally, there are case reports of foreign body stones formed around needle fragments in the ureter (56) and bladder. (57) As mentioned above, such embedded needles are not part of modern acupuncture.

Before administering acupuncture, special care should be taken to examine the patient for any suspected organ enlargement. Abnormal changes in the internal organs may come from a variety of diseases. Changes in heart size may be a result of chronic hypertension and congestive heart failure. Hepatomegaly may be a result of a number of diseases including alcoholism, chronic active hepatitis, hepatocellular carcinoma, infectious mononucleosis, Reye's syndrome, primary biliary cirrhosis, sarcoidosis, steatosis, or tumor metastases. Splenomegaly may be caused by infections such as infectious mononucleosis, AIDS, malaria, and anaplasmosis (formerly known as ehrlichiosis); cancers, including leukemia and both Hodgkins and non-Hodgkins lymphoma; and diseases associated with abnormal red cells such as sickle cell disease, thalassemia, and spherocytosis.

Puncturing the liver or spleen may cause internal bleeding, although severe responses are rare and no cases of liver or spleen injury have been reported in English in the past twelve years. (6) Symptoms of such organ injury include abdominal pain, rigidity of the abdominal muscles,

and/or rebound pain upon pressure. Puncturing the kidney may cause pain in the lumbar region, tenderness and pain upon percussion around the kidney region, and bloody urine.

Central Nervous System Injury

Acupuncture-related central nervous system injuries are reported more often in Eastern literature. (3,53) Xu et al. (6) report nine cases of central nervous system injury over the 12 year period reported in that document. Like the heart injury cases reported above, a few spinal cord injuries were caused by migrating broken needles. Deep needling may also cause damage to the spinal cord. According to Peuker and Grönemeyer, "The distance from the surface of the skin to the spinal cord or the roots of the spinal nerves ranges from 25 to 45 mm, depending on the constitution of the patient. Deep needling of points of the inner line of the bladder meridian (BL11 to 20) was particularly likely to cause lesions of the spinal cord or the spinal nerve roots." (53)

Safety Guidelines to Avoid Organ and Central Nervous System Injury

Critical	• Observe safe needling depth and angles to avoid cardiac injury.
	  ○ To avoid penetration at a sternal foramen, use an oblique angle to needle on the sternum.
	  ○ Limit the depth of acupuncture needle insertion to the subcutaneous layer.
	• Needling Du 22 (Xinhui) in an infant is prohibited.

Strongly Recommended	• All patient histories should include information about current or past diseases that might lead to a change in the size of the organs. • Do not cup over needles on the abdomen to avoid tissue compression that can cause needle penetration to internal organs. • Limit vertical manipulation of the needles on the abdomen.
Recommended	• If there are indications or suspicions that an organ may have been punctured, emergency transport should be called to take the patient to an emergency medical facility. • Avoid using needles that are longer than the safe needling depth for any given body area.

Traumatic Tissue Injury

Peripheral Nerves

Peripheral nerve injuries are reported infrequently (53) and may include a needle fragment within the carpal tunnel causing median neuropathy, median sensory neuropathy from needle injury, (59) peroneal nerve palsy, (60) and in one case resulting in drop foot. (61) Four cases of peripheral nerve injury are reported in China, three related to needling of LI 4 (Hegu) on the hand. Included in this report was the observation that a forceful needle manipulation at this

point can cause peripheral nerve injury. (53) A case of Bell's palsy 24 hours after acupuncture is reported by Rosted & Woolley. (62)

Blood Vessels

Two cases of vascular injury are reported in the U.S.: acute intracranial hemorrhage in a patient given acupuncture for neck pain (63) and cerebrospinal fluid fistula in a patient treated for low back pain with embedded needles. (64)

Acupuncture needle nicks to a capillary or vein resulting in minor bleeding or superficial hematoma are not uncommon. Injuries to blood vessels resulting in more serious complications, such as compartment syndrome, deep vein thrombosis, popliteal artery occlusion, aneurysm and pseudoaneurysm as well as arterial injury are rare but are reported. (4,65) More recently a serious thigh hematoma resulted from acupuncture treatment in an 82-year-old woman taking warfarin. (66) Her INR was stable at 2.4; it appears the additional risk factors in this case related to deep needling and the age of the patient complicated by anticoagulant therapy.

Safety Guidelines to Avoid Traumatic Tissue Injury

Critical	• Follow *Safety Guidelines to Prevent Bruising, Bleeding and Vascular Injury.*
Strongly Recommended	• To reduce risk of peripheral nerve injury, avoid aggressive needle manipulation in anatomical areas with a record of risk such as the hand and wrist, ankle and fibular head. • If a patient experiences acute severe pain from needling a point do not continue to manipulate the needle but withdraw to a shallower depth or remove it entirely.

Infections

Infections may be local or systemic, due to an autogenous source (the patient) or be a cross infection (from the practitioner or others). One in three people are carriers of *Staphylococcus aureus*, and 1 in 10 is a carrier of MRSA. Likewise, *Mycobacterium* may be part of common skin flora. A carrier may have no symptoms or indications they are a carrier unless they are tested, typically with swabs of the skin, nose or mouth. *S. aureus* or MRSA can infect wounds and prevent healing, cause blood infection (septicemia), or infect organs, bone, heart valve/lining or lung, and/or create an internal abscess. Patients are often hospitalized, may require surgery, months of IV antibiotics and may experience lifelong sequelae or even death.

Recent reports of acupuncture-related infection are of skin and soft tissue such as mycobacterium including *Mycobacterium abscessus* and *Staphylococcus aureus* including MRSA. Of the 239 cases reported for the period of 2000-2011, 193 were mycobacterium infection. The source of most of these infections was traced to reuse of improperly disinfected

needles or therapeutic equipment or use of contaminated disinfectant or gel used for related procedures. (6)

While infections associated with acupuncture needling are a rare occurrence, any disruption of the normal barriers to infection, such as puncturing through the skin and epidermal flora, can allow a pathogen to enter the body. Those with a reduction in normal immune function may then not respond adequately to the pathogen, allowing an infection to start. Reduction in normal immune function may take place due to a number of life situations and diseases such as in persons who have significant stress, use corticosteroids and other immune suppressing drugs, or who have cancer or immune suppressing diseases such as AIDS. As other conditions and diseases may also compromise immune function, acupuncture practitioners should take care to use Clean Needle Technique with all patients to prevent infections.

Care should be taken to limit even the rare but measurable risk of infection associated with needling. The Clean Needle Technique discussed in Part II of this manual is designed to limit exposure of patients from both autonomous and cross infections, and to limit exposure of practitioners and their staff from infections which are part of any medically-related practice.

See Part IV for a more thorough discussion of healthcare associated infections.

Safety Guidelines to Prevent Infection

Critical	• Follow Clean Needle Technique. • Follow Standard Precautions: Consider all patients as if they are carriers of bloodborne pathogens such as Hepatitis (HBV), Hepatitis C (HCV), HIV, Staph or MRSA. • Follow *Safety Guidelines for Hand Sanitation.* • Follow *Safety Guidelines for Preparing and Maintaining a Clean Field.* • Follow *Safety Guidelines for Skin Preparation.* • Use only single-use sterile needles and lancets. • Check needles before use for sterilization expiration dates, breaks in the packaging or any evidence that air or water has entered the needle packaging prior to use. • Wear gloves or finger cots or otherwise cover up any areas of broken skin on the practitioner's hands. • Maintain clean procedure at all times while handling needles before insertion. If needles or tubes become contaminated, they should be discarded. • Do not needle into any skin lesion. Acupuncture needles should never be inserted through inflamed or broken skin. • Use only sterile instruments when breaking the skin surface (needles, plum blossoms, and lancets). • Immediately isolate used needles in an appropriate sharps container.

	• When using a multi-needle pack of sterilized needles, once the packaging is opened for one patient visit, any unused needles must be discarded properly and not saved for another patient treatment session. • Follow guidelines for disinfecting reusable adjunct therapy tools after every use. • Use new table paper (or clean linen if using cloth coverings) on each treatment table for each new patient visit. • Wipe down each treatment chair or table with a disinfectant solution or disinfectant cloth between each patient visit.
Strongly Recommended	• Guide tubes must be sterile at the beginning of the treatment and must not be used for more than one patient. • When needle stabilization is needed, the practitioner should use sterile cotton or sterile gauze to stabilize the shaft of the needle. • If you stick yourself with a used or contaminated needle, seek medical advice. • Clean all treatment room surfaces with approved disinfectants daily.
Recommended	• While it is acceptable to palpate the cleaned area of skin to precisely locate the acupuncture point after the skin is cleaned and before needling, the practitioner should not trace fingers or hands across a wide area of skin to locate an acupuncture point after the skin is cleaned and before needling. • When desired after needle withdrawal, apply pressure to the acupuncture point with clean cotton or gauze. • Clean all office common use areas with an approved disinfectant daily.

Broken Needle

The advent of the single-use disposable sterile stainless steel acupuncture needle has significantly reduced the previously uncommon but occasionally occurring broken needle. Metals are made brittle by the heating and cooling associated with autoclave sterilization procedures; moreover, the quality of metal materials used for needles has advanced. With single-use needles, the risk of the broken needle approaches zero. However, manufacturing errors may still allow for such events and the practitioner should be aware of how to handle such a situation. Neither White (3) nor McPherson (14) reports any broken needles during their prospective studies. Witt et al. reports 2 broken needles out of 229,230 patients treated. (5)

A broken needle may occur if: (a) there are cracks or erosions on the shaft of the needle, especially at the junction with the handle; (b) the quality of the needle is poor; (c) the patient has changed position to too great an extent; (d) there is a strong spasm of the muscle; (e) excessive force is used in manipulating the needle; (f) the needle has been struck by an external

force; or (g) a bent needle has been rigidly withdrawn. In an era when only single-use disposable needles should be used, needle breakage has become a highly unlikely occurrence.

To manage a broken needle, the acupuncturist should remain calm and advise the patient not to move so as to avoid causing the broken part of the needle to draw deeper. If a part of the needle is still exposed above the skin, remove it with forceps. If it is on the same level with the skin, press the tissues around the site gently until the broken end is exposed, then take the needle out with forceps. If it is completely under the skin, seek medical help immediately. Do not cut the flesh to get access to the needle. Remove all other needles. Call for emergency transport to a hospital or medical facility where a physician can remove the needle shaft.

The most effective way to prevent a broken needle is compliance with single-use disposable needles. If needles or packaging appear defective in any way, do not use those needles for patient care. Dispose of the defective needle in a sharps container and use another sterile needle. Use the appropriate needle size and length for the location and technique to be used.

Safety Guidelines to Prevent Broken Needles

Critical	• Inspect needle for defects in manufacturing before use.
Strongly Recommended	• Use only single-use sterilized needles. • Never insert a needle to the handle.

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2. Moxibustion

Safety/Adverse Events – A Review of the Literature

In modern U.S. AOM practice, moxibustion is most often used as a complement to the practice of acupuncture. Moxibustion is the heating of a point on the skin utilizing moxa in various forms. The most commonly used herb material used for moxa comes from *Artemisia vulgaris*, also called mugwort. Practitioners use a number of different materials for moxibustion, including various shapes of mugwort including loose moxa, various sizes of moxa cones, and the more commonly used moxa roll, both the traditional type and the "smokeless" type. Practitioners may utilize moxa cones or moxa sticks for warm moxibustion, warm cylinder moxibustion, and, in certain cases, burning/scarring moxa.

Most TCM practitioners utilize moxibustion therapy along with needling acupuncture points for a wide range of disorders. A general overview can be found in the text *Chinese Acupuncture and Moxibustion.* (1) The use of moxibustion is widespread and studies have reported effectiveness in a wide variety of conditions from musculoskeletal complaints, gastrointestinal symptoms, gynecologic disorders, breech presentations, stroke rehabilitation, and complementary care for cancer symptoms, to the treatment of infectious diseases. (2) Licensed acupuncture practitioners have extensive training in the many and varied uses of moxibustion therapy.

There have been few retrospective studies of the safety of direct and indirect moxibustion treatment. In 2010 Park et al. (2) attempted to review the medical literature and provide an overview of adverse events associated with moxibustion. While data was limited, the clinical trials they reviewed identified "rubefaction, blistering, itching sensations, discomfort due to smoke, general fatigue, stomach upsets, flare-ups, headaches, and burns" as adverse events. In general, they concluded that practitioners should be prepared to deal with burns, allergic reactions and infections as probable adverse events of moxa therapies. In the 2013 report, Xu et al. (3) report AEs associated with moxibustion were found to be primarily bruising, burns, and cellulitis.

Prospective studies of moxibustion therapy alone are not available in the English literature. In 1999, a Japanese study (4) failed to differentiate between adverse events associated with acupuncture needling and that associated specifically from moxibustion. Their conclusion was that "serious or severe adverse events are rare in standard practice."

While practitioners can probably understand the association of burns with any type of heat therapy, the possibility of infection, nausea or allergies associated with moxa therapy is less self-evident. Infections can be the result of burns that disrupt the normal function of the skin and subcutaneous barriers to infection. One case associated with scarring moxa therapy identified an epidural (cervical) abscess, cellulitis and osteomyelitis in a diabetic woman after

repeated direct moxa therapy. (5) Burns from any therapeutic modality are more common in diabetic patients. (6)

Infections associated with moxibustion may also be a result of other practices that are used along with the moxa such as needling or scarring therapies. (2)

Allergies to the moxa smoke, or response to the volatile substances such as borneol in the moxa smoke may create nausea or allergic reactions. “Under normal operating conditions neither volatile nor carbon monoxide [associated with moxa smoke] would present a safety hazard.” (6) With proper ventilation, the toxicity of moxa smoke is probably minimal. (7,8)

Chinese medical literature also reports only minimal AEs associated with moxibustion techniques. A few reports in the Chinese literature on the adverse events associated with moxibustion mainly detail some local AEs such as burning of the skin, and skin allergies associated with moxibustion practice. (9)

Effects of moxibustion on chemical parameters of health are limited, suggesting that except for AEs such as burns, moxibustion is a relatively safe procedure. In a study published in 2011, researchers found that indirect moxibustion is generally considered safe. (10)

One case report of hepatitis in the medical literature was inaccurately identified as being associated with moxa use. This report stated that a patient “presumably acquired hepatitis C through sharing of infected knives during the process of scarification or through moxibustion if it involved the use of needles . . .” (11)

Contraindications for direct or scarring moxibustion involve the sensitive areas of the body, such as the face (due to the possibility of burns, and also to avoid getting smoke directly into the eyes or nose), the nipples and the genitals (due to sensitivity) and within the hairline (as hair can burn). O'Connor and Bensky in *Acupuncture: A Comprehensive Text* (12) reinforce the need to avoid the head and face for moxibustion by reporting that ancient texts advised caution or prohibition when applying moxibustion to the following points: Shangxing (DU 23), Chengqi (ST 1), Sibai (ST 2), Touwei (ST 8), Jingming (BL 1), Zanzhu (BL 2), Sizhukong (SJ 23), Heliao (LI 19), Yingxiang (LI 20), and Renying (ST 9).

Preventing Moxibustion Adverse Events

Burns

Practitioners performing moxibustion should avoid causing burns (except when performing scarring moxibustion) and be aware that each person has a different tolerance to heat. It is important to be especially careful with persons who have conditions where sensitivity of local

nerves may be diminished, such as in neural injury, diabetes mellitus, or pathology resulting in paralysis, because such persons are especially susceptible to burns.

When using indirect moxa on the needle, be sure to protect the patient's skin from any falling moxa or ashes. If using direct moxa or scarring techniques, it is suggested that the practitioner fully explain the technique to the patient and ask the patient to sign an informed, written consent form before using this technique.

If a patient has been burned, infection is the primary concern. If the burn is a very small first degree burn, current practice is to run cool water over the burn (never ice), and then apply sterile gauze secured to the skin with medical tape. Over-the-counter burn creams may also be used as per the package directions. If a burn is severe, or if there is a concern with infection, refer the patient to a physician.

Burns to the practitioner can also occur when proper precautions are not taken. See Part III for details of safe moxa practices.

Safety Guidelines to Prevent Moxa Burns

Critical	• Take a careful patient history to identify neuropathies or other conditions that might limit a patient's response to pain or the ability to sense heat. • During moxa therapy the practitioner must remain in the room at all times. • Avoid direct moxibustion on the face, within the hairline, or in other highly sensitive areas. • Anticipate and shield a patient from falling ash when utilizing needle-top moxa.
Strongly Recommended	• The practitioner should not attempt to multi-task during the application of moxa therapies. • The practitioner should monitor the skin temperature and amount of heat generated by moxa, and not rely solely on patient feedback about heat sensations when utilizing any form of moxibustion.
Recommended	• Rooms in which moxa is to be used should be equipped with water and a fire extinguisher.

Secondary Infection from Moxa Burns

Infections associated with moxibustion are secondary adverse events related to burns. Burn. Burn prevention is critical.When more than 1 cm of skin is involved with a burn, practitioners need to assess the amount of skin damage and consider a referral to a medical practitioner for treatment.

Safety Guidelines to Prevent Secondary Infection from Moxa Burns

Critical	• Prevent moxa burns. • Paying close attention to patient comfort and skin reactions during all treatments can prevent second degree burns, which are more likely to become infected due to depth of tissue damage. • Follow *Safety Guidelines for Hand Sanitation* before and after treating any burns as potentially infectious material may be present. • Wash all burns that do occur with cool running water immediately.
Strongly Recommended	• Measure and chart the diameter and location of any burns occurring as a result of moxa therapies.
Recommended	• Assess the amount of damage and refer to a western medical practitioner if needed.

Nausea or Other Adverse Reactions to Moxa Smoke

Both practitioners and patients may have a reaction to inhaling moxa smoke. Such reactions are usually temporary and can be minimized by proper ventilation of the treatment room.

Safety Guidelines to Prevent Adverse Reactions to Moxa Smoke

Critical	• Rooms in which moxibustion is performed must have proper ventilation.
Strongly Recommended	• Practitioners should utilize air filter units which include HEPA filters when performing moxibustion.
Recommended	• Consider other options for treatment instead of burning moxa for patients with a history of significant asthma or other reactions to smoke.

Other Heat Therapies

Infrared and TDP (Teding Diancibo Pu) lamps are used by practitioners to warm the patient, or specific areas of a patient. TDP lamps consist of a heating element on an adjustable arm that may be placed above the patient and is used to warm the patient's skin. The heating element in the lamp may reach a temperature that will burn a patient. It is imperative that a TDP lamp be monitored carefully when in use, and that unexpected movements of the heating element are prevented. Some lamps may slowly lower during the course of a treatment, resulting in a burn over the area being warmed. Mechanical failure of the heat lamp itself may occur during treatment allowing the arm and heating element to rapidly descend near or onto the patient's skin. To prevent such a burn, TDP lamps should be carefully checked for defects before use. Defective or dysfunctional heating devices including TDP lamps should not be used in any clinic. In the event of such a burn, the injured area should be evaluated by a physician.

There are no prospective studies on the use of heat lamps or other heat therapies in AOM practice. One study utilizing heat therapies in cancer treatment identified AEs of "thermal lesions" from this practice. (13) Heat can affect skin in a variety of ways, including biological and molecular changes (14) although these effects appear minimal when applied intermittently in clinical practice. Significant adverse events of heat lamps and other heat therapies is most likely limited to burns, the secondary effects of burns (infection) and the possibility of fire. See above information about moxibustion for common practices to limit these AEs.

In one retrospective study of the frequency of burns from therapeutic modalities performed in Korea, hot packs were twice as likely to cause a burn as was the application of moxibustion. Other heat therapies that were sources of burns in patient care included the use of electric heating pads and radiant heat/heat lamps. (15)

Safety Guidelines for Heat Therapies Other than Moxa

Critical	• Heat lamps should not be used on infants, children, incapacitated persons, or sleeping or unconscious persons. • Prevent water, moisture, liquids or metal objects from coming in contact with the lamp. Do NOT use this lamp in wet or moist environments. • Do not use if any part of the lamp is cracked. Do not allow any part of the lamp to touch accessory equipment. • When heat lamps are used on patients who have a reduced response to heat, the use of heat must be monitored at all times.
Strongly Recommended	• Do not use heat lamps in close proximity to combustible materials (litter, paper, etc.) or to materials adversely affected by heat or drying. • Take a careful patient history to identify diabetes, neuropathies or other conditions that might limit a patient's response to pain or the ability to sense heat. • Do not use oversensitive skin or persons having poor blood circulation. Sufficient temperatures are generated that may cause burns. • Heat therapies must be closely monitored by practitioners. • The practitioner should monitor the skin temperature and amount of heat generated by a heat lamp and not rely solely on patient feedback about heat sensations.
Recommended	• When patient information is unclear, request an opinion from a physician before using a heat lamp on the limbs of a patient with diabetic or other neuropathies.

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3. Cupping

Safety/Adverse Events – A Review of the Literature

Cupping is a commonly used therapeutic procedure used by AOM and other healthcare practitioners. Cupping uses a partial vacuum that causes the tissue to tumefy and stretch into the cup. Cupping intentionally creates therapeutic petechiae and ecchymosis that appear in round or "nummular" areas. (1)

There are three types of cupping, each with different safety profiles: fire cupping, suction cupping, and wet cupping (cupping after the use of a lancet for blood withdrawal). Fire cupping and suction cupping are variations of dry cupping. Both dry and wet cupping are used in traditional East Asian medicine, the traditional medicine of Gulf Arabs (hijamah), (2) in European countries, and in early Western medicine and its lineage of early Greek, Roman and Egyptian medicine. Cups used in the modern setting are made of glass, plastic, or silicone.

Cupping is utilized by practitioners to treat conditions including acute or chronic pain; mild to severe conditions such as colds, flu, and fever; respiratory problems such as asthma, bronchitis, and emphysema; functional internal organ problems; musculoskeletal problems; and in any case of recurring or persistent fixed pain. (1,3) "Since 1950…cupping therapy has been applied as a formal modality in hospitals throughout China and elsewhere in the world." (4)

Xue et al. (5) report that over a 12-year period most AEs associated with cupping were minor and were primarily keloid scarring, burns and bullae. Other reviews similarly report no serious AEs from cupping. (1,3,6) However, there are adverse events, serious adverse events and negligent errors reported in the literature from cupping and, while not common, most can and must be avoided.

Fire Cupping

Burns from fire cupping are reported in the literature; they are an avoidable medical error/adverse event. (6-11) In this procedure, a ball of burning cotton or a lit alcohol swab is briefly placed inside a glass cup to heat the air inside, which then creates a partial vacuum as it cools. Glass cups are used, as glass is impervious to heat at the levels used for this procedure. Typically, cups are left on the patient's skin for 2-10 minutes, but may be left in place for up to 20 minutes, and leave a temporary reddish mark that is a result of cutaneous petechiae and ecchymosis. Unintentional expression of blood or fluid into cups may occur as a result of fire cupping when the skin is not intact, or from previous needling, local pimples or other local skin pathologies.

Burns may be a result of placing the flame too close to the lip of the fire cup so that the edge becomes very hot, or from dropping the burning material into the fire cup, then placing the cup

on the skin with the hot material inside the cup. While this latter procedure has been used traditionally, modern cupping should limit this process.

Suction Cupping

Suction cupping involves the use of plastic or silicone cups with valves at the top that attach to hand pumps; the pumps create suction by removing a quantity of air after the cups have been placed on the skin. Typically cups are on for 2-10 minutes, but may be left in place up to 20 minutes and leave a temporary reddish mark that is a result of cutaneous petechiae and ecchymosis. Unintentional expression of blood or fluid into cups may occur as a result of suction cupping when the skin is not intact, or from previous needling, local pimples or other local skin pathologies.

Wet Cupping

In this procedure, the skin is punctured with a lancet or sterile needles, such as those used for plum blossom tapping, before the cups are applied. Wet cupping may be done with either suction cups or fire cups. The technique, which draws out blood and OPIM, carries obvious risk of exposure to and transfer of bloodborne pathogens.

Other Cupping Procedures

Practitioners also use cupping techniques that include moving or sliding cupping during which practitioners gently move the cup along a lubricated surface area, channel, or along muscle fibers; empty cupping, which means the cups are removed after suction without delay; or needle cupping, during which the practitioner applies the acupuncture needle first, then applies the cups over the needles. The risks of the first two techniques are quite limited. In the last technique, the risks are more related to the needling than the cupping. Cupping may compress the tissue, causing acupuncture needles to penetrate more deeply with needle cupping, or subcutaneous tissues may be pulled upward with the same effect, increasing the risk of pneumothorax or other organ puncture if done over the thoracic region. If needling cupping is done over other areas of the body, there may be risk to the central or peripheral nerves or blood vessels. Needle cupping should be applied with caution and with needles inserted at an oblique angle.

Cupping Adverse Events

Skin Reactions

Some reactions to cupping may be part of the therapeutic process but be interpreted by other practitioners or observers as “harms” (12) or even child abuse. (13, 14) These include swelling, petechiae, ecchymosis, and persistent hyperpigmentation. Typically these reactions resolve in a few days to 2 weeks. (1) Research has not established standards for the appropriate time for cups to be left in place or the amount of vacuum suction that is ideal; excessive cupping time or

suction can create bruising and hyperpigmentation that is uncomfortable and persists for much longer.

Fluid blisters called bullae are not an infrequent outcome of cupping. (14-17) If these contain blood they are called hemorrhagic bullae, and are less common and may be more likely in patients on anticoagulant medications and supplements that may act as blood thinners. They can form crusting scabs as they heal, which can take up to 2 weeks. (18) The opening of the skin barrier over time creates exposure and risk of infection. In the inadvertent event of suction bullae, patients should be instructed on use of antibiotic topical ointment, and on keeping the area clean and covered, if necessary, until healed.

Other unusual skin lesions reported in the cupping literature are panniculitis and keloid scarring. Factitial (self-inflicted) panniculitis (fatty layer inflammation) can be produced by mechanical, physical or chemical trauma. (19) It presents as red nodules, inflammation within the circular area where cups were applied. It is typically self-limiting and fades like a deep bruise within 6 weeks, but can become infected and require surgery. (16) If a patient develops red subcutaneous nodules, avoid further cupping and refer for medical observation.

Two articles in the literature establish that it is possible to induce Köebner phenomenon in psoriasis patients. (20, 21) These articles describe the appearance of psoriasis lesions from pressure or trauma to the surface. History or presentation of psoriasis in a patient might caution against aggressive cupping, or cupping at all.

One case in the literature reported the development of a keloid scar at the upper back from a cupping treatment for cough. (22) The patient had not had previous keloid scarring, making this an unanticipated adverse event. It is recommended to proceed with caution, to avoid cupping or strong cupping in patients who already have keloid scars.

Cardiovascular

Cupping is associated with adverse events involving the blood and heart. Iron-deficiency anemia (IDA) in men in Korea not identified from other known causes is suggested (but not established) as related to wet cupping. (23) Lee et al. (24) do report on a single case of excessive wet cupping over 6 months inducing IDA where other causes were ruled out. The patient recovered after stopping wet cupping and supplementing with iron. Sohn et al. (25) report on a woman who self-applied wet cupping over 10 years, and created severe iron deficiency anemia and an enlarged heart (cardiac hypertrophy) that regressed over time once she stopped wet cupping, and supplemented with prescription medicine and iron. Some of her cardiac symptoms persisted at 3 months.

Kim et al. (26) report on a case of repeated dry cupping causing anemia but offer no evidence other than persisting hyperpigmentation. (27) They also assert that traditional cupping caused a delay in care when the patient had already consulted conventional doctors for back pain.

A rare complication of acquired hemophilia A was caused by cupping in a 58-year-old woman. (28) It presented as extensive and compressive bruising which led to pending compartment syndrome of her left thigh 2 days after cupping, resulting in hospitalization. Acquired hemophilia A is very rare but can develop in association with autoimmune disease, allergic drug reactions, malignancies, and pregnancy with higher risk in depression and anxiety. For our purposes to note, the patient was cupped on the medial aspects of the thigh and arm.

Vasovagal syncope, a rare AE of cupping, (16) is more likely to occur with underlying conditions that may increase the risk for syncope (diabetes, renal disease, seizure disorders, fasting or low blood sugar).

An interesting case of stroke 14 hours after cupping was attributed to cupping points in the location of application. Cups were applied to the neck close to an artery. A pre-existing condition of partial arterial occlusion was not identified. The force of cupping was thought to have either elevated blood pressure creating hemorrhage or stroke (least likely), or to have precipitated an intimal tear of the lining of the artery, or have created sufficient local stress as to disturb a “thin cap” at an occlusion site. (29) Consideration must be given to applying cups over the areas of the neck that are close to arteries.

Infections

Infection has been reported as an adverse event of cupping. Lee et al. (30) describe a case of cervical epidural abscess (C1-C3) from acupuncture with cupping that resolved with oral antibiotic treatment. Jung et al. (31) report a case of herpes simplex from acupuncture and cupping where the herpes lesion developed in a circular pattern that matched the circumference of the cups, and at the acupuncture puncture sites that had been applied. The patient had no personal or family history of recurrent cutaneous herpes simplex virus (HSV). HSV can be spread by abraded skin. Traditional cupping was also one risk factor for high prevalence of HTLV-I infection in Northeast Iran, along with blood transfusion and hospitalization. (32) Turlay et al. (33) describe a lumbar abscess from scarification wet cupping. These cases point to the possibility of transfer of bloodborne pathogens from cups. Hon et al. (34) report a case of an 11-year-old girl who developed *Staphylococcus aureus* infection from cupping, resulting in hospitalization. The patient was being treated for chronic eczema. Colonization of *S. aureus* is commonly seen in chronic eczema patients.

Preventing Cupping Adverse Events

Burns

Burns are associated with fire cupping only. General safe practices for use of an open flame should be followed.

Safety Guidelines to Avoid Fire Cupping Burns

Critical	• Take a careful patient history to identify diabetes, neuropathies, or other conditions that might limit a patient's response to pain or the ability to sense heat. Assess this patient carefully when utilizing fire cupping.
Strongly Recommended	• The burning material must be placed in the deepest part of the cup, not near the rim. • Remove the burning material before applying the cup to the patient's skin. • Never retain the burning material inside the cup when the cup is placed onto the skin.

Infections

The same procedures are recommended as in preparation for acupuncture: follow *Safety Guidelines for Establishing and Maintaining a Clean Field*, for *Hand Sanitation* and *Skin Preparation*. Wear personal protective equipment (PPE) (gloves and protective eyewear) when blood or OPIM may be present, if performing wet cupping, or cupping after needling.

Avoid cupping over lesions, rashes, injuries or breaks in skin barrier. Colonization of pathogens such as *Staphylococcus aureus* is a common complication of atopic conditions such as eczema. (35) While there are studies on the use of cupping for herpes zoster and other skin lesions (6) practitioners should be specifically trained in cupping for active skin lesions before applying cups.

Safety Guidelines for Wet Cupping advises that practitioners must wear gloves and protective eyewear when engaging in wet cupping. Each area to be wet cupped should be thoroughly cleaned. Skin can be cleaned with 70% isopropyl alcohol or soap and water or another method, but must be cleaned immediately before performing wet cupping. The skin at the site should be punctured using sterile lancets, pre-sterilized traditional three-edged needles, or a plum blossom tool, with a new lancet being used for each puncture and then immediately discarded in a proper sharps container. Apply the cups that have been properly disinfected for use over nonintact skin and retain as needed for the desired effect.

When removing cups that contain blood, allow the vacuum to be compromised slowly then remove the cup. The practitioner should utilize PPE including gloves and eye protection when blood is present in a cup and the cup is being lifted to be removed. Some of the blood can aerosolize or splash, exposing the practitioner's hands, wrists, eyes and other surfaces. Clean the site of the punctures with an appropriate skin cleanser. Discard the extravasated blood collected by cotton swab, gauze, paper towel or cloth in the biohazard trash. The cup itself may be discarded in the biohazard trash after a single-use or, if intended for reuse, must be cleaned using soap and water and then sterilized. (1)

Safety Guidelines to Prevent Cupping-Related Infections

Critical	• Follow Standard Precautions. • Follow *Safety Guidelines for Establishing and Maintaining a Clean Field.* • Follow *Safety Guidelines for Hand Sanitation.* • Cupping should be applied on clear skin only. Do not apply cups over any active lesions. • When performing wet cupping, use PPE such as gloves and protective eyewear. • If lubricants are used, decant a portion into a secondary disposable container or onto a surface such as a paper towel for use on a single patient. Dipping back into the original lubricant container or re-touching the spout of a pump container must be avoided.
Strongly Recommended	• If specifically cupping over active herpes zoster lesions, do so only with advanced training in how to safely treat lesions with cups.

Standards for Reuse of Cupping Devices

The CDC establishes levels of criticality for medical instruments intended for reuse to prevent infection. (36). Recommendations are established by the FDA for required levels of disinfection depending on instrument criticality. (37) Recent observational studies report that the mechanical operation from cupping may provide sufficient pressure as to cause the leaking of fluid and blood from the surface. (1) According to the authors, unintentional expression of blood or fluid into cups may result from open blemishes or pimples, and may or may not relate to excessive suction force, skin fragility, or hydration. (1,38)

Cupping devices are commonly reused on multiple patients and if the cup is intended to be used on nonintact skin, it would need to be disinfected based on the CDC level of "semi-critical instruments intended for reuse." (36) Cups, like any semi-critical reusable medical device, must be cleaned and disinfected using a high level disinfection (HLD) solution. A number of chemicals cleared by the Food and Drug Administration (FDA) are dependable high-level disinfectants for medical devices. (37) It is critical that the practitioner chooses the chemical disinfectant that is

indicated for the intended use of the device, and follows label instructions, including use of PPE while disinfecting the devices. See Part VI for more information about cleaning reusable medical devices.

Because the skin, which is a normal barrier to cross infection, has been pierced and is no longer intact, cups used for wet cupping are unquestionably semi-critical reusable devices. (36) In such cases, the requirement is to use a disposable cup (and dispose of it in the biohazard trash), or, if intended for reuse, wash the cup with soap and water, and then disinfect it using a high-level disinfectant, according to label instructions. (1,36) These cups can alternatively be sterilized using an autoclave. All safety procedures and packaging instructions must be followed for cup disinfection. Due to their corrosive nature, some high-level disinfection solutions are harmful or fatal if swallowed. Do not get in eyes, on skin, or on clothing. Use ventilation, proper containers, safety glasses, and gloves as per label instructions.

Practitioners should carefully consider what type of disinfecting solution to utilize. Many commercial products have similar product names. The practitioner must carefully read about a product's instructions of use, and hazards of use and disposal when choosing the appropriate product. For more information concerning high-level disinfectants for medical devices see http://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofreusablemedicaldevices/ucm437347.htm .(37)

Cleaning and Disinfecting Cups

At the time of the writing of this manual, the literature is unclear about the level of disinfection required for cups. If cupping is performed on intact skin only, cups would be treated as non-critical reusable medical devices that need to be cleaned with soap and water, and then disinfected in an appropriate intermediate-level disinfectant in accordance with label instructions. Cups should be rinsed and dried with clean towels, and placed in a clean, closed container. Whenever cups have been or will be placed over nonintact skin, they need to be treated as semi-critical reusable devices. In these cases, the cups need to be cleaned with soap and water to remove the lubricant (if used) and biological material before disinfecting with a high-level disinfectant in accordance with label instructions. If the cups will be used on nonintact skin, they should rinsed with sterile, distilled or filtered water. After rinsing, dry and store in a manner that prevents recontamination. (36)

The current controversy is about how often the skin barrier is compromised when cupping over intact skin. Researchers from Beth Israel Medical Center have indicated that microscopic amounts of blood and OPIM are regularly present in cupping procedures. (1,38) However, few infections are reported in the literature reviews of cupping AEs. (3,4,5,6) Cupping over intact skin is a modality of treatment used safely worldwide by lay and licensed practitioners. In the 2013 review by Xu et al., there were only 10 reports of AEs: "In six cases, there was no

information on practitioner training; in the other four, treatment was self-administered." Of those 10 reports, none were of infections. (5) The one case report we do have of herpetic lesion infection is based on cupping over zoster lesions, not intact skin. (31) At this time, there are no reports of licensed acupuncturists or other practitioners from the U.S. who use cupping, such as massage therapists, chiropractors or physical therapists, causing infections with cupping over intact skin. More studies need to be performed to determine how frequently the intact skin is disrupted in cupping procedures not associated with bleeding techniques.

Further issues surround the safety of using high-level disinfecting solutions in the clinical setting. (39-41) Many are caustic and require ventilation hoods and other safety procedures not readily available to a private practitioner. A few solutions are approved for clinical use including those that contain at least 7.5% hydrogen peroxide solution along with other chemicals because such solutions do not require special ventilation. (38) However, none are without risk to the practitioner or healthcare personnel completing the disinfection tasks. Choosing the appropriate chemical solution and following label instructions is critical not only to prevent infection, but also for safe use by the practitioner.

The individual practitioner must gauge the condition of the patient, whether or not the area to be cupped has nonintact skin, and the extent to which their technique of cupping disturbs the intact nature of the skin's surface. Blood being extruded, or open blisters created during cupping are obvious signs that the practitioner's technique disrupts the skin barrier. The practitioner must keep in mind that visual inspection alone may not be adequate to assess the degree that skin has been disrupted by cupping. Because the practitioner cannot know that the skin has become disrupted until after it has become disrupted, and taking into consideration the potential risk to patients, it is the editor's opinion that is prudent to consider high-level disinfection of all cups until additional studies are completed to demonstrate the degree to which cupping compromises the skin barrier. Having one method of disinfection increases the practical considerations that the practitioner will always have prepared and be using devices that have been properly disinfected.

Safety Guidelines for Cup Disinfection

Critical	• Clean all cups of all lubricants and biological material using soap and water before disinfecting. • Disinfect all cups using an appropriate FDA-cleared intermediate to high-level disinfecting solution in accordance with label instructions. • Use appropriate PPE while cleaning and disinfecting cups.
Strongly Recommended	• Disinfect all cups using a high-level disinfecting solution following package directions for semi-critical devices.
Recommended	• Use disposable cups for wet cupping and dispose of used wet cups in the biohazard trash.

Extensive Bruising & Other Skin Lesions

While petechiae and ecchymosis are expected after cupping, extensive bruising can result from either applying the cups for too long or with too strong of a vacuum. Extensive bruising is a risk with patients who have bleeding disorders such as hemophilia or Von Willebrand's disease and/or certain supplements.

Practitioners must take a thorough history, including bleeding disorders and medication history, before applying cups. Cup using caution in patients with a history of bleeding disorders, or who are currently taking blood thinning medications or some supplements. Avoid wet cupping for patients with a history of bleeding disorders, blood thinning medications, or some supplements. Apply cups with caution, conservatively, and continually observe the process to gauge when to remove cups.

Limit the retention time of cups to that of the physical tolerance of the patient, and the intended appearance of transitory therapeutic petechiae and ecchymosis. Observe the process of cupping to avoid bullae blisters.

Take a patient history to establish the presence or absence of keloids and psoriasis. Explain the risk of keloid formation to all patients and of Köebner phenomenon for patients with psoriasis.

Safety Guidelines for Preventing Cupping Skin Lesions

Critical	Take a careful patient history to: • Screen patients for the potential for reactive skin lesions such as keloid scarring (previous keloids) and Köebner phenomenon (history of psoriasis). • Screen for bleeding disorders including hemophilia and Von Willebrand's disease.
Strongly Recommended	• Limit the retention time of cups to that of the physical tolerance of the patient, and the intended appearance of transitory therapeutic petechiae and ecchymosis. Observe the process of cupping to avoid bullae formation.

Unintended Deep Penetration of the Needle

During needle cupping, when applying cups over inserted needles, be aware that the needle may travel beyond a safe depth due to the compression of the tissue. This risk is only for needle cupping. All standard needle and cupping guidelines must also be followed.

Safety Guidelines for Needle Cupping

Strongly Recommended	• Apply over needles that are inserted obliquely in the thoracic region to avoid pneumothorax.

Safety Guidelines to Prevent Cupping Adverse Events

Critical	• Cupping should not be applied 48 hours before or 24 hours after chemotherapy treatment.
Strongly Recommended	• If a patient is taking anticoagulant and antiplatelet therapies, cupping should be applied with an awareness of patient conditions; the cupping process should be carefully observed. • Limit the retention time of cups to that of the physical tolerance of the patient, and the intended appearance of transitory therapeutic petechiae and ecchymosis. • Application of cupping for children should be done in the presence of a parent or assigned guardian.
Recommended	• There is a risk that cupping petechiae and ecchymosis may be misinterpreted as illness, injury or abuse. It is critical to explain the therapeutic intention of cupping as well as the intended therapeutic petechiae/ecchymosis, and the timeline of their resolution. A handout explaining cupping in clinical practice may protect the patient from the stress of misinterpretation.

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4. Electroacupuncture (EA)

Safety/Adverse Events – A Review of the Literature

Electroacupuncture (EA) is used by many acupuncturists as an adjunctive therapy for conditions associated with qi, blood, or phlegm stagnation. Prior to the advent of modern electrical appliances, hand manipulation of the needles was used to strongly stimulate qi flow. EA is used to replace prolonged needle manipulation for conditions in which there is an accumulation of qi, such as in chronic pain syndromes, or in cases where the qi is difficult to stimulate. (1)

There are very few studies of the potential adverse events of electroacupuncture (EA). One recent review of the literature from 1979-2010 found only 44 incidences of AEs reported during that time frame in either English or Chinese databases. (2) While a number of the AEs were probably associated with the acupuncture (faintness, hyperventilation) a few were associated with the application of an electrical current (electrical injury, atrioventricular block, dislocation of the wrist joint from muscle spasm and others). (2)

A report from a one practitioner concluded that "most of the safety implications related to the application of EA are theoretical, and there are few reports in the literature of serious adverse events that relate to the electrical stimulus as opposed to the trauma of needling." (3) Zhao et al. (4) report no adverse events in use of EA in their report of 60 patients receiving EA therapy for muscle spasticity after brain injury.

There may be increased risks associated with the needling techniques needed for EA. A practitioner must be aware of guidelines for insertion depth when using EA. Both the depth and direction of insertion of the needles is often adjusted by practitioners for the application of EA in order to ensure that the needles can support the weight of the electrical leads and clips for the period of stimulation without falling out. EA is often applied for 20–30 minutes and may involve strong muscle contraction. Both the use of increased depth of insertion and the need to alter insertion angle at certain points require the practitioner to have an excellent grasp of the anatomy underlying the points in order for safe needling.

Needle type and size is also important with EA. Certain types of metal should be avoided for use in EA such as silver needles, which are softer than stainless steel and may electrolyze in the body very quickly resulting in a toxic reaction. Additional studies need to be done to identify the best types of needles to use during EA. It may be advisable to avoid needles with a plastic handle due to diminished conduction; and, there is a theoretical concern about very narrow gauge needles and possible breakage from electrical conduction. Stainless steel needles are safe to use with electrical stimulation.

Excessive Current

The current used for therapeutic EA ranges from about 0.5 to 6 mA. In an otherwise healthy subject with no implanted electrical devices, the medical literature associated with the use of nerve stimulating devices suggests that this level of current should be safe. (5,6)

Higher levels of current may cause significant spasms of local muscles; skeletal, cardiac and smooth muscle fibers can all be stimulated through the use of electrical currents leading to inadvertent muscle spasms. The level of electrical stimulation should remain just below the level of pain as perceived by the patient and muscle contraction should be avoided in most applications of EA. While there are applications of EA that involve muscle contraction as part of the therapy (such as treatment for palsy), such treatments need to be closely monitored.

Anatomical Considerations

A 2008 study of the safety of EA reported, "When the needles are placed in closely adjacent acupuncture points in a limb, there is little or no detectable spread of the currents along the limb or into the chest. By contrast, when the needles are placed far apart, the electrical currents spread widely." (7)EA should be avoided in the following locations to prevent theoretical AEs:

1. Anterior triangle of the neck. Due to the location of the carotid sinus which regulates blood pressure, the laryngeal muscles associated with breathing, and the vagus nerve (cranial nerve 10), EA should not be utilized in this area.
2. Posterior cervical area. The presence of the brainstem may prohibit the use of EA.
3. Crossing the spine. EA may interfere with normal nerve conduction.
4. Crossing the heart. EA may affect the function of the electrical system in the heart and the contraction of the cardiac muscle.
5. In any patient with implanted medical devices: ICDs (implantable cardioverter defibrillator) and pacemakers.

Adverse events (or potentially adverse events) related to the use of EA have been reported; these have mostly related to cardiac effects (angina, cardiac arrest, interference with a demand pacemaker). (7,8,9) In one report, however, the use of EA in the limbs in someone with a pacemaker did not interfere with the action of the cardiac pacemaker, and the authors of that study suggest that this restriction be re-thought. "The results of this case study suggest that EA might be a safe alternative for patients with a pacemaker. . . .Every patient should be considered with care, individually." (10)

According to Low and Reed's textbook on electrotherapy, 5 mA direct current (DC) applied to human tissues in vivo results in chemical changes at the sites of contact with the electrodes. A negative charge at the cathode results in an alkaline environment and liquefaction of proteins.

A positive charge at the anode results in an acidic environment and coagulation of proteins. (11) The use and function of the two poles of EA for different AOM applications needs further research and elucidation.

Preventing EA Adverse Events

There are no common adverse events associated with EA reported in the English literature. Uncommon AEs can mostly be prevented by proper training and an awareness of contraindications for the therapy.

Certain types of metal should be avoided for use in electroacupuncture such as silver needles, which are softer than stainless steel and may electrolyze in the body very quickly resulting in a toxic reaction. Stainless steel needles are safe to use with electrical stimulation. (3)

Safety Guidelines for Preventing EA Adverse Events

Strongly Recommended	• Electrical stimulation should not be applied from one side of the chest across to the other side of the chest (front to back or side to side) in the region of the heart. A circuit should not cross the midsagittal line of the patient.
Recommended	• Avoid applying EA near the brainstem. • Avoid crossing the spine with the electrical stimulus. • Consult with the primary physician of any patient with a history of a seizure disorder before instituting EA.

Injuries Due to Muscle Contraction

Excessive electrical current can cause significant muscle spasms which may then cause local tissue or bone damage. EA should never be employed in such a manner as to cause continuous, strong muscle spasms.

Safety Guidelines for Preventing Excessive Muscle Contraction During EA

Critical	• EA should not be used on infants, children, incapacitated,sleeping or unconscious persons. • Turn up the amperage of the EA machine slowly and ask for constant feedback from the patient about sensation of pain; electrical stimulation should be turned off before needles are removed from the body. • The level of stimulus should never approach the sensation of pain.
Strongly Recommended	• Apply EA in such a manner as to avoid muscle contraction except in those cases where muscle stimulation is the expected outcome.

Electrical Injury

Guidelines for use of electrical safety must be followed. (See https://www.osha.gov/dte/grant_materials/fy09/sh-18794-09/electrical_safety_manual.pdf for an overview of electrical safety)

Safety Guidelines for Preventing Electrical Injury During EA

Critical	• Prevent water, moisture, liquids or metal objects from coming in contact with the patient or treatment table. Do NOT use EA in wet or moist environments. • Do not use if any part of the EA machine is cracked or otherwise damaged. • Do not use if the wires or leads are not in good condition.

Interference with a Cardiac Pacemaker

Electrical stimulation can interfere with the functioning of pacemakers. Patient histories must be specific for ruling out that your patient has a pacemaker.

Safety Guidelines for Preventing Interference with a Cardiac Pacemaker During EA

Critical	Avoid use of EA on the trunk of anyone with an implanted cardiac device, including a pacemaker.
Strongly Recommended	EA should not be used on any part of the body of patients with pacemakers or other electronic implants.

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5. Therapeutic Blood Withdrawal

Safety/Adverse Events – A Review of the Literature

Therapeutic blood withdrawal is referred to in the literature as “bloodletting” (MeSH term: “Puncture of a vein to draw blood for therapeutic purpose”), “pricking,” “bleeding,” or the “use of the three-edge needle.” For the purposes of this review, we will use the term “bleeding” to cover all variations of therapeutic blood withdrawal.

Bleeding is an original form of medicine found in every early culture, including early Western medicine. (1) There is evidence, in chronological iterations of the Nei Jing Su Wen, that acupuncture itself evolved from bloodletting. (2) In AOM, bleeding is done removing only drops of blood until its quality and color lightens. It is possible that even minor bleeding or hematomas at an acupuncture needle site might be considered part of the therapy. (3)

The bleeding of specific points is an acupuncture therapy that continues to be used to treat, for instance, fevers, pain, or itching. (4)

There is increasing interest, including articles and studies, on acupuncture therapy bloodletting. A PubMed search on “acupuncture bloodletting” had 97 results, many in the Chinese literature with some in English. (http://www.ncbi.nlm.nih.gov/pubmed/?term=acupuncture+bloodletting). Bloodletting is studied as a stand-alone therapy or paired with acupuncture, cupping, gua sha, moxibustion or in multiple combinations of therapies. A review of Medline and Cochrane databases with the terms "bloodletting puncture" and “needle pricking” yielded only limited case studies and studies in Chinese, many of which combine bleeding therapy with EA and acupuncture or cupping. No AEs were reported in any of the studies available in English.

There are no overviews of safety or adverse events in English regarding bleeding therapies. But in their systematic review on adverse events of auricular therapy, Tan et al. (5) report on minor infections associated with auricular bloodletting. The literature does establish that the use of lancets for drawing blood from the heels of infants for lab testing carries a risk of infection, though rare. (6) A systematic review of wet cupping for herpes zoster reported no adverse events in any of the trials. (7) However, there are case reports of infection related to wet cupping (see cupping section).

A review of the literature regarding the use of lancets for capillary blood collection was similarly limited. Studies focused on limiting pain and producing enough blood for proper testing, not on any adverse events. (8) One report of transmission of HBV from a multi-use lancing device points out the need for using single-use only devices for bleeding techniques. This study identified that an identical HBV viral strain was present for patients using a multi-patient

lancing device, demonstrating that multiple patients were cross contaminated with HBV when lancets for bloodletting were reused. (9)

Only pre-sterilized single-use disposable lancets, rather than devices designed for home or office blood sugar monitoring, should be used in acupuncture practice. No part of any lancing device should be reused on other patients or reused at multiple sites on a single patient. Since blood droplets may collect within the fingerstick or lancing device, each new puncture presents a risk for cross infection. Lancets cannot be used for multiple patients even when they are changed for each new puncture.

According to the CDC, “Fingerstick devices, also called lancing devices, should never be shared, even with close family and friends. This guidance includes both the lancet (i.e., the sharp instrument that actually punctures the skin) and the pen-like device that houses the lancet. Neither should be used for more than one person.”
http://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html

Lancing Device:

Once the lancet has been used, discard it in a sharps container immediately. Single-use spring loaded lancets can be used and discarded but they are more difficult to control in terms of specific point location and depth.

Preventing Acupuncture Bleeding Therapy Adverse Effects

As with acupuncture needling, bleeding carries a risk of infection, local pain, bleeding, and bruising; safety guidelines for preventing these adverse events are listed in the previous acupuncture section. This includes screening patients for medications or supplements that may thin the blood, such as anticoagulant and antiplatelet therapies and pain medications such as NSAIDS, as well as some supplements.

Because the lancets break the skin surface, blood and OPIM are present on the lancets and may be a source of needlestick injuries. Practitioners must take care to limit the risk of needlestick injuries. Retractable single-use lancets may allow bleeding techniques to be practiced with

reduced risk to the practitioner. Retractable devices need to be new for each new patient to prevent cross contamination with bloodborne pathogens.

Safety Guidelines for Acupuncture Bleeding Therapy

Critical	• Follow *Safety Guidelines for Hand Sanitation.* • Follow *Safety Guidelines for Skin Preparation.* • Practitioners must take a thorough history including bleeding disorders, medication, and supplement history before using bleeding techniques. • Personal protective equipment (PPE) is required. Wear gloves at all times as blood and OPIM will be present. • Inspect area to be treated for evidence of inflammation, lesion, infection, or a break in the skin barrier. Do not bleed in these areas. • Lancing devices must be limited in use to a single patient. • Lancets cannot be reused after a single insertion; not on another site. • Lancets should be used only once and then discarded in a sharps container.
Recommended	• Utilize eye protection, such as goggles, when performing bleeding techniques. • Utilize lancets engineered to retract after use to significantly reduce the risk of needlestick injuries.

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6. Gua Sha

Safety/Adverse Events – A Review of the Literature

Gua sha is a traditional East Asian healing technique defined as the "closely-timed unidirectional press-stroking of the body surface with a smooth-edged instrument to intentionally raise transitory therapeutic petechiae and ecchymosis (sha) representing extravasated blood in the subcutis." (1,2) The petechiae and ecchymosis resolve in 2-4 days.

Gua sha is used in the treatment of pain, pain on palpation, and accompanied "blanching that is slow to fade" indicating sha in the tissue. Gua sha treats both acute and chronic pain, acute respiratory infection, influenza, and fever, as well as internal organ diseases where the identified ferroheme metabolism can reduce inflammation and offer immune protection. (3).

Traditional gua sha tools have included Chinese soup spoons, edge-worn coins, various bone devices, pieces of honed jade, various stainless steel devices, or simple, round, smooth-edged metal caps. The latter is recommended as a single-use disposable instrument or one that can be easily cleaned and decontaminated. (1). Lubricants such as oil, balms, or water are applied to the skin prior to gua sha. Gua sha is then applied in closely timed press strokes until petechiae and ecchymosis appear. Press stroking is then continued at the next stroke line sequentially until the entire region of interest is complete. (1)

Similar techniques are used by other healthcare practitioners and are identified as "instrument assisted soft tissue techniques." Risks associated with such techniques would be comparable to those of gua sha.

Recent articles searching the Medline and Chinese language databases for gua sha AE find no reports of transfer of bloodborne pathogens, but cite exposure to bloodborne pathogens as a potential risk. (3) The primary reported risk with gua sha is the mistaking of the petechiae for signs of disease, injury, or abuse by other practitioners. (3) Therefore, communication becomes a safety issue, and precautions are recommended to inform patients during and after gua sha.

Gua sha has been shown to be effective in randomized trials for neck pain, (4) neck and back pain, (5) and breast engorgement/mastitis. (6) No serious AEs were reported in these trials. Gua sha has been shown to increase surface microperfusion (2) and upregulate heme oxygenase-1 (HO-1) through what is called ferroheme metabolism. (7) As the blood cells that have been extravasated are absorbed, the metabolizing of ferroheme upregulates genetic expression of HO-1, creating an anti-inflammatory and immune protective effect. (8)

Preventing Gua Sha Adverse Events

There are no common adverse events reported for gua sha. (9, 10) General guidelines to prevent risk of exposure to bloodborne pathogens should be followed.

Gua sha is contraindicated over rash or broken skin, swelling, inflammation, burn, or sunburn. Gua sha is indicated for inflammation and tissue injury, but not directly at the site of active inflammation or injury to the skin or underlying tissue. Gua sha is not contraindicated for patients with a stable INR who are taking anticoagulant medication. The use of gua sha for those currently taking anti-coagulant medication, NSAIDs, Vitamin E, or fish oils or for those who have bleeding disorders should be limited to those practitioners with the necessary background to evaluate the subcutaneous bleeding and tissue response.

Because the intended therapeutic goal of chemotherapy for cancer is apoptosis, and because gua sha's upregulation of HO-1 is anti-apoptotic, (8) it is recommended to avoid applying gua sha (or cupping) for 48 hours before and 24 hours after chemotherapy.

Safety Guidelines for Gua Sha

Critical	• Follow Standard Precautions. • Follow *Safety Guidelines for Establishing and Maintaining a Clean Field.* • Follow *Safety Guidelines for Hand Sanitation.* • Take a careful patient history to identify if the patient is taking medications that thin the blood, such as anticoagulant and antiplatelet therapies, pain medications such as NSAIDS and supplements such as vitamin E and fish oils. Gua sha is not contraindicated but should be applied with awareness of the patient's condition. • Gua sha should not be applied 48 hours before or 24 hours after chemotherapy treatment. • When reusing gua sha tools, select only tools that are disposable or that have been properly disinfected. • If lubricants are used, decant a portion into a secondary disposable container or onto a surface such as a paper towel for use on a single patient. Dipping back into the original lubricant container or re-touching the spout of a pump container must be avoided. • Gua sha should be applied on clear skin only. Do not apply gua sha over any active rash, lesion, inflammation, infection, or break in the skin barrier. • Do not gua sha over swelling or recent trauma, including over burns or sunburns.
Strongly Recommended	• Any application of gua sha for children should be done in the presence of a parent or assigned guardian.

Recommended	• Explain the therapeutic intention of gua sha as well as the timeline for the resolution of intended therapeutic petechiae with a handout on gua sha.

Disinfection of Gua Sha Devices

At the time of the writing of this manual, the literature is unclear about the level of disinfection required for gua sha devices. When used on intact skin only, gua sha devices would qualify as non-critical reusable medical devices. The CDC definitions of non-critical devices can be found in *Guidelines for Disinfection and Sterilization in Healthcare Facilities.* (11) As non-critical devices, reusable gua sha spoons and other devices would be cleaned of lubricants and biological material with soap and water, and then disinfected in an appropriate intermediate-level disinfectant, in accordance with the label instruction. They should be rinsed and dried with clean towels, and placed in a clean, closed container. Whenever gua sha has been or will be used over nonintact skin, the tools need to be treated as semi-critical reusable devices. In these cases, the gua sha tools need to be cleaned and scrubbed with soap and water to remove the lubricant (if used) and biological material before disinfecting with a high-level disinfectant in accordance with the label instruction. If the tools will be used on nonintact skin, they should be rinsed with sterile, distilled, or filtered water. After rinsing, dry and store in a manner that prevents recontamination. (11) Practitioners must strictly follow FDA and manufacturer guidelines for the use of any high-level chemical disinfectant. (12) If the gua sha devices are heat-stable, terminal processing of sterilization in an autoclave may be used. Single-use, disposable gua sha tools may also be considered.

There is a current controversy regarding how often the skin barrier is compromised during gua sha. Researchers from Beth Israel Medical Center have indicated that the intentional or unintentional expression of blood or fluid onto gua sha devices demonstrates the potential exposure to, and risk of transfer of, bloodborne pathogens and/or OPIM. (1) However, no infections are reported in the literature reviews of gua sha AEs. (9,10) Gua sha, like cupping, is a modality of treatment used worldwide by lay and licensed professionals. Similar tools are used in the massage therapy, chiropractic, and physical therapy professions, with no adverse event reports. More studies are needed to determine how frequently the intact skin is disrupted in gua sha.

Further issues surround the safety of using high-level disinfecting solutions in the clinical setting. (12-14) Many are caustic, and require ventilation hoods and other safety procedures not readily available to a private practitioner. A few solutions are approved for clinical use including those that contain at least 7.5% hydrogen peroxide solution along with other chemicals, because such solutions do not require special ventilation. (3) However, none are without risk to the practitioner or healthcare personnel completing the disinfection tasks.

Choosing the appropriate chemical solution and following label instructions is critical not only to prevent infection, but also for safe use by the practitioner.

Each individual practitioner must gauge the condition of the patient and the extent to which their technique of gua sha disturbs the intact nature of the skin's surface. Blood being extruded during gua sha is an obvious sign that the practitioner's technique disrupts the skin barrier. The practitioner must keep in mind that visual inspection alone may not be adequate to assess the degree that skin has been disrupted by gua sha. Because the practitioner cannot know that the skin has become disrupted until after it has become disrupted, and taking into consideration the potential risk to patients, it is the editor's opinion that is prudent to consider high-level disinfection of all gua sha tools until additional studies are completed to demonstrate the extent to which gua sha compromises the skin barrier. Having one method of disinfection increases the practical considerations that the practitioner will always have prepared and be using devices that have been properly disinfected. Single-use disposable tools may also be considered.

Safety Guidelines for Disinfection of Gua Sha Tools

Critical	• Clean all tools of all lubricants and biological material using soap and water before disinfecting. • Disinfect all tools using an appropriate FDA-cleared intermediate- to high-level disinfecting solution, in accordance with label instructions. • Use appropriate PPE while cleaning and disinfecting gua sha tools.
Strongly Recommended	• Disinfect all tools using an FDA-cleared high-level disinfecting solution for semi-critical devices, in accordance with label instructions.

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7. Plum Blossom Needling

Safety/Adverse Events – A Review of the Literature

Plum blossom needles are used for cutaneous acupuncture treatments. These devices have a number of needle projections carried within a single hammer-like device which strike the skin in a much broader area than do single filiform acupuncture needles. Due to the shape of the sharp projections in the device, the instrument is often referred to as a "seven-star" hammer. In general, these devices do not puncture subcutaneous tissue but rather stimulate the superficial or cutaneous acupuncture channels. (1)

There are currently 40 study articles on plum blossom therapy in PubMed, almost all in Chinese. AEs are not reported. There is one text on plum blossom therapy (2) and a mention in the O'Connor and Bensky text. (1) A very few studies, mostly in Chinese, reported information about adverse events and in all cases, no AEs were identified. (3,4,5)

Using plum blossom/seven star needling for treatment of a variety of pain syndromes including neuropathies can be found in the medical databases. But as most of these articles are written in Chinese, their effect on U.S. practices is quite limited. (6-9)

Preventing Plum Blossom Needling Adverse Events

While no AEs associated with plum blossom/seven star hammer treatments are reported in the literature, the use of this device is not without risk. Because the individual needle-like projections may break the skin surface and are used over a broad area of skin rather than a single discrete point, transient pathogens can be moved from one area to another. Also, while bleeding is generally to be avoided, blood and OPIM may be brought to the surface and released into the air.

Safety Guidelines for Plum Blossom (Seven Star) Therapy

Critical	• Follow *Safety Guidelines for Establishing and Maintaining a Clean Field*. • Follow *Safety Guidelines for Skin Preparation*. • Follow *Safety Guidelines for Hand Sanitation*. • The area to be treated with plum blossom must be clean and free of any skin lesions or traumatic injury. (9) • Personal protective equipment (PPE) is required; wear gloves at all times as blood and OPIM will be present. • Use only single-use sterile plum blossom/seven star needles or devices with single-use removable heads. • The head of the plum blossom device must be sterile. Do not touch the tips of the needles at the device head. • Discard used plum blossom needles in a sharps container

	immediately after use. To remove a replaceable head, use hemostats or tweezers. If a single-use device is used, discard the entire device in the sharps container. • If a reusable handle is used, it must be sterilized before the next single-use removable "head" is applied.
Strongly Recommended	• Avoid raising the hand holding the hammer too high, or tapping too forcefully to prevent puncturing the skin. • Avoid "flinging" the hammer around to prevent particulate spray of blood or OPIM.
Recommended	• Practitioners should consider utilizing eye protection while using the plum blossom device.

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8. Press Tacks and Intradermal Needles

Safety/Adverse Events – A Review of the Literature

Press tacks and intradermal needles are used for techniques describing superficial needle insertion where the needles are retained in the body without removal for one to several days. Press tacks (enpishin), which are typically left in the ear for one to five days, are a form of auricular therapy. Reports of ear stapling for weight loss, a variant of auricular acupuncture, indicate intradermal retention for much longer. (1) Intradermal needles (hainishin) are inserted superficially, and retained at various body points. Intradermal needling is also called micro needle therapy, and is used as a form of aesthetic treatment.

Auricular Therapy/Press Tacks

Auricular therapy consists of press tacks, electrical stimulation, bloodletting, or acupressure achieved with the taping of *Semen vaccarria* seeds or small magnetic pellets to ear points. In a systematic review with meta-analysis, auricular acupressure and auricular acupuncture were found to be effective for pain, (2) and in preventing and treating pelvic and back pain in pregnancy. (3) A systematic review of RCTs showed promise for auricular therapy in treating chemotherapy-induced nausea and vomiting in cancer patients (4) and in a separate systematic review, auricular treatment was as effective as drug therapy for perioperative anxiety. (5)

There are multiple case reports in the literature of chondritis (inflammation of cartilage) (6,7) and perichondritis (inflammation and infection of the overlying skin and perichondrium of the ear) from auricular needles. (8-14)

In a recent systematic review no serious adverse events were detected and reported events, such as tenderness or pain at insertion site, dizziness, local discomfort, minor bleeding and nausea for press tacks, skin irritation, local discomfort, and pain for auricular electroacupuncture and minor infection for auricular bloodletting, were minor. (15) The authors of the review postulated that the infected cases were reported 20-30 years ago, and that single-use sterile needles and “awareness of strict hygienic procedures” have contributed to the low incidence of infection in their systematic review. (15)

Ear stapling techniques have been adapted from auricular acupuncture in the treatment of obesity. However, since the staples may be retained for 2-4 months, there is an increased risk of complications and infection. (1,16,17) Qualified training and strict CNT practice should be followed to avoid infection.

Intradermal Needling

Intradermal needling (Hinaishin) consists of superficial insertion and temporary retention of small needles, typically affixed to the skin with tape. Preoperative intradermal acupuncture for

thoracotomy has shown equivocal results. (18,19) Micro needling for facial rejuvenation has become more widely used without data to support safety, and there are some reports of complications and risk of complications such as allergic granulomatous reaction, hypersensitivity (20) and *Mycobacterium* infection. (21,22) Qualified training and strict CNT guidelines must be followed; patient self-administration of intradermal or micro needles should be discouraged.

Because tweezers are used for needle placement and because they touch the patient's intact skin, they can be disinfected with hospital grade surface disinfectant wipes.

Safety Guidelines for the Use of Press Tacks or Intradermal Needling

Critical	• Follow Clean Needle Technique. • Follow Standard Precautions. • Follow *Safety Guidelines for Establishing and Maintaining a Clean Field.* • Follow *Safety Guidelines for Skin Preparation.* • Clean skin before inserting a press tack. Skin can be cleaned with 70% isopropyl alcohol, soap and water, or another method. • Inspect area to be treated for evidence of inflammation, lesion, infection, or a break in skin barrier. Do not insert needles into these areas. • Only use single-use sterile instruments, including press tacks, when breaking the skin surface. • Maintain clean procedure at all times while handling intradermal needles prior to insertion. If needles become contaminated, they should be discarded. • Do not reinsert a press tack, intradermal, or micro needle that has already been inserted in the skin. • Instruct patients to never reinsert a press tack, intradermal, micro needle that has already been inserted in the skin. • Immediately isolate used press tacks in an appropriate sharps container.
Strongly Recommended	• Request patients return to the office so that the practitioner can remove the press tacks at the end of retention of press tacks; or provide the patient with a sharps container to use at home when removing the press tacks or intradermal needles. • Advise patients on safe removal and disposal of press tacks or intradermal needles. • Provide each patient with direct contact information in the event of complications or questions. • Instruct each patient to observe and respond to signs of needle complications such as tenderness, redness, pain, inflammation, or

	possible infection. • Discourage use of patient self-administered press tacks, intradermal, or micro needles.
Recommended	• For immunocompromised or immunosuppressed patients, consider the use of ear seeds or magnets instead of press tacks or intradermal needles for auricular therapy. • Take a careful patient history to identify if the patient is allergic to the medical tape used in this procedure. • After intradermal needle withdrawal, apply pressure to the acupuncture point with clean cotton or gauze.

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9. Ear Seeds

Safety/Adverse Events – A Review of the Literature

Ear seeds (sometimes also referred to as "press balls") are used to stimulate acupuncture points, usually on the auricle of the ear, without breaking the skin. Most are made from metals such as surgical stainless steel or magnets. Traditionally, seeds from plants such as *Caryophyllus aromaticus* (clove) and *Vaccaria hispanica* (cowherb), were used thus giving the name "vaccaria" to all such ear seeds. These metal (or naturally occurring) seeds can be used to stimulate points in other areas of the body, such as at Neiguan (P6) for nausea of pregnancy and motion sickness.

There are no prospective studies or retrospective reviews in the English literature regarding the safety of the use of ear seeds/vaccaria. There are a few studies which reviewed the uses of and therapeutic effects of ear seeds for back pain, (1) weight loss, (2) and constipation. (3)

These studies reviewed patient acceptance and therapeutic outcomes with seeds being left in for up to 7 days. None reported AEs or patient intolerance.

Preventing Ear Seed Adverse Events

There are no common AEs associated with the use of ear seeds/vaccaria. General clean techniques and vigilance to avoid use of the seeds where there is an active skin infection or trauma should be sufficient to maintain the safety record of vaccaria treatments.

Safety Guidelines for the Use of Ear Seeds

Recommended	Take a careful patient history to identify if the patient is allergic to the medical tape used in this procedure.

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10. Tui Na

Safety/Adverse Events – A Review of the Literature

Tui na is a manual therapy which uses Chinese massage and manipulation techniques. There are no prospective studies or retrospective reviews in the English literature regarding the safety of the use of tui na. Tui na is extensively used in China for a variety of pain and musculoskeletal syndromes. A recent study which reviewed the uses of and therapeutic effects of tui na for pain (1) and Parkinson's disease (2) found no adverse events or reactions associated with tui na therapy.

Similarly, a Cochrane review of the use of massage (not tui na) for neck pain (3) reported infrequent reports of post-treatment pain and rare occurrences of low blood pressure following massage as side effects.

A recent practitioner journal article listed the following contraindications to tui na: (4)

- Wounds
- Dematoses
- Diseases with hemorrhagic tendencies
- Acute infectious diseases
- Diseases of the brain, heart, liver, kidney, and other viscera
- Menstruation and pregnancy

This list is similar to that used by massage therapists since the time of JH Kellogg who in 1895 listed the following contraindications to massage: (5)

> Massage is contra-indicated in nearly all forms of skin disease, except in thickened condition of the skin left behind by chronic eczema. It is also contra-indicated in acute cases of apoplexy and in the early stages of neuritis, when irritability still exists, and should never be administered to abscesses, tumors or tubercular joints.

A more recent article on creating standards for massage in the hospital setting also elucidated similar precautions: (6)

> Contraindications and cautions: Under the UMHS policy, therapeutic massage is locally contraindicated in or near areas of infection, tumors, or incisions. Other contraindications include but are not limited to impairment by alcohol or drugs, the presence of contagious rashes, and failure of the patient to consent to massage therapy.

There are a few of cases reported AEs (complications) associated with tui na in the Chinese language medical literature. Most of these cases are due to improper use of force during the tui

na practice which led to such AEs as soft tissue injury, peripheral nerve injury, visceral injury, dislocation of a joint, bone fracture, epidural hemorrhage, injury of central nerve system especially cervical spine injury, etc. (7-10) It is clear that while these are rare occurrences, proper understanding of anatomy and physiology is needed to prevent AEs associated with the over-use of force.

Preventing Tui Na Adverse Events

There are no common AEs associated with the use of tui na. General clean techniques and vigilance to avoid using tui na where there are active skin infections, open wounds, fractures, or acute trauma, and consultation with other physicians when using the technique after surgery or during treatments for cancer should be sufficient to maintain the safety record of this procedure.

Safety Guidelines for Tui Na

Critical	• Follow *Safety Guidelines for Hand Sanitation*. • Never apply tui na to areas that have dermatitis, active lesions or other wounds.
Strongly Recommended	• Provide appropriate pressure and adjust tui na treatments according to age, location, body constitution and medical history.

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11. Other Acupuncture-Related Tools

Manaka/Japanese Acupuncture Tools

A Review of the Literature

There is no evidence in the English language medical databases that there are any AEs associated with either Manaka pumping chords or Manaka hammer treatments.

Preventing Adverse Events

There are no common AEs associated with the use of Manaka products. General clean techniques and vigilance to avoid use of the Manaka pumping chords or Manaka hammer where there is an active skin infection or trauma should be sufficient to maintain the safety record of these treatments.

Shonishin Pediatric Japanese Acupuncture Tools

A Review of the Literature

There is no evidence in the English language medical databases that there are any AEs associated with Shonishin treatments.

Preventing Common Adverse Events

There are no common AEs associated with the use of Shonishin products. General clean techniques, proper disinfection of such devices as noncritical devices, and vigilance to avoid use of the any reusable medical device where there is an active skin infection or trauma should be sufficient to maintain the safety record of these treatments.

Part II: Best Practices for Acupuncture - CNT

There are a wide variety of applications and techniques for all acupuncture procedures. Many follow oral traditions. The following recommendations utilize practices as described in *Chinese Acupuncture and Moxibustion* (1) and *Acupuncture – A Comprehensive Text* (2), and apply safety practices based on the evidence from Part I. There are any number of other methods with safety protocols applicable to various styles of acupuncture practices. This section is not meant to be exhaustive or prohibitive, but rather to be instructive. Schools and practitioners are encouraged to implement additional and alternative methods to reduce risk utilizing additional and alternative needling techniques, moxa applications, and practices utilizing other AOM clinical traditions. See, for instance, the discussion of Toyohari contact needling acupuncture.

For the purposes of this manual, the following terms will be utilized to help practitioners apply best practices to their personal practices: critical, strongly recommended and recommended. See the *Introduction* for explanation of these terms.

1. CNT Protocol

Clean Needle Technique (CNT) is the standard by which acupuncturists prevent occupational exposure to healthcare associated pathogens, including bloodborne pathogens and surface pathogens, and reduce the risk for some other adverse events associated with acupuncture. CNT consists of the following components:

1. Hand sanitation.
2. Establishing and maintaining a clean field.
3. Skin preparation.
4. Isolation of contaminated sharps.
5. Standard precautions.
6. The use of sterile single-use needles and other instruments that may break the skin, such as seven-star hammers, press tacks/intradermal needles, and lancets.

In addition, as needed:

7. Follow appropriate emergency procedures in the event of a needlestick incident or some other clinical accident in the course of an acupuncture treatment.

It should be stated at the outset that a more comprehensive risk management protocol is beyond the scope of this manual. Any risk management course should be adapted to the unique requirements of the specific acupuncture treatment environment in which the acupuncturist is treating patients.

Clean Needle Technique must be distinguished from sterile technique. Sterile or aseptic technique, which is used in surgical procedures and many laboratory procedures, involves procedures that are kept sterile by the appropriate use of sterile supplies and the maintenance of a sterile field. While acupuncture involves the use of sterile acupuncture needles that must be maintained in a sterile condition prior to the acupuncture procedure, CNT is a clean rather than sterile procedure.

The insertion site is clean rather than sterile. Hands are in a clean condition rather than covered with sterile gloves. Gloves do not need to be worn except under specific conditions where exposure of the practitioner to blood or other potentially infected body fluids is possible.

Gloves are worn:

1. When bleeding occurs, or is likely to occur (e.g., during bleeding techniques, wet cupping and seven-star/plum blossom treatments).
2. When needling in the genital region or in the mouth.
3. While palpating near an area where there are lesions on the patient's skin.
4. In the event that there are skin lesions or open wounds on the acupuncturist's hands.
5. When cleaning blood or OPIM from a surface.

Hand Sanitation

Handwashing is a critical component of the CNT protocol. Washing hands with soap and water is the best way to reduce the number of microbes on them in most situations. If soap and water are not available, use an alcohol-based hand sanitizer that contains at least 60% alcohol. (3) Make sure to use enough sanitizer that the hands are completely covered and wet. Wash hands rather than use hand sanitizer if hands are visibly dirty.

Safety Guidelines for Hand Sanitation

Critical	• Follow instructions for "How to Wash Hands" or "How to Use Hand Sanitizer." • If using hand sanitizer, use sanitizer that contains at least 60% alcohol upon entering a room with a patient and after touching or treating a patient. • DO NOT use alcohol-based hand products to wash hands after exposure of non-intact skin to blood or body fluids; in such cases, wash hands with antibacterial or plain soap and running water, then dry them using single-use paper towels. • Wash hands upon entering a patient's room. • Wash hands immediately prior to inserting acupuncture needles or performing other clinical procedures. If hands come into contact with such items as clothes, keyboards, hair, skin, pens, or charts, rewash

	hands. • Wash hands after touching or treating a patient. • Wash hands before and after eating. • Wash hands with soap and water after using the restroom. • Wash hands after coughing or sneezing. • Glove for procedures where there may be exposure to blood or body fluid. • Remove gloves immediately after exposure. Wash hands or sanitize.

How to Wash Hands (4)

Critical	• Wet your hands with clean, running water (neutral or warm) and apply soap. • Lather your hands by rubbing them together with the soap. Be sure to lather the backs of your hands, between your fingers, and under your nails. • Scrub your hands for 10-20 seconds. • Rinse your hands well under clean, running water, with your hands lower than your elbows. • Dry your hands using a clean paper towel. • Turn off the faucet using a paper towel. • Open any doors between you and your patients using a paper towel, or re-clean hands upon entering the patient's room.

How to Use Hand Sanitizer (3)

Critical	• Apply the product to the palm of one hand (read the label to learn the correct amount). • Rub your hands together. • Rub the product over all surfaces of your hands and fingers until your hands are dry.

Preparing and Maintaining a Clean Field

A clean field is the area that has been prepared to contain the equipment necessary for acupuncture in such a way as to reduce the possible contamination of sterile needles and other clean or sterile equipment.

Safety Guidelines for Preparing and Maintaining a Clean Field

Critical	• Follow *Safety Guidelines for Hand Sanitation*. • Select a clean, dry, flat surface to serve as the setting for the

	clean field. A treatment table is not suitable. • Establish a new clean field for each patient. • Place materials such as acupuncture needles in blister packs on the clean field. • Place clean cotton balls or unopened swabs on the field. If desired, these items may be kept in a clean jar near the clean field. • Clean the surface used for the clean field with a low-level disinfectant at least once daily.
Strongly Recommended	• Place clean cotton balls or unopened swabs on the clean field. If desired, these items may be kept in a clean jar near the clean field. • Keep sterile items near the center of the clean field with clean items nearer the edges. • Clean blister packs of sterile needles may be handled and replaced back onto the clean field. • Clean previously sterilized guide tubes may be handled and replaced back onto the clean field.

Skin Preparation

Acupuncture needles should be used only where the skin is clean and free of disease. Acupuncture needles should never be inserted through inflamed, irritated, diseased, or broken skin. Otherwise, infections can be carried directly into the body past the broken skin barrier. The areas to be needled should be clean prior to treatment. Alcohol swabbing is recommended but not essential before acupuncture needle insertion as long as an area is clean. If swabbing an area, 70% alcohol or ethanol is required. Skin can be cleaned with 70% isopropyl alcohol, soap and water, or other methods as determined by the practitioner or clinic administrator. While soap and water may be acceptable, many patients come in for treatment after work and treatment is often given to areas of the body where soap and water are not practical in the office. In most cases, it is practical to clean the skin to be needled with an alcohol-impregnated swab. If body parts (e.g., the feet) are grossly dirty, they should be washed with soap and water or an appropriate cleansing cloth. The practitioner may then determine whether the skin also needs to be swabbed as needed with an alcohol swab or other cleansing agent.

According to the World Health Organization, both soap and water and 60-70% isopropyl (or ethanol) alcohol is adequate for preparing a patient's skin for procedures such as needle insertion. (5) Isopropyl alcohol at a concentration above 70% is unacceptable because it evaporates too quickly to have an antiseptic effect.

There are no studies which compare skin preparation prior to acupuncture needle insertion with no skin preparation. The closest information available pertains to skin preparation prior to injections, (6) such as insulin injections for diabetics and vaccinations. Research conducted as early as the 1960s by Dann (7) and Koivisto & Felig (8) with diabetic patients indicated that although skin preparation with alcohol prior to injection markedly reduced skin bacterial counts, such treatment is not necessary to prevent infection at injection sites. (9)

Many practitioners believe it follows best practice guidelines to clean the skin prior to injection to reduce the risk of contamination from the patient's transient skin flora. The NIH, in its patient instructions, clearly states, "Since the skin is the body's first defense against infection, it must be cleansed thoroughly before a needle is inserted." (10)

Skin that is currently inflamed, or which has an active lesion should not be used for needle insertion. These areas often carry higher risk for infection. According to NIH guidelines, "injections are not given if the skin is burned, hardened, inflamed, swollen, or damaged . . ." (10)

The evidence suggests that both the practitioner's hands and the patient's skin at the acupuncture point need to be clean prior to administration of a needle, whether that needle is being inserted to an intradermal, subcutaneous, or intramuscular depth. Risk assessment of potentially contaminated skin should be conducted to ensure appropriate cleaning of the skin is undertaken where required. In other words, if soiled, the patient's skin should be cleaned prior to needle insertion. There is no clear evidence that skin cleansing with soap and water, alcohol swabs, or antibacterial substances like chlorhexidine is better or worse than the other options. Even if skin is visibly clean, mild disinfection may still be performed prior to needle insertion as all OPIM (other potentially infectious materials) are not necessarily visible to the naked eye.

If the insertion site is cleaned with an alcohol swab, it should be allowed to dry prior to needle insertion to prevent pain from alcohol being inserted under the skin along with the acupuncture needle.

Some states mandated the use of an antiseptic swab before insertion of an acupuncture needle in their practice acts and/or rules. This manual should not be interpreted as advising against a practice outlined in state law. Practitioners have a duty to investigate and comply with state regulation. For a more detailed discussion of this topic, see CCAOM's position paper on skin preparation in Part IV of this manual.

Alcohol Swab Method

Swab the points and allow the alcohol on the skin to dry. The same swab may be used for several points. A new swab should be used if the swab begins to change color, becomes visibly

dirty, becomes dry, or has come into contact with any skin break, lesion, inflammation or infection. The alcohol should be allowed to dry to reduce the potential for discomfort during needling. A separate swab should be used for areas of high bacterial load, such as axilla or groin.

Safety Guidelines for Skin Preparation

Critical	• Follow *Safety Guidelines for Hand Sanitation.* • Inspect area to be treated for visible dirt or soiling. Soap and water washing is required for visibly soiled areas. • Inspect area to be treated for evidence of inflammation, lesion, and infection or break in skin barrier. Do not insert needles into these areas. • Alcohol swabbing continues to be recommended for intramuscular needle penetration. (5) • If alcohol swabs are used, 70% isopropyl or ethanol alcohol is required. • If alcohol swabbing is used to clean points before needle insertion, allow the alcohol on the skin to dry. • Do not use a swab at any additional site if it has come into contact with skin that has visible inflammation, lesion, and infection or break in skin barrier. • A separate swab should be used for areas of the body that have high bacterial load. • Do not reuse an alcohol swab on another patient.
Strongly Recommended	• Do not pre-soak cotton wool in a container as these become highly contaminated with hand and environmental bacteria. • The same alcohol swab may be used for cleaning several point sites as long as the swab itself has not dried, has not changed color or become visibly dirty and has only come into contact with intact skin.
Recommended	• Alcohol swabbing of areas to be treated with intradermal or subcutaneous methods is recommended but not essential as long as the area appears to be clean. (5) • Investigate and follow local and state regulation concerning skin preparation.

Isolation of Used Sharps

Another critical component of CNT is the isolation of used sharps. Sharps should be isolated in a sharps container specifically designed for this use. Appropriate containers are available commercially. Sharps containers are made of a material impervious to needles and fluids, such as plastic, and are designed to receive contaminated sharps without being able to retrieve them

after the sharps are placed in the container. These containers are labeled as to contents and bear the biohazard symbol.

Standard Precautions

Standard Precautions are outlined by the Centers for Disease Control.(11) For those used to the term Universal Precautions, Standard Precautions combine the major features of Universal Precautions (UP) and Body Substance Isolation (BSI), and are based on the principle that all blood, body fluids, secretions, excretions except sweat, non-intact skin, and mucous membranes may contain transmissible infectious agents. Standard Precautions include a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, in any setting in which healthcare is delivered. These include: hand hygiene; use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure; and safe injection practices. (The CDC switched from the term Universal Precautions to Standard Precautions in 2007.)

Standard Precautions are widely used to prevent exposure to potentially infectious materials in the course of clinical work, including acupuncture. These precautions are summarized below:

1. Assume all patients are a potential source of infection.
2. Utilize correct and frequent handwashing.
3. All healthcare practitioners must understand the appropriate use of personal protective equipment (PPE) such as gloves, eye protection, and masks.
4. Healthcare facilities apply appropriate engineering controls, such as properly equipped handwashing stations.
5. Isolation of sharps in appropriate sharps containers.
6. Isolation of contaminated medical waste in a red bag or other appropriate container.
7. Correct use of disinfectants.
8. Appropriate caution when handling sharps, including acupuncture needles, seven-star hammers, and lancets.

Basic Steps of the Clean Needle Technique for Acupuncture

1. The provider follows *Safety Guidelines on Hand Sanitation*.
2. A clean field is set up on a stable surface near the treatment table. The clean field may consist of a piece of paper toweling, table paper, a clean metal tray either prepared with a paper barrier or cleaned with an appropriate disinfectant between each patient visit, or a clean field purchased for this purpose.
3. Needles, in their original packaging, are placed on the center of the clean field.

4. Non-sterile cotton balls and skin cleansing materials (e.g., alcohol swabs) are placed either nearby the treatment table in a clean container or on the periphery of the clean field.
5. Sharps and trash containers are placed away from the clean field.
6. The acupuncture points on the patient's skin should be clean. For the purposes of Clean Needle Technique, skin can be cleaned with 70% isopropyl alcohol, soap and water, or another method but must be clean when inserting a needle or lancet.
7. If using alcohol to clean the skin, use a new swab/cotton ball whenever the alcohol swab becomes dirty or contaminated or is too dry to leave a thin layer of alcohol solution on the skin. The insertion point can then be palpated with the washed finger.
8. The needle should be inserted without touching its sterile shaft. Should the needle be long, such as a three to six inch needle, the shaft may be held with sterile gauze or sterile cotton between the fingers and the needle shaft. Insert the needle only once. In the event that the needle location is changed, the needle should be withdrawn and placed in the sharps container. A new needle must be used for each insertion.
9. The needle is then stimulated for therapeutic effect.
10. After the appropriate amount of time, the needle should be withdrawn and placed in a sharps container. Do not place the needle in a tray for later transfer to the sharps container as this increases the risk of an accidental needlestick. Do not hand the used needle to an assistant. This transfer also increases the risk of exposure by accidental needlestick.
11. At the end of treatment, the practitioner washes his or her hands and cleans up the clean field, including replacing or disposing of unused supplies. In the event that the practitioner has used some, but not all, of the needles in a multi-pack of acupuncture needles, all unused needles must also be disposed of in the sharps container. Opened needle packs may not be used for a different patient or a treatment at a later time.

2. CNT Basic Principles

Clean Needle Technique (CNT) includes the following basic principles:

1. Always wash hands between patients, and before and after needling.
2. Always establish a clean field before performing acupuncture.
3. Always use sterile single-use needles and other instruments that may break the skin, such as seven-star hammers, press tacks/intradermal needles, and lancets.
4. Always immediately isolate used needles and other sharps.
5. Follow Standard Precautions.

Besides the obvious necessity for sterile needles, lancets, and seven-star hammers, handwashing is the single most important action in preventing cross-infection. Hands should be washed with liquid soap under running water between patients, as well as before and after performing acupuncture or other procedures, and whenever the practitioner's hands may have become contaminated with potentially infectious material. (See section on handwashing in Part V of this manual.) Potential sources of contamination include touching the hair, clothes, or unclean skin of the patient (or practitioner); paperwork; computers or phones; or any other unclean surface or object in the treatment environment. The main goal of Standard Precautions is safety and specifically the prevention of exposure to and transmission of nosocomial disease.

In the event that it is impractical or impossible for the practitioner to wash his or her hands with soap and water, an alcohol-based hand sanitizer may may be substituted. Alcohol-based hand sanitizers are effective for reducing the presence of potentially infectious agents but will not be effective in the event that the practitioner's hands are soiled. When the practitioner's hands are soiled, washing hands with soap and water remains the best way to remove contamination. The CDC also allows for the use of disinfecting hand wipes when soap and water handwashing is not an option. For proper use of alcohol-based hand sanitizers and disinfecting hand wipes, please see the manufacturer's instructions.

Contaminated needles are the greatest source of infection risk to the practitioner and patient. It is essential to minimize handling of used needles during disposal. These basic principles will be discussed in the sections that follow. It is essential to be meticulous in following all aspects of Clean Needle Technique protocol and Standard Precautions. This includes the use of sterile needles, handwashing between treatments, and isolation of used sharps. Skin and mucus membrane contacts frequently can be prevented with the use of barrier precautions such as gloves, masks, gowns, and goggles when necessary; however, the greatest risk of bloodborne pathogen transmission comes from needlestick injuries. Such accidents are not prevented by barriers but instead require strict adherence to CNT protocols by practitioners, including the immediate isolation of used sharps, the continuing recognition of the need to handle all

patients as if they were potentially infectious, and the need to train all staff in clean needle protocols and Standard Precautions.

Precautions are the same for hepatitis and AIDS as well as for other diseases that might be transmitted by needlestick accidents. Healthcare workers are advised to develop standard and habitual procedures for all patients that provide the necessary protection against the transmission of potentially infectious agents. (12)

Setting Up the Clean Field

A clean field is the area that has been prepared to contain the equipment necessary for acupuncture in such a way as to reduce the possible contamination of sterile needles and other clean or sterile equipment.

A clean field for acupuncture needling is established in the treatment setting by placing a clean paper towel, clean table paper or other clean barrier that will serve as a clean field on an appropriate work surface. (If a tray is used as the clean field, it must be cleaned with an appropriate disinfectant between each patient visit or covered with clean paper or other barrier for each patient visit.) This field should be used for needles (before use) and any clean items the practitioner needs close at hand for needling and other procedures. The clean field should be changed after each treatment session. The work surface used for the clean field should be cleaned at least once daily using appropriate low-level disinfectants.

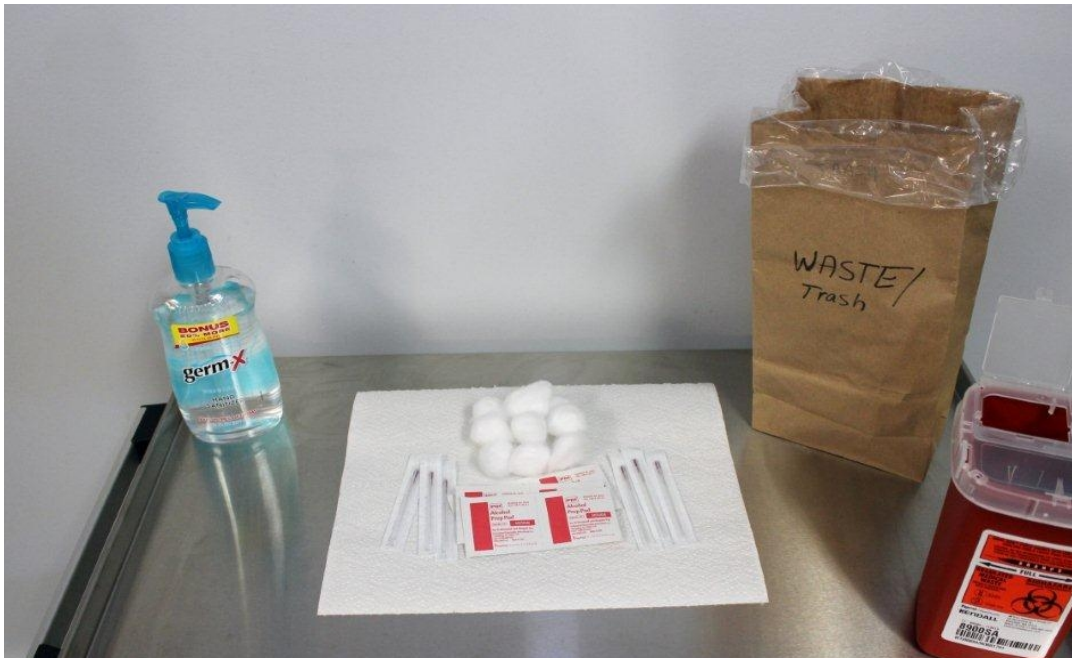

Photo by Darlene Easton and Morris Houghton.

Inspecting Needle Packaging Prior to Use

Prior to use, acupuncture practitioners need to inspect the packaging of any single-use sterile needles (and other sterile sharps) to ensure that the protective barrier has not been breached or damaged by exposure to water. The expiration date of all needles in a clinic should be checked regularly (i.e., monthly) and all expired needles be discarded. Discard any package of needles that has been punctured, torn or damaged, or past the expiration date of sterilization.

When using acupuncture needles from packages that contain more than one needle, all needles left over at the end of a treatment must also be treated as non-sterile sharps and must therefore be discarded in an appropriate sharps container. Any unused but unsterile needles should not be set aside for use later in the day on a different patient or for use on the same patient on a different day. They should be treated as contaminated sharps and discarded appropriately. This should not prevent a practitioner from using the multi-needle packages if that is his or her preference; proper clean technique can still be followed using this type of needle packaging.

Skin Preparation

Acupuncture needles should be used only where the skin is clean and free of disease. Acupuncture needles should never be inserted through inflamed, irritated, diseased, or broken skin. Otherwise, infections can be carried directly into the body past the broken skin barrier. The areas to be needled should be clean prior to treatment. Alcohol swabbing is recommended but not essential before acupuncture needle insertion as long as an area is clean. If swabbing an area, 70% alcohol or ethanol is required. Skin can be cleaned with 70% isopropyl alcohol, soap and water, or another method as determined by the practitioner or clinic administrator. See *Safety Guidelines for Skin Preparation.*

Palpating the Point

It is acceptable clean technique to palpate the acupuncture point after cleaning the skin, as long as the hands are clean and have not been contaminated. However, it is strongly recommended that before picking up the needle or palpating the point, the hands should be washed with soap and water or an alcohol-based hand sanitizer if they have been contaminated since the last handwashing by some activity such as arranging clothing or taking notes. After this second cleaning of the hands, nothing should be touched but the needle handle, guide tube, and the skin over the point. If anything else is touched, the fingers should be cleaned again as described above before proceeding.

Inserting Needle to Correct Depth

While there is no absolute standard for the depth of acupuncture needling, there are studies on methods of establishing safe depths (13) and recommendations from reliable practice textbooks. (1,2,14) Following are some general guidelines and recommendations:

1. Follow the suggested needle depths indicated in standard texts, being sure to allow for variation in body size, age, underlying disease and risk factors. For instance, in puncturing the point Ren 12 (Zhongwan), a strong sensation may be obtained when a depth of 0.5 inch is reached in a thin patient. On the other hand, sensation may only be induced when the needle is inserted to a deeper level for an obese patient. Clinical careful analysis should be made of each patient. For children, needle depths should be less than for an adult.
2. Safe needling depth of the thoracic region to avoid pneumothorax and cardiac tamponade on most patients can be as little as 10-20 mm. Limiting the depth of acupuncture needle insertion to the subcutaneous layer is critical and avoiding use of needles that are longer than the safe needling depth for a particular body area is strongly recommended. (See *Safety Guidelines to Avoid a Pneumothorax, Organ Injury, and Traumatic Tissue Injury*)
3. Soft tissue abdominal depths in an adult can vary from 2-4 cm. and will be less if the patient is thin or the tissue is compressed by palpation. (15)

Can I touch the needle during needle insertion?

If you need to support the shaft of the needle during needle insertion, either because you are using a thin needle (e.g., 0.15 mm width) or a long needle (e.g., more than 25 mm length) or both, you must use a sterile barrier between your fingers and the shaft of the needle. While washing your hands removes most of the transient bacteria from the skin of the hands and fingers, it does not dislodge the resident bacteria. Some people carry resident bacteria on their skin that is pathogenic to other people, such as MRSA. (See information about Healthcare Associated Infections, Part IV, for more information about skin bacteria; and Part V of this Manual for more information about handwashing.) Any object that pierces the skin must be sterile. To support the shaft of the needle, when necessary, use sterile gauze or sterile cotton between your fingers and the needle shaft; then discard the gauze or cotton after completing the needle insertion. This will greatly reduce the possibility of cross infections (practitioner to patient) from acupuncture needling. While many older practitioners do hold the needle shaft with their clean (but not sterile) hands, this practice is to be strongly discouraged in those following the rules of best practices.

Needle Removal

There are no specific standards regarding needle removal techniques. While some will find using a one-handed method (use the same hand to withdraw the needle and cover the point with cotton) less likely to cause a needlestick than a 2-handed method (use different hands for needle removal and covering the point with a cotton ball), no specific studies have shown either method as being superior.

Similarly, there are no studies identifying the safest method for needle removal. While it is clear that removed needles need to be placed immediately into a sharps container, there is no evidence indicating that needles must be removed and placed in a sharps container one at a time. Limiting time and distance between removing the needle and placing used needles in a sharps container is strongly recommended. Walking around or gesticulating with used needles in your hands needs to be avoided as much as possible.

Always use a cotton ball or other clean, absorbent materials (swab, gauze) for covering the hole after needle removal; never use your hand or finger. Some blood may be present, especially in the ear or on the scalp and best practices dictate that for safety, a barrier between the practitioner's hands and the open area of skin is best to reduce the likelihood of transfer of pathogens from the patient to the practitioner or vice versa.

Dealing with Blood to Blood Contact

Acupuncture practitioners and office personnel are at risk for exposure to bloodborne pathogens, including hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). Exposures occur through needlesticks or cuts from other sharp instruments contaminated with an infected patient's blood or through contact of the eye, nose, mouth, or skin with a patient's blood. The vast majority of blood to blood contacts resulting from AOM procedures do not result in infection. Of the bloodborne pathogens, HBV is the most likely to be passed by needlestick exposure. HBV infection is usually preventable through a vaccine series. However, the only sure method of preventing HIV and HCV is abstinence from activities that involve the exchange of potentially infected body fluids. In the healthcare workplace, accidental contact with potentially contaminated blood or body fluids may be unavoidable. However, strict observance of Standard Precautions can prevents infection from exposure, including bloodborne pathogens such as HBV, HCV, and HIV. (16)

Managing Used Needles

Used instruments that have penetrated the skin must be isolated immediately in an appropriate sharps container. Used needles, lancets and the head of a seven star/plum blossom hammer should not be reused, or sterilized for reuse. Used needles present risk for practitioners, staff, and children waiting for their parents.

When using needles from packages that contain more than one needle, all needles left over at the end of a treatment must also be treated as non-sterile sharps and must therefore also be discarded in an appropriate sharps container. These unused but unsterile needles should not be set aside for use later in the day on a different patient or for use on the same patient on a different day. They should be treated as contaminated sharps.

A sharps container for the used needles should be right beside the treatment table, on a flat, stable surface (not directly on the treatment table) so that there is no delay in placing used sharps in the container and away from potential accidental contact. Alternatively, sharps containers can be securely fastened to a wall close to the treatment table. Sharps containers should be of official construction and labeled with the biohazard symbol.

Sharps containers should be replaced regularly and not be filled above the fill mark or filled in such a way that used needles are sticking out of the top. Replace a container when it is three-quarters full; do not attempt to push down the contents so that more may be placed inside. This is critical for staff as well as practitioners, as studies document that a significant percentage of staff experience needlesticks while cleaning up sharps containers. (17)

Counting Needles

One way to ensure that needles are not left in a patient or left on treatment tables or floors where they may cause a needlestick injury to office personnel is to count the number of needles used during a treatment and then count the number of needles removed and discarded after a treatment is completed. These needle counts can be documented in the patient's chart. At the end of a treatment, if one or more needles are not located during needle removal, the practitioner should check the treatment table and floor around the table for needles that may have fallen out during the treatment session.

3. CNT in an Office Setting

First, upon entering the room with a patient, wash or clean hands. Then proceed with clinical intake and pulse/tongue diagnosis. Wash hands again as needed prior to palpating any areas for pain or lesions.

Treatment Protocol in an Office Setting

1. Select a clean, dry, flat surface to serve as the setting for the clean field. (Note: The selected location CANNOT be the treatment table as the patient may move his or her body!) [critical]
2. Wash hands for at least 10 - 15 seconds under running water, lathering well with soap. Liquid soap is recommended rather than bar soap, which may become contaminated. Or, if soap and water are unavailable, clean hands with the alcohol-based hand sanitizer. [critical]
3. Place a clean paper towel, clean table paper or other barrier that will serve as a clean field on the work surface in a way that does not compromise the cleanliness of the surface that will serve as the clean field. [strongly recommended]
4. Set out the materials needed for a treatment. Sterile items such as acupuncture needles in blister packs (in their original packaging) should be placed on the center of the clean field first. It is acceptable to utilize either individually wrapped needles or needles in multi-packs as long as they are sterile, single-use needles. [recommended]
5. Clean items such as cotton balls and unopened swabs may either be placed on the clean field or kept in jars or containers near the clean field so as to be at hand for the practitioner. [recommended]
6. Ensure the skin at the acupuncture points to be used is clean. If 70% alcohol swabs are used, allow the alcohol to dry. [strongly recommended]
7. If a practitioner must place the needle inside a guide tube, the needle should be dropped into the tube, handle first, to minimize the risk of contaminating the point of the needle. [strongly recommended]
8. Insert, manipulate, and withdraw the needle without touching the shaft of the needle that enters the patient's skin at any time. [critical] If a guide tube is to be reused, it should be placed on the clean field between uses. [strongly recommended]
9. If the needle is long or thin and cannot be inserted without touching the shaft, the practitioner should use sterile gauze or cotton to hold the shaft of the needle during needle insertion and manipulation. [strongly recommended] The needle shaft should never be touched with the bare hand, even if that hand has been cleaned.
10. If the practitioner misses the point on the first insertion and has to re-needle, a new needle must be used. Practitioners may not reinsert a needle because once a needle has been inserted, it is no longer sterile and must be disposed of.[critical]

11. Count the number of needles used, including those discarded due to improper needle placement. [strongly recommended]
12. Retain needles and stimulate as needed for therapeutic effect.
13. Remove needles, putting used needles immediately into an appropriate sharps container. [critical]
14. If the practitioner wishes to cover the skin where a needle has been removed, a clean, dry cotton ball should be used. [strongly recommended] The cotton ball need not be sterile.
15. Count the number of needles withdrawn from the patient. Confirm that the same number of needles inserted has been withdrawn and discarded. [strongly recommended]
16. Dispose of all cotton balls and alcohol swabs as they are used, placing them immediately in an appropriate trash container. They are not to be placed on the clean field after use. [critical]
17. Wash/cleanse hands before leaving the treatment room. [strongly recommended]

4. CNT for House Calls/Travel Setting

Travel Kit /Travel Kit Carrier

The travel kit should be carried in an appropriate hard-sided container or plastic case large enough to carry all the recommended equipment. The kit must be hard-sided inside and out so that all surfaces can be thoroughly cleaned. It must have a tight closure. Plastic bags or soft-sided containers are not acceptable because they are not puncture-proof. (Examples of acceptable containers would include a fishing tackle box, toolbox, a make-up or art box, or a plastic craft supply box. An example of an unacceptable case would include a leather briefcase with a flap top that leaves a gap at the sides.) The container to be used must be able to accommodate a sharps container in an upright position so as to limit needle loss from the sharps container.

Clean Items

The following items should be placed inside a gallon-size ziplock plastic bag. Note that some of these items will be placed inside their own smaller bag (i.e., cotton balls and paper towels) and that these items must remain in their own bag when they are placed inside the larger bag.

- Sealed packages of sterile, disposable single-use acupuncture needles of the length and gauge required by the practitioner. (It is recommended that travel kits contain at least 20 needles; for purposes of the CNT course, CCAOM requires that participants bring at least twenty 1 inch and twenty 1.5 inch needles to the CNT practical exam.)
- Commercially prepared clean fields, clean paper toweling, or any other clean surface (such as a tray). This will serve as a clean field and must be packed in its own ziplock plastic bag or container.
- Clean, dry cotton balls (at least 20) packed in their own ziplock plastic bag. Cotton balls need not be sterile.
- Five commercially sealed individual 2 x 2 inch gauze pads. These will be used to hold the shaft of the needle if support is needed upon insertion.
- One pair of gloves in a commercially-sealed packet or in its own plastic ziplock bag. Thin gloves used for medical examination or surgery are sold in most drug stores and are best suited for travel kits. (Keep in mind that some people are allergic to latex.) These gloves are used in case of emergencies. For example, the gloves may be needed to clean up accidental spills of contaminated needles or waste. They may also be used according to OSHA guidelines such as when blood is likely to be present during a treatment (e.g., bleeding techniques).
- 70% isopropyl alcohol prep pads in commercially sealed packets (at least 30).

Non-Clean Items

The following two items in the kit are kept in two separate gallon-sized ziplock plastic bags inside the travel container so as to keep them separate from the clean equipment:

- A small paper bag with a plastic liner to receive trash (used cotton balls, etc.). This bag should be clearly marked in ink as “Waste” or “Trash.”
- A small, red, commercial sharps container. This container must be impervious, unbreakable, clearly marked "Contaminated," and bear the official biohazard symbol. These containers can be purchased in a medical supply store or from an acupuncture supply company. (Note: anything that qualifies as medical waste, such as blood-soaked cotton balls would need to be removed by a medical waste disposal firm and would therefore need to be discarded in the sharps container for travel kit use only. OSHA defines cotton balls soaked with blood that can be wrung out as being medical waste; less blood than that should be considered trash and should be placed in the trash bag. (17,18,19)

After use, these items should be replaced in their individual gallon-sized ziplock bags. These bags should then be securely sealed and placed inside the travel container.

Travel Kit Items Not in Bags

- Hemostat or tweezers (used to remove broken or stuck needles or to pick up needles from the floor if dropped).
- Alcohol-based hand sanitizer

Photo by Darlene Easton and Morris Houghton.

Hand Cleanser

A bottle of alcohol-based hand sanitizer should also be included in the travel kit. This should not be placed in either the clean items bag or the bags for the non-clean items, but should be placed independently inside the travel carrier. Such cleansers have been found to be effective in reducing contamination on the practitioner's hands if soap and water are not readily available at the treatment site.

Travel Sharps Container

Each state has different rules regarding sharps containers for use at home and for use in medical offices. Many states require the use of commercially prepared sharps containers for medical personnel. Contact your local health department or see the website http://www.safeneedledisposal.org/ for information by state regarding sharps disposal regulations. In ALL states, use of a commercially prepared sharps container will meet the regulations for sharps disposal. If a non-commercial container is legal for use (such as a pill bottle with a screw-on cap), be sure to mark the container with the biohazard symbol and dispose of the container following all rules for biohazardous waste.

Preparing the Kit

The kit should be prepared in such a way that all items in it remain clean.

1. The hard-sided container must be washed inside and out in hot, soapy water and dried with a clean paper towel. Ziplock bags should be fresh from the package and free of rips and holes.
2. Hands should be washed before assembling the kit.
3. Paper toweling should be taken directly from its package and placed in a small ziplock plastic bag to ensure continued cleanliness. A commercially available clean field will come individually wrapped.
4. Cotton balls should be taken directly from the stock bag and placed in a small plastic bag or other container.
5. Pre-packaged alcohol swabs should be taken directly from their original box and placed in the kit. If the individual packages have been sitting on a shelf, the outer surfaces of the packets are no longer considered clean.
6. Disposable needles should be placed into the travel kit directly from the original box.

Treatment Protocol in a Travel Setting

1. Select a clean, dry, flat surface to serve as the setting for the clean field. If necessary, clean it with soap and water and dry it thoroughly. [recommended]
2. Open the travel kit and remove the alcohol-based hand sanitizer. Set it up near where the clean field will be placed, so that it is easily accessible.

3. Wash hands for at least 10-15 seconds under running water, lathering well with soap. Liquid soap is recommended rather than bar soap, which may become contaminated. Or, if soap and water are unavailable, disinfect hands with the alcohol-based hand sanitizer that should be included in the travel kit. [critical]
4. Remove the clean paper towel that will serve as a clean field. Place it on the clean, dry work surface in a way that does not compromise the cleanliness of the surface that will serve as the clean field. [strongly recommended] For example, a clean folded towel should be handled by the four corners in order not to contaminate the center of the field. If alcohol is spilled or wet cotton is dropped on a previously clean field, it can no longer be considered clean since contaminants can wick into the field. A new clean field must be established before proceeding.
5. Set out the materials from the travel kit. Sterile items such as acupuncture needles in blister packs (in their original packaging) should be placed on the center of the clean field first. [strongly recommended] Clean items such as cotton balls and unopened swabs should be placed on the clean field near the edges of the field. The waste bag and the opened sharps container should be placed last, outside the clean field, in such a way that you will not need to cross the clean field to discard a used needle or waste. [recommended]
6. Ensure the skin at the acupuncture points to be used is clean. If 70% alcohol swabs are used, allow the alcohol to dry. [strongly recommended]
7. If a practitioner must place the needle inside a guide tube, the needle should be dropped into the tube, handle first, to minimize the risk of contaminating the point of the needle. [strongly recommended]
8. Insert, manipulate, and withdraw the needle without touching the shaft of the needle that enters the patient's skin at any time. [critical] If a guide tube is to be reused, it should be placed on the clean field between uses, since it has been handled and is no longer sterile. [strongly recommended]
9. If the practitioner misses the point on the first insertion and has to re-needle, a new needle must be used. [critical] Practitioners may not reinsert a needle because once a needle has been inserted, it is no longer sterile and must be disposed of.
10. Count the number of needles used, including those discarded due to improper needle placement. [strongly recommended]
11. Retain needles and stimulate as needed for therapeutic effect.
12. Remove needles, putting used needles immediately into an appropriate sharps container. [critical]
13. If the practitioner wishes to cover the skin where a needle has been removed, a clean, dry cotton ball should be used. [strongly recommended] The cotton ball need not be sterile. A wet cotton ball or swab can wick up blood or other potential infectious

material, bringing it into contact with the practitioner's fingers and increasing the risk of cross-infection.

14. Count the number of needles withdrawn from the patient. Confirm that the same number of needles inserted has been withdrawn and discarded. [strongly recommended]
15. Dispose of all cotton balls and any alcohol swabs as they are used, placing them immediately in the plastic-lined paper waste bag carried for that purpose. They are not to be placed on the clean field after use and are not to be set down anywhere else but in the waste bag. Close the waste bag securely after the last used materials are placed inside.
16. Close the lid of the sharps container securely when you are done with the treatment. [critical]
17. Wash hands immediately after removing needles and before handling anything else. [strongly recommended]
18. Pack equipment correctly, placing the sharps container and waste bag into their separate ziplock bag as the last step in packing the kit.
19. Wash hands since the sharps container and waste bag were the last items handled. [strongly recommended]

It is important to keep in mind that fundamentally, there is no difference between clean protocol in the office and in a travel situation. The biomedical requirements for safety are the same.

5. CNT in a Community Acupuncture Clinic or NADA Setting

The Clean Needle protocol is essentially the same for every acupuncture patient in any setting. The critical items remain the same: always establish a clean field, always wash hands before every acupuncture treatment, always use single-use disposable sterile filiform needles, follow Standard Precautions, and always immediately isolate used sharps in appropriate containers. In a community acupuncture setting or NADA treatment setting, multiple patients may be treated at the same time in the same room while sitting in chairs. While there may not be a specific type of chair that is best for this setting, the practitioner needs to consider that all chair surfaces need to be cleaned between patient visits; use of cloth chairs makes this more difficult. Additionally, if a sheet or table paper is used as a barrier on the treatment chairs, these need to be changed for each new patient. Armrests or other surfaces that are exposed to bare skin during treatments should be cleaned between each patient session. Note that if care is not taken to account for all needles used in these setting, seat cushions hide many fallen needles. Those persons cleaning treatment surfaces must be assured that all needles are accounted for before cleaning treatment chairs.

Treatment Protocol in a Community Clinic or NADA Setting

1. Select a clean, dry, flat surface to serve as the setting for the clean field. (Note: The selected location CANNOT be the treatment table!) For community acupuncture or NADA, an instrument tray, instrument cart or a table in a central location is appropriate. If desired, a small basin or container for used materials (cotton balls, alcohol swabs and guide tubes) may be placed on the same tray near the clean field. This container should not touch the clean field. [strongly recommended]
2. Wash hands for at least 10-15 seconds under running water, lathering well with soap. Liquid soap is recommended rather than bar soap, which may become contaminated. Or, if soap and water are unavailable, clean hands with the alcohol-based hand sanitizer. [critical]
3. Place a clean paper towel, clean table paper or other barrier that will serve as a clean field on the work surface in a way that does not compromise the cleanliness of the surface that will serve as the clean field. [strongly recommended]
4. Set out the materials needed for all the treatments to be performed in a single session. Sterile items such as acupuncture needles in blister packs should be placed on the center of the clean field first. [strongly recommended] Cotton balls, gauze, and other materials should be placed closer to the edges of the field. [recommended]
5. Clean items such as cotton balls and unopened swabs may either be placed on the clean field or kept in jars or containers near the clean field so as to be at hand for the practitioner. [recommended]

6. Ensure the skin at the acupuncture points to be used is clean. If 70% alcohol swabs are used, allow the alcohol to dry. [strongly recommended]
7. If a practitioner must place the needle inside a guide tube, the needle should be dropped into the tube, handle first, to minimize the risk of contaminating the point of the needle. [strongly recommended]
8. Insert the needles without touching the shaft of the needle that will be inserted into the patient's skin. [critical] If a guide tube is to be reused, it should be placed on the clean field between uses, since it has been handled and is no longer sterile. [strongly recommended]
9. If the practitioner misses the point on the first insertion and has to re-needle, a new needle must be used. [critical] Practitioners may not reinsert a needle because once a needle has been inserted; it is no longer sterile and must be disposed of. [strongly recommended]
10. Use hand cleanser between each patient treatment. [strongly recommended]
11. Ensure the skin at the acupuncture points to be used is clean. [critical]
12. Repeat steps 8-11 for each patient being treated during a single session.
13. Remove needles from the patient one at a time, putting used needles immediately into an appropriate sharps container. [critical]
14. If the practitioner wishes to cover the skin where a needle has been removed, a clean, dry cotton ball should be used. The cotton ball need not be sterile. [strongly recommended]
15. Dispose of all cotton balls and alcohol swabs as they are used, placing them immediately in a container on the treatment cart or in an appropriate trash container. They are not to be placed on the clean field after use. [recommended]
16. Wash/cleanse hands before leaving the treatment room. [strongly recommended]

6. CNT in a Public Health Setting

There is a growing use of acupuncture in public health settings such as addiction treatment facilities, clinics that treat large numbers of HBV, HCV, and HIV patients, and clinics with high populations of patients at risk of TB, as well as in institutions such as jails, public hospitals, community centers, and other social agencies that have group treatment rooms where several patients sit and receive ear or body acupuncture.

Patients may arrive together or separately, but usually do not have individual appointments. Many of these rooms do not have a sink. Some may have access to one nearby, but it is not always guaranteed. Many of these settings aim at treating persons who are drug- and/or alcohol-addicted and who present with related and frequently multiple health and social problems such as TB, HIV infection, mental illness, homelessness, hunger or malnutrition, or poverty. These individuals frequently present with a long history of illness and a debilitated immune system. Staff performing acupuncture treatments are appropriately trained acupuncturists and/or acupuncture chemical dependency specialists, depending on state regulations. There are often other providers from different disciplines involved such as physicians, social workers, nurses, counselors, community workers, physician assistants, and nurse practitioners. The characteristics of these clinics mandate some special discussion.

Handwashing

Handwashing is one of the most problematic topics within a public health or group treatment setting. It is not realistic to expect that the practitioner will wash his or her hands in a sink after each treatment due to the volume of patients to be treated, the time and logistics that would be required, and frequently, the lack of facilities for handwashing. It is critical, however, that practitioners utilize alcohol-based hand sanitizers or disinfecting wipes between each patient treatment. It is also strongly recommended by CDC that practitioners:

1. Wash hands with soap and water on arrival and before leaving work, before eating, and after restroom use. [critical]
2. If hands are dirty with some organic matter such as blood, they must be washed with running water and soap. [critical]
3. An alcohol-based hand sanitizer should be used between treatments, provided that only the needles, sterile packages, and other materials needed for the treatment were touched. [strongly recommended]
4. Hands must be cleansed between patient treatments. [critical]
5. An alcohol-based hand sanitizer or hand wipe can be utilized as needed during treatments and between patient treatments. [recommended]

6. Gloves should be available in the treatment area and should be worn when there is an open wound on the practitioner's hand or there is risk of blood or OPIM contamination, such as significant bleeding from an auricular acupuncture point. [critical]
7. Practitioners should wash their hands immediately with soap and water after critical instances, such as contact with blood or a break in the clean field between or during treatments. [critical] (20)
8. Practitioners must have appropriate hand cleansers available to them at all times in the public health treatment environment. [critical]

Acupuncture Equipment

Disposable needles are recommended for all acupuncture treatments. Some states mandate that only disposable needles can be utilized by practitioners, including those working in public health facilities treating chemical dependency. Guide tubes are not recommended for auricular acupuncture. As always, care should be taken to monitor press needles for potential infections.

Positioning the Patient

When the patient is sitting up, it is important to make sure that, where possible, the patient has his or her head and neck supported, that the legs and arms are not crossed, and that the person is comfortably seated. Patients should be encouraged to use the bathroom prior to treatment. If a patient does need to use the restroom during treatment, all needles should be removed and then replaced when he or she returns.

Removing Needles

When a practitioner is removing needles, it is critical for a sharps container to be in the immediate vicinity, preferably where the container is secure and cannot be knocked over. In many public health settings it is important that needles be accounted for by counting the needles used. In settings such as jails, the patients often may not leave until all needles are accounted for. In some detox clinics patients remove their own needles. In these instances the practitioner should always check for needles that may have dropped and for bleeding that may have occurred. In all cases, practitioners should check chairs and surrounding areas for fallen needles before, during, and after each session, and after each patient's needles are removed. If a needle falls out of the ear onto the clothing of the patient during treatment, it should be removed with a minimum of disturbance. Practitioners should instruct patients not to handle needles if the needles fall out or after removing them as this may create a situation in which a needlestick injury may occur. It is also critical that practitioners be able to identify the number of needles used and the number properly discarded in a public health setting.

Potential Complications

If a patient faints while sitting up, all needles should be removed immediately, legs elevated and the head lowered. It is also recommended that patients be placed safely on the floor if possible, making sure that the airways are not obstructed. Acupuncturists may use a finger to press Du 26 (Renzhong) to help revive the patient; calling for medical help may be necessary in some cases.

Delayed bleeding is common. Practitioners must be aware of this possibility. Patients should be monitored after needle removal and before leaving the premises.

7. Toyohari Acupuncture

Contact needling (or non-insertion needling) is sometimes utilized in Japanese meridian therapy and has been developed in depth in Toyohari acupuncture. In this style of acupuncture, “The needle does not penetrate into the body; the needle tip is held at the skin surface or perhaps touches the skin but does not penetrate the skin.”(21) When performing contact needling, the needle may be placed between the clean thumb and index finger of the non-dominant hand, which are resting on the skin at the acupuncture point. This is called the “oshide” in Japanese meridian therapy. (22) Since the shaft of the needle is not penetrating the skin, the needle shaft does not have to be protected as sterile. However, the practitioner’s hands, and especially the fingers, must be clean. Handwashing must take place immediately before contact needling as with needling with insertion. When practitioners perform this technique, the thumb and index finger of the non-dominant hand must be on the patient’s skin and the needle is held between the fingers because the changes in the qi at the tip of the needle must be felt to do this technique properly. (22,23)

Modifications to Standard Clean Needle Technique for Contact Needling

The standards of handwashing, setting up a clean field, immediately isolating used sharps and following Standard Precautions remain the same as with all acupuncture needling techniques. The variation here is that the shaft of the needle may be touched by the practitioner’s fingers in this style.

In Toyohari acupuncture, the needle itself does not penetrate the skin. Therefore, when performing contact needling, the needle removal can be followed with placing a clean finger on the spot where the needle had been in contact with the skin, since there is no chance of blood or OPIM being present when using this technique. (21)

8. Summary of Safety Recommendations for Clean Needle Technique

- Critical: Follow Clean Needle Technique.
- Critical: Always establish a clean field before starting acupuncture or any technique which breaks the skin.
- Critical: Only use single-use sterile instruments when breaking the skin surface (needles and lancets).
- Critical: Always wash hands immediately prior to starting acupuncture or any technique which breaks the skin.
- Critical: Do not touch the tip or shaft of the acupuncture needle that will enter the patient's skin prior to or during needle insertion with anything which is not itself sterile.
- Critical: Do not needle into any skin lesion. Acupuncture needles should never be inserted through inflamed or broken skin.
- Critical: Immediately isolate used needles in an appropriate sharps container.
- Critical: Use new table paper on each treatment table for each new patient visit.
- Critical: Wipe down each treatment chair or table with an approved disinfectant solution or disinfectant cloth between each patient visit.
- Critical: Wear gloves or finger cots, or otherwise cover up any areas of broken skin on the practitioner's hands.
- Critical: Check needles prior to use for sterilization expiration dates, breaks in the packaging, or any evidence that air or water has entered the needle packaging prior to use.
- Critical: Maintain clean procedure at all times while handling needles prior to insertion. If needles or tubes become contaminated, they should be discarded.
- Critical: Needle manipulation must be performed without the practitioner coming into contact with the part of the shaft of the needle that will enter the patient's skin.
- Critical: Never insert a needle all the way to the handle.
- Critical: When using a multi-needle pack of sterilized needles, once the packaging is opened for one patient visit, any unused needles must be discarded properly and not saved for another patient treatment session.
- Critical: All patients need to be treated as if they are carriers of bloodborne pathogens such as Hepatitis B or HIV.
- Critical: Ensure that the part of the body to be treated is clean.
- Critical: Obtain a medical history from a patient regarding lung function, lung diseases and smoking history before needling the thorax. Assess the physique of the patient. Atrophy or poor muscle development in the thorax may increase the risk of pneumothorax.

- Critical: Identify those acupuncture points which lie over or next to major vessels.
- Critical: If alcohol is used to clean the acupuncture sites, allow alcohol to dry before needling.
- Strongly Recommended: Count and write down the number of needles used, including those discarded due to improper needle placement. Count the number of needles withdrawn from the patient. Confirm that the same number of needles inserted has been withdrawn and discarded.
- Strongly Recommended: Document needle counts in the patient chart.
- Strongly Recommended: Ensure that the patient's skin is clean before inserting a needle or lancet. Skin can be cleaned with 70% isopropyl alcohol or soap and water or other method; if 70% alcohol is used, allow alcohol to dry before needling.
- Strongly Recommended: Use only single-use sterile filiform needles for acupuncture treatments.
- Strongly Recommended: When needle stabilization is needed, the practitioner should use sterile cotton or sterile gauze to stabilize the shaft of the needle.
- Strongly Recommended: Palpate subcutaneous structures, including major vessels, before preparing an acupuncture site for needle insertion.
- Strongly Recommended: Identify the proper depth of needle insertion and utilize proper stimulation techniques for needles placed below the subcutaneous level.
- Strongly Recommended: Angle acupuncture needles obliquely when inserting needles from the top of the shoulders to the T-10 area on the back, or to below the xiphoid level on the chest.
- Strongly Recommended: Limit the depth of acupuncture needle insertion to the subcutaneous layer and initial perimysium of the intercostal muscles.
- Strongly Recommended: Never insert a needle to the handle.
- Strongly Recommended: All patient histories should include information about current or past diseases that might lead to a change in the size of the organs.
- Strongly Recommended: If there are signs that an organ may have been punctured, emergency transport should be called to take the patient to an emergency facility.
- Strongly Recommended: Wash hands or use CDC-approved hand cleanser upon entering a patient room and after completing any patient treatment.
- Strongly Recommended: Guide tubes must be sterile at the beginning of the treatment and must not be used for more than one patient.
- Strongly Recommended: Establish a new clean field for each new patient.
- Strongly Recommended: Replace any cloth table coverings after each patient visit.
- Strongly Recommended: Utilize gloves when removing needles from locations where bleeding is likely.

- Strongly Recommended: After needle removal, apply pressure to the acupuncture point with clean cotton or gauze.
- Strongly Recommended: Clean all treatment room surfaces with approved disinfectants daily.
- Strongly Recommended: If you stick yourself with a used or contaminated needle, seek medical advice immediately.
- Recommended: Clean all common use areas with an approved disinfectant daily.
- Recommended: Practitioners should remove all jewelry and artificial nails prior to handwashing.
- Recommended: Explain acupuncture procedures in detail and answer all patient questions about the procedures to be performed prior to acupuncture to allay concerns and nervousness. Make sure the patient is aware of the likely effects of acupuncture.
- Recommended: Inform patients that they should eat 1-2 hours prior to acupuncture treatments.
- Recommended: While it is acceptable to palpate the cleaned area of skin to precisely locate the acupuncture point after the skin is cleaned and before needling, the practitioner should not trace fingers or hands across a wide area of skin to locate an acupuncture point after the skin is cleaned and before needling.
- Recommended: Palpate subcutaneous structures, including blood vessels, tendons, muscles and bones, before preparing the site for insertion.
- Recommended: Limit needle manipulation during the first acupuncture treatment or until clinical assessment of the patient's response to acupuncture has been established.
- Recommended: Remind patients to remain still during acupuncture treatments.
- Recommended: Needle manipulation should be limited or bi-directional when twirling is involved as indicated by desired therapeutic effect to limit the likelihood of a stuck needle.
- Recommended: If a needle is stuck when attempting removal, try (1) twisting the needle in the opposite direction from the initial stimulation; (2) stimulating the meridian near the stuck needle with simple finger pressure; (3) tapping near the stuck needle; (4) inserting another needle nearby the stick needle; or (5) wait a few minutes then try to remove the needle again.
- Recommended: After needle withdrawal, apply pressure to the acupuncture point with clean cotton or gauze.
- Recommended: Have the same practitioner remove the needles as the one who inserted the needles for better memory cues about possible hidden needle sites.
- Recommended: Keep used/empty needle packets in the treatment room until the end of the patient's treatment; confirm all needles removed from the packaging are

accounted for either by removal from the patient, discarded unused, or discarded after contamination.

- Recommended: If unexpected aggravation of symptoms occurs as a result of acupuncture treatment, consider consultation with or referral to another practitioner for further evaluation prior to performing additional acupuncture treatments.
- Recommended: Investigate and follow local and state regulation concerning skin preparation.

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Part III: Best Practices for Related AOM Office Procedures

In the healthcare field, best practices are procedures that could be followed to limit dangers to the patients, practitioner and staff. Best practices can be revised as needed to keep up with the latest research. Best practice guidelines produced specifically for practicing health professionals are based on the best available research evidence as reported in systematic reviews, case reports, reference texts, and other sources of evidence.

The following recommendations utilize practices as described in *Chinese Acupuncture and Moxibustion* (1) and *Acupuncture – A Comprehensive Text,* (2) and apply safety practices based on the evidence from Part I of this manual to AOM clinical practice procedures. The best practice guidelines below outline critical procedures and offer options for recommended procedures.

There are a number of other methods with safety protocols applicable to various styles of AOM office procedures. This section is not meant to be exhaustive or prohibitive, but rather to be instructive. Schools and practitioners are encouraged to implement additional and alternative methods to reduce risk, utilizing additional and alternative techniques for moxa and other practices utilizing AOM clinical traditions.

As noted in Part I, unlike acupuncture needling, many of these procedures have received far less scrutiny in the medical literature. Few prospective or retrospective studies have been conducted to enumerate the safety issues associated with AOM clinical practices other than needling. The best practices noted herein have been designed based on the literature available, traditional AOM training or have been adapted from medical practices utilizing similar processes.

Each of the following recommendations is only one version of best practices that could be utilized wherein a practitioner applies the critical and strongly recommended cautions to each AOM practice. These are not meant to identify standard practices for any of these techniques. Practitioners need to determine their own methodologies to implement clinical best practices given the information available in this manual, the medical and AOM literature, and other sources of information that apply to their specific style of practice.

For the purposes of this manual, the following terms will be utilized to help practitioners apply best practices to their personal practices: critical, strongly recommended and recommended. See the introduction for an explanation of these terms.

1. Moxibustion

Moxibustion Overview

Moxibustion is the burning of mugwort (*Artemesia vulgaris*) herb (moxa) on or near the skin, with or without acupuncture needles for the purpose of warming tissues in order to stimulate circulation of qi and blood, transform fluids, or warm the yang. Moxa may also be used to resolve heat toxins and drive heat outward, nourish yin, descend the qi, and to otherwise balance the meridians, substances and zang-fu depending upon the location and type of moxibustion performed. The effectiveness of moxibustion has been shown in a wide range of conditions from musculoskeletal disorders, gynecologic conditions, and digestive complaints to the treatment of Herpes zoster and other infections.

Moxibustion may occasionally cause burning and blistering of the skin (first or second degree burns). Patients must always be asked for consent before a practitioner applies moxibustion techniques.

Practitioners performing moxibustion should avoid causing unnecessary burns (see scarring moxa below for the exception to this rule) and be aware that each person has a different tolerance to heat. It is important to be especially careful with persons who have conditions where sensitivity of local nerves may be diminished, such as in neural injury, diabetes mellitus, or pathology resulting in paralysis, because such persons are especially susceptible to burns. Even chemical heat devices such as Hot Spots and heat lamps have been known to burn diabetic patients.

When using indirect moxa on the needle, be sure to protect the patient's skin from any falling moxa or ashes. If using direct moxa, it is suggested that the practitioner fully explain the technique to the patient and ask the patient to sign an informed, written consent form before using this technique.

If a patient has been burned, infection is the primary concern. If the burn is a very small first degree burn, current practice is to run cool water over the burn (never ice), and then apply sterile gauze. (If this is not possible, use an over-the-counter burn cream followed by the application of sterile gauze.) If a burn is severe, or if there is a concern with infection, refer the patient to a physician.

The risks of exposure to moxa smoke are probably similar to that for any other smoke, and total exposure time, particularly when it involves prolonged exposure, is the key concern. Occasional use of ordinary moxa would be associated with low risk, while routine exposure to moxa smoke during much of the day would be a moderate risk. Therefore, using a space in which there is

proper ventilation (or the use of a HEPA filter) is appropriate when moxibustion is being performed.

The risk of setting a fire during moxa therapies is small but possible. All necessary fire safety protocols should be followed. It is strongly recommended that rooms in which moxa treatments are to be performed be equipped with either fire extinguishers or sprinkler systems. Water should be present and available to extinguish small burns on treatment surfaces or patients during all moxa therapies. Practitioners should not walk from room to room with lit moxa materials. Instead, moxa should be lit as close as possible to the treatment table or chair and extinguished as soon as treatment is concluded. Lighting of moxa should be done without an open flame coming close to the patient's hair, skin or clothing. In the methods discussed below, an incense stick is used to light the moxa; other methods for lighting the moxa without utilizing an open flame can be utilized based on practitioner preference.

General Moxibustion Precautions

- Critical: Practitioners must wash hands thoroughly before starting moxibustion, and before and after treating any burns as OPIM may be present.
- Critical: Prevent second degree burns from moxa by paying close attention to a patient's comfort and skin reactions during all treatments.
- Critical: Take a careful patient history to identify neuropathies or other conditions that might limit a patient's response to pain or the ability to sense heat.
- Critical: During moxa therapy the practitioner must remain in the room at all times.
- Critical: Anticipate and shield a patient's skin from falling ash when utilizing needle-top moxa.
- Critical: Avoid moxibustion on the face or in the hairline.
- Critical: Rooms in which moxibustion is being performed must have proper ventilation.
- Strongly Recommended: The practitioner should not attempt to multi-task during the application of moxa therapies.
- Strongly Recommended: The practitioner should monitor the skin temperature and amount of heat generated by moxa and not rely solely on patient feedback about heat sensations when utilizing any form of moxibustion.
- Strongly Recommended: Measure and chart the diameter and location of any burns occurring as a result of moxa therapies.
- Strongly Recommended: Practitioners utilize air filter units which include HEPA filters when performing moxibustion.
- Recommended: Rooms in which moxa is to be used should be equipped with water and a fire extinguisher.

- Recommended: Consider options other than moxa for patients with a history of significant asthma or other reactions to smoke.

Moxa Best Practice Guidelines

After reviewing the literature about moxibustion safety and using the information about the possible AEs associated with moxa therapies, the following best practice guidelines have been developed. As stated at the start of this section of the manual, these procedures are designed to limit dangers to the patients, practitioner and staff. In all cases, the following procedures can be revised as needed to keep up with the latest research and modified as needed for specific styles of practice as long as safety remains the priority.

Direct Moxibustion - Technique for Non-Scarring Moxibustion with Moxa Cones

A moxa cone is placed on a point and ignited. When about 2/3 of it is burnt or the patient feels a burning discomfort, the moxa is removed.

Method

1. A thorough patient history is performed to identify any conditions that being performed that might limit a patient's response to pain or the ability to sense heat [critical] or may increase a reaction to the moxa smoke. [recommended]
2. Proper ventilation is assured through use of windows or air filters or other air filtering process. [critical]
3. Moxa cones are prepared prior to lighting any moxa.
4. All equipment is placed on a stable surface directly next to the treatment table Equipment: moxa cones, tweezers/hemostat (if desired), cup of water (if desired), ashtray (if desired), lubricant or skin lotion, lighter, incense stick, and other equipment as needed.
5. The practitioner washes his or her hands. [critical]
6. The area to which moxa will be applied is prepared with skin lotion or lubricant, if desired, based on the type of moxa practice.
7. The first cone of moxa, unlit, is applied to the skin location.
8. A material such as an incense stick is lighted, using the lighter, away from the patient. Other materials can be used as long as an open flame is kept some distance from the patient's skin. [recommended]
9. If desired, a hemostat or tweezers may be applied to the moxa and the incense (or other material) is then used to light the moxa. [recommended]Practitioners may also choose to use their fingers for moxa application and withdrawal based on personal preference and training.
10. The practitioner monitors the skin temperature and amount of heat generated by the moxa cone. [strongly recommended]

11. When about 2/3 of the moxa is burnt or the patient feels a burning discomfort, remove the cone and place the moxa in the cup of water or ashtray; this step prevents the patient's skin from being burned and prevents the still-burning moxa from burning the practitioner, patient, or furniture and keeps burning ash out of the trash. [recommended]
12. Use fingers or the hemostats/tweezers to place the next cone on the skin and repeat as necessary.

Single or multiple cones are continuously burnt to cause an increase in blood flow/flush at the local site, but no blister should be formed.

Safety Considerations

1. Always have access to water to:
    a. Be able to snuff any burning ash that falls.
    b. Cool any small burns to the patient's or practitioner's skin immediately.
    c. Be a receptacle for burnt moxa, unless a suitable ashtray or other non-flammable receptacle is preferred.
2. Never leave a patient alone when moxa is being applied.
3. Make sure no clothing is close to the area being treated with moxibustion.
4. Pay very close attention to the patient during moxibustion application – do not look away from the patient or moxa, write in the chart, or talk to anyone besides the patient during moxibustion application.
5. Consider using a hemostat/tweezers/forceps to apply and remove the moxa cones. This prevents the practitioner's fingers from being burned and reduces the risk of dropping burning moxa onto the patient or treatment surface.
6. Once the treatment is complete, the cup of water with the burnt moxa should be flushed down the sink. Do not put moxa ash directly into a trash can as this may ignite a trash fire.
7. Never apply direct moxa to the face or within the hairline.

Direct Moxibustion - Technique for Scarring Moxibustion with Moxa Cones

A moxa cone is placed on a point and ignited. In this method, the moxa is not removed until after it has burned down to the end or a blister forms.

Method

1. A thorough patient history is performed to identify any conditions that being performed that might limit a patient's response to pain or the ability to sense heat [critical] or may increase a reaction to the moxa smoke. [recommended]
2. Proper ventilation is assured through use of windows or air filters or other air filtering process. [critical]
3. Moxa cones are prepared prior to lighting any moxa. [recommended]

4. All equipment is placed on a stable surface directly next to the treatment table Equipment: moxa cones, hemostat/forceps/tweezers, cup of water (if desired), ashtray (if desired), lubricant or skin lotion, lighter, incense stick, and other equipment as needed. [recommended]
5. The practitioner washes his or her hands. [critical]
6. The area to which moxa will be applied is prepared with skin lotion or lubricant, if desired, based on the type of moxa practice.
7. The first cone of moxa, unlit, is applied to the skin at the point or location chosen by the practitioner. [recommended]
8. A material such as an incense stick is lighted, using the lighter, away from the patient. Other materials can be used as long as an open flame is kept some distance from the patient's skin. [recommended]
9. If desired, a hemostat or tweezers may be applied to the moxa and the incense (or other material) is then used to light the moxa. [recommended] Practitioners may also choose to use their fingers for moxa application and withdrawal based on personal preference and training.
10. The practitioner monitors the skin temperature and amount of heat generated by the moxa cone. [strongly recommended]
11. When the cone of moxa has burned down, or there is a visible blister, remove the cone and place the moxa in the cup of water or ashtray.
12. Use fingers or the hemostats/tweezers to place the next cone on the skin and repeat as necessary to achieve the desired effect.
13. Once a small blister has formed, the burn must be treated properly: Cool the burn with cold running water until the pain is relieved; apply sterile gauze and use surgical tape to keep the gauze in place; alternately, a commercially prepared bandage may be used to cover the burned area. [critical]

As many as three or more cones of moxa are continuously burnt to cause the formation of a small blister. This method is very infrequently used except for severe conditions.

Safety Considerations

1. Always have access to water to:
    a. Be able to snuff any burning ash that falls.
    b. Cool any small burns to the patient's or practitioner's skin immediately.
    c. Be a receptacle for burnt moxa, unless a suitable ashtray or other non-flammable receptacle is preferred.
2. Never leave a patient alone when moxa is being applied.
3. Make sure no clothing is close to the area being treated with moxibustion.

4. Pay very close attention to the patient during moxibustion application – do not look away from the patient or moxa, write in the chart, or talk to anyone besides the patient during moxibustion application.
5. Consider using a hemostat/tweezers/forceps to apply and remove the moxa cones. This prevents the practitioner's fingers from being burned and reduces the risk of dropping burning moxa onto the patient or treatment surface.
6. Once the treatment is complete, the cup of water with the burnt moxa should be flushed down the sink. Do not put moxa ash directly into a trash can as this may ignite a trash fire.
7. Never apply direct moxa to the face or within the hairline.

Indirect Moxibustion – Technique with Interposed Moxibustion

The ignited moxa cone does not contact the skin directly, but is insulated from the skin by a layer of ginger, salt, garlic, or aconite cake. Depending on the technique used, this kind of moxa may induce blistering, but it is most frequently used for non-scarring moxibustion.

Method

1. A single moxa cone is prepared prior to use.
2. A thorough patient history is performed to identify any conditions that might limit a patient's response to pain or the ability to sense heat [critical] or may increase a reaction to the moxa smoke. [recommended]
3. Proper ventilation is assured through use of windows or air filters or other air filtering process. [critical]
4. All equipment is placed on a stable surface directly next to the treatment table. Equipment: moxa cones, hemostat/forceps/tweezers, herbal insulation (aconite cake, garlic, and ginger), cup of water (if desired), ashtray (if desired), lubricant or skin lotion, lighter, incense stick, and other equipment as needed. [recommended]
5. The practitioner washes his or her hands. [critical]
6. The area to which moxa will be applied is prepared with skin lotion or lubricant, if desired based on the type of moxa practice.
7. The herbal insulation is then applied to the area to be heated.
8. The cone of moxa, unlit, is applied to the herbal insulator.
9. If desired, a hemostat or tweezers may be applied to the moxa and the incense (or other material) is then used to light the moxa. [recommended] Practitioners may also choose to use their fingers for moxa application and withdrawal based on personal preference and training.
10. A material such as an incense stick is lighted, using the lighter, away from the patient. Other materials can be used as long as an open flame is kept some distance from the patient's skin. [recommended]

11. When about 2/3 of the moxa is burnt or the patient feels a burning discomfort, remove the cone and insulator and place the moxa in the cup of water or ashtray. [recommended]

Safety Considerations

1. Always have access to water to:
    a. Be able to snuff any burning ash that falls.
    b. Cool any small burns to the patient's or practitioner's skin immediately.
    c. Be a receptacle for burnt moxa, unless a suitable ashtray or other non-flammable receptacle is preferred.
2. Never leave a patient alone when moxa is being applied.
3. Make sure no clothing is close to the area being treated with moxibustion.
4. Pay very close attention to the patient during moxibustion application – do not look away from the patient or moxa, write in the chart, or talk to anyone besides the patient during moxibustion application.
5. Consider using a hemostat/tweezers/forceps to apply and remove the moxa cones. This prevents the practitioner's fingers from being burned and reduces the risk of dropping burning moxa onto the patient or treatment surface.
6. Once the treatment is complete, the cup of water with the burnt moxa should be flushed down the sink. Do not put moxa ash directly into a trash can as this may ignite a trash fire.
7. Never apply interposed moxa to the face or within the hairline.

Indirect Moxibustion - Warming Needle Moxibustion

This method uses both a needle and moxa. After the acupuncture point is needled and stimulated as desired or needed for the arrival of qi, a small section of a moxa stick (about 2 cm long) or a moxa cone is placed on the handle of the needle. The moxa stick is then ignited from its bottom and allowed to burn out.

The method below uses no additional material to secure the moxa on the needle. Instead, a protective cover of cardboard is placed on the skin to avoid burning ashes from falling on the patient. Other methods and devices have been utilized safely to prevent the moxa from falling on the patient. The specific method or device to be used can be chosen based on safety evidence and practitioner preferences.

Method

1. Moxa sticks or cones are prepared prior to lighting any moxa.
2. All equipment is placed on a stable surface directly next to the treatment table. Equipment: moxa sticks or loose moxa to make cones, tweezers/forceps/hemostat, cup

of water (if desired), ashtray (if desired), protective skin cover, lighter, and incense stick. [recommended]

3. The practitioner washes his or her hands. [critical]
4. A clean needle tray is prepared as discussed in the CNT section of this manual. [critical]
5. The acupuncture is performed following CNT guidelines. [critical]
6. Insert metal-only needles to the depth required to retain the needle upright securely. Do not use plastic tipped needles as the plastic may melt during the moxa therapy. [recommended]
7. A disc of insulator cardboard or other material is placed on the patient's skin around the base of the needle. Alternately, a device or insulator material is attached to the needle below where the moxa will sit. Both methods prevent ash from falling on the patient's skin. [strongly recommended]
8. A small stick or cone of moxa is placed on the handle of the needle.
9. The incense is lighted, using the lighter, away from the patient. [recommended]
10. The incense is used to light the moxa, which has been placed on the handle of the needle. [recommended]
11. When about 2/3 of the moxa is burnt or the patient feels a warm sensation around the needle, remove the cone and place the moxa in the cup of water or ashtray. [recommended]
12. Should the patient indicate that there is an uncomfortable amount of heat, use the tweezers or hemostat to immediately remove the needle and moxa. The hot needle must be removed with an instrument, since it will be too hot to manipulate safely by hand. [recommended]

Safety Considerations

1. Always have access to water to:
   a. Be able to snuff any burning ash that falls.
   b. Cool any small burns to the patient's or practitioner's skin immediately.
   c. Be a receptacle for burnt moxa, unless a suitable ashtray or other non-flammable receptacle is preferred.
2. Never leave a patient alone when moxa is being applied.
3. Make sure no clothing is close to the area being treated with moxibustion.
4. Pay very close attention to the patient during moxibustion application – do not look away from the patient or moxa, write in the chart, or talk to anyone besides the patient during moxibustion application.
5. Consider using a hemostat/tweezers/forceps to apply and remove the moxa cones. This prevents the practitioner's fingers from being burned and reduces the risk of dropping burning moxa onto the patient or treatment surface.

6. Once the treatment is complete, the cup of water with the burnt moxa should be flushed down the sink. Do not put moxa ash directly into a trash can as this may ignite a trash fire.
7. Never apply warming needle moxa to the face.

Indirect Moxa – Technique with Moxa Stick

Moxa sticks may be used either (1) by holding the moxa 2-3 cm over the site to be treated to bring mild warmth to the area/point for up to 15 minutes, or until the skin becomes slightly red or warm to the practitioner's touch; or (2) the ignited moxa stick is moved up and down over the point or near or around an acupuncture needle.

Because moxa sticks can be very difficult to be lit properly, for practitioner safety, it is recommended that a candle, or fireplace flame torch be used. In the method below, a candle is used. Other methods that keep the flame away from the patient and the practitioner's fingers may be utilized based on practitioner preference.

Method

1. All equipment is placed on a stable surface directly next to the treatment table. Equipment: moxa stick, moxa extinguisher, cup of water (if desired), lighter, and candle. [recommended]
2. The practitioner washes his or her hands. [critical]
3. Light the candle using the lighter. Then light the moxa stick using the candle. [recommended]
4. Immediately extinguish the candle once the moxa is lit. [recommended]
5. Apply moxa using one of the methods above.
6. Every few minutes, tap any ash from the moxa stick into the moxa extinguisher to prevent falling ash from falling on the patient or the table. [strongly recommended]
7. When the patient feels warmth, remove the stick and apply to the next point to be warmed, as needed. [recommended]
8. After the requisite points have been warmed as indicated for the treatment desired, place the moxa stick in the extinguisher, lit end downward. [critical]
9. Use the cup of water, if necessary, to extinguish ash that falls outside of the moxa extinguisher tray. [recommended]

Safety Considerations

1. Always have water on hand to:
    a. Be able to snuff any burning ash that falls.
    b. Cool any small burns to the patient's or practitioner's skin immediately.
2. Never leave a patient alone when moxa is being applied.

3. Pay very close attention to the patient during moxibustion application – do not look away from the patient or moxa, write in the chart, or talk to anyone besides the patient during moxibustion application.
4. Tap moxa to remove ash as needed; avoid scraping the ash from the moxa stick as this may loosen the burning tip of moxa which then may fall on the patient or treatment surface.
5. Once the treatment is complete, moxa should be retained in the moxa extinguisher for at least one hour to ensure that the moxa is fully extinguished.
6. The moxa in the extinguisher can be removed from the extinguisher after 1 hour, wet down in a sink and then thrown away in metal cans or other ash receptacles, but not in the regular trash to prevent trash fires.

Moxa Disposal

To prevent burns and fires, all moxa not flushed down a sink must be properly disposed of in metal or other containers specifically designed for ashes.

1. Make sure all used moxa sticks are contained in an appropriate extinguisher for no less than 1 hour after use.
2. Put all used moxa and moxa sticks that have not been flushed down the sink in a metal bucket with a tight fitting metal lid, after the 1 hour extinguishing period is complete. An alternative is to use a metal smoking receptacle designed for used cigarette disposal.
3. When ¾ full, the metal bucket (or receptacle) can then have its cover secured tightly and the bucket can then be disposed of in the regular trash.

2. Heat Lamps

Best Practice Protocols for Heat Lamps

Heat lamps are designed for use in applications specifically requiring a short-wave infrared radiation source. Infrared radiation from this lamp causes surfaces to be heated. For most of the commonly used commercial heat lamps (such as TDP lamps), lamps should never be placed closer than 12 inches to any person or surface. Some heating lamps are designed for much lower temperatures and may be brought closer to the patient's skin surface if that can be accomplished safely and according to the manufacturer's manuals.

Method

For use when heating is needed over a general area for therapeutic warming.

1. Check lamp for any defects. [critical]
2. Check the area to be treated for skin lesions. [strongly recommended]
3. Make sure all clothing and combustible materials are moved sufficiently out of the area to be heated. [strongly recommended]
4. Plug lamp into the wall socket.
5. Position lamp head at least 12 inches from the area to be heated. [strongly recommended]
6. Turn on the heat lamp then set time for no more than 10-15 minutes. [recommended]
7. Because the heat of the lamp may cause the head of the unit to drop toward the patient, never leave the immediate area of a patient being treated with a heat lamp. [strongly recommended]
8. Check the area being heated at least once every 5 minutes to be sure that the skin does not become too hot or that the lamp arm position has not changed. [strongly recommended]
9. Unplug the lamp once the heating period has ended. [recommended]

Safety Considerations

- Critical: Heat therapies must be closely monitored by practitioners.
- Critical: Heat lamps should not be used on infants, children, incapacitated, sleeping, or unconscious persons.
- Critical: When heat lamps are used on patients who have a reduced response to heat, the use of heat must be monitored at all times.
- Critical: Prevent water, moisture, liquids or metal objects from coming in contact with the lamp. Do not use a heat lamp in wet or moist environments.
- Critical: Do not use if any part of the lamp is cracked. Do not allow any part of the lamp to touch accessory equipment.

- Strongly Recommended: Heat lamps should not be used without a responsible attendant present during the entire duration of use.
- Strongly Recommended: Do not use over-sensitive skin or persons having poor blood circulation. Sufficient temperatures are generated that may cause burns.
- Strongly Recommended: Take a careful patient history to identify diabetes, neuropathies, or other conditions that might limit a patient's response to pain or the ability to sense heat.
- Strongly Recommended: The practitioner should monitor the patient's skin temperature and the amount of heat generated by a heat lamp and not rely solely on patient feedback about heat sensations.
- Strongly Recommended: Do not use this heat source in close proximity to combustible materials (litter, paper, etc.) or to materials adversely affected by heat or drying.
- Recommended: When a patient's information is unclear, request an opinion from a physician before using a heat lamp on the limbs of a patient with diabetic or other neuropathies.

3. Cupping

Cupping Overview

Cupping (ba guan fad) is a therapeutic procedure used by AOM and other healthcare practitioners around the world. Cupping, one of the oldest methods of traditional Chinese medicine, is accomplished by having a cup applied to the skin; the pressure in the cup is reduced by using a change in heat or by suctioning out air, so that the skin and superficial muscle layer is drawn into and held in the cup. Cupping uses a partial vacuum to intentionally create therapeutic petechiae and ecchymosis in the dermis. There are a number of cupping styles, including suction cupping, fire cupping, empty cupping, sliding or gliding cupping. Best practice guidelines are provided for three of these styles: fire cupping, suction cupping, and wet cupping or cupping after the use of a lancet for blood withdrawal.

General Recommendations for Cupping

- Critical: Follow Standard Precautions.
- Critical: Follow *Safety Guidelines for Establishing and Maintaining a Clean Field*.
- Critical: Follow *Safety Guidelines for Hand Sanitation*.
- Critical: Cupping should not be applied 48 hours before or 24 hours after chemotherapy treatment.
- Critical: Cup over clear skin only. Do not cup over an active skin lesion, moles, swelling, trauma, inflammation, infection, or burns (including sunburn).
- Critical: Practitioners must take a thorough history, including bleeding disorders and medication history, before applying cups.
- Critical: Practitioners must take a thorough history to identify diabetes, neuropathies or other conditions that might limit a patient's response to pain when planning to utilize fire cupping.
- Critical: Screen patients for history of reactive skin lesions such as keloid scarring or Köebner phenomenon.
- Critical: Assess carefully the use of fire cupping on patients who have a decreased response to pain (e.g., those with diabetes or neuropathies).
- Critical: Practitioners must wash hands before starting the procedure and again after removing gloves (if used).
- Critical: Personal protective equipment (PPE) - wear gloves and eye protection at all times when blood or OPIM may be present (wet cupping, cupping after needling).
- Critical: Each area to be wet cupped must be cleaned immediately before cupping by the practitioner.
- Critical: Lancets used for wet cupping should be sterile, used only once, then discarded in a proper sharps container.

- Critical: If blood or other OPIM are present, collect with cotton swab, gauze, paper towel, or cloth and dispose in biohazard trash.
- Critical: When blood or other OPIM are present, allow the vacuum to be compromised slowly, and then remove the cup.
- Critical: If lubricants are used for gliding cupping or moving cupping, decant a portion for use. Do not dip back into lubricant container or touch the spout of a pump container while cupping.
- Critical: Use appropriate PPE while cleaning and disinfecting cups.
- Critical: Clean all cups of all lubricants and biological material using soap and water before disinfecting.
- Critical: Disinfect all cups using an appropriate FDA-cleared intermediate- to high-level disinfecting solution in accordance with label instructions.
- Strongly Recommended: Use caution if cupping patients currently taking anti-coagulant medications.
- Strongly Recommended: Cupping over needles may cause needles to travel beyond a safe depth. Either insert the needle obliquely, or avoid the therapy in areas with underlying organs.
- Strongly Recommended: Place burning material into the deepest part of cup, and never retain the burning material inside the cups when the cups are placed onto the skin.
- Strongly Recommended: Observe careful and limit retention time to the physical tolerance of the patient.
- Strongly Recommended: Disinfect all cups using a high-level disinfecting solution following package directions for semi-critical devices.
- Strongly Recommended: Explain therapeutic intention of cupping and present a timeline of resolution. Cup children only in the presence of a parent or assigned guardian.
- Recommended: Use disposable cups for wet cupping and dispose of used wet cups in the biohazard trash.
- Recommended: A handout explaining cupping in clinical practice, including skin changes and a timeline for their resolution, may protect the patient from the stress of misinterpretation.

Sample Best Practice Protocols for Cupping

After reviewing the literature about cupping safety (Part I of this manual), the safety recommendations above, and using the information about the possible AEs associated with cupping therapies, the following best practice guidelines have been developed. As stated at the start of this section of the manual, these procedures are designed to limit dangers to patients, practitioners and staff. In all cases, the following procedures can be revised as needed to keep up with the latest research and modified as needed for specific styles of practice as long as safety remains the priority.

Fire Cupping Method

This procedure involves the use of an open flame near a patient. This may, if the technique is not done smoothly, occasionally cause burning and blistering of the skin (first or second degree burn). In addition, the cupping may leave red or bruise-like circular marks where the cups are applied. The patient should be educated that these marks are commonplace with this technique. The patient should also be informed that they should keep the cupped area protected from wind or cold drafts. It is strongly recommended that patients be asked for consent before applying cupping techniques.

1. All equipment is placed on a stable surface directly next to the treatment table. Equipment: cupping jar, hemostat, lighter, cotton ball, alcohol, and burn cream. [recommended]
2. The practitioner washes his or her hands. [critical]
3. If the area to which cupping will be applied needs to be cleaned, cleaning can be accomplished with alcohol, soap and water, or another cleansing technique [critical]
4. The flame apparatus is prepared by clamping a cotton ball in the hemostat and then slightly moistening the cotton with alcohol. Alternately, an alcohol swab may be used.
5. The jar is held with the mouth facing perpendicularly to the skin surface in the non-dominant hand. [strongly recommended]
6. The flame apparatus is lit and then in one single motion:
    a. The flame is introduced deep into the cup quickly and pulled away at the same time that the cup is then applied to the skin surface [critical]
    b. The hemostat is removed obliquely away from the patient's skin surface in order to ensure safety. [strongly recommended]
    c. The flame is extinguished. [critical]
    d. Once the flame has been extinguished and the flame apparatus removed to the equipment surface, the practitioner will determine the level of suction induced and will retain the cup for 2-10 minutes or more or repeat the above procedure to create a stronger vacuum.
7. The cup is removed when the therapy is done by gently prying the jar edge up from the skin or depressing the skin next to the rim of the cup to defeat the vacuum. The cup is then put aside and processed for cleaning and disinfecting. [strongly recommended]

Safety Considerations

- A live flame is utilized and so all proper precautions as indicated elsewhere in this manual must be followed, including setting up equipment on a work surface that is not flammable near, but not on, the treatment table. [critical]
- The work space must be kept clear of obstructions. [strongly recommended]

- Have access to water to put out the flame if necessary or to cool the skin if a small burn does occur. [recommended]
- Pay very close attention to the patient during the cup application. [strongly recommended]
- Have a fire extinguisher on hand in a room in which you are using fire-throwing cupping. [recommended]
- In order to prevent skin injury, check the rim of each cup before use and make sure that there is no broken or cracked area. [critical]

Suction Cupping

Cupping may leave red or bruise-like circular marks where the cups are applied. The patient should be educated that these marks are commonplace with this technique. The patient should also be informed that he or she should keep the cupped area protected from wind or cold drafts. It is strongly recommended that patients be asked for consent before applying cupping techniques.

As this method uses no flame, burns are not an adverse event associated with this method of cupping.

Method

1. All equipment is placed on a stable surface directly next to the treatment table. Equipment: cupping jars, pump extractor, lubricant. [recommended]
2. The practitioner washes his or her hands. [critical]
3. If the area to which cupping will be applied needs to be cleaned, use alcohol, soap and water, or another cleansing technique. [strongly recommended]
4. A small amount of lotion or lubricant is applied to the skin. [recommended]
5. Place the cup on the skin, attach the pump extractor, and remove enough air to bring some skin into the cup.
6. The cup is removed when the therapy is done by releasing the suction valve to defeat the vacuum. The cup is then put aside and processed for cleaning and disinfecting. [recommended]

Wet Cupping

This method involves both blood-letting and cupping. Best practices for both parts of this treatment are incorporated below.

Method

1. All equipment is placed on a stable surface directly next to the treatment table. Equipment: cupping jars, lubricant, and a clean field with lancets, cotton balls, alcohol swabs, sterile gauze, sharps container, and skin cleanser. [recommended]
2. The practitioner washes his or her hands. [critical]
3. Practitioners must use gloves and should also utilize eye protection to prevent exposure to blood. [critical]
4. The area to which cupping will be applied is cleaned with alcohol (or may be thoroughly cleaned with appropriate materials such as soap and water). [critical]
5. The skin at the site should be punctured using sterile lancets, with a new lancet being used for each puncture. [critical] Discard the lancets directly into the sharps container after use. [critical]
6. Apply the cups (pump or flame cupping as described above) and retain for the desired length of therapy.
7. If the practitioner has removed either gloves or goggles, put the personal protective equipment (PPE) back on for cup removal. [critical]
8. Allow the vacuum to be compromised slowly then remove the cup, taking care to prevent body fluid from spreading or splashing. [critical]
9. Immediately isolate the cups.
10. Stop any continued bleeding through use of appropriate pressure using sterile gauze. [critical]
11. Clean up any bleeding that has occurred. Clean the site of the punctures with an appropriate skin cleanser. [strongly recommended]
12. Discard extravasated blood in the biohazard trash. [critical]
13. Immediately wash cups with soap and water.
14. Remove goggles, gown and gloves. Dispose of PPE as indicated by the clinic's OSHA standard.
15. Wash hands with soap and water. [critical]
16. Remove cups to processing area for instrument decontamination.
17. Clean the cups of any biological material with soap and water and lubricant THEN sterilize the cups. [critical] Or, discard contaminated cups in the biohazard trash. [recommended]
18. Sterilize with a autoclave or by following label instruction for high-level disinfection solution (for example, immerse for 6 hours in 7.3% hydrogen peroxide solution).[critical]
19. Clean equipment surface and table with an appropriate disinfectant solution. [critical]

4. Therapeutic Blood Withdrawal

Bleeding Overview

In *Chinese Acupuncture and Moxibustion,* (1) the use of the three-edged needle (lance) is said to have been historically used for high fever, mental disorders, sore throat, and local congestion or swelling. Modern practitioners may use bleeding techniques to clear heat syndromes, strongly disperse points, and strongly stimulate specific points. As to technique, the point to be bled is pricked superficially, just 0.05-0.1 cun (inches) deep, which should be light and superficial and the amount of bleeding to be "determined by the pathological condition." In general, acupuncturists should use caution if employing bleeding therapy for persons who have weakness of their yin or yang qi, a bleeding disorder, a weak constitution, or who take anticoagulant medication.

General Recommendations for Bleeding Techniques

- Critical: Personal protective equipment (PPE) - wear gloves at all times as blood and OPIM will be present.
- Critical: Lancing devices must be limited in use to a single patient.
- Critical: Lancets should be used only once, and then discarded in a proper sharps container.
- Critical: Lancets should be used only once and cannot be reinserted into another site on the same or a different patient.
- Critical: Practitioners must take a thorough history, including bleeding disorders and medication history, before using bleeding techniques.
- Critical: Do not bleed in an area of an active skin lesion.
- Recommended: Utilize eye protection, such as goggles, when performing bleeding techniques.
- Recommended: Utilize single-use lancets engineered to retract after use to significantly reduce the risk of needlestick injuries.

Sample Best Practice Protocol for Bleeding Acupuncture Points

After reviewing the literature about bleeding safety (in Part I of this manual), the safety recommendations above, and the information about the possible AEs associated with bleeding practices, the following best practice guidelines have been developed. As stated at the start of this section of the manual, these procedures are designed to limit dangers to patients, practitioners and staff. In all cases, the following procedures can be revised as needed to keep up with the latest research and modified as needed for specific styles of practice as long as safety remains the priority.

Method

1. Select a clean, dry, flat surface to serve as the setting for the clean field. (Note: The selected location CANNOT be the treatment table!)[strongly recommended]
2. Wash hands for at least 10-15 seconds under running water, lathering well with soap. Or, if soap and water are unavailable, clean hands with an alcohol-based hand sanitizer. [critical]
3. Place a clean paper towel, clean table paper or other barrier that will serve as a clean field on the work surface in a way that does not compromise the cleanliness of the surface that will serve as the clean field. [critical]
4. Set out the materials needed for a treatment. Lancets should be placed on the center of the clean field first. [recommended]
5. Clean items such as cotton balls and unopened alcohol swabs may either be placed on the clean field or kept in jars or containers near the clean field so as to be at hand for the practitioner. [recommended]
6. Put on gloves [critical] and goggles or other eye protection as indicated by the safety committee or officer at your clinic. [recommended]
7. Ensure that the patient's skin is clean before inserting a lancet. Skin can be cleaned with 70% isopropyl alcohol, soap and water, or another method. [critical] If using an alcohol swab, allow the alcohol to dry. [critical]
8. Pull the skin taut near the area to be lanced. [recommended]
9. Press the lancet quickly into the point. Some practitioners position the lancet bevel side down over and just lateral to the intended point, then roll the lancet over and into the point in order to avoid the discomfort of a sudden deep needlestick. Use a retractable single-use lancet if the method being used allows for the use of such. [recommended] Such devices tend to produce a deeper needlestick and may cause more patient discomfort but may limit needlestick risk. However, retractable devices must be used on a single patient and discarded.
10. Dispose of the lancet immediately into an appropriate sharps container. [critical]
11. "Milk" or "squeeze" enough blood from the lanced point as indicated for the result you expect.
12. Use a sterile cotton ball or gauze to remove blood from the lanced area. [recommended]
13. Dispose of the cotton ball in the biohazard trash. [strongly recommended]
14. Reexamine needled sites a second time for signs of bleeding or hematoma, and apply pressure with a sterile cotton ball or gauze if necessary. [recommended]
15. Clean the site of the lanced skin and cover with a bandage as necessary if it is still bleeding. [strongly recommended]
16. Remove gloves and goggles. Dispose of PPE as indicated by the clinic's OSHA standard.

17. Wash hands immediately after completing the procedure and removing gloves. [critical]

5. Plum Blossom/Seven Star Needle

Plum Blossom Overview

Plum blossom/seven star needles (or cutaneous acupuncture) is described in *Acupuncture: A Comprehensive Text* (2) as being useful to treat the cutaneous channels and internal diseases associated with the meridian over which the skin will be tapped. Seven star needling is used in AOM practices for the treatment of a variety of pain syndromes.

General Recommendations for Plum Blossom

- Critical: Follow *Safety Guidelines for Establishing and Maintaining a Clean Field.*
- Critical: Follow *Safety Guidelines for Hand Sanitation.*
- Critical: Follow *Safety Guidelines for Skin Preparation*.
- Critical: PPE is required – wear gloves at all times as blood and OPIM will be present.
- Critical: The area to be treated must be clean and free of any skin lesions or traumatic injury.
- Critical: The area of patient's skin to be treated must be clean prior to treatment.
- Critical: The head of the plum blossom device must be sterile. Do not touch the tips of the needles.
- Critical: Use only single-use sterile plum blossom needles.
- Critical: Used plum blossom needles must be discarded into a proper sharps container immediately after use.
- Strongly Recommended: Avoid bringing the hand holding the hammer up too high or tapping too forcefully so as to prevent puncturing the skin.
- Strongly Recommended: Avoid flinging the hammer around so as to prevent the spread of blood or OPIM.
- Recommended: Practitioners should wear gloves and eye protection while using the plum blossom device.

Best Practice Protocols for Plum Blossom

After reviewing the literature about plum blossom safety (Part I of this manual), the safety recommendations above, and using the information about the possible AEs associated with seven star needling practices, the following best practice guidelines have been developed. As stated at the start of this section of the manual, these procedures are designed to limit dangers to patients, practitioners, and staff. In all cases, the following procedures can be revised as needed to keep up with the latest research and modified as needed for specific styles of practice as long as safety remains the priority.

Method

1. Select a clean, dry, flat surface to serve as the setting for the clean field. (Note: The selected location CANNOT be the treatment table!)[strongly recommended]
2. Wash hands for at least 10-15 seconds under running water, lathering well with soap. Or, if soap and water are unavailable, clean hands with an alcohol-based hand sanitizer. [critical]
3. Place a clean paper towel, clean table paper or other barrier that will serve as a clean field on the work surface in a way that does not compromise the cleanliness of the surface that will serve as the clean field. [recommended]
4. Set out the materials needed for a treatment. Seven star hammers should be placed on the center of the clean field first. [recommended]
5. Clean items such as cotton balls and unopened alcohol swabs may either be placed on the clean field or kept in jars or containers near the clean field so as to be at hand for the practitioner. [recommended]
6. Put on gloves [critical] and goggles or other eye protection. [recommended]
7. Ensure that the patient's skin is clean before utilizing the plum blossom needle. [critical] Skin can be cleaned with 70% isopropyl alcohol, soap and water, or another method. If using an alcohol swab, allow the alcohol to dry. [critical]
8. The seven star hammer is held 1-2 inches above the surface of the skin and tapped rapidly along the area to be stimulated. Avoid bringing the hand holding the hammer up too high or tapping too forcefully so as to prevent puncturing the skin. Avoid flinging the hammer around so as to prevent spread of blood or OPIM. [recommended]
9. When the skin becomes red, or proper reaction has been observed, stop utilizing the plum blossom device. [recommended]
10. Dispose of the plum blossom hammer immediately into an appropriate sharps container. [critical]
11. Clean the site of the treatment and cover with a bandage as necessary (if bleeding). [recommended]
12. Remove gloves and goggles. Dispose of used PPE as indicated by the clinic's OSHA document.
13. Wash hands immediately after completing the procedure and removing gloves. [critical]

6. Gua Sha

Gua Sha Overview

Gua sha is the process of closely-timed unidirectional press-stroking of the body surface with a smooth-edged instrument to intentionally raise transitory therapeutic petechiae and ecchymosis representing extravasated blood in the subcutis. Gua sha is not associated with significant adverse events except misinterpretation of therapeutic petechiae as illness, injury, or abuse by other practitioners. Study with a qualified gua sha instructor is recommended to learn precisely how and where to gua sha and how to use gua sha in a clinical practice. (See Part I for the literature review.)

Summary of Gua Sha Recommendations

- Critical: Follow Standard Precautions.
- Critical: Follow *Safety Guidelines for Establishing and Maintaining a Clean Field.*
- Critical: Follow *Safety Guidelines for Hand Sanitation.*
- Critical: Practitioners must take a thorough patient history, including bleeding disorders and medication history, before utilizing gua sha in order to plan for any excessive petechiae production.
- Critical: Gua sha should not be applied 48 hours before or 24 hours after chemotherapy treatment.
- Critical: If reusable gua sha devices are being used, they must be cleaned of lubricant and biological material and then disinfected using an approved intermediate- or high-level disinfecting solution following package directions for reusable medical devices.
- Critical: Lubricants should be dispensed from a pump or squeeze bottle to prevent contaminating the lubricant reserve. Do not touch the spout of the pump or the nozzle of the squeeze bottle.
- Critical: Gua sha should be applied to clear skin only. Do not apply to active rash, lesion, inflammation, infection, moles, swelling, trauma, burns (including sunburn), or breaks in the skin barrier.
- Critical: Use appropriate PPE while cleaning and disinfecting reusable gua sha tools.
- Strongly Recommended: Any application of gua sha for children should be done in the presence of a parent or guardian.
- Strongly Recommended: Disinfect all gua sha devices using a high-level disinfecting solution, following package directions for the disinfection of semi-critical reusable medical devices.
- Recommended: Immediately prior to the practice of gua sha, the expected result of petechiae should be explained to the patient.

- Recommended: Consider having a handout explaining expected gua sha effects and skin changes to give to patients before applying gua sha.

Gua Sha Best Practice Protocols

After reviewing the literature about gua sha safety (Part I of this manual), the safety recommendations above, and using the information about the possible AEs associated with gua sha practices, the following best practice guidelines have been developed. As stated at the start of this section of the manual, these procedures are designed to limit dangers to patients, practitioners and staff. In all cases, the following procedures can be revised as needed to keep up with the latest research and modified as needed for specific styles of practice as long as safety remains the priority.

It is possible to spread irritation or infection from one area to another when practicing gua sha. It is also possible to contaminate both a container of lubricant used for multiple patients and the gua sha tool itself, and then spread that contamination through the use of gua sha to multiple patients. Therefore, the method for best practice in gua sha is as follows:

Method

1. Prepare your tools:
    a. Set a clean, disinfected multi-use gua sha tool (or a clean disposable tool) on a clean field. [recommended]
    b. Put a small amount of lubricant in a disposable paper cup (using a tongue depressor or another disposable device such as a plastic knife), or set a squeeze bottle of lubricant at hand but not on the clean field. [strongly recommended]
2. Wash your hands. [critical]
3. Ensure the area to be treated is free of cuts, inflammation, infection, swelling, trauma, burns, and active lesions through visual inspection. [critical]
4. Reiterate the fact that petechiae will be raised and bruising is common; get a verbal confirmation that the patient understands the expected skin discoloration from the treatment. [recommended]
5. Apply gua sha to area to be treated.
6. Discard any lubricant in the cup (if used) and any disposable gua sha tool (if a disposable tool is used). [recommended]
7. Wash hands. [critical]
8. Inspect the patient's skin again for reaction to the gua sha treatment, remind him or her to keep the area covered and warm. [recommended]
9. Wash and disinfect any reusable gua sha tools. [critical]

7. Acupoint Injection Therapies

There are a few states in which acupuncturists may use injections (such as saline, B-12 or herbal extracts) to stimulate acupuncture sites. According to *Acupuncture: A Comprehensive Text,* (2) these injections may be given at front (*Mu*) or back (*Shu*) points, or "points of positive response."

For those practitioners who wish to utilize injection therapies and for whom the scope of practice allows injections, the following resources are suggested:

WHO Best Practices for Injection Therapies and Related Procedures Toolkit: (5)
http://whqlibdoc.who.int/publications/2010/9789241599252_eng.pdf

CDC: http://www.cdc.gov/injectionsafety/CDCsRole.html (6)
and http://www.oneandonlycampaign.org (7)

According to the WHO: (5) "Methods for reducing exposure and preventing infection transmission include hand hygiene, barrier protection (gloves), minimal manipulation of sharp instruments (including injection equipment), and appropriate segregation and disposal of sharps waste (note: sharps are items such as needles that have corners, edges or projections capable of cutting or piercing the skin).

Injections are unsafe when given with unsterile or improper equipment or technique. It is important to avoid contamination of injectable medications. Physically separating clean and contaminated equipment and supplies helps to prevent cross-contamination. For example, immediate disposal of a used syringe and needle in a safety box placed within arm's reach is the first step in safe waste management."

The CDC has published the results of the investigation of four large outbreaks of HBV and HCV among patients in ambulatory care centers and identified that not only is proper injection technique required, but basic principles of aseptic technique must be adhered to for the preparation of injection syringes. (8) The CDC recommends the use of single-dose vials of injectable medication instead of multiple-dose vials. Where multiple dose vials are used, the use of a separate preparation work area, away from the patient treatment room is required.

The following practices are strongly recommended to ensure the safety of injections:

- Proper hand hygiene.
- Use of gloves where appropriate.
- Use of other single-use personal protective equipment.
- Utilization of aseptic practices in syringe preparation.

- Patient skin preparation and skin pathogen reduction techniques (use of topical antiseptics).
- The use of single-use disposable sterile injection equipment.
- The immediate isolation of used syringes in a proper sharps container.

Risks of injection therapies are similar to those of needling and include pain, bruising, bleeding, infections, injury to organs and nerve tissue, patient dizziness or fainting. However, there are additional risks of infection or skin reaction due to injection of material under the skin. It is critical that all material to be injected be manufactured specifically for that purpose and be maintained in a sterile state prior to use.

According to the CDC, “Only when patients and providers both insist on One Needle, One Syringe, Only One Time for each and every injection will the risk of contracting infectious disease through injections be eliminated.” (7)

In general, practitioners should use the same Clean Needle Technique set-up for injections. Additional precautions are needed for the substances to be injected. These substances must be prepared for injection and remain sterile before use.

When using a sterile single-use syringe or hypodermic needle:

- Use a new device for each procedure, including for the reconstitution of a unit of medication.[critical]
- Inspect the packaging of the device to ensure that the protective barrier has not been breached.[critical]
- Discard the device if the package has been punctured, torn or damaged by exposure to water, or when the expiration date has passed. [critical]

Acupoint Injection Therapy Best Practice Protocols

1. Keep the injection preparation area free of clutter so all surfaces can be easily cleaned.
2. Before starting the injection session, and whenever there is contamination with blood or body fluids, clean the preparation surfaces with EPA-registered low to intermediate level disinfectant. [critical]
3. Assemble all equipment needed for the injection:
    - Use a sterile single-use needles and syringes
    - Reconstitution solution such as sterile water or specific medication
    - Alcohol swab or cotton wool
    - Sharps container
4. Put on PPE (gloves). [strongly recommended]
5. Read the label checking the medication and expiration dates. [critical]

6. Swipe the top of the medication vial/bottle with 70% alcohol. [critical]
7. If using a multi-dose vial, the air equivalent to the dose should be drawn up into the syringe first and injected into the vial to facilitate easier withdrawal. Do not inject air into a single-dose vial or ampule.
8. Once the loaded syringe and needle have been withdrawn from a multi-dose vial, administer the injection as soon as possible. [critical]
9. If air bubbles are seen in the syringe, hold it with the needle uppermost, tap the barrel to bring them to the top and then remove the bubbles by pushing the plunger to expel the air.
10. Double check to ensure the correct amount of solution is in the syringe.
11. Prepare the patient's skin with 70% alcohol.
12. Allow the skin to dry.
13. Insert the syringe to the depth required for the type of therapy or where qi sensation is noted following guidelines for safe insertion depth.
14. For an intramuscular injection, draw back on the syringe to check for evidence of bleeding (if bleeding is present, remove the needle and begin procedure again with a new device and new medication).
15. If no blood flashback, inject the solution at a moderate rate.
16. Withdraw needle and immediately dispose of the needle in the sharps container without re-capping.
17. Cover the injection site with a cotton ball for 5-20 seconds.
18. Use a new sterile syringe and needle for each insertion into a multi-dose vial. [critical] It is strongly recommended that single-use vials of injectable solutions be utilized whenever possible.

Safety Considerations

- DO NOT allow the needle to touch any contaminated surface.
- DO NOT reuse a syringe, even if the needle is changed.
- DO NOT touch the medication vial diaphragm after disinfection with the 60–70% alcohol (isopropyl alcohol or ethanol).
- DO NOT enter several multidose vials with the same needle and syringe.
- DO NOT re-enter a vial with a needle or syringe used on a patient.
- Avoid injection in hair roots, scars, moles and other skin abnormalities.
- Avoid injection into any area of skin with an active lesion.
- Keep injectable solution at room temperature prior to injection.
- Use needles of shorter length and smaller diameter whenever possible.
- Use a new needle for each injection.
- Insert the needle in a quick smooth movement through the skin.

- Inject slowly and evenly. Ensure that the plunger of the syringe has been fully depressed before withdrawing the syringe from the skin.
- Inject only when the alcohol used to clean the skin has fully dried.

Summary of Safety Recommendations for Clean Injection Technique

- Critical: Follow Clean Needle Technique.
- Critical: Always establish a clean field before starting an injection.
- Critical: Only use single-use sterile injection instruments.
- Critical: Always wash hands immediately prior to starting an injection.
- Critical: Only use sterile, prepared medications, including sterile water and herbal preparations, meant for injection use; NEVER use home-prepared substances for injections.
- Critical: All material to be injected must be manufactured specifically for that purpose and be maintained in a sterile state prior to use.
- Critical: Do not inject into any skin lesion.
- Critical: Immediately isolate used needles in an appropriate sharps container.
- Critical: Do not inject substances directly into a blood vessel.
- Critical: Wear gloves for all injection procedures.
- Critical: Check syringes prior to use for sterilization expiration dates, breaks in the packaging or any evidence that air or water has entered the packaging prior to use.
- Critical: All patients need to be treated as if they are carriers of bloodborne pathogens such as Hepatitis B or HIV.
- Critical: Ensure that the part of the body to be treated is clean.
- Strongly Recommended: Clean skin with 70% isopropyl alcohol prior to inserting a syringe.
- Strongly Recommended: Use single vials of injectable solutions whenever possible.

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Part IV – Infections Associated with Acupuncture and Related Healthcare Practices

1. Pathogens

It is essential that practitioners understand the mechanisms of disease transmission and know the characteristics of infectious diseases, particularly bloodborne pathogens such as hepatitis and HIV, skin infections from *Staphylococcus* and *Streptococcus* and other common healthcare associated infections (HAI). It is imperative for an acupuncturist to consider the safety of patients, clinicians, and other members of the clinic staff. Knowledge of the mechanisms and characteristics of common HAI and adherence to Clean Needle Technique will reduce the risk of the spread of bloodborne and surface pathogens.

Readers of this manual should note that there are hundreds of pathogens that are not addressed herein. Acupuncture practitioners must keep abreast of developments in healthcare associated infections and state and national standards to control such infections in clinical settings.

2. Mechanisms of Disease Transmission

A fundamental role of the immune system is to differentiate self from non-self. This differentiation allows the immune system to attack foreign or pathogenic viruses and bacteria while protecting the body's own constituents. Failure of this ability to differentiate self from non-self may result in various infections and autoimmune disorders. The presence of viruses or bacteria activates immune factors to respond to pathogenic organisms. The immune system consists of humoral and cellular components. Humoral components consist of the constitutive complement protein system and immunoglobins. These proteins are found in the liquid fraction of the blood, as well as in other tissues. Cellular components include neutrophils, macrophages/monocytes, as well as B cells and T cells. The immune response, including the response to infection, results from the complex interaction between the humoral and cellular components of the immune system.

The body is constantly exposed to infectious agents, some of which are normally found in or on specific areas of the body, especially on the skin, in the mouth, respiratory passageways, urinary tract, colon, and mucous membranes of the eyes. Many of these organisms that are normally present are capable of causing disease if they gain access to other tissues or if the immune system is ineffective in controlling the infectious agent. In addition, a person is intermittently exposed to virulent bacteria and viruses from outside the body that can cause specific diseases, such as pneumonia, streptococcal and staphylococcal infections. These infectious agents may be very invasive and overcome the natural barriers to infection.

Natural barriers include intact skin and mucous membranes of the nose, throat, urethra, and rectum. Natural barriers also include stomach acid (gastric acid provides nonspecific immunity to ingested bacterial pathogens) and a healthy respiratory mucosa, which can expel inhaled pathogens. Other factors in the immune response that protect the body from invasion and infection are the activity of the epithelial skin layer and mucus membranes, and the cleansing effects of tears, urine, and vaginal secretions.

Microbes can enter the body through a break in the skin, such as a cut or wound, or through an orifice (mouth, nose, urethra, etc.). Any infectious agent can cause infection if it gains access to tissues and spaces in the body where it is allowed to proliferate and initiate an immune response. There are many potential sources of infectious diseases in an acupuncture practice setting. These include contaminants on the skin of practitioners' and patients' hands, blood, saliva, sweat, nasal and other bodily secretions, dust, clothing, and hair. Infections associated with acupuncture may be classified into two types according to the source of the disease agent – autogenous and cross-infections.

Autogenous Infections

Autogenous (from the Latin "auto" – self and "genous" – generated) infections are created when pathogens already present in a person are moved into the body or to another location within the body where they are pathogens. An example of this is impetigo where normal skin bacteria enter into subcutaneous areas through a break in the skin and set up a pustule. While there are no specific studies identifying when acupuncture may cause an autogenous infection, the incidence of localized skin infections as consequence of acupuncture is low but persistent and implies a possible autogenous source. (1,2)

One of the dangers of reusing a needle during treatment is the transfer of an infectious agent from one location to another. Organisms that may exist in large quantities in one area can lead to potentially life threatening infections in other locations. *Escherichia coli* (*E. coli*), a common intestinal organism, may cause serious infections in the urinary bladder, a region where the organism is not normally found. Intestinal organisms such as *E. coli* can cause life-threatening peritonitis following injury to the bowel. As another example, the common skin organism *Staphylococcus epidermidis* can cause serious infections when this otherwise common bacterium begins proliferating in open wounds.

Cross-Infections

These infections are caused by pathogens acquired from another person or by the environment. They may be acquired directly (e.g., from contact between patient and practitioner), or by transfer (e.g., carried from one patient to another on the unwashed hands of the practitioner or contaminated implements). Cross-infections may be acquired by the

practitioner and office personnel as well as by patients. Some of the most serious organisms that are associated with cross-infections include the hepatitis B virus, HIV, and methicillin-resistant staph aureus (MRSA). Tuberculosis is also a significant public health concern in the United States, including strains of *Mycobacterium tuberculosis* resistant to antitubercular antibiotics.

Under normal circumstances natural barriers prevent the infectious agent or virus from gaining access to a new host and causing an infection. But when the natural defenses are weakened, or the infectious agent has a large enough quantity, or bioload, to overwhelm the body's defenses, the organism or virus in question can cause disease. As a practitioner, the acupuncturist must always be alert to the potential for transferring disease-causing agents to patients.

An infectious agent can travel from one host to another in a variety of ways, including being carried on dust or droplets of moisture in the air, being transferred in body fluids, and by mechanical transfer from one surface to another. The density of an infectious agent is one of the factors in risk of cross infection. While a low bioload may be controlled by the body's properly functioning, a high bioload may overwhelm the immune system, more easily resulting in an infection. For example, the hepatitis B virus is a high-density virus, one of the factors that facilitate the transfer of this organism from person to person.

3. Bloodborne Pathogens

Hepatitis

A review of the literature suggests that hepatitis may be a complication of acupuncture. While reports of hepatitis related to acupuncture in the U.S. are limited to reports prior to 1988, there are a number of retrospective studies and reports of hepatitis related to acupuncture in other parts of the world. (3,4,5)

There are currently five recognized types of hepatitis viruses which are labeled alphabetically as: A, B, C, D, and E. Hepatitis A and E are transmitted mainly through fecal contaminated food and water. The others are transmitted by blood or sexual contact. Hepatitis is such a concern in healthcare settings the Occupational Safety and Health Administration (OSHA) has adopted specific language regarding the transmission of hepatitis and recommendations for training and vaccination of at-risk staff members. The CDC strongly recommends that all healthcare workers be vaccinated for the hepatitis B virus (HBV). When an employee is hired for a position where there is a risk of infection with HBV, OSHA requires that the employer must offer vaccination to that healthcare worker at no charge. If the employee refuses to be vaccinated for HBV, this employee should be required to complete and sign a document stating that he or she understands the risks of not being vaccinated and is refusing the vaccination in spite of the risk of HBV infection. (See Section 6 for an overview of OSHA regulations.)

Hepatitis A (HAV)

Hepatitis A (HAV), formerly called infectious hepatitis or short-incubation hepatitis, is a common infection in conditions of poor sanitation and overcrowding. Although transmission is mainly through fecal contaminated food and water, contaminated blood on hands can pose a potential hazard in acupuncture practice. Additionally, in those clinics that prepare medicinal teas or other foods for patients, an awareness of the transmission routes and prevention practices is critical. In institutional or incarcerated settings HAV may spread from person to person through sexual contact. Good personal hygiene and proper sanitation can help prevent the transmission of HAV. The incubation period of HAV is 15 to 50 days, with an average incubation period of 28 days. (6)

Unlike hepatitis B (HBV) or C (HCV), HAV infection results in the abrupt onset of symptoms. Symptoms include abdominal discomfort, loss of appetite, fatigue, nausea, dark urine, and jaundice. Symptoms usually last less than 2 months. Although there is no chronic infection, approximately 15% of people infected with HAV have a prolonged or relapsing course of illness lasting as long as 6-9 months. Individuals who have had HAV cannot be re-infected.

In the United States, hepatitis A has occurred in large nationwide epidemics approximately every 10 years, with the last increase in cases in 1989. (7) The HAV infection rate has declined steadily since the last peak in 1995, when there were 356,000 cases. Historically, children 2 through 18 years of age have had the highest rates of hepatitis A (15 to 20 cases per 100,000 in the early to mid-1990s). Since 2002, rates among children have declined and the incidence of hepatitis A is now similar in all age groups. (7) Credit for the changes is given to the issuance of routine childhood vaccinations for HAV since 1999. Fortunately, most cases of HAV are relatively mild, complications are uncommon, and chronic carrier states are not known. There is a vaccination for HAV. The HAV vaccine is recommended for people in communities where outbreaks of hepatitis A are occurring and for anyone who has been exposed to hepatitis A virus. The CDC does not routinely recommend HAV vaccination for healthcare workers since they are not at increased risk. (8) Routine infection control precautions, particularly handwashing, will prevent transmission.

Hepatitis A Survival in the Environment

The Hepatitis A virus is extremely hearty. HAV can live outside the body for months, depending on the environmental conditions. The virus is killed by heating to >185 degrees F (>85 degrees C) for one minute. However, the virus can still be spread from cooked food if it is contaminated after cooking. Adequate chlorination of water, as recommended in the United States, kills HAV that enters the water supply. See http://www.cdc.gov/hepatitis/hav/havfaq.htm.

Hepatitis B (HBV)

Hepatitis B is caused by the hepatitis B virus (HBV), a double-stranded DNA-containing virus. Between 1990 and 2005 the incidence of acute hepatitis B declined 79%. Among persons aged 6 years or older, 0.27% had chronic HBV infection (corresponding to approximately 704,000 persons nationwide. (9,10)

In adults, ongoing HBV transmission occurs primarily among unvaccinated persons with behavioral risks for HBV transmission (e.g., heterosexuals with multiple sex partners, injection-drug users [IDUs], and men who have sex with men [MSM]) and among household contacts and sex partners of persons with chronic HBV infection. (11)

An estimated 700,000-1.4 million persons in the United States have chronic HBV infection. (12)

Hepatitis B virus (HBV, "serum hepatitis" or "long-incubation hepatitis") is one of the bloodborne pathogens presenting a significant risk of infection in the acupuncture clinic environment. HBV is the second sub-type of hepatitis for which a vaccine exists. HBV can cause lifelong infection, cirrhosis of the liver, liver cancer, liver failure, and death. Although chronic infection is more likely to develop in persons infected as infants or young children, rates of new infections and acute disease are highest in adults. Persons with chronic disease then serve as a reservoir for continued HBV transmission. (13) Healthcare personnel who have received HBV vaccine and developed immunity to the virus are at virtually no risk for HBV infection. (14)

Transmission of HBV

HBV is spread through contact with contaminated blood and body fluids. Infected individuals and those caring for them, sharing living space, or participating in high risk behaviors (unprotected sex with multiple partners and drug use) should follow careful infection prevention procedures. The infected person should not share any items that may be contaminated with blood, including razors and toothbrushes. (Both razors and toothbrushes are regularly contaminated with microscopic amounts of blood and need to be treated as contaminated.) Barrier precautions such as gloves for handling waste, or condoms and dental dams when involved in sexual activities, should be utilized.

For those who have a personal history of chronic, active disease, illicit drugs and alcohol should be avoided to reduce the risk of long-term complications of HBV, such as liver cirrhosis. Good cleaning of the patient's environment and personal care items is important. These precautionary measures should be followed until the person tests negative for active HBV infection.

HBV Survival in the Environment

HBV can survive outside the body at least 7 days and still be capable of causing infection. http://www.cdc.gov/hepatitis/hbv/hbvfaq.htm.

Individuals at Risk of HBV Infection

It is estimated that there are an estimated 800,000-1.4 million people in the United States who have chronic HBV infection. (13) The number of new infections has declined yearly since the 1980s. Routine vaccination is the primary reason for this decline. (13)

Individuals at risk for HBV infection through occupational exposures are those who are not immune to HBV and who come into frequent contact with blood and blood products. Healthcare workers such as acupuncturists, physicians, dentists, nurses, blood bank workers, paramedical personnel, and laboratory staff have a significant risk of occupational exposure and are at risk of HBV infection if not vaccinated. Others who are at risk include those who come in contact with blood or bodily fluids from an individual with a high risk of infection. The risk of HBV infection in the workplace is primarily related to the degree of contact with blood in the workplace and to the HBV status of the source person.

While HBV can be treated, the risk of chronic hepatitis is significant, and prevention remains the most important way to reduce the potential for a negative outcome. In the workplace, the risk of contracting hepatitis B is associated with contact with infected body fluids such as blood. The risk of a healthcare worker developing hepatitis following exposure to HBV is 22%-31%. The risk of developing serologic evidence of infection is 37%-62%. (15)

One of the most common modes of HBV transmission in the healthcare setting is the unintentional injury of a healthcare worker from a needlestick or cut by a contaminated instrument. The rate of HBV transmission to susceptible healthcare workers ranges from 6% to 30% after a single needlestick exposure to an HBV-infected patient, but is virtually zero if that healthcare worker has been immunized against HBV. (15) Hepatitis B surface antigen (HBsAg) positive individuals who are Hepatitis B “e” antigen (HBeAG) positive have more virus in their blood and are more likely to transmit disease. The presence of HBeAg suggests that HBV is in an acute stage and should be considered highly infectious. The numbers of occupationally spread HBV have declined since the 1980s from over 10,000 annually to below 400 in 2001. Reports of infections in 2006 were infrequent. In 1992, the CDC began a comprehensive strategy to eliminate HBV transmission in the United States, including through vaccination. In 2005 it was noted in follow-up surveillance that 75% of healthcare workers have been vaccinated. (15)

Other groups at risk include those who live in crowded or unsanitary conditions (including prisoners and certain immigrant populations), have multiple sexual contacts, men who have homosexual contact, live in the same house with someone who has chronic HBV, have sex with

someone infected with HBV, have hemophilia, are a patient or work in a home for the developmentally disabled, travel to areas where hepatitis B is endemic, are injection drug users, or have several of these risk factors. (13)

Exposure to HBV

HBV is transmitted through percutaneous or parenteral contact with infected blood, body fluids, and by sexual intercourse. HBV is only spread when blood, semen or other bodily fluids (OPIM) enter the body of another person through an orifice, a break in the skin or through mucus membranes. HBV may also be transmitted perinatally. HBV is not spread through sharing eating utensils, casual contact, or breastfeeding. It is not spread by contaminated water or food. HBV is able to remain on any surface it comes into contact with for about a week, e.g., table-tops, razor blades, blood stains, without losing infectivity. HBV does not cross the skin or the mucous membrane barrier. Some break in this barrier, which can be minimal and insignificant, is required for transmission. (12, 16)

Healthcare workers who are not immune are at a higher risk for HBV than the general public due to their potential for frequent occupational exposure to and blood products, as well as other body fluids.

Hepatitis B must be recognized as an occupational hazard for acupuncturists, as it is for other healthcare professionals whose procedures commonly include the penetration of the skin or cause exposure to blood and other body fluids. Invasive procedures, where there is considerable risk of exposure to contaminated blood and body fluids, pose the greatest risk of occupational infection from HBV. The CDC strongly recommends that all personnel working in such areas should scrupulously follow Standard Precautions. Disposable equipment and protective clothing should be used when appropriate, and appropriate disinfection protocols employed.

In the event of exposure, hepatitis B immune globulin and hepatitis B vaccine have been shown to be effective responses. For the healthcare worker, multiple doses of hepatitis B immune globulin or hepatitis B vaccine alone is 70%-75% effective in preventing sequelae of HBV exposure. (15)

HBV Vaccination

A vaccine against hepatitis B was developed in 1981. Any healthy adult with an intact immune system will likely respond to one series of the vaccine. At this time it is clear that immunity clearly lasts well over twenty years, but since the vaccine has only been in existence since 1981, no one yet knows exactly how long immunity will last. There is no testing recommended before vaccination; but 1-2 months following completion of the series, a titer is recommended to assess the response. If there is a response, no further boosters or series are recommended. If

there is no response, then a second series may be given and will usually be successful. There are a low number of non-responders even after the second series; no further vaccine is recommended for them. (17)

Vaccination is recommended for personnel performing invasive procedures, cleaning contaminated equipment, or performing duties in an area where there is a risk of exposure. The CDC recommends that all healthcare workers be vaccinated against HBV. OSHA requires all employers to offer HBV vaccination to personnel performing invasive procedures or cleaning contaminated equipment. (14) In October 1997, the Advisory Committee on Immunization Practices expanded its hepatitis B vaccination recommendations to include all children aged 0-18 years.

The HBV Infection Process

The incubation period for HBV is 45 to 160 days. (6) During this period, the infectious virus appears in the blood, and it may appear in the feces and semen. During this period the infection may be spread to other people even though no symptoms are present. HBV early symptoms often begin with mild flu-like signs and symptoms such as a fever (in 60% of cases), general malaise, or the insidious onset of anorexia and abdominal pain. Other symptoms may include chills, nausea, joint pains, rash, and diarrhea. Typically these symptoms last from two to six weeks. These symptoms are frequently followed by a period of extreme fatigue and depression that can extend for several months.

Practitioners should be aware that some individuals infected with the virus develop mild symptoms or are asymptomatic. Approximately 30% of those infected have no signs or symptoms. (17) Children with HBV are often asymptomatic. However, asymptomatic patients are as infectious as those who are symptomatic. Only a blood test will tell whether an individual is infected with HBV.

Fully 70% of people who have recovered from the symptomatic stage of the disease are still infectious for three months or more after symptoms have subsided. Among infants who acquire HBV infection from their mothers at birth, up to 90% become chronically infected. The older you are when infected, the lower the rate of chronic infection, with 25%–50% of children infected at age 1–5 years becoming chronically infected, and among older children and adults approximately 6-10% of all acute HBV infections progress to chronic infection. (6)

If a practitioner becomes infected with HBV, he or she may unknowingly transmit HBV to patients or office staff through transmission of blood from cuts or open sores. Professionally and legally the ramifications of this form of transmission are enormous. High standards of hygiene and Clean Needle Technique will greatly reduce the risk of HBV infection for practitioners, as well as patients. A practitioner with acute HBV should not practice during the

infectious period. If a provider is found to be infected, he or she should consult with a physician before going back to work. (14)

Treatment of HBV

While HBV can be treated, the risk of chronic hepatitis is significant, and prevention remains the most important way to reduce the potential for a negative outcome. In the workplace, the risk of contracting hepatitis B is associated with contact with infected body fluids such as blood. The risk of a healthcare worker developing hepatitis following exposure to HBV is 22%-31%. The risk of developing serologic evidence of infection is 37%-62%. This risk is significantly higher than the approximately 0.3% cited for HIV. (15)

In the event of exposure, hepatitis B immune globulin and hepatitis B vaccine have been shown to be effective responses. For the healthcare worker, multiple doses of hepatitis B immune globulin or hepatitis B vaccine alone is 70%-75% effective. (14-19)

Combining these two treatments increases efficacy. The HBV vaccine is safe and effective.

Hepatitis C (HCV)

Hepatitis C virus (HCV) infection is the most common chronic bloodborne viral infection in the United States. First identified in 1988, HCV is the causative agent for what was formerly known as non-A non-B hepatitis, and is estimated to have infected as many as 242,000 Americans annually during the 1980s. Many of those infected are not aware of their infection, resulting in chronic liver disease that may not become apparent for 10-20 years.

HCV is a virus containing a single strand of RNA that is most effectively transmitted by percutaneous contact through injection drug use or exposure to infected blood or blood products.

Today, most people become infected with the hepatitis C virus by sharing needles or other equipment to inject drugs. Before 1992, when widespread screening of the blood supply began in the United States, Hepatitis C was also commonly spread through blood transfusions and organ transplants. (20)

While HCV may be transmitted through sexual contact, contracting a HCV infection through this route is considerably less efficient. The risk of transmission from sexual contact is believed to be very low. The risk increases for those who have multiple sex partners, have a sexually transmitted disease, engage in “rough sex”, or are infected with HIV. (21)

In 2013, there were an estimated 29,718 new hepatitis C virus infections in the United States. The CDC estimates that 2.7-3.9 million people in the United States have chronic Hepatitis C

infection. Many people who are infected never have symptoms and therefore never come to the attention of medical or public health officials. (21)

Peak rates of HCV occurred in the 1980s, and have declined due to a reduction in infections resulting from injection drug use. While new infections are lower than 1980 peak infection rates, HCV infection is still the most common blood-borne infection in the United States. (20)

The risk of seroconversion after percutaneous occupational exposure is approximately 1.8% if the source blood is seropositive for HCV. This is considerably higher than the risk of percutaneous occupational exposure due to HIV seropositive blood and lower than the risk of seroconversion after percutaneous occupational exposure to HBV seropositive fluids. (15)

Acute Symptoms of Hepatitis C

Those who manifest symptoms of acute hepatitis C will experience symptoms similar to the other cases of acute hepatitis, including flu-like symptoms, joint aches, jaundice and/or mild skin rash. Other symptoms include a loss of appetite, abdominal pain, darker-than-normal urine color and light or grey colored stools. Practitioners should be aware that less than 30% of those infected with hepatitis C manifest acute disease symptoms.

Risk Factors for HCV Infection

Individuals who inject drugs, even if they did so only on one occasion many years previously, have the highest risk of HCV infection. Individuals with a history of injection drug use represent 60% of those infected. HCV is rapidly acquired following injection drug use through sharing needles and other equipment. As many as 80% of injection drug users are found to be infected with HCV and are often co-infected with HIV (30-50%). (22) Other risks of HCV infection include transfusions and transplants before the screening that is currently in place (before 1992) and, to a lesser degree, sexual contact (15%). There is a risk of occupational exposure for HCV, particularly where there is exposure to large amounts of blood, such as hemodialysis and surgeries. HCV is spread from mother to baby. About 10% of those infected have no recognizable source of infection. While it is possible for HCV to be transmitted from percutaneous exposure to blood, exposures such as acupuncture, tattooing, or body piercing have not been shown to place people at increased risk for HCV infection. HCV is most efficiently transmitted by exposures that involve direct passage of blood through the skin, particularly with hollow-bore needles.

While the risk of occupational exposure leading to HCV seroconversion may be limited to needles with a lumen, it is important to state that as with HIV and HBV, exposure following a needlestick involving an acupuncture needle must be treated as a possible source of infection.

HCV has been associated with acupuncture in some retrospective studies of acupuncture AEs. (5, 23)

HCV Survival in the Environment

The hepatitis C virus (HCV) can remain viable outside the body for 4-5 days. (24)

Consequences of HCV Infection

About 15-25% of those infected clear their HCV infection without further problems. The remainder (75-85%) will develop chronic infection and approximately 60-70% will go on to develop chronic hepatitis. (A chronic infection is the chronic presence of the agent, HCV, and the patient's immune response. Chronic hepatitis is chronic inflammation of the liver that may be caused by chronic infection. While they often go together, they are defined differently and as such as not interchangeable.) Cirrhosis of the liver occurs in at least 5-20% of patients over a 20-30 year period and hepatocellular carcinoma (liver cancer) occurs in 1-5% of cases. HCV-associated chronic liver disease is the most frequent indication for liver transplantation among adults. (6, 25) Drug treatment is an important adjunct to care for many persons with HCV. There is no vaccine for this disease. People infected with HCV should be vaccinated for HAV and HBV to prevent further complications of their disease.

The incubation period of HCV is 14-180 days, with most cases occurring 5 to 10 weeks after exposure. (6, 25) The period of communicability extends from one week after exposure through the chronic stage. The onset is insidious and accompanied by anorexia, nausea, vomiting, and jaundice. The course is similar to HBV but more prolonged.

Therapy for hepatitis C is a rapidly changing area of biomedical clinical practice. Treatment decisions are based on liver enzyme levels, genotype of the infecting virus, and condition of the liver, including the extent of scarring. Current treatment most commonly includes drug cocktails utilizing SOVALDI® (sofosbuvir) and Harvoni (ledipasvir/sofosbuvir). (26)

Hepatitis D (HDV)

HDV, sometimes known as delta hepatitis, is a defective virus that requires concurrent HBV infection for development of disease. In the U.S., most cases of hepatitis D occur in injection drug users and hemophiliacs. Transmission of hepatitis D is through percutaneous or mucosal contact with infectious blood. There is no vaccine for HDV; however, since the HDV virus requires the presence of HBV, vaccination against HBV is effective against HDV related disease. The outcome of simultaneous HBV and HDV is no different from the outcome of HBV alone. However, when chronic HBV infection is accompanied by HDV, it may lead to severe, fulminating hepatitis or transform a mild or asymptomatic chronic HBV into a more severe disease process, or a disease process that may be accelerated due to increased scarring of the

liver. Prevention of Hepatitis D in persons who are not already HBV-infected can be accomplished through Hepatitis B vaccination. (27)

HDV Survival in the Environment

HDV is found with HBV. HBV can be capable of causing infection for a week. Most experts believe that HDV does not last as long but it is best to take the same precautions as with HBV.

Hepatitis E (HEV)

Hepatitis E, like hepatitis A, is spread by fecal-oral transmission (28). Most outbreaks are found in developing countries, where drinking water is contaminated by feces from infected animals and humans. HEV is rarely seen in the U.S., with the exception of travelers to developing countries, particularly South Asia and North Africa. Infection from person to person is less frequent than with hepatitis A. The incubation period is 15 to 60 days, with an average of 40 days. The time period is 15 to 60 days, with an average of 40 days. The time period of communicability is unknown. The disease is characterized by sudden onset of fever, malaise, nausea, and anorexia. The disease varies in severity from a mild illness lasting 7 to 14 days to a severely disabling disease lasting several months. Jaundice may be present. Pregnant women have a mortality rate of 20%. There is no evidence of a chronic infection in long-term follow-up of patients with HEV. There is no vaccine for HEV.

Chronic Carriers of Hepatitis

Chronic carriers are individuals who continue to shed hepatitis virus through bodily fluids and excretions long after infection. They are classified into two categories: Chronic Persistent and Chronic Active. A chronic persistent carrier is asymptomatic or has minimal symptoms but can continue to infect others. A chronic active carrier has progressive symptomatic disease that continues to damage the liver. Symptoms include malaise, weight loss, loss of appetite, and often jaundice. Patients with hepatitis A and E never develop chronic states. Hepatitis B becomes chronic in 5 to 10% of infections (this rate varies depending on the age of the patient), HCV in 75-85% of infections. To get a good hepatitis history as part of the patient intake, ask about contact with blood products such as transfusions, dialysis, and injection drug use. Patients who have received transfusions or dialysis before 1990 or who have a history of injection drug use present an increased risk. Also, many patients in a public healthcare setting, such as chemical dependency, HIV, and TB clinics, may have a history of some form of hepatitis, but may not know what type and may not know whether they are chronic carriers. The use of Clean Needle Technique and Standard Precautions is the only effective way to prevent transmission of viral hepatitis diseases.

Prevention of Hepatitis

One of the most compelling reasons for the development of the Clean Needle Technique protocol in 1984 was to provide guidelines to prevent the transmission of hepatitis within acupuncture clinic settings. Since that time, the incidence of hepatitis B through acupuncture has dramatically decreased. (2,3) Continuing strict adherence to Clean Needle Technique is essential in order to prevent transmission of HBV or a related virus to patients, practitioners and staff.

The lack of any evidence of transmission of viral disease from acupuncture needles in the U.S. since 1990 can be directly associated with the introduction of CNT course and the use of single-use disposable sterile needles.

Table 1: Summary of Hepatitis Characteristics

(See http://www.cdc.gov/hepatitis/resources/professionals/pdfs/abctable.pdf) for details about Hepatitis A, B and C)

Hepatitis	Incubation	Transmission	Onset	Vaccine	Chronic
A	**15-50 days**	**Fecal-oral**	**Abrupt**	**Yes**	**No**
B	**45-160 days**	**Bloodborne**	**Insidious**	**Yes**	**Depends on age group (6-10% in adults; higher in children)**
C	**14-180 days**	**Bloodborne**	**Insidious**	**No**	**75-85%**
D	**Unknown**	**Percutaneous or mucosal contact with infectious blood**	**Insidious**	**No**	**Unknown**
E	**15-60 days**	**Fecal-oral**	**Abrupt**	**No**	**No**

Human Immunodeficiency Disease (HIV)

The human immunodeficiency virus (HIV) is an RNA-containing virus that in humans leads to a constellation of problems extending from declining immune function that leads to an end-stage syndrome in untreated patients, called the acquired immune deficiency syndrome (AIDS). These medical problems may be exacerbated by co-infection with other disease-causing agents such as the herpes viruses. HIV continues to be a growing medical challenge worldwide. Mathers and

Loncar indicate that over the 25 year period from 2006 to 2030, between 89 million and 117 million people will die of HIV/AIDS. (29)

The Centers for Disease Control and Prevention (CDC) reports that in 2012, 41,505 cases of HIV were diagnosed in the United States. (30)

To date, there are no confirmed cases of occupational HIV transmission following an accidental needlestick involving an acupuncture needle in the United States. There was a case report from 2003 of a patient in Thailand indicating that acupuncture was the only known risk for the seroconversion of a previously HIV seronegative 60 year-old female.(31)

Scientists have identified a type of chimpanzee in West Africa as the source of the HIV that infects humans. The virus most likely jumped to humans when they hunted these chimpanzees for meat and came into contact with their infected blood. Over several years the virus spread across Africa and later into other parts of the world. Two types of HIV have been identified: HIV-1 and HIV-2. Although they have similar epidemiological and pathological characteristics, they are different serologically and geographically. Generally, HIV-2 has a slower, somewhat milder course. It seems to be less infectious early on in the disease, but becomes more infectious over time. It is predominately found in West Africa. Cases are seen infrequently in the U.S. and usually have some association with West Africa. HIV-1 is the more virulent virus and is more easily transmitted. It is the cause of the majority of HIV infections globally. (32)

HIV Transmission

Blood-to-blood contact is the most direct method of transmitting HIV (as well as HBV). When infected blood enters the bloodstream of an uninfected individual, there is a probability of infection, although this risk is much lower than that for HBV. Prospective studies of healthcare workers (HCWs) have estimated that the average risk for HIV transmission after a percutaneous exposure is approximately 0.3%, the risk of HBV transmission is 6 to 30%, and the risk of HCV transmission is approximately 1.8%. (33) The most common mode of transmission is percutaneous exposure that occurs from contaminated instruments (mostly from suturing and needlesticks), or contact of contaminated blood with non-intact skin. The risk, however, is extremely low if Standard Precautions are followed. Standard Precautions, as defined by the CDC, include the use of barriers as gloves, masks, gowns, goggles, and prevention techniques appropriate to the particular healthcare setting, depending on the specific risks involved. (34)

There is no evidence that HIV is spread by casual contact. Casual contact consists of any activity that does not involve the exchange of body fluids such as blood, semen, or vaginal secretions. Non-risk casual contact includes shaking hands, touching, hugging, holding hands, or kissing. The use of objects handled or touched by an HIV-infected person (for example, a telephone or toilet seat) has also not been shown to spread the virus.

HIV Survival in the Environment

HIV does not survive long outside the human body (such as on surfaces), and it cannot reproduce outside of the body. Outside of the body, the virus dies within minutes without the temperature necessary for its survival. http://www.cdc.gov/hiv/basics/transmission.html

Risk of Transmission through Invasive Procedures

In general, the risk for HIV transmission between patients and healthcare workers is very low. (29, 31) Adherence to CDC-recommended procedures for Standard Precautions reduces the risk significantly. Practitioners should prevent direct blood contact and carry out proper disinfection procedures as described in this manual and at the website: http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-gl-standared-precautions.html

Individuals at Risk of HIV Infection

The first cases of AIDS in the United States were reported in 1981. By the end of 1981, a total of 316 cases of this newly discovered syndrome were reported to the CDC. During the 1980s as many as 150,000 people became HIV infected each year. By the early 1990s the infection rate dropped to about 40,000 each year. At the end of 2009, an estimated 1,148,200 persons aged 13 and older were living with HIV infection in the United States, including 207,600 (18.1%) persons whose infections had not been diagnosed. (35) The number of AIDS cases began to fall dramatically in 1996 with the advent of protease inhibitors.

It is important to note that the population distribution of HIV has changed. Initially HIV was found primarily among men who had sex with men, injection drug users, sex workers, and transfusion recipients. Today HIV is no longer limited to these initial populations. Recently, more cases are associated with unprotected sex between mixed gender couples. Due to successful protocols for perinatal cases, newborns are acquiring HIV from their mothers much less frequently. Efforts to test all expectant mothers and start those found HIV positive on antiretroviral medication have been successful. However, anyone who engages in at-risk behaviors (mainly sex with an infected partner without barrier methods and needle sharing) or is in a profession with a risk of blood exposure (such as healthcare workers) is in danger of contracting HIV.

HIV seroconversion in healthcare workers is rare, but Standard Precautions must be maintained. Of those healthcare personnel for whom case investigations were completed from 1981-2010, 57 had documented seroconversion to HIV following occupational exposures. The routes of infection included 48 that were due to puncture or cut injuries. Forty-nine healthcare personnel were exposed to HIV-infected blood; three to concentrated virus in a laboratory; one to visibly bloody fluid; and four to an unspecified fluid. (36)

The CDC is also aware of 143 other cases of HIV infection or a diagnosis of AIDS among healthcare workers who have not reported other risk factors for HIV infection and who report a history of occupational exposure to blood, body fluids, or HIV-infected laboratory material, but for whom seroconversion after exposure was not documented. In order to prevent HIV infection, it is critical to use Standard Precautions with every patient. (36)

There remains a significant risk of infection in the healthcare workplace. In 1996, there were 786,885 percutaneous and mucocutaneous exposures to potentially infectious substances among healthcare workers (HCWs) in the United States. (37)

Because of the long incubation period of HIV (an average of 8-10 years from infection to the development of AIDS in individuals not on effective antiretroviral therapy), the vast majority of HIV-infected individuals have no symptoms and may not know they are infected. However, anyone infected with HIV may be able to transmit the virus to others through bodily fluids, including blood, semen, or vaginal secretions, regardless of whether or not they have developed AIDS. It is beneficial to routinely incorporate risk assessment strategies into the patient evaluation to determine the likelihood of exposure to, or the presence of, HBV or HIV infections such as:

1. Patient's history regarding exposure to blood and blood products. ("Have you had a blood transfusion?")
2. Patient's history of drug use. ("What drugs have you used in the past ten years?")
3. Patient's sexual history/history of sexually transmitted diseases. ("How many sex partners have you had in the last two years?")

Testing

Voluntary testing is encouraged. Rapid tests can be done now with results being available within 20 minutes. As part of its strategic plan to reduce HIV, the CDC has recommended that everyone between the ages of 13 and 64 be tested at least once as a baseline. (38) Anyone falling into high risk categories can continue to be tested regularly as part of routine medical care. Testing is especially important for those who fall into the following categories:

1. Persons in professions with a high risk of exposure.
2. Persons who have had a sexually transmitted disease.
3. Those who have a history of injection drug use and shared needles.
4. Men who have had sex with other men since 1978.
5. Men and women who have traded sex for money, food, drugs, or other items.
6. People who have had multiple sex partners and used intravenous injected drugs.
7. Sexual or needle-sharing partners of the above.
8. Any woman thinking of becoming pregnant.

For specific information on testing for HIV check with your local health department.

Reporting

A uniform case definition and case report form is now used in all fifty states for the reporting of diagnosed cases of AIDS. Revisions in the definition of clinical AIDS have broadened the range of AIDS-indicator diseases and conditions. Using HIV diagnostic tests has improved the sensitivity and specificity of the definition over the past 20 years.

The HIV Infection Process

HIV targets several cell types, including the CD4 (T4) lymphocyte, which interrupts the cell-mediated response to antigens. (39) This T4 lymphocyte population in turn replicates HIV. Damage results in a lower CD4 (T4) cell count leading to a reduction of this cell population, producing immune deficiency. Since the CD4 (T4) lymphocyte plays a crucial role in regulation of the immune system, depletion of these cells due to HIV infection reduces the immune response.

HIV causes progressive damage to the human immune system over a long period, making the individual vulnerable to a host of infections and malignancies. The syndrome known as Acquired Immune Deficiency Syndrome (AIDS) represents the late stage of HIV infection. This syndrome is assessed when the patient is HIV seropositive and has an absolute CD4 count of less than 200 cells per microliter, or one or more AIDS defining illnesses, such as Pneumocystis carnii pneumonia, cryptosporidiosis, or Kaposi's sarcoma.

Infection with HIV can present along a continuum ranging from asymptomatic to symptomatic. Patients can exhibit one or more of the symptoms associated with impaired immune function. Initial HIV infection is sometimes followed within 2 to 4 weeks by a febrile illness resembling mononucleosis or influenza which resolves spontaneously and which many people do not note as significant at the time. It is during this early time that people are very infectious. Some people infected with HIV remain relatively healthy for many years before the symptoms of HIV infection appear. Approximately half of the people with HIV develop AIDS within 10 years after becoming infected. The most common symptoms of HIV include fever, malaise, body aches, maculopapular rash, lymphadenopathy, and headache. Other symptoms include persistent fever and night sweats; rapid, unexplained weight loss; chronic diarrhea not explained by other causes; persistent cough that is not associated with smoking or influenza; and flat or raised pigmented lesions on the skin ranging in color from faint pink to red, brown, or blue. Many of these symptoms are non-specific and are seen in other conditions. Data indicate that most people infected with HIV eventually develop AIDS. These individuals develop opportunistic infections and neoplastic disorders rarely seen in individuals with a healthy immune system. These infections include esophageal candidiasis, cytomegalovirus, Kaposi's sarcoma, and

Pneumocystis carinii pneumonia, the most common opportunistic infection and cause of death in AIDS patients.

The clinical presentations of AIDS patients vary extensively. Individuals may present with HIV wasting disease, which is characterized by severe, involuntary weight loss, chronic diarrhea, constant or intermittent weakness, and fever for 30 days or longer. If HIV infects cells in the cerebrospinal fluid, individuals may develop HIV encephalopathy, myelopathy, or dementia with symptoms ranging from apathy and depression to memory loss, motor dysfunction, and death.

Presently, it is not known why some people infected with the HIV virus develop symptoms more quickly than others. Researchers have proposed that certain co-factors such as stress, poor nutrition, alcohol or drug abuse, and certain sexually transmitted diseases (STDS), such as syphilis or hepatitis, may trigger the virus to more rapidly replicate or place other stressors on the body systems. It is clear that when HIV is identified early and good healthcare is provided, including antiretroviral treatment regimens, HIV can be managed as a long term chronic medical condition. Today there are many infected individuals living very long lives. (38)

Treatment of HIV

AIDS represents the end stage of the clinical spectrum of HIV. At the present time there is no cure or vaccine for AIDS, although a variety of medications are being used to slow the progression of the disease and treat some of the opportunistic infections. (38)

The number of drugs and the variety of treatment approaches have grown exponentially since the approval of AZT in 1987. Those practitioners who routinely work with HIV positive and AIDS patients should keep abreast of the drug combinations being used for treatment, their side effects and any herb-drug interactions. The list of those drugs, side effects and interactions are changed and updated regularly; inclusion of an updated list in this manual is not feasible.

Additional Risks to Healthcare Workers (HCWs)

An additional risk to practitioners working with persons with HIV is that some of the common secondary infections in this population are themselves contagious. These may include tuberculosis, staphylococcal infections, herpes viruses, and hepatitis. (38). Appropriate control precautions should be taken and may include masks in case of respiratory infection and gloves in case of skin lesions. Standard Precautions should be practiced with all patients. It is imperative to assume any patient may be HIV seropositive and to use Standard Precautions with all patients.

4. Other Healthcare Associated Infections

Healthcare-associated infections (HAIs) are infections that patients develop during the course of receiving healthcare treatment for other conditions. They can happen following treatment in healthcare facilities including hospitals as well as outpatient centers and community clinics. They can be caused by a wide variety of bacteria, fungi, and viruses. Some of the more common HAIs that may be related to therapeutic needling and other clinical procedures are discussed below.

Tuberculosis

Tuberculosis (TB) is caused by the bacterium *Mycobacterium tuberculosis*. This organism is an acid-fast bacterium with a waxy coat, is transmitted through the air, and has a long incubation period of up to 12 weeks. (40, 41)

A total of 9.421 TB cases (a rate of 2.96 cases per 100,000 persons) were reported in the United States in 2014. Both the number of TB cases reported and the case rate decreased; this represents a 1.5 % and 2.2% decline, respectively, compared to 2013. The number of reported TB cases in 2014 was the lowest recorded since national reporting began in 1953. (42)

While TB infection rates are in decline in the United States, it remains a significant source of risk in the healthcare environment. Jensen et al. (41) list the following populations who are especially at risk for TB:

- Foreign-born persons, including children, especially those who have arrived in the United States within 5 years after moving from geographic areas with a high incidence of TB disease (e.g., Africa, Asia, Eastern Europe, Latin America, and Russia) or who frequently travel to countries with a high prevalence of TB disease.
- Residents and employees of congregate settings that are high risk (e.g., correctional facilities, long-term-care facilities [LTCFs], and homeless shelters).
- Healthcare workers (HCWs) who serve patients who are at high risk.
- HCWs with unprotected exposure to a patient with TB disease before the identification of TB and institution of correct airborne precautions for this patient.
- Certain populations who are medically underserved and who have low income, as defined locally.
- Populations at high risk who are defined locally as having an increased incidence of TB disease.
- Infants, children, and adolescents exposed to adults in high-risk categories.

Persons who are infected are more likely to progress to active disease if they were infected within the previous two years, are HIV seropositive or in some other way

immunocompromised, an infant or child less than four years of age, have one of several disorders such as silicosis or diabetes mellitus, or have a history of improperly treated TB.

The presence of HIV contributes to the TB infection rate, possibly by reducing immunity and therefore resistance to TB infection. Another factor that increases the potential for harm from TB is the presence of strains of TB that are resistant to multiple antitubercular antibiotics. Since 1993, when the TB surveillance system was expanded to include drug-susceptibility results, reported multidrug-resistant (MDR) TB cases have decreased in the United States. Among TB cases in the United States with initial drug-susceptibility testing results who did not have prior treatment, the percentage of primary MDR TB cases changed slightly from 1.2% (86 cases) in 2012 to 1.4% (95 cases) in 2013. (42)

While most strains of *M. tuberculosis* can be treated by antitubercular antibiotics, the treatment takes nine months to complete, and in the event the strain of *M. tuberculosis* involved is drug resistant, treatment may be difficult and take longer. As with the virally mediated diseases discussed previously, TB is most effectively managed by preventing infection. Preventing the transmission of TB is done by the following:

1. Healthcare workers (HCWs) including acupuncturists should have an annual skin test for TB. This test should be repeated after two weeks if the previous test was not within one year. An alternative test, the QuantiFERON blood test is now approved for TB testing. This test has the advantage that only one contact is required, results are available more rapidly, and is not impacted by prior BCG (bacilli Calmette-Guerin) vaccination.
2. Individuals who were vaccinated for TB or have a history of a positive skin test should get a chest x-ray and an annual physical examination.
3. If a patient presents in your clinic with a chronic cough of unknown origin, the patient should be asked to wear a mask. It is a good policy to have masks available for any patient with a cough of unknown origin to prevent transmission of airborne pathogens, including TB.
4. If you suspect your patient may have TB, the patient must be referred to a physician for diagnosis and treatment.

A number of small studies have been completed looking at the effects of acupuncture and moxibustion on the treatment or symptoms of tuberculosis, often with good results. While there are no reports of tuberculosis transmission in a licensed practitioner's practice location, there is one case of tuberculosis being caused by an illegal acupuncturist, (43) highlighting the need to understand and identify this disease.

Transmission of *Mycobacterium tuberculosis* is a recognized risk to patients and healthcare personnel in healthcare facilities. Transmission is most likely to occur from patients who have

unrecognized pulmonary tuberculosis or tuberculosis related to their larynx, are not on effective anti-tuberculosis therapy, and have not been placed in tuberculosis isolation. Transmission of *Mycobacterium tuberculosis* in healthcare settings has been associated with close contact with persons who have infectious tuberculosis. (44)

TB Survival Outside Host

M. tuberculosis can survive for months on dry inanimate surfaces and can survive in soil for 4 weeks, and in the environment for more than 74 days. Exposure to light inactivates the bacterium. (45)

Acupuncture TB Safety

Ultimately the most important component in a clinical safety program is safe practice on the part of the practitioner. The safe use of sharps, prevention of transmission of bloodborne pathogens, and other appropriate risk management techniques prevent harm to the practitioner, his or her family members, and the public. Utilizing respiratory etiquette and Standard Practices will limit exposure of the practitioner and patients to TB. Safe practice remains the most important obligation for the acupuncturist. Clean Needle Technique and Standard Practices are a vital part of safe practice for the acupuncturist.

Skin Infections

Prospective and retrospective studies of acupuncture safety point to a small number of localized skin infections occurring as a result of acupuncture. (1)

Common resident bacteria of the skin include *Staphylococcus* and *Streptococcus* species. Impetigo and other local skin infections can occur when a break in the skin allows the staph or strep to enter the dermis or lower structures. (46)

Staphylococcus

Staphylococcus species are gram–positive bacteria normally found on the skin. “Staph” bacteria, such as *Staphylococcus epidermidis* or *Staphylococcus aureus*, are common bacterial contaminants found on the skin that can enter the body of a practitioner or patient. This type of contamination is thought to occur when the bacteria on the skin is passed into the body through insertion of a needle into the skin. (47)

Skin infections caused by staph are usually red and painful. Some start as painful bumps that seem like spider bites, but quickly become abscesses (boils) filled with pus. (48)

Staphylococcus aureus accounts for more than half of the reported cases of acupuncture-related bacterial infections of the skin. (49)

Individual case reports of staph infections after acupuncture include cases of pericardial abscess, (50) necrotizing fasciitis, (51) bacteremia, (52) and spinal subdural empyema. (53)

Preventing *Staphylococcus* infections involves standard practices of handwashing and avoiding needling or other procedures in areas with active skin lesions.

Methicillin-Resistant Staphylococcus Aureus (MRSA)

The bacterium *Staphylococcus aureus* is a gram positive, coagulase positive aerobic coccus associated with wound infections and other medically significant infections. One strain of staph aureus, resistant to the antibiotic methicillin (methicillin-resistant *Staphylococcus aureus*, MRSA) has become a significant source of antibiotic resistant infections. (54, 55) This organism is spread by skin-to-skin contact and can be readily transmitted from patients to healthcare providers, staff and other patients. Between 25% and 30% of the population may be carriers of MRSA. (55) While the majority of MRSA infections appear to be nosocomial (infections acquired from the healthcare setting), 12% are community-acquired. (55)

Prevention

It is imperative to prevent the spread of MRSA to patients and co-workers. Appropriate prevention strategies include the following: (56, 57)

1. Appropriate handwashing and the use of hand cleansers.
2. The use of barrier protection such as gloves, lab coats or gowns, and face masks as necessary.
3. Proper handling of potentially contaminated materials such as sharps, disposable supplies such as cotton and gauze, and soiled or blood-stained linen.
4. Avoid contact with draining wounds, pimple-like lesions, or other skin lesions that may be a site of infection.
5. Avoid acupuncture and other AOM techniques in inflamed or infected skin regions.
6. Use of Clean Needle Technique.
7. Scrupulous use of the appropriate disinfectants.
8. Referral of patients that may be infected to a physician for appropriate treatment.

MRSA has been reported after acupuncture treatments and may cause significant damage. (2, 58) In one case study the transmission of MRSA was clearly from the medical practitioner to the patients. (59) There are significant risks associated with treating a patient that has lesions consistent with MRSA, including draining wounds, suppurating lesions, or pustules that have not been assessed by a physician. There are also risks associated with treating patients when the practitioner currently has active skin lesions that have not been assessed by a medical professional. It is imperative that an assessment of any active skin lesions in either a patient or

practitioner be made as soon as possible. It is appropriate to delay AOM treatment until such an assessment is made and appropriate antibiotic therapy initiated.

MRSA Survival in the Environment

Most studies suggest that MRSA can live up to 90 days on inanimate objects and dry surfaces. MRSA bacteria can remain viable on surfaces longer than other bacteria and viruses because they can survive without moisture. (24) MRSA can survive longer on hard surfaces than soft surfaces but can be inactivated using appropriate EPA-approved disinfecting solutions.

Streptococcus

Group A *Streptococcus* (GAS) is a bacterium often found in the throat and on the skin. GAS disease may occur when bacteria from the throat or skin enters parts of the body where bacteria usually are not found, such as subcutaneous tissues, the blood, or the lungs. These bacteria are spread through direct contact with mucus from the nose or throat of persons who are infected or through contact with infected wounds or sores on the skin. (60)

Strep A may cause a skin infection such as impetigo or other skin infections. Pyogenic skin infections associated with acupuncture may be Streptococcal infections. While rare (approximately 50 cases reported globally in the 1970s and 1980s) (61) Streptococcal infections may occur as a result of acupuncture.

Preventing Streptococcal infections involves standard practices of handwashing, Standard Practices and avoiding needling or other procedures in areas with active skin lesions. (62)

Mycobacteria Other than Tuberculosis (MOT)

(*Mycobacterium abscessus, Mycobacterium fortuitum, Mycobacterium haemophilum*)

Mycobacterium abscessus can be found in water, soil, and dust. It has been known to contaminate medications and products, including medical devices. Healthcare-associated *Mycobacterium abscessus* can cause infections of the skin and the soft tissues under the skin. It can also cause lung infections in persons with various chronic lung diseases. (61)

Mycobacteria other than tuberculosis (MOT) are of special significance to the acupuncturist because of a number of reports of AOM-associated skin lesions caused by MOT. MOT-related skin diseases have been reported in outbreaks associated with specific acupuncture clinics in Canada and Korea. (2) The recognition and management of MOT diseases are in the domain of the dermatologist. (63) MOT are slow-growing bacteria that can cause disease in both immunocompetent and immunocompromised patients. The most common clinical presentations of infection are the appearance of suppurative and ulcerated skin nodules. (64)

MOT are widely distributed in the environment, particularly in wet soil, marshland, streams, rivers and estuaries. (65) MOT are generally found in the environment as free-living organisms and therefore may persist in wet or dry environments for a significant period of time.

Mycobacterium (MOT) infections have been reported as related to acupuncture "probably associated with the inadequate sterilization of the needles or the puncture site." (66) *Mycobacterium* infections are probably not associated with acupuncture when the practitioner follows all critical components of the CNT protocols. However, a number of cases have been discussed in the literature. (2,66-70) It is likely that some of these infections associated with acupuncture are a result of dirt carried in by patients and then left behind on towels used for hot packs, treatment table linens and other cloth that has not been changed between each and every patient visit.

Preventing Mycobacterium other than Tuberculosis (MOT) in the clinic:

1. Appropriate handwashing and the use of alcohol-based hand cleansers.
2. Scrupulous use of CNT procedures.
3. Proper handling of potentially contaminated materials such as sharps, and disposable supplies such as cotton and gauze.
4. Scrupulous use of the appropriate disinfectants for the treatment room and treatment tables.
5. Meticulous replacement of any sheets or towels between each and every patient visit.
6. Referral of patients that may be infected to a physician for appropriate treatment.

Herpes Simplex

Two serotypes of herpes simplex virus (HSV) have been identified: HSV-1 and HSV-2. HSV-1 is usually associated with oral lesions (i.e., cold sores), although both HSV-1 and HSV-2 may be found in oral or genital mucosal lesions. HSV-1 is typically transmitted by saliva or by the infection on hands of healthcare personnel. (70) HSV can be transmitted by direct contact with epithelial or mucosal surfaces. HSV can be transmitted by ingestion, parenteral injection, droplet exposure of the mucous membranes (eyes, nose or mouth), and inhalation of aerosolized materials. (70, 71)

Both forms of HSV are characterized by recurring lesions. After the initial infection, which is often the most severe outbreak, the virus will go into quiescence for varying lengths of time. The next stage is a prodromal stage, which may include localized itching, pain or tingling at the site of the infection. At this point, the virus is being shed and others can become infected. The last stage is called an outbreak. Outbreaks are characterized by the same symptoms in the same location as the initial attack, but tend toward becoming milder over time. If blisters form,

they will typically heal in 7-10 days. The person with HSV is still shedding virus at this point and can spread the infection through touch. The HSV viral cycle will then start again.

Acupuncture, moxibustion, cupping and other AOM procedures have been associated with decreasing the pain and improving health of those with herpes-related lesions. (72-74)

Acupuncture and cupping may also be associated with spreading the HSV if Standard Precautions are not taken. (75)

To prevent transmission of the HSV virus, Standard Precautions should be followed. Practitioners should refrain from touching active lesions and avoid treatment procedures in the area of any lesions. Since patients' hands contact practice location surfaces, and the virus could reach an object that is touched by another person, all surfaces must be disinfected daily. (76, 77) The HSV 1 and HSV 2 virus can survive for several hours on work surfaces, such as treatment tables and countertops. (76)

Influenza

Influenza is primarily a community-based infection that is transmitted in households and community settings, including healthcare clinics.

Healthcare-associated influenza infections can occur in any healthcare setting and are most common when influenza is also circulating in the community. Therefore, infection control measures need to be utilized in all acupuncture practice locations to reduce transmission of the influenza virus. (78)

For more information visit:

Infection Control in healthcare Facilities
(http://www.cdc.gov/flu/professionals/infectioncontrol/index.htm)

Influenza Survival in the Environment

Influenza viruses can survive in the environment for up to 24 hours. (79) Proper cleaning is required to prevent transfer from treatment surfaces to patients, staff and family members.

Acupuncture can be effective in treating or helping prevent upper respiratory infections. (80, 81) However, having patients acutely ill in a healthcare setting increases the risk of transmission of the virus to healthcare workers and other patients. Standard Precautions need to be followed in terms of handwashing and treatment room disinfection.

CDC Fundamental Elements to Prevent Influenza Transmission

Preventing transmission of influenza virus and other infectious agents within healthcare settings requires a multi-faceted approach. Spread of influenza virus can occur among patients, healthcare workers, office staff, and visitors. The core prevention strategies include: (78)

- Influenza vaccination of HCWs and at-risk public annually.
- Implementation of respiratory hygiene and cough etiquette.
- Implementation of Standard Precautions.
- Adherence to infection control precautions for all patient-care activities and aerosol-generating procedures.
- Implementing environmental and engineering infection control measures.

Healthcare workers must stay home when acutely ill. In most cases, personnel should not be actively seeing patients until free of fever for at least 24 hours without the use of NSAIDs.

Norovirus

Noroviruses are a group of viruses that cause gastroenteritis, causing an acute onset of severe vomiting and diarrhea. This virus is very contagious and can spread rapidly throughout healthcare facilities. (82) People can become infected with the virus in several ways:

- Having direct contact with another person who is infected (a healthcare worker, visitor, or another patient).
- Eating food or drinking liquids that are contaminated with norovirus.
- Touching surfaces or objects contaminated with norovirus, and then touching your mouth or other food items.

Norovirus is transmitted by hands contaminated through the fecal-oral route, directly from person to person, through contaminated food or water, or by contact with contaminated surfaces. (83) The norovirus is relatively stable in the environment and can persist for weeks on hard surfaces.

Noroviruses have not been linked to acupuncture or related AOM procedures in the medical literature. Estimates are 19-21 million cases of norovirus are reported in the U.S. each year. (84) As norovirus diseases are one of the most common infections in the U.S., all healthcare practitioners need to follow Standard Precautions to prevent the spread of this highly contagious organism.

Prevention of Norovirus

The core prevention strategies include: (83)

- Follow hand-hygiene guidelines, and carefully wash hands with soap and water after contact with patients with norovirus infection.
- Use gowns and gloves when in contact with, or caring for patients who are symptomatic with norovirus.
- Routinely clean and disinfect high touch patient surfaces and equipment with an Environmental Protection Agency-approved product with a label claim for norovirus.
- Remove and wash contaminated clothing or linens.
- Healthcare workers who have symptoms consistent with norovirus should be excluded from work for at least 3 days after symptoms resolve.

Appropriate hand hygiene is likely the single most important method to prevent norovirus infection and control transmission. Reducing any norovirus present on hands is best accomplished by thorough handwashing with running water and antiseptic soap. Alcohol-based hand sanitizers do not demonstrate efficacy against the norovirus. (84, 85) Healthcare workers should stay away from work while ill and for at least 48 to 72 hours following resolution of symptoms. (83)

Clostridium difficile

Clostridium difficile is a spore-forming, gram-positive anaerobic bacillus that produces two exotoxins: toxin A and toxin B. It is a common cause of antibiotic-associated diarrhea (AAD). It accounts for 15-25% of all episodes of AAD. (86)

Nearly all antimicrobials have been implicated in the development of *Clostridium difficile* associated disease (CDAD). Persons with normal healthy gastrointestinal flora and the ability to mount a brisk immune response are at lower risk for CDAD. (87)

Clinical symptoms of *Clostridium difficile* include watery diarrhea, fever, loss of appetite, nausea, and abdominal pain and tenderness.

Clostridium difficile is shed in feces. Any surface, device, or material (e.g., commodes, rectal thermometers) that becomes contaminated with feces may serve as a reservoir for the *Clostridium difficile* spores. *Clostridium difficile* spores are transferred to patients mainly via the hands of healthcare personnel who have touched a contaminated surface or item. (86)

The two primary agents used to treat CDAD are metronidazole and oral vancomycin. Adjunctive therapies for refractory disease include efforts to replenish colonic flora with the use of orally administered probiotics, usually *Lactobacillus* species or *Saccharomyces boulardii*. (87)

Clostridium difficile spores resist killing by usual hospital disinfectants and may survive on surfaces for up to five months. (88) Special procedures need to be followed when caring for patients with *Clostridium difficile* – associated disease.

Prevention of Spread of Clostridium difficile

CDC recommendations to prevent transmission of Clostridium difficile in practitioners' offices: (86)

- Use gloves when entering patients' rooms and during patient care when the patient is a known carrier of *Clostridium difficile*.
- Perform hand hygiene after removing gloves.
    - Because alcohol does not kill *Clostridium difficile* spores, use of soap and water is more efficacious than alcohol-based hand sanitizers. However, early experimental data suggest that, even using soap and water, the removal of *Clostridium difficile* spores is more challenging than the removal or inactivation of other common pathogens.
    - Preventing contamination of the hands via glove use remains the cornerstone for preventing *Clostridium difficile* transmission via the hands of healthcare workers; any theoretical benefit from instituting soap and water must be balanced against the potential for decreased compliance resulting from a more complex hand hygiene message.
    - If your institution or clinic experiences an outbreak, consider using only soap and water for hand hygiene when caring for patients with *Clostridium difficile* infection
- Use gowns when entering patients' rooms and during patient care when the patient is a known carrier of *Clostridium difficile*.
- Dedicate or perform cleaning of any shared medical equipment from a treatment room when the patient is a known carrier of *Clostridium difficile*.

Implement an environmental cleaning and disinfection strategy when the patient is a known carrier of *Clostridium difficile*:

- Ensure adequate cleaning and disinfection of environmental surfaces and reusable devices, especially items likely to be contaminated with feces and surfaces that are touched frequently.
- Consider using an Environmental Protection Agency (EPA)-registered disinfectant with a sporicidal claim for environmental surface disinfection after cleaning in accordance with label instructions. Hypochlorite-based disinfectants may be most effective in preventing *Clostridium difficile* transmission.

5. Summary of Prevention of Disease Transmission in Acupuncture Practice

Basic Critical Principles

- Follow Clean Needle Technique for acupuncture and related AOM procedures.
- Use only single-use sterile filiform needles.
- Use single-use sterile devices that enter the skin, including lancets and seven-star hammers.
- Clean hands immediately before any clinical procedure, including inserting needles, between patient visits, after contact with any bodily fluids or OPIM.
- Always establish a clean field ensuring the cleanliness of the practitioner's and patient's skin and the sterility of the shaft of the needle and other medical devices.
- Immediately isolate used needles and other sharps in an appropriate sharps container.
- Do not needle or otherwise treat areas of the skin with active lesions.

Preventing Patient to Patient Cross Infections – Critical Recommendations

- Use single-use sterile needles and other devices that enter the skin, including acupuncture needles, lancets, and seven-star hammers.
- Utilize proper handwashing techniques between patient visits.
- Institute and follow procedures for proper cleaning of the treatment table and treatment room.
- Casual contacts between patients or between patients and the practitioner such as contact with clothing etc. are not cause for concern. However, it is strongly recommended that policies be put in place to limit the contact between patients if a patient is displaying symptoms of active acute infections.

Preventing Patient to Practitioner Cross Infections

- Avoid touching the shaft or tip of a used needle or other used healthcare sharp.
- Always immediately isolate used sharps in proper containers.
- Use a dry cotton ball or gauze to close the point. Never use the bare finger to cover the skin where a needle has been removed.
- Keep all skin breaks on the practitioner's hands covered.
- Consider vaccination against Hepatitis B.

Preventing Practitioner to Patient Cross Infections

- Handwashing is critical.
- Avoid touching the shaft of a needle that will penetrate the patient's skin prior to insertion.

- Avoid all patient contact if you have an overt clinical infection. Do not treat patients if you have a fever and/or productive cough.
- Keep all open cuts, wounds or other lesions on your skin covered.
- Have a yearly physical with appropriate testing as described by OSHA/CDC.

Review

While it is impossible to avoid all infections in a healthcare workplace, there are a number of critical factors in limiting infections to the rare occurrences they have been shown to be in prospective studies. These practices are:

- Ensuring the hands of the practitioner are clean through handwashing.
- Proper preparation of the needling sites, including avoiding needling skin with active lesions and proper skin preparation.
- Utilizing sterile needles and other devices that enter the skin, and their proper storage.
- Clean Needle Technique.
- Careful management and disposal of used needles and other equipment.
- A clean working environment.

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Part V: Personnel Health, Cleanliness and Safety Practices

This section addresses the practices to reduce transmission of diseases through hygienic methods. Since there are no studies of handwashing, skin preparation, and glove use specifically in acupuncture practices, general healthcare standards (CDC, WHO) are the primary resources for recommendations in this section.

1. Handwashing

The most common mode of healthcare-associated infection transmission is via the hands!

Please note: both the CDC and World Health Organization have published extensive information about handwashing techniques and best practices. What is presented here is just an overview. For those interested in reading more see:

- http://www.cdc.gov/handhygiene/download/hand_hygiene_core.pdf
- http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf
- http://www.jointcommission.org/assets/1/18/hh_monograph.pdf
- http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm

It is strongly recommended that acupuncturists always wash their hands:

1. Immediately before acupuncture or other clinical procedures.
2. After contact with blood or body fluids or obvious environmental contaminants.
3. At the end of a treatment.

A History of Handwashing for Healthcare Workers (HCWs):

Louis Pasteur demonstrated in the 1860s that microbes caused diseases. In the mid-1800s, Ignaz Semmelweis in Vienna, Austria, and Oliver Wendell Holmes in Boston, U.S., established that hospital-acquired diseases were transmitted via the hands of HCWs. (1) The first U.S. national hand hygiene guidelines were published in the 1980s. In 1995 and 1996, the CDC/Healthcare Infection Control Practices Advisory Committee (HICPAC) in the U.S. recommended that either soap and water or a waterless antiseptic agent be used for cleansing hands upon leaving the rooms of patients.

Importance of Handwashing:

The hands of healthcare workers (HCWs) are the main source of hospital infection, and therefore handwashing is the most important procedure for preventing nosocomial infections.

Clean hands are the single most important factor in preventing the spread of pathogens and antibiotic resistance in healthcare settings. (2) Good hand hygiene reduces the incidence of healthcare-associated infections.

Healthcare specialists generally cite handwashing as the single most effective way to prevent the transmission of disease. (3) Hygienic hand cleaning by hospital personnel to remove the transient bacteria which contaminates the hands and skin of HCWs is critical for infection control in all healthcare settings. (4-6)

Despite evidence for the importance of handwashing in the prevention of nosocomial infection, studies have demonstrated that compliance with the recommendation that HCWs wash their hands between each and every patient visit remains low in patient care settings. (7)

Effective Handwashing Technique

Handwashing with soap and running water is the most effective form of handwashing. However, when there is no sink available, practitioners may use an alcohol-based hand sanitizer. An alcohol-based hand sanitizer can enhance killing of transient hand flora without the use of running water, soap, and hand drying, but cannot replace handwashing for removing all hand contaminants.

Duration - Soap and Water:

Although there is no accepted optimal length of time for handwashing, a number of studies have looked at 15-second protocols for hand cleansing. (8-14)Unfortunately, most HCWs generally wash their hands for much shorter durations, so the effectiveness of handwashing as actually practiced has not really been studied.

Soaps are detergent-based products whose cleaning activity can be attributed to their detergent properties, which result in removal of dirt, soil, and various organic substances, including pathogens, from the hands. Plain soaps have minimal, if any, direct antimicrobial activity. (1) Handwashing with plain soap can and does remove loosely adherent transient flora. However, in several studies, handwashing with plain soap failed to remove pathogens from the hands of hospital personnel. (14,15) Handwashing with plain soap and water does decrease the transmission of HAI. Therefore, while the best practice in handwashing remains unclear what is clear is that soap and water should be utilized as indicated by Standard Practices.

Hand Hygiene Technique: Soap and Water

When washing hands with soap and water: (16, 17)

- Remove all jewelry and roll up the sleeves of your shirt, if necessary.
- Wet hands first with cool to warm water.

- Apply an amount of antibacterial soap recommended by the manufacturer to hands.
- Rub hands together vigorously for 10-20 seconds, covering all surfaces of the hands and fingers.
- Rinse hands well with running water.
- Dry thoroughly with a clean, disposable towel.
- Use towel to turn off the faucet using the disposable towel, not your clean hands.

Avoid using hot water, because repeated exposure to hot water may increase the risk of dermatitis. (18, 19)

Hand Drying

Because wet hands can more readily acquire and spread microorganisms, the proper drying of hands is an integral part of routine handwashing. Careful hand drying is a critical factor determining the level of bacterial transfer associated with touch contact after hand cleansing. Reusing or sharing towels should be avoided because of the risk of cross-infection. Reusable cloth towels or roll-type towels are not recommended for use in healthcare settings. Instead, always use paper towels for hand drying. (20, 21)In a comparison of methods to test the efficiency of hand drying for the removal of bacteria from washed hands, warm air drying performed worse than drying with paper towels. (22) When clean or disposable towels are used, it is important to pat the skin rather than rub it, to avoid skin cracking. Skin excoriation may lead to bacteria colonizing the skin and possible spread of bloodborne viruses as well as other microorganisms.(23) Use paper towels to turn off faucets and to open doors between the handwashing station and the patient care room.

Hand Hygiene Technique - Alcohol-Based Sanitizers

When decontaminating hands with an alcohol-based hand sanitizer, apply product to palm of one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry.(24,25) Follow the manufacturer's recommendations regarding the volume of product to use. In healthcare practices, always used approved products for hand cleansing; "home remedies" such as various combinations of essential oils and lotions may not reduce transient bacterial load significantly.

Handwashing - Antiseptic Towelettes

Antimicrobial-impregnated wipes (i.e., towelettes) may be considered as an alternative to washing hands with soap and water even when the hands are visibly soiled. (12) However, the use of soap and water is still considered the best method for cleaning hands that have been soiled with blood and OPIM, after removal of gloves, after using the restroom and before and after eating.

Hand Flora

There are two types of infectious agents on the skin: resident and transient. In 1938, Price (26) established that bacteria recovered from the hands could be divided into these two categories.

Resident Hand Flora: The resident flora of the skin consists of microorganisms residing under the superficial cells of the *stratum corneum* and can also be found on the surface of the skin.(27,28) *Staphylococcus epidermidis* is the dominant species. (29) Other resident bacteria include *S. hominis* and other staphylococci, followed by coryneform bacteria and other bacteria. (30) Resident flora has two main protective functions: it prevents colonization of the skin by pathogenic organisms and competes with any organisms for nutrients, thus preventing permanent association with those organisms.(31) In general, resident flora is less likely to be associated with healthcare associated infections, but may cause infections in sterile body cavities, the eyes, or on non-intact skin. (32)

Transient skin flora: Transient or temporary skin flora refers to the microorganisms that transiently colonize the skin. This includes bacteria, fungi and viruses, which reach the hands, for example, by direct skin-to-skin contact or indirectly via touching surfaces of desks, light switches, utensils, and other objects. Handwashing is aimed at reducing or eliminating transient pathogenic skin flora. (33)

Rings/Jewelry

Several studies have demonstrated that skin underneath rings is more heavily colonized than comparable areas of skin on fingers without rings. One study found that 40% of nurses harbored gram-negative bacilli (e.g., *E. cloacae*, *Klebsiella*, and *Acinetobacter*) on skin under rings and that certain nurses carried the same organism under their rings for several months. (34-36)

Healthcare workers and Actual Handwashing Practices

Unfortunately, many HCWs do not wash their hands as often as is recommended for being in a healthcare practice. (37) Studies have consistently demonstrated rates of handwashing compliance are less than 50% in many hospitals.

Necessity of Handwashing

The necessity of handwashing between patients/patient visits and the use of Standard Precautions reflects the importance of treating all patients as if they were carriers of hepatitis or HIV. Beyond this, the need to wash the hands is based on whether the hands become contaminated during the course of treatment. Practitioners must wash their hands between patients, before and after inserting needles, and after contact with potentially infectious body fluids.

Sources of contamination include body fluids such as blood and saliva, vaginal secretions, and fecal contamination, and fluids from open lesions. Body fluids may contain bacteria such as *Staphylococcus* species, and viruses associated with hepatitis and HIV/AIDS. It is absolutely imperative that potentially infectious fluids not be transferred from one person to another through the acupuncture provider's hands, or from the patient to the practitioner and/or other members of the clinic staff. This is most effectively done by carefully washing hands whenever needed. Handwashing should also take place before and after answering the phone, whenever the practitioner touches his or her face or hair, eats, or engages in any other non-clinical activity.

What is the right way to wash your hands?

- Remove all jewelry and roll up the sleeves of your shirt, if necessary.
- Wet hands first with cool to warm water.
- Apply an amount of soap (plain or antibacterial) recommended by the manufacturer to hands.
- Rub hands together vigorously for 10-15 seconds, covering all surfaces of the hands and fingers.
- Rinse hands well with running water.
- Dry thoroughly with a clean, disposable towel.
- Use a disposable towel to turn off the faucet, not your clean hands

The CDC recommends specific types of handwashing under the following circumstances: (2)

1. When hands are visibly dirty or are visibly soiled with blood or other body fluids, wash hands with soap and water.
2. If hands are not visibly soiled, practitioners may use either an alcohol-based hand sanitizer, or soap and water for routinely decontaminating hands in clinical situations.
3. Decontaminate hands before having direct contact with patients.
4. Decontaminate hands after contact with a patient's intact skin (e.g., when taking a pulse or blood pressure, or palpating points).
5. Decontaminate hands after contact with body fluids or excretions, mucous membranes, nonintact skin, and wound dressings even if hands are not visibly soiled.
6. Decontaminate hands if moving from a contaminated-body site to a clean-body site during patient care.
7. Decontaminate hands after removing gloves with soap and water.
8. Before eating and after using a restroom, wash hands with soap and water.
9. Antimicrobial-impregnated wipes (i.e., towelettes) may be considered as an alternative to washing hands with soap and water.

Handwashing with soap and running water is the most effective form of handwashing. However, when there is no sink available, practitioners may use an alcohol-based hand sanitizer. An alcohol-based hand sanitizer can de-germ hands in less than 30 seconds and enhance killing of transient hand flora without the use of running water, soap, and hand drying.

Studies have shown that clinicians find alcohol-based hand sanitizers convenient, accessible, and less irritating to the skin. (38) The CDC has also accepted the use of antiseptic hand cleansers or towelettes except when circumstances require the use of soap and water. (39)

The necessity of handwashing between patients and the use of Standard Precautions reflects the importance of treating all patients as if they were carriers of hepatitis or HIV. Beyond this, the need to wash the hands is based on whether the hands become contaminated during the course of treatment. Practitioners must wash their hands between patients, before and after inserting needles, before and after other clinical procedures, and after contact with potentially infectious body fluids.

Recommendations

- Critical: Wash hands between every patient visit.
- Critical: Wash hands immediately prior to inserting acupuncture needles or performing other procedures that break the skin.
- Critical: Wash hands after entering the clinic and before starting any patient care.
- Critical: Wash hands before and after eating.
- Critical: Wash hands with soap and water after using the restroom.
- Critical: Wash hands after removing gloves.
- Strongly Recommended: Wash hands before performing any clinical procedure, including those that do not break the skin (e.g., cupping).
- Strongly Recommended: Wash hands after taking a patient's pulse and after palpating points.
- Recommended: Wash hands after decontaminating reusable equipment.

2. Patient Skin Preparation

There are no prospective studies demonstrating either the need for or lack of need for skin preparation before acupuncture and other AOM practices. The best evidence is that having the patient's skin be clean and having the practitioners hands be clean through proper handwashing are most important.

There are no studies which compare skin preparation prior to acupuncture needle insertion with no skin preparation. The closest information available pertains to skin preparation prior to injections, (40), such as insulin injections for diabetics and vaccinations. Research conducted as

early as the 1960s by Dann (41) and Koivisto & Felig (42) with diabetic patients indicated that although skin preparation with alcohol prior to injection markedly reduced skin bacterial counts, such treatment is not necessary to prevent at injection sites. (43) In 1999 some standards for immunizations and other subcutaneous injections were re-written such that skin preparation was not absolutely necessary. (44)

Healthcare research has reinforced the importance of ensuring that the skin of the patient is physically clean and that healthcare providers maintain high standards of hand hygiene prior to instituting any procedure that includes a break in the skin. (45)

The World Health Organization no longer recommends swabbing clean skin with an antiseptic solution before giving intradermal or subcutaneous needle injections, although intramuscular injections do require skin preparation with 60-70% alcohol. (46) The CDC states that alcohol, soap and water or chemical agents are not needed for preparation of the skin prior to vaccination, unless the skin is grossly contaminated or dirty. (47) In order to be consistent with WHO and CDC guidelines, skin cleansing should be carried out whenever the practitioner expects to needle below the subcutaneous layer; in other words into the muscle layer or below.

Other researchers have recommended the cleaning of the injection site in order to minimize the risk of infection. (48-50) Many practitioners believe it follows best practice guidelines to clean the skin prior to injection to reduce the risk of contamination from the patient's transient skin flora.

There is one case report of a patient who reportedly had septicemia after acupuncture during which the skin was not swabbed. The case was reported from Scotland in which a 69-year-old man died from an infection after acupuncture treatment at the thigh. The patient was later found to have a preexisting pancytopenia (i.e., low total blood cell count, including leukocytes), resulting in an increased susceptibility to infection. The case report author, who is also the practitioner, admitted that the patient's skin at the acupuncture point was not cleaned before the needle insertion and later found local muscle infection which led to septicemia. (51)

The most common and convenient procedure for cleaning a patient's skin is the use of an alcohol swab. An alcohol pump dispenser and cotton balls may also be used in a treatment setting as long as the cotton balls are discarded when dry or contaminated and the pump dispenser is cleaned with an approved disinfectant on a daily basis (as with any other surface in the treatment room).

Since many patients come to the AOM treatment location from work, at the end of the day, after exercising, and in general less frequently immediately after showering, it is likely that the acupuncture point locations are not completely clean. Hands, feet, and the face are commonly

used areas for acupuncture and are regularly exposed to transient organisms during the course of regular home and work activities.

According to a July 2013 letter from the CDC, (52) “The procedures outlined in the CNT Manual are reasonable” regarding skin preparation.

Does this mean that skin must be cleaned with alcohol swabs prior to needle insertion? What is clear is that the skin must be clean, and that the skin to be treated should be free from overt infections or lesions. How individual practitioners choose to make sure the skin is clean and free of lesions is a clinical decision each practitioner must make, based on the principles and safety manuals in use in the clinical setting in which they practice.

Some states mandate the use of an antiseptic swab before insertion of an acupuncture needle in their practice acts and/or rules. This manual should not be interpreted as advising against a practice outlined in state law. Practitioners have a duty to investigate and comply with state regulation.

Alcohol Swab Method

When desired, prepared alcohol swabs are used to clean all sites expected to be needled after setting up the clean field and before needling. Allow the site to dry. Alternatively, apply a 60–70% alcohol-based solution (isopropyl alcohol or ethanol) on a single-use swab or cotton-wool ball. Do not use methanol or methyl-alcohol as these are not safe for human use. (46)

Swabbing the acupuncture insertion site with a saturated 60-70% alcohol swab and allowing the skin to dry is a good practice to reduce both dirt and the number of pathogens at an acupuncture site. Allowing the site to dry prevents stinging which may occur if alcohol is taken into the tissues upon needle entry. (50)

Options for Skin Preparation

Options for cleaning the skin before acupuncture besides 70% alcohol include requiring patients to wash all skin surfaces to be treated with soap and water; or applying a disinfecting solution containing chlorhexidine gluconate. (53) (Note: For topical application as a skin disinfecting solution, chlorhexidine is marketed under many brand names, including Spectrum-4, Hibistat, Calgon Vesta, Betasept, Dyna-Hex, and Hibiclens.)

Use of povidone iodine antiseptic ointment or bacitracin/gramicidin/ polymyxin B ointment is not recommended as iodine may be absorbed and may create changes in thyroid function, (54) and overuse of bacitracin and other antibiotic ointments may lead to bacterial resistance to these products.

No AOM procedure should be conducted where there are active lesions on the skin. All locations should be cleansed before proceeding with acupuncture or other procedures. Use of 70% alcohol swabs or cotton soaked in 70% alcohol is a convenient and cost-effective method to improve skin cleanliness. Skin can be cleaned with soap and water or other methods that ensure cleanliness.

If alcohol is being used, swab the points and allow the alcohol on the skin to dry. The same swab may be used for several points as long as the swab itself is not dry and has only touched intact skin. A new swab should be used if the swab begins to change color, becomes visibly dirty, becomes dry, or has come into contact with any skin break, lesion, inflammation or infection. The alcohol should be allowed to dry to reduce the potential for discomfort during needling. A separate swab should be used for areas of high bacterial flora load, such as the axilla or groin.

Recommendations

- Critical: Avoid acupuncture in areas of active skin lesions.
- Critical: Perform AOM procedures only in areas of clean skin.
- Critical: Ensure the patient's skin is clean before inserting needles or lancets.
- Critical: When using alcohol swabs, use a new alcohol swab for each patient and a new swab if the swab begins to change color, becomes visibly dirty, becomes dry, or has come into contact with any skin break, lesion, inflammation or infection.
- Strongly Recommended: Swab every point with 70% alcohol or other cleansing agent prior to "wet" cupping, use of lancets or 7-star hammers.
- Strongly Recommended: Use a separate swab for areas of high bacterial flora load, such as axilla or groin.
- Recommended: Have patients clean hands and face with soap and water prior to acupuncture in these areas.
- Recommended: Investigate and follow local and state regulation concerning skin preparation.

3. Recommendations for Practitioner Health and Hygiene

Review: Handwashing is critical. The most common mode of healthcare-associated infection transmission is via the hands! In the acupuncturist's practice location sources of hand contamination include body fluids such as blood and saliva, and fluids from open lesions. Body fluids may contain bacteria such as *Staphylococcus* species, and viruses associated with hepatitis and HIV/AIDS. It is absolutely imperative that potentially infectious fluids not be transferred from one person to another through the acupuncture provider's hands, or from the patient to the practitioner and/or other members of the clinic staff. This is most effectively done by carefully washing hands whenever needed. Handwashing should also take place before

and after answering the phone, after using a computer, whenever the practitioner touches his or her face or hair, eats, or engages in any other non-clinical activity.

Yearly Physical

It is recommended that healthcare professionals, including acupuncturists, have a yearly physical that includes testing for tuberculosis.Note that TST and PPD testing are similar. The term “tuberculin skin tests” (TSTs) is used instead of purified protein derivative (PPD) in most up-to-date CDC information. (55)

Clothing

It is recommended that acupuncturists wear clean, washable, or disposable protective clothing while performing treatments. The fabric should be chosen to avoid trapping and shedding contaminating particles or infectious agents in the clean field. Loose or large jewelry, clothing, and hairstyles that touch the patient or break the clean field should be avoided. Open-toed shoes should not be worn, as they pose a risk of needlestick in the event that a needle is dropped. Clothing should cover the practitioner’s legs and feet to prevent the risk of a needlestick accident in the event that a needle is dropped.

Hand Care

Acupuncturists must take great care to maintain the cleanliness of their hands, keeping the nails short. Hand cleanliness is a part of Clean Needle Technique. It is strongly recommended that all cuts and wounds on the practitioner’s hands be washed and dressed immediately for the protection of both patient and practitioner. All cuts, wounds, abrasions, chapped hands, hang nails, torn cuticles, etc. must be covered by wearing a finger-cot or non-sterile non-latex gloves.

Personal Health

An acupuncturist who is suffering from an infectious disease can transmit the disease to his or her patient in various ways. Appropriate medical attention should be sought for infectious diseases. Generally speaking, patient care personnel having overt clinical infection, such as streptococcal pharyngitis (strep throat), active influenza, or a staphylococcal furuncle (boil), should restrict themselves from patient contact. Personnel with minor infections of the skin and minor viral infections of the upper respiratory tract may work so long as they are scrupulous in their practice of personal hygiene and Standard Precautions are followed. (56)The CDC recommends that HCWs be “excluded from work until at least 24 hours after they no longer have a fever (without the use of fever-reducing medicines such as acetaminophen). Those with ongoing respiratory symptoms should be considered for evaluation by occupational health to determine appropriateness of contact with patients.” (57)

- Strongly Recommended: That acupuncturists refrain from treating patients when they are actively ill.
- Recommended: That acupuncturists cancel patient care until at least 24 hours after they no longer have a fever for any acute infection.

Testing for TB, HBV, HCV and HIV

TB testing

In addition to a yearly physical, the CDC suggests that practitioners who work in high TB incidence inner city clinics, or those who work with AIDS patients or drug addicts, obtain a baseline TB test, either 2-step TST or a chest radiograph on hire. Education regarding the symptoms of TB should be provided by appropriately trained personnel, and healthcare workers should be screened for symptoms annually. Settings where there is a high risk of infection should be evaluated for environmental infection control, such as air handling. The transmission of TB is a recognized risk in some healthcare settings. In the CDC's 2005 *Recommendations for Preventing TB Transmission in Healthcare Settings*, a detailed risk stratification is given for low risk settings, medium risk settings, and potential ongoing transmission settings. This last classification should always be temporary, corrective steps taken, and the return to medium risk made within one year.

Effective TB infection control programs should be implemented in healthcare facilities and other institutional settings (e.g., shelters for homeless persons and correctional facilities). (55) It is recommended that healthcare providers have annual TB skin tests or QuantiFERON© testing. In the event that the practitioner is from a part of the world where TB is endemic, or has been vaccinated with Bacillus Calmette-Guerin (BCG), he or she should have a baseline chest x-ray and an annual physical from a qualified provider.

Along with their TB status, healthcare workers who perform exposure-prone procedures should know their HBV or HIV antibody status.

HBV testing

Various tests for HBV can detect either the presence of the virus itself or antibodies to the virus. Testing for evidence of hepatitis B infection should be routine for healthcare providers, especially those with occupational exposure potential. Hospitals and blood banks are required to test for HBV with a very sensitive test that identifies HBV antigen markers.

HCV testing

Generally, the initial laboratory test that is done for HCV is to determine if the person has antibodies to the virus. If the test is positive, it means that the person has been exposed to the

virus and may or may not have active hepatitis C. Additional testing will need to be done to determine if the person is a carrier, has chronic hepatitis, or is immune.

HIV testing

Generally, the initial laboratory test that is done for HIV is to determine if the person has antibodies to the virus. This test can help determine if the person has been infected with the virus but cannot determine the stage of disease. There are rapid HIV tests that can provide results within 20 minutes of testing. A positive test should be confirmed with a western blot or IFA (immunoflourescent assay) test. (58)

Healthcare workers who are infected with HIV or HBV should not perform exposure-prone procedures unless they have received counseling from an expert review panel regarding the circumstances under which they may continue to perform these procedures. The review panel should include experts who represent a balanced perspective and may include all of the following:

1. The healthcare worker's personal physician.
2. An infectious disease specialist with expertise in the epidemiology of HIV and HBV transmission.
3. A health professional with expertise in the procedures performed by the healthcare worker.
4. State or local public health officials.

If the healthcare worker is institution-based, the panel could include the hospital epidemiologist or other infection control staff. Healthcare workers based outside the hospital/institutional setting should seek advice from appropriate state and local public health officials regarding the review process. (59)

It goes without saying that such panels would be required to observe the confidentiality and privacy rights of infected healthcare workers. Infected healthcare workers should notify prospective patients of their seropositive status before undertaking exposure-prone invasive procedures. Acupuncture is not considered an exposure-prone invasive procedure. Mandatory testing of healthcare workers for HIV antibodies, HBsAg, or HBeAg is not recommended. The risk is not sufficient to justify the costs such mandatory testing programs would incur. Education, training, and appropriate confidentiality safeguards are the best means to insure healthcare worker compliance by healthcare workers with recommended prevention procedures.

4. Personal Protective Equipment (PPE)

See also: http://www.cdc.gov/HAI/prevent/ppe.html

Standard Precautions is an outgrowth of Universal Precautions. Universal Precautions were first recommended by the CDC in 1987 to prevent the transmission of bloodborne pathogens to healthcare personnel. In 1996, the application of the concept was expanded and renamed Standard Precautions. Standard Precautions are intended to prevent the transmission of common infectious agents to healthcare personnel, patients and visitors in any healthcare setting. During care for any patient, one should assume that an infectious agent could be present in the patient's blood or body fluids, including all secretions and excretions except tears and sweat. Therefore appropriate precautions, including use of PPE, must be taken. Whether PPE is needed, and if so, which type, is determined by the type of clinical interaction with the patient and the degree of blood and body fluid contact that can be reasonably anticipated and by whether the patient has been placed on isolation precautions such as Contact or Droplet Precautions or Airborne Infection Isolation. (60)

Personal protective equipment, or PPE, as defined by the Occupational Safety and Health Administration, or OSHA, is "specialized clothing or equipment, worn by an employee for protection against infectious materials." (61)

OSHA issues regulations for workplace health and safety. These regulations require use of PPE in healthcare settings to protect healthcare personnel from exposure to bloodborne pathogens and *Mycobacterium tuberculosis.* However, under OSHA's General Duty Clause PPE is required for any potential infectious disease exposure. Employers must provide their employees with appropriate PPE and ensure that PPE is disposed or, if reusable, that it is properly cleaned or laundered, repaired and stored after use. The employer must cover the purchase and cleaning costs for the PPE for all personnel.

The Centers for Disease Control and Prevention (CDC) issues recommendations for when and what PPE should be used to prevent exposure to infectious diseases.

OSHA issues workplace health and safety regulations. Regarding PPE, employers must:

- Provide appropriate PPE for employees at no cost to the employees.
- Ensure that PPE is disposed of properly; or, if reusable, the employer ensures that the PPE is cleaned, laundered, repaired, and stored after use.

OSHA also specifies circumstances for which PPE is indicated. The CDC recommends when, what, and how to use PPE for HCWs.

Types of PPE Used in Health Care Settings: (62)

- Gloves – protect hands
- Gowns/aprons/lab coats – protect skin and/or clothing

- Masks and respirators– protect mouth/nose from infectious substances
- Goggles – protect eyes
- Face shields – protect face, mouth, nose, and eyes

Gloves are the most common type of PPE used in healthcare settings. Most patient care activities that involve mucus membranes, blood, or OPIM require the use of a single pair of nonsterile gloves made of either nitrile or vinyl. Avoid the use of latex gloves due to patient and HCW allergies. Gloves should fit the user's hands comfortably – they should not be too loose or too tight. They also should not tear or damage easily. Gloves protect the HCW against contact with infectious materials. However, once contaminated, gloves can become a means for spreading infectious materials to you, other patients or environmental surfaces. Gloves do not prevent needlestick injuries.

Under Standard Precautions, gloves should be used when touching blood, body fluids, secretions, excretions, or contaminated items and for touching mucous membranes and non-intact skin. (62)

Are gloves needed for acupuncture needle insertion?

Gloves generally do not need to be used to insert an acupuncture needle. Gloves need to be used, however, when blood or OPIM is expected to be present during a healthcare procedure and when performing procedures on areas of mucus membranes. (63, 64) Occupational Safety and Health Administration (OSHA) regulations do not require gloves to be worn when administering vaccines unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on the hands. (65) According to the World Health Organization (WHO), routine intradermal, subcutaneous, and intramuscular injection administration does not require the use of gloves if the health worker's skin is intact. (42) Acupuncture needle insertion is similar to a subcutaneous or intramuscular needle insertion. Since bleeding occurs only extremely rarely during needle insertion, gloves are not needed for acupuncture needle insertion.

This interpretation was echoed in a letter from OSHA to an inquiry of May 11, 2005, from the Director of the Department of Veterans Affairs regarding the use of gloves for acupuncture:

> According to the WHO, the needle penetration used for acupuncture is described to be similar to a subcutaneous or intramuscular injection. In general, OSHA does not consider it necessary to use gloves when giving subcutaneous or intramuscular injections as long as bleeding that could result in hand contact with blood or OPIM is not anticipated. The same would be true with acupuncture procedures as long as contact with blood is not anticipated. (66)

A very few point locations do require glove use during needling due to their location on or near mucous membranes. These include Ren 1 (Huiyin), Du 1 (Changqian), Du 27 (Duiduan), Du 28 (Yinjiao), Jinjin and Yuye (M-HN-20).

Are gloves needed for acupuncture needle removal?

In general, there is no need to use gloves when removing an acupuncture needle. The risk of bleeding during most acupuncture needle removal is less than 4%. (67) There is generally no need for gloves during needle removal. However, some types of needling of the scalp or ears may increase the risk for bleeding. Further, OSHA states that "If an employee is required to clean and dress the acupuncture sites following the extraction of the needles and any bleeding is anticipated, then gloves must be worn when doing so." (66)

Please note that like needle insertion, removing needles from points located in or near mucous membranes does require the use of gloves.

Under OSHA BBP standard 29 CFR 1910.1030, acupuncturists must follow employer policies and procedures about when gloves need to be used. According to OSHA, "an employer must establish policies to implement this provision (29 CFR 1910.1030(c)). The individual employee performing acupuncture does not make the determination whether gloves are to be worn." (68) If an acupuncturist is self-employed, he or she should have a set of guidelines to follow regarding the use of gloves for all procedures.

Additional CDC guidelines for wearing gloves (60) include:

- Wear gloves with fit and durability appropriate to the task.
- Wear disposable medical examination gloves for direct patient care.
- Remove gloves after contact with the patient and/or medical equipment or the environment (room surfaces).
- Do not wear the same gloves for the care of more than one patient.
- Remove gloves using proper technique to prevent hand contamination.

Note that handwashing is required after removal of gloves. It is critical that proper hand hygiene is practiced along with glove use to best protect healthcare personnel. (61)

Goggles:

Goggles provide barrier protection for the eyes; personal prescription lenses do not provide optimal eye protection and in most circumstances should not be used as a substitute for goggles. Goggles should fit snugly over and around the eyes. Goggles prevent the splashing of blood or OPIM into the eyes. They also keep hands that may be contaminated from healthcare practices from touching the eyes.

Goggles or a face shield should be used during patient care activities that are likely to generate splashes and sprays of blood, body fluids, secretions, or excretions. Examples in AOM include bleeding techniques, including wet cupping.

Lab Coats:
Lab coats are personal protective equipment and should be worn in the lab when working with chemicals and biologicals to protect the skin and clothing from splatter and spills. Appropriate lab coats should be fully buttoned with sleeves rolled down. In order to prevent the spread of contaminants do not wear lab coats in public places, such as offices, lunch rooms, lounge areas, or elsewhere as they can transfer hazardous materials and contaminate these areas. Do not bring lab coats home because you may contaminate others in the household. Do not launder lab coats at home or with other clothing. Lab coats used for PPE should be laundered by a medical or laboratory laundry service. (61)

In addition to wearing PPE, you should also use safe work practices. Avoid contaminating yourself by keeping your hands away from your face and not touching or adjusting PPE. Also, remove your gloves if they become torn and perform hand hygiene (wash hands) before putting on a new pair of gloves. You should also avoid spreading contamination by limiting surfaces and items touched with contaminated gloves.

5. Needlestick Information

(http://www.cdc.gov/niosh/docs/2000-108/) (68)

If you experience a needlestick or sharps injury or are exposed to the blood or OPIM of a patient**,** follow these steps**:**

- Wash needlestick locations and cuts with soap and water.
- Flush splashes to the nose, mouth, or skin with water.
- Irrigate eyes with clean water, saline, or sterile irrigants.
- Seek medical advice from a licensed physician as soon as possible.

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Part VI: Cleaning and Pathogen Reduction Techniques in Healthcare and AOM Practice Locations

The WHO, CDC and OHSA standards for cleaning and disinfection apply to all types of healthcare practices. These practices are not specific to acupuncture practices. Acupuncture schools and clinics offer training in the practical applications of these regulations for the acupuncture practitioner.

An acupuncturist's treatment location should be kept clean and sanitary. OSHA requires that the workplace be maintained in a clean and sanitary condition and that there is an appropriate written schedule for cleaning and decontamination. The cleanliness of the general environment also has a direct impact on the practitioner's ability to create a clean field. If a custodial contractor is responsible for clinic maintenance, the contractor must be instructed regarding maintenance and the presence of biohazardous materials. The clinic manager must provide written notification to cleaning contractors regarding the presence of contaminated sharps and the potential for bloodborne contamination. A sink with hot and cold running water must be located in or near the treatment rooms. Liquid hand soap and paper towels must be available at handwashing stations. Alcohol-based hand sanitizers may also be available.

Single-use, disposable towels should be used to dry the hands. Clean paper towels are appropriate. Any paper or other disposable material used as a covering on a chair, seat, couch, or treatment table, and any towel, cloth, sheet, gown, or other article that contacts the patient's skin should be clean, and should not previously have been used in connection with any other patient unless laundered before reuse.

The treatment room table tops, shelves and other working surfaces should have a smooth, impervious surface, be in good repair, and be cleaned with a suitable disinfectant at least once a day and whenever visibly contaminated or whenever a patient may have contaminated the surface by coming in contact with the surface directly. Hepatitis B virus can survive on surfaces for at least one week at room temperature. (1)Treatment tables and chairs used for treatments need to be disinfected between each patient visit.

1. Disinfectants

Disinfectants are recommended for office surfaces and equipment. Disinfectants do not kill all germs or spores, but they will reduce the danger of infection. EPA-registered disinfectants for clinical settings neutralize most viruses, including hepatitis B. These solutions lose strength over time and must be remade at specified intervals, as per the manufacturer's label instructions for the types of surfaces being disinfected.

EPA-registered disinfectants for room surfaces and FDA-cleared disinfectants for reusable medical devices need to be mixed as per package directions for clinical practice settings. Check with the manufacturer for dilution protocols and expiration times on commercial disinfectants. The manufacturer's directions must be strictly followed. Disinfectants must be labeled if not in the original bottle. The label should state what the solution is, when it was mixed, and the concentration. Used disinfectants must be carefully discarded according to the manufacturer's instructions.

Classifications of Disinfectants

Chemical germicides are classified by several different systems. The Environmental Protection Agency (EPA) classifies them according to claims by the manufacturer, but the EPA does not perform independent tests of efficacy. It is important, therefore, to understand the manufacturer's label to interpret the usefulness of a product for its stated purpose. Potential confusion in reading labels is shown in the discussion below comparing CDC and EPA classifications.

"Sterilant" is the term used to describe a germicide that is used in such a way that it can actually sterilize. The same substance, called a sporicide by the EPA, might function as either a sterilant or a high-level disinfectant, depending on concentration, contact time, and the temperature at which it is used. These chemicals are quite toxic and are not used for office cleaning/disinfecting.

The CDC classification system establishes three categories of items requiring sterilization and disinfection: critical, semi-critical, and non-critical. The classifications relate to what part of a patient the items will contact. Critical objects enter the vascular system or any sterile internal part of the body. The CDC classifies processes or methods to achieve these levels to be sterilants. Semi-critical items touch mucus membranes and non-intact skin, and non-critical items touch intact skin.

Disinfectants may be classified as high-level disinfectants, intermediate-level disinfectants, and low-level disinfectants. "Sanitizers" (an EPA classification frequently used in discussion) correspond to the CDC's low-level disinfectants. Product labels often describe the level of germicidal action in terms of the infectious agents they challenge.

Types of Disinfectants

Chlorine and Chlorine Compounds

The most prevalent chlorine products in the United States are aqueous solutions of 5.25%–6.15% sodium hypochlorite. These products have a broad spectrum of antimicrobial activity, do not leave toxic residues, are unaffected by water hardness, are inexpensive and fast acting, and

have a low incidence of serious toxicity. (2) Sodium hypochlorite at the concentration used in household bleach (5.25-6.15%) can produce ocular irritation or oropharyngeal, esophageal, and gastric burns. (3) Other disadvantages of hypochlorites include corrosiveness to metals in high concentrations (>500 ppm), inactivation by organic matter, discoloring or "bleaching" of fabrics, and release of toxic chlorine gas when mixed with ammonia or acid (e.g., household cleaning agents). (4) After reviewing environmental fate and ecologic data, EPA has determined the currently registered uses of hypochlorites will not result in unreasonable adverse events to the environment. (5) Commercial, EPA-approved dilutions of sodium hypochlorite should be prepared according to manufacturer instructions but may need to be used within 24 hours of preparation. Follow manufacturer directions for use on both smooth, impervious surfaces and porous surfaces or organic material. Practitioners need to follow label directions for the appropriate concentrations for non-critical and semi-critical reusable devices as well as for cleaning of common surfaces with hypochlorite solutions.

The CDC no longer accepts household bleach as a suitable instrument disinfecting solution in the health care setting.

Microbiocidal Activity

Hypochlorite concentrations approved for use on non-critical items and common surfaces have a biocidal effect on mycoplasma and bacteria in seconds. (6) Higher concentrations are required to kill *M. tuberculosis*, *Clostridium difficile* spores, and other HAI. (7) One study reported that 25 different viruses were inactivated in 10 minutes with high concentration hypochlorite solution.(8) Several studies have demonstrated the effectiveness of diluted sodium hypochlorite and other disinfectants to inactivate HIV. (9)

Glutaraldehyde

Glutaraldehyde is a saturated dialdehyde that has gained wide acceptance as a high-level disinfectant and chemical. (2) Aqueous solutions of glutaraldehyde are acidic and generally in this state are not sporicidal. Only when the solution is "activated" (made alkaline) by use of alkalinizing agents to pH 7.5–8.5 does the solution become sporicidal. Once activated, these solutions have a shelf-life of minimally 14 days. (2) Glutaraldehyde gives off vapors that are respiratory irritants and cause contact dermatitis. It has limitations in its mycobacteriocidal activity and coagulates blood and tissue to surfaces. (10)

Glutaraldehyde is used most commonly as a high-level disinfectant for medical equipment such as endoscopes, dialyzers, transducers, anesthesia and respiratory therapy equipment, and other medical devices that enter the body. Glutaraldehyde should not be used for cleaning noncritical surfaces because they are too toxic and expensive.

Hydrogen peroxide

Stabilized hydrogen peroxide in 6% to 25% concentrations is also capable of high-level disinfection. The substance is not toxic and does not need hood ventilation for use. The hydrogen peroxide sold over-the-counter in pharmacies is 3% and is often old, resulting in less effectiveness than that provided by a fresh 3% peroxide solution. Over-the-counter hydrogen peroxide solutions will not sterilize effectively. (2) FDA-cleared hydrogen peroxide solutions are available under numerous brand names, including Sporox.

Iodophors

Iodine solutions or tinctures have been used by health professionals primarily as antiseptics on skin or tissue. Iodophors, on the other hand, have been used both as antiseptics and disinfectants. FDA has not cleared any liquid chemical high-level disinfectants with iodophors as the main active ingredient. (2)

Phenol

Phenol has occupied a prominent place in the field of hospital disinfection since its initial use as a germicide by Lister in his pioneering work on antiseptic surgery. Many phenolic germicides are EPA-registered as low-level disinfectants for use on environmental surfaces (e.g., bedside tables, bedrails, and laboratory surfaces) and noncritical medical devices. Phenolics are not FDA-cleared as high-level disinfectants for use with semicritical items. (2)

EPA and FDA Approval of Disinfectants

In the United States, chemical germicides formulated as sanitizers, disinfectants, or sterilants are regulated in interstate commerce by the Antimicrobials Division, Office of Pesticides Program, EPA, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947. (11)Under FIFRA, any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest (including microorganisms but excluding those in or on living humans or animals) must be registered before sale or distribution.

A list of products registered with EPA and labeled for use as sterilants or tuberculocides or against HIV and/or HBV is available through EPA's website at:
http://www.epa.gov/oppad001/chemregindex.htm

A list of FDA approved high-level disinfectants can be found here:
http://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofreusablemedicaldevices/ucm437347.htm

Monitoring and Labeling of Disinfectants

All disinfectants should be handled according to the manufacturer’s instructions. Hypochlorite solutions should be made fresh daily according to the use for which the solution is intended.

OSHA regulations require that containers of disinfectant must be labeled if not in their original bottle. The label must include what the solution is, when it was mixed, and its concentration. An MSDS (Manufacture Safety Data Sheet) should always be available in case of accidents.

2. Indications for Sterilization, High-Level Disinfection, and Low-Level Disinfection

According to the CDC: (2)

- Sterilization is required for instruments that enter normally sterile tissue or the vascular system.
- High level disinfection is required for equipment that touches either mucous membranes or nonintact skin. After high-level disinfection, rinse all items. Use sterile water, distilled or filtered water. After rinsing, dry and store in a manner that prevents recontamination.
- Low-level disinfection is required for noncritical patient-care surfaces (treatment tables, equipment trays) and equipment (e.g., blood pressure cuff) that touch intact skin. Ensure that, at a minimum, noncritical patient care surfaces are disinfected when visibly soiled and on a regular basis (such as after use on each patient or once daily depending on the type of surface and the frequency of use).

Reusable medical and AOM equipment must be disinfected between use on patients. The table below has guidelines for disinfecting as described in CDC materials. (http://www.cdc.gov/HAI/prevent/sd_medicalDevices.html)

3. Cleaning Equipment

Reuse of Single-Use Medical Devices

The reuse of single-use medical devices does not follow best practices for an AOM practice for devices that break the skin. Before the late 1970s most medical devices (including acupuncture needles) were considered reusable. However, the AIDS epidemic and the growing awareness of HBV infection associated with reusing medical sharps rendered such use unacceptable in the U.S. Reuse of single-use devices involves regulatory, ethical, medical, legal and economic issues. (12) No acupuncturist should reuse needles or other equipment that breaks the skin.

Pre-cleaning of Reusable Medical Equipment

Cleaning is the removal of foreign material (e.g., soil and organic material) from objects and is normally accomplished using water with detergents or enzymatic products. Thorough cleaning is required before low-, intermediate-, or high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the

effectiveness of these processes. Also, if soiled materials dry onto the instruments, the disinfection or sterilization process is ineffective.

Instrument Cleaning

Reusable medical and AOM equipment must be disinfected between use on patients. See *Safety Guidelines for Disinfecting Reusable Medical Equipment* as described in CDC materials above. (http://www.cdc.gov/HAI/prevent/sd_medicalDevices.html)

Safety Guidelines for Disinfecting Reusable Medical Equipment

Sterility Category of Equipment:	**Acupuncture Practice Examples**	**Disinfectant Level Required before Reuse**	**Disinfecting Procedure**
Non-Critical	BP cuff, Stethoscope, e-stim clips.	Low or intermediate disinfecting agents acceptable.	Fabric equipment (BP cuffs) may be disinfected with isopropyl alcohol EPA approved solutions for non-critical items. Smooth surfaces can be disinfected through 2 steps: soap and water cleansing followed by wiping with a low or intermediate disinfecting agent.
	Cups or gua sha tools used over intact skin.	Intermediate disinfecting agents required.	Step 1 Removal of all biological and foreign material (e.g., soil, organic material, skin cells, lubricants) from objects using soap and water. Step 2 Soak in appropriate FDA-cleared disinfectant for the time indicated for reusable equipment. Follow label directions for use as an intermediate disinfecting agent.
Semi-Critical	All cups used for wet cupping; cups and gua sha spoons used on non-intact skin.	Sterilize before reuse; or high-level disinfectant required.	Step 1 Removal of all biological and foreign material (e.g., soil, organic material, skin cells, lubricants) from objects using soap and water. Step 2 Option 1: Autoclave. Option 2: Soak in high-level disinfectant (e.g., Sporox, Sterrad, Acecide, Endospore, Peract) as per product label instructions.

Sterility Category of Equipment:	Acupuncture Practice Examples	Disinfectant Level Required before Reuse	Disinfecting Procedure
Reusable Critical	Equipment that breaks the skin or enters the vascular system; No AOM equipment falls in this category.	Must be sterilized.	Example: autoclave.
Sterility Critical; non-reusable	Needles, 7-star hammers, lancets, press tacks, ear seeds.	Cannot be reused.	Example: ethylene oxide gas.

Instruments used in performing invasive procedures should be appropriately sterilized prior to use. All instruments that enter the skin for AOM procedures should be single-use pre-sterilized equipment.

Equipment and devices that do not touch the patient or that only touch intact skin of the patient need only be cleaned with a low-level disinfectant or detergent.

Equipment and devices such as cups and gua sha tools that have touched intact skin, but where that skin has been subjected to compression should be cleaned with at least intermediate level disinfectants. Contaminated equipment that is reusable should be cleaned of visible organic material by washing and scrubbing with soap and water, and then disinfected using an intermediate-level disinfecting solution (such as CaviCide, Sterilox, Spor-Klenz, DisCide, or Super Sani-Cloth). Whenever the tools will be placed over nonintact skin (such as in cupping after needling or wet cupping), they need to be treated as semi-critical reusable devices. In these cases, the equipment needs to be cleaned with soap and water to remove the lubricant (if used) and biological material before disinfecting with an FDA-cleared high-level disinfecting solution (e.g., Sporox, Sterrad, Acecide, Endospore, or Peract), or autoclaved.

The current controversy is about how often the skin barrier is compromised when using equipment such as cups and gua sha tools. In a 2014 article Nielsen et al. maintains, “Gua sha and Baguan [cupping] instruments have been mistaken as non-critical instruments because they appear to contact ‘intact’ skin. However, the contact is not incidental but involves enough repeated or sustained pressure as to (intentionally) cause extravasation of blood and fluids that can seep or be let from the skin even if not immediately visible.” (13) More studies need to be

performed to determine how frequently the intact skin is disrupted in cupping procedures not associated with bleeding and gua sha techniques. Taking into consideration the potential risk to patients, it is the editor's opinion that is prudent to consider high-level disinfection of all cups and gua sha instruments until additional studies are completed to demonstrate the degree to which cupping and gua sha compromise the skin barrier. Having one method of disinfection increases the practical considerations that the practitioner will always have prepared and be using devices that have been properly disinfected.

Wrapping or packaging helps to identify that proper disinfection has been completed and prevents contact contamination that may occur by directly placing the device in a travel kit or on a counter.

4. Clean Use of Lubricants

Lubricants in open-mouth jars can become contaminated by the transient bacteria from the practitioner's hands. To prevent this, either use pump or squeeze bottles of lubricants for use with cupping or gua sha, or decant a treatment-sized portion of lubricant into a small disposable cup or other clean disposable container using a clean tongue depressor or other clean disposable device prior to starting the procedure. Dispose of leftover lubricant without returning any lubricant to the primary container. This prevents contamination of the primary lubricant container and its contents.

5. Cleaning and Disinfecting Environmental Surfaces in Healthcare Facilities

- Clean housekeeping surfaces (e.g., floors, tabletops) on a regular basis (e.g., daily, or at least three times per week), when spills occur, and when these surfaces are visibly soiled.
- Follow manufacturers' instructions for proper use of disinfecting products — such as recommended use-dilution, material compatibility, storage, shelf-life, and safe use and disposal.
- Clean walls, blinds, and window curtains in patient-care areas when these surfaces are visibly contaminated or soiled.
- Decontaminate mop heads and cleaning cloths regularly to prevent contamination (e.g., launder and dry at least daily).
- Detergent and water are adequate for cleaning surfaces in non patient-care areas (e.g., administrative offices).
- Do not use high-level disinfectants/liquid chemical sterilants for disinfection of non-critical surfaces.

- Disinfect noncritical surfaces with an EPA-registered hospital disinfectant according to the label's safety precautions and use directions.
- Promptly clean and decontaminate spills of blood and other potentially infectious materials (OPIM). Discard blood-contaminated items in the biohazard containers as per compliance with federal regulations.

Use of Disinfectants for Surface Cleaning

The effective use of disinfectants is part of any healthcare setting strategy to prevent health-care–associated infections (HAI). Surfaces such as floors and door handles are considered noncritical items because they contact intact skin. Contact with noncritical surfaces carries only a minor risk of causing an infection in patients or staff, (14) primarily HAI such as influenza. Medical equipment surfaces (e.g., blood pressure cuffs and stethoscopes) can become contaminated with infectious agents and may contribute to the spread of health-care–associated infections. For this reason, noncritical medical equipment surfaces should be disinfected with an EPA-registered (for surfaces)/FDA-cleared (for medical devices) low- or intermediate-level disinfectant (e.g. CaviCide, Sani-Dex, DisCide, or Sterilox) between each patient use.

6. Blood or Body Fluid Spills

The CDC recommends decontamination of spills of blood or other potentially infectious materials (OPIM), using the following procedures: (2)

- Use protective gloves and other PPE (e.g., when sharps are involved use hemostats to pick up sharps, and discard these items in a puncture-resistant container) appropriate for this task.
- Wash the area with soap and water first.
- Disinfect areas contaminated with blood/OPIM spills using an EPA-registered commercial hypochlorite solution. Follow manufacturer’s label directions for spills based on the type of surface (porous or non-porous) and the amount of blood present.
- If the spill contains large amounts of blood or body fluids, clean the visible matter with disposable absorbent material, and discard the contaminated materials in appropriate, labeled biohazardous waste container.

Cleaning accidental spills of blood or body fluid (or OPIM) requires a three-step procedure: (1) Using rubber gloves, pick up the visible matter with disposable absorbent material; then (2) clean the area with a detergent soap and water; then (3) clean the area of the spill with an approved disinfecting solution appropriate to the type of surface being disinfected. Use a gown or impervious apron if there is a risk of contaminating your clothing during the clean-up. Where

there may be a risk of splashing or a very large spill, safety glasses and a disposable or sterilizable clothing protector should be worn. When disinfecting an extensive area with disinfecting solution, disposable gloves may not be adequate and may fail during the disinfecting process. Heavier gloves should be worn if this is a possibility. All disposable materials used in the cleanup job should be discarded in double wrapping in biohazard bags or containers; and hands should be washed at the end of the cleanup.

When cleaning accidental spills of needles contaminated with blood, pick up the needles using gloves and hemostats first and discard these into an appropriate sharps container, then follow the directions above to deal with the blood or OPIM spill.

7. Laundering Sheets, Towels or Other Linens

All linens, gowns, etc., must be changed between patient treatments/visits. This includes the sheets on a treatment table, even if protected by a layer of table paper. Unless a patient is fully clothed in street clothes during the treatment, all linens or any other material such as Mylar "space" blankets, that are used over the patient for draping or warmth must also be changed between patients.

Cloth gowns, sheets, etc. are safe for reuse after laundering with hot water and soap or detergent. Adding hypochlorite (bleach) solution to the wash provides an extra margin of safety.

Acupuncture practice locations that use a high volume of linens may want to consider the use of a commercial laundry facility for washing towels and linens. Commercial laundry facilities often use water temperatures of at least 160°F and 50-150 ppm of chlorine bleach to remove significant quantities of microorganisms from grossly contaminated linen. In the home, normal washing and drying cycles, including hot or cold cycles, are adequate to ensure patient safety. Instructions of the manufacturers of the machine and the detergent or wash additive should be followed closely. (15)

Commercial dry cleaning of fabrics soiled with blood also renders these items free of the risk of pathogen transmission.

8. Sharps and Non-Sharps Biohazard Equipment and Disposal

(See also http://www.cdc.gov/niosh/docs/97-111/ and *Occupational Safety and Health Act* of 1970 [OSHA Act] or the requirements of 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens.)

Sharps containers must either be labeled with the universal biohazard symbol and the word "biohazard" or be color-coded red. Sharps containers must be maintained upright throughout use, replaced routinely, and not be allowed to overfill. Also, the containers must be:

- Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
- Placed in a secondary container if leakage is possible. The second container must be:
    - Closable.
    - Constructed to contain all contents and prevent to leakage during handling, storage, transport, or shipping.
- Labeled or color-coded according to the standard.
- Reusable containers must not be opened, emptied, cleaned manually, or used in any other manner that would expose employees to the risk of percutaneous injury.
- Upon closure, duct tape may be used to secure the lid of a sharps container, as long as the tape does not serve as the lid itself.

Sharps containers must be easily accessible to employees and located as close as feasible to the immediate area where sharps are used (e.g., patient care areas).

Most states have regulation regarding the types of sharps containers that may be used and the appropriate disposal of the sharps containers. Contact your local health department for help understanding the regulations, check the website http://www.safeneedledisposal.org/, or contact your state's OSHA office for state-specific details.

9. Regulated Waste

The Bloodborne Pathogens Standard uses the term "regulated waste" to refer to the following categories of waste which require special handling: (1) liquid or semi-liquid blood or OPIM; (2) items contaminated with blood or OPIM and which would release these substances in a liquid or semi-liquid state if compressed; (3) items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; (4) contaminated sharps; and (5) pathological and microbiological wastes containing blood or OPIM.

In the typical acupuncture practice, there is rarely any regulated waste besides that which goes in the sharps container. (Items to be disposed in the sharps container include the acupuncture needles, lancets and plum blossom hammers.) In some types of practice, the blood from wet cupping would need to be disposed of in a biohazard bag, rather than the sharps container. Also, any blood spills, vomit or other OPIM would be disposed of in a biohazard bag.

Disposal

Disposal of all regulated waste must be in accordance with applicable state regulations. These rules are typically published by state environmental agencies and/or state departments of health. In addition to state rules for disposing of regulated waste, there are basic OSHA requirements that protect workers. The OSHA rules state that regulated waste must be placed in containers which are:

- Closable.
- Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping.
- Labeled or color-coded in accordance with the standard.
- Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
- If outside contamination of the regulated waste container occurs, it must be placed in a second container meeting the above standards.

Contaminated Laundry

Contaminated laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated laundry must be handled as little as possible with a minimum of agitation; it must be bagged or containerized at the location where it was used and must not be sorted or rinsed in the location of use. Other requirements of the BBP standard 1910.1030(d)(2)include: (16)

- Contaminated laundry must be placed and transported in bags or containers labeled and color-coded in accordance with the bloodborne pathogens standard.
- Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.
- The employer must ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.
- When a facility ships contaminated laundry off-site to a second facility which does not utilize Standard Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with the standard.

- Employees are not permitted to take their protective equipment home and launder it. It is the responsibility of the employer to provide, launder, clean, repair, replace, and dispose of personal protective equipment.

Summary of Recommendations – Part VI

- Critical: All instruments that break the skin should be single-use pre-sterilized equipment.
- Critical: Never reuse single-use medical devices.
- Critical: If a custodial contractor is responsible for clinic maintenance, the contractor must be instructed regarding maintenance and the presence of biohazardous materials.
- Critical: A sink with hot and cold running water must be located in or near the treatment rooms.
- Critical: Disinfect surfaces only with products registered with EPA and labeled for use in the healthcare office.
- Critical: Clean housekeeping surfaces (e.g., floors, door handles and light switches) immediately when spills occur, and when these surfaces are visibly soiled.
- Critical: Promptly clean and decontaminate spills of blood and other potentially infectious materials (OPIM). Discard blood-contaminated items in the biohazard containers in compliance with federal regulations.
- Critical: Cups and gua sha equipment that have been contaminated and are reusable should be cleaned of visible organic material, then disinfected using appropriate intermediate- or high-level disinfecting solution, then rinsed and dried before being reused.
- Critical: Table paper and draping must be changed between each patient visit.
- Critical: Sharps containersmust either be labeled with the universal biohazard symbol and the word "biohazard" or be color-coded red.
- Critical: Sharps containers must be maintained upright throughout use, replaced routinely, and not be allowed to overfill.
- Strongly Recommended: Noncritical medical equipment surfaces (e.g., blood pressure cuffs, treatment tables) should be disinfected with an EPA-registered low- or intermediate-level disinfectant between each patient use, following label directions.
- Strongly Recommended: The clinical workplace must be maintained in a clean and sanitary condition and there must be an appropriate written schedule for cleaning and decontamination.
- Strongly Recommended: The treatment table tops, shelves and other working surfaces should be cleaned with a suitable disinfectant at least once a day and whenever visibly contaminated or whenever a patient may have contaminated the surface by coming in contact with the surface directly.

- Strongly Recommended: All linens, gowns, etc., must be changed between patient treatments/visits.
- Recommended: The treatment table tops, shelves and other working surfaces should have a smooth, impervious surface and be in good repair.
- Recommended: Low-level disinfectants should be used for cleaning office surfaces, not just detergents.

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Part VII: Office Procedures for Risk Reduction

This section addresses federal and other legal standards required for ambulatory healthcare offices. This information is not meant to replace school training in practice management, but to offer a resource for practitioners to locate sources and examples for federal standards from OSHA, CDC and other sources.

Please use the websites referenced herein as needed to identify legal standards and practices that apply to your office or clinic.

State and local rules and regulations vary. Practitioners need to keep abreast of changes in the legal landscape of healthcare practice regulation.

Risk reduction is a term used to describe a variety of techniques employed to reduce the likelihood and consequences of an unintended event, namely an accident that may result in risk to or injury of practitioners, other clinic employees, or the public. These techniques, policies, and procedures may be recommended, or mandated by statute or rule. Regardless of origin, risk reduction is a process of reducing the probability of an unintended event causing injury, loss, or legal action that brings harm to the provider or other individuals. Risk reduction techniques are for the most part common sense, whether or not they are required by statute or rule, or are recommended. Examples of risk reduction techniques include the use of CNT and Standard Precautions with every patient. However, in addition to complying with the specific requirements of acupuncture practice acts, practitioners must comply with local, state, and federal statutes regarding general medical practice such as informed consent, recordkeeping, patient confidentiality, reporting of communicable disease, and maintenance of an Exposure Control Plan. Additionally, the provider must comply with other safety requirements, such as:

- Hazard Communication Standard with respect to toxic chemicals such as disinfectants and other chemicals such as isopropanol in the workplace.
- Fire department regulations with respect to fire protection and electrical safety.
- Building and safety codes when modifying a clinic or office space.
- State and federal standards with respect to documenting safety-related policies and procedures.
- The proper documentation of accidents leading to property loss, injury, or death.
- Safe and legal interaction with patients who may be a danger to themselves or others.
- The prevention of workplace violence.

- Completion of all mandated reporting with regard to safety-related incidents.

A broad discussion of the topic of risk reduction is beyond the scope of this manual. The reader is referred to an appropriate risk reduction text for more information. Practitioners must also comply with all requirements mandated by state statutes that allow non-physician acupuncturists to practice acupuncture in that state. These rules include compliance with state or federal law pertaining to informed consent, recordkeeping, and patient confidentiality. This also includes the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Ethically, practitioners should practice in accordance with these general medical guidelines; not to do so may cause practitioners to be vulnerable to civil and criminal penalties.

Included in this manual is a summary of some of the principles of risk management, especially where these ideas are germane to the practice of acupuncture. This text is not intended to replace comprehensive training in an AOM program in acupuncture recognized by the Accreditation Commission on Acupuncture and Oriental Medicine.

1. Federal Standards and Guidelines

OSHA: Bloodborne Pathogens Standard

OSHA has developed procedures to help healthcare workers protect themselves from a variety of possible infections, including HBV and HIV. In general, these precautions include the use of an appropriate barrier (gloves, gowns, masks, goggles, etc.) to prevent contact with infected body fluids. Additionally, standard sterilization and disinfection measures as well as infectious waste disposal procedures must be followed.

These practices are especially important for all healthcare professionals who participate in invasive procedures. In addition to gowns, gloves, and surgical masks, protective eyewear or face shields should be worn where the generation of droplets or the splashing of body fluids is possible. If the protective barrier becomes torn, it should be replaced immediately or as soon as patient safety permits. In the event of injury to the healthcare practitioner, the barrier should be removed and the wound treated promptly. Any such injury should also be followed up with an incident report.

Since medical history and examination cannot reliably identify all patients infected with HBV/HIV or other bloodborne pathogens, infection prevention methods should be used consistently for all patients.

It is a fact that exposure to bloodborne pathogens poses a significant risk to healthcare workers and their patients. This exposure can be eliminated or greatly reduced through work practice habits, personal protection, training, vaccination, labeling, and medical surveillance. (1) Therefore, two federal agencies have established standards that apply to all medical

practitioners, including licensed acupuncturists. The CDC has established procedures that are to be followed with regard to occupational exposure to bloodborne pathogens in healthcare settings in the United States. These procedures are known as Standard Precautions. OSHA has codified the CDC standards into recommendations that apply to all healthcare providers. The application of Standard Precautions and the other protocols that constitute the best practices for acupuncturists in the United States is referred to as Clean Needle Technique (CNT). It is important to remember that the application of CNT in a clinical setting is a thoughtful process based on an understanding of principles rather than a rote application of memorized guidelines.

Standard Precautions

Standard Precautions include: 1) hand hygiene, 2) use of personal protective equipment (e.g., gloves, gowns, masks), 3) safe injection practices, 4) safe handling of potentially contaminated equipment or surfaces in the patient environment, and 5) respiratory hygiene/cough etiquette.

(See http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-gl-standared-precautions.html (2) for more details.) All healthcare workers should adhere to Standard Precautions, including the appropriate use of handwashing, protective barriers, and care in the use and disposal of needles and other sharp instruments. Hands should be washed before and after patient contact, and immediately if hands become contaminated with blood or other body fluids. Hands should also be washed after removing gloves. Healthcare workers should comply with current guidelines for handwashing to reduce possible transient pathogenic organisms from being passed between patients. Instruments and other reusable equipment used in performing invasive procedures should be appropriately disinfected and sterilized. Gloves should be worn whenever there is a possibility of contact with body fluids. (Body fluids to which standard/universal precautions apply: blood, serum/plasma, semen, vaginal secretions, cerebrospinal fluid, vitreous fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, and wound exudates.) Healthcare workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment and devices used in performing invasive procedures. Sharp objects represent the greatest risk for exposures. Contaminated needles should never be bent, clipped, or recapped. Immediately after use, contaminated sharp objects should be discarded into a puncture-resistant biohazard container designed for this purpose. Needle containers should never be overfilled; containers should be sealed and discarded when two-thirds to three-quarters full.

NSPA

The Needlestick Safety and Prevention Act (NSPA) of 2000 gives practitioners and employees in healthcare facilities the power to participate in selecting and evaluating devices that would be most effective for their own and their patients' safety. Besides requiring the use of safety-

engineered needles and sharps devices in the workplace, NSPA requires employers to develop and update exposure-control plans annually.

BBP standard 1910.1030(d)(2) incorporates the NSPA as an "amplification" of OSHA standards: [CPL 2-2.69] "Where exposures to blood and other potentially infectious materials (OPIM) are reasonably anticipated and engineering controls will reduce employee exposure either by removing, eliminating, or isolating the hazard, they must be used. . .If you have not already evaluated and implemented appropriate and available engineering controls (safer medical devices), you must do so immediately. . .and. . .the evaluation, implementation, and use. . .must be documented in the employer's Exposure Control Plan." (3)

Those using therapeutic needling techniques, bleeding techniques and other types of sharp instruments in healthcare settings must evaluate their current use of these devices. Employers and employees in healthcare settings need to evaluate if they can shift from conventional to safety-engineered devices (such as auto-lancets for bleeding) based upon best practices.

See http://www.osha.gov/needlesticks/needlefaq.html for more information about NSPA.

OSHA: Exposure Control Plan

Employers of healthcare workers are encouraged to participate in the task of controlling risks in the workplace, including the spread of blood-borne pathogens such as HBV/HIV, by disseminating preventive information in the workplace through a detailed exposure control plan (ECP). Each employer having an employee(s) with occupational exposure must develop such a plan designed to eliminate or minimize the incidence of employee exposure to workplace risks.

Practitioners who have employees, whether they be a receptionist or a custodian, who may be exposed to bloodborne pathogens by pulling needles, emptying the trash, assisting patients in dressing and undressing, should have an ECP. This ECP must include information about preventing the spread of BBP, including availability of HBV vaccination, for all workers in an acupuncturist's employ who may come in contact with blood or OPIM. Practitioners who share office space with other practitioners, including a treatment room or storage area for biohazardous waste, must also develop an ECP.

All healthcare practices must create, maintain, update and train all personnel (including the owner/acupuncturist) on possible exposures to infectious agents and other hazards. Training must take place before personnel may be exposed to hazards and again annually. All healthcare facilities must maintain an Exposure Control Plan for Bloodborne Pathogens (BBP) as well as a Hazardous Communication Plan for chemical exposures. (4)

An exposure control plan (ECP) for BBP consists of:

1. **WRITTEN POLICIES** (Including the plan)
2. **PROGRAM ADMINISTRATION** (Name of responsible officer for policies, training, and reports)
3. **EMPLOYEE EXPOSURE DETERMINATION** (List of employee titles of those that may become exposed; includes anyone who treats patients or enters a treatment room wherein a loose needle may be found.)
    a. A list of job classifications where all employees have occupational exposure.
    b. A list of job classifications where some employees have occupational exposure.
    c. A list of all tasks and procedures (or closely related groups of activities) in which occupational exposure occurs.
4. **METHODS OF IMPLEMENTATION AND CONTROL**
    a. Exposure Control Plan.
    b. Engineering Controls and Work Practices: Includes requirements for handwashing facilities, sharps containment, maintenance and use of work areas, procedures involving blood or potentially infectious materials, and handling of equipment that may become contaminated.
    c. Personal Protective Equipment (PPE): Covers the provision and use of items such as gloves, gowns, masks, and other pieces of clothing or equipment when occupational exposure is possible. Latex-free gloves must be provided if an employee is allergic to latex.
5. **REGULATED WASTE**
    a. Housekeeping: Includes requirements for maintaining the worksite in a clean and sanitary condition.
    b. Sharps containment and disposal.
    c. Laundry: policies and procedures for cleaning all laundry and policies for handling contaminated laundry.
    d. Labels: for all containers which may have contaminated waste or sharps.
    e. Disposal of biohazard materials and contaminated waste.
6. **HEPATITIS B VACCINATION**
7. **POST-EXPOSURE EVALUATION AND FOLLOW-UP**
    a. Administration of post-exposure evaluation and follow-up.
    b. Procedures for evaluating the circumstances surrounding an exposure incident.
8. **EMPLOYEE COMMUNICATION**: Includes standards for labels and signs such as biohazard labels and warning signs, containers, and bags.
9. **EMPLOYEE TRAINING**
    a. New employees must be offered a hepatitis B vaccine and receive bloodborne pathogen education before having contact with blood or body fluids.
    b. All employees must receive annual training regarding the OSHA BBP standard.

10. RECORDKEEPING

a. Employee training (maintain for at least 3 years after the duration of employment).
b. Medical records of those exposed (maintain for the duration of employment PLUS 30 years).
c. OSHA Recordkeeping (maintain for a minimum 5 years).
d. Sharps Injury Log (log is reviewed as part of the annual program evaluation and maintained for at least five years following the end of the calendar year covered).

11. HEPATITIS B VACCINE DECLINATION STATEMENT/POLICY (maintain for the duration of employment PLUS 5 years)

The ECP should also provide a schedule and methods for implementing precaution procedures, and procedures for evaluating exposure incidents. A copy of the plan must be made available to all employees. The plan must be reviewed and updated annually, or whenever new or revised tasks or procedures are added to the practice, or if new positions are created that may have exposure potential.

Sample ECPs for BBP can be found here:

- http://www.osha.gov/Publications/osha3186.pdf (pdf version)
- http://www.osha.gov/Publications/osha3186.html (html version)
- http://www.osha.gov/OshDoc/Directive_pdf/CPL_2-2_69_APPD.pdf (specific small business plan version)

OSHA documents relating to ECPs include:

- http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=1574&p_table=DIRECTIVES
- http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051

A model BBP ECP and a model Hazardous Communication document can both be found in the following OSHA publication:

- http://www.osha.gov/Publications/osha3186.pdf

Additional information for those working in California can be found here:

- http://www.dir.ca.gov/dosh/dosh_publications/expplan2.pdf

A sample ECP for TB can be found here:

- http://www.osha.gov/SLTC/etools/hospital/hazards/tb/sampleexposurecontrolplan.html

OSHA: Hazardous Communication

http://www.osha.gov/dsg/hazcom/index.html (5)

In order to ensure chemical safety in the workplace, information about the identities and hazards of the chemicals must be available and understandable to employees. OSHA's Hazard Communication Standard (HCS) requires the development and dissemination of such information. All employers with hazardous chemicals in their workplaces must have labels and safety data sheets for their exposed workers, and train them to handle the chemicals appropriately. This includes all healthcare/acupuncture practice settings as the use of such chemicals for cleaning and disinfecting falls into this standard.

A Hazardous Communication Plan consists of:

1. Company Policies regarding chemical exposures – written records
2. Container Labeling – Lists of labels and plans for labeling of chemicals after being put in new containers or changes
3. Chemical List – List of all hazardous chemicals found at the practice location. This will include cleaning solutions, alcohol for swabbing, and hand cleaning solutions
4. Material Safety Data Sheets (MSDSs)
5. Employee Training and Information
6. Hazardous Non-Routine Tasks (list)
7. Policies regarding Informing Other Employers/Contractors who may enter the premises (e.g., outside cleaning agencies)
8. How the employer has trained and made this policy and program available to employees

A sample Hazardous Communication policy can be found here:
http://www.osha.gov/Publications/osha3186.html

An excellent checklist and more readable explanation of the requirements can be found here:

http://www.lni.wa.gov/IPUB/413-012-000.pdf

While the above checklist is from the Washington State offices, the information can be used for all acupuncturists looking to comply with the Hazardous Communication Standard.

OSHA: Other Hazards

Due to the use of moxa, standards regarding indoor air quality and fire safety apply to most AOM practice locations. A list of the standards and their applications should be reviewed by the practice's safety officer annually. OSHA standards can be found here:

Fire:

- http://www.osha.gov/SLTC/firesafety/index.html
- http://www.osha.gov/SLTC/etools/hospital/hazards/fire/fire.html
- http://www.osha.gov/Publications/laboratory/OSHA3403laboratory-safety-guidance.pdf

Indoor air quality: http://www.osha.gov/dts/osta/otm/otm_iii/otm_iii_2.html#5

The use of electrical equipment is regulated by various state and federal standards. Those utilizing heat lamps, electroacupuncture, and any electrical equipment (computers, fax machines, etc.) need to have some policies in place for meeting these standards. A list of the standards and their applications should be reviewed by the practice's safety officer annually. OSHA standards can be found here:

- http://www.osha.gov/SLTC/electrical/index.html
- https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGISTER&p_id=19269

Practitioners should contact their local health department to obtain further information regarding OSHA training and state- or town-specific requirements for healthcare offices.

Note that once you have identified the existing and potential hazards in your treatment location, your state OSHA Consultation Program can help you implement the systems that prevent or control those hazards. The state consultation program is free for all employers and having the state inspect your practice setting will not result in a fine, even if all standards have not been met. Usually, you will have 90 days after receiving a report from your state consultation to create a plan to address all deficiencies. Utilizing this service is a great way to prevent problems in the future.

OSHA: Disposing of Biohazardous Waste

When discussing biohazardous waste, the following terms are applicable:

Biohazardous waste: Any solid waste or liquid waste that may present a threat of infection to humans (including non-liquid human tissue and body parts), laboratory disease-causing agents, discarded sharps, human blood, or clinic waste such as table paper or cotton balls that contain

human blood, human blood products, or body fluids. (Note: OSHA has determined that a cotton ball containing enough blood that it can be wrung out must be classified as medical, or biohazard, waste; less than that amount on a cotton ball means that it should be considered trash. OSHA refers to biohazardous waste as “regulated waste.”) (5)

Biohazardous waste generator: A facility or person that produces or generates biohazardous waste including a wide range of facilities from hospitals to medical offices, from veterinary clinics to funeral homes. (6) Licensed acupuncturists are included in this category.

OSHA has enacted specific rules concerning the handling and disposal of biohazardous or infectious waste in order to eliminate the exposure of employees, patients, and the public to disease-causing agents. These rules require:

1. Waste generators must prepare, maintain, and implement a written plan to identify and handle such waste. Any employee who works in an area where biohazardous waste is kept must be provided with an employee training program that explains procedures for on-site separation, handling, labeling, storage, and treatment of biohazardous materials.
2. Biohazardous waste, except sharps (devices capable of puncturing, lacerating, or penetrating the skin), must be packaged in impermeable, red, polyethylene or polypropylene bags (“red bags”), and sealed.
3. Discarded sharps must be separated from all other waste and placed in leak-resistant, rigid, puncture-resistant biohazard containers. All containers must be labeled properly, especially if the treatment and disposal are to take place off-site.
4. In storing the packaged waste, care must be taken to place it in a designated area away from general traffic flow and accessible only to authorized personnel. One option is to store biohazardous waste awaiting pick up in a locked closet not used for storage of clean items or food.

All waste should be disposed of by removal by a medical waste disposal company. Do not throw medical waste into the trash for removal. This is especially true for sharps which pose a hazard to custodial and waste removal personnel. OSHA regulations contain minimum standards established by the federal government. However, state and local regulations are permitted to be, and often are, more stringent, regarding the disposal of hazardous waste. (7,8) These waste laws differ greatly from state to state and may vary at the county and even municipal level. For example, some city, county, or state governments require a permit and inspection for all offices that generate hazardous waste. Others require that used needles and other contaminated waste be picked up by a licensed contaminated disposal service (and may require proof such as a valid contract and receipts of pick up and disposal held by an acupuncturist). Still others require a permit to transport contaminated waste which may prevent a practitioner from carrying a sharps container in a travel kit unless a special permit is acquired. (9) It is important

to be thoroughly familiar with the regulations in your locality. The state or county pollution control agency and/or health department is the best source for information and recommendations. Whenever possible, it is advisable to have hazardous waste transported by an approved carrier.

Discarding gloves, cotton balls and other material contaminated with blood

OSHA defines regulated waste as: liquid or semi-liquid blood or other potentially infectious materials (OPIM); contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials. (10)

Gauze, cotton balls, gloves, etc. that are used during the patient visit, but are not saturated or soaked with blood or OPIM, can be discarded in regular waste. Any of these items that are saturated with blood such that they would release blood or OPIM during routine handling of the trash must be discarded in red biohazardous waste bags.

What should patients do with press tacks or other imbedded devices that they need to remove at home?

Safe sharps disposal is important whether you are at home, at work, at school, traveling, or in other public places. As of 2004, the FDA/CDC no longer allows simple trash disposal of biohazard sharps at home (including lancets for diabetics). All sharps must be disposed of through a proper sharps container or mail-back program. When using press tacks/intradermal needles, either have the patient with the intradermal needles and press tacks still imbedded return to the practitioner for proper removal and disposal; (7) or the patient can be given a sharps container to take home, use it for intradermal needles when removed at home, and then the sharps container would need to be returned to the practitioner for proper disposal. (6) See the websites listed below for more information:

http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/UCM278775.pdf

http://www.cdc.gov/niosh/topics/bbp/disposal.html

http://www.hercenter.org/osha.cfm

The best practice (safest option) when sending a patient home with press tacks or other sharps is to provide them with a small sharps container. Once the patient removes the press tacks, he or she should discard them in the sharps container and then bring the container back to the practice location at his or her next visit.

2. Safety Considerations Regarding the Practice Environment

Acupuncturists must conduct their practice in such a way as to ensure, so far as is reasonably possible, that persons who may enter the practice environment are not exposed to risks to their health or safety. This duty extends to both patients and employees. It is by following recognized standards established by OSHA that this duty can be fulfilled. In particular, attention should be focused on the following:

1. All floors, passages, and stairs shall be of sound construction, properly maintained, and should be kept free from obstruction and from any substance likely to cause persons to slip.
2. A substantial handrail and adequate lighting should be provided for every staircase.
3. Adequate lighting must be provided and maintained in all office spaces.
4. All structures and equipment should be subjected to regular inspection and preventative maintenance.
5. All electrical installations should be in accordance with local codes.
6. Every chair, seat, or couch on the premises should be kept clean and maintained in proper repair.
7. Floors should be easily cleaned. Carpeting in areas where biohazardous waste is generated or stored is not recommended since it is difficult to clean up spilled needles or fluids.
8. All modifications to the clinic should be done in such a manner that all construction, plumbing, and wiring meet local construction codes and are done in a competent and safe manner.
9. All fire extinguishers, fire sprinkler systems, and other fire safety equipment should be maintained according to the manufacturer's instructions and local fire regulations.
10. The location of handwashing facilities, sharps containers, biohazard containers, and the availability of safety equipment should be such that these materials are readily available to the acupuncturist in the workplace.
11. All providers and other clinic personnel should know where material safety data sheets and safety manuals are located and have access to them on a demand basis.

Practitioners should also consult OSHA requirements, Section 3 (*Engineering Controls and Work Practice Controls Regulations, Standards – 29 CRF, 1910.1030 d 2*) for provisions regarding maintenance and use of work areas and signs. Other sources of information regarding a proper office environment for the practice of acupuncture should also be consulted.

3. Recordkeeping

Charting

General Charting Considerations

Patient records should be kept of all patient visits and treatments performed. The treatment record should be a complete, accurate, up-to-date report of the medical history, condition, and treatment of each patient.

Treatment records are maintained primarily to provide accurate and complete information about the care and treatment of patients. They are the principal means of communication between health practitioners in matters relating to patient care and serve as a basis for planning the course of treatment. They are also the practitioner's record of what occurred if there is a complaint or lawsuit. Legislation and regulations concerning medical records vary from state to state. Many states require medical records to be kept for a specific length of time after treatment. Some states detail the information required concerning the patient's treatment. Others simply declare that the medical record should be adequate, accurate, or complete. All patient records should be completed in black ink, be complete with respect to the data from the patient contact, and not be erased or otherwise rendered illegible after the patient contact. In the event the practitioner wishes to make a change in the record during a treatment, such as deciding not to use a specific point, if the practitioner utilizes paper records, the acupuncturist should draw one line through the text in question, initial the change, and then record the updated information. Do not scratch out or render illegible any information recorded in a chart note.

Patient records must be protected against theft, fire or water damage. Each office should set policies and implement procedures that will prevent the loss of patient records, whether electronic or paper-based.

There are nine critical parts of any chart. These are:

1. Patient information
2. Past medical history
3. Allergies and adverse reactions
4. Family history
5. Dated and signed records of every visit
6. Flow sheets for organization of health maintenance, chronic conditions, well-care visits, etc.
7. Narrative notes describing conversations with patients regarding treatments (accepted and refused) and preventative testing

8. Consent documentation
9. Flow sheets or narratives indicating that unresolved problems from previous office visits are addressed in subsequent visits

Treatment records are legal documents and are therefore required to meet certain standards. Some basic standards for charting include:

- Date of the visit should be included on all entries into the record. The date must appear immediately above the first entry for each visit or procedure. Also, the date must be on every page of a chart for any one day's information, including front and back of the same page, so that if records need to be copied, all pages are clearly identified.
- A person's full name and other identifiers (i.e., medical record number, date of birth) should be included on all records. These identifiers must be on every page of a chart, including front and back of the same page, so that if records need to be copied, all pages are clearly identified.
- Continued records should be marked clearly (i.e., if a note is continued on the reverse side of a page).
- Each page of documentation should be initialed (including both sides of a record) with a full signature on the last page of the record; and each progress note must be signed.
- Blue or black non-erasable ink should be used on handwritten records.
- Records should be maintained in chronological order.
- Disposal or obliteration of any records or portions of records should be prevented. This includes taking reasonable precautions to have records protected from fire and water damage, as well as theft.
- Documentation errors and corrections should be noted clearly, i.e., by drawing one line through the error and noting the presence of an error, and then initialing the area. All such corrections should be made so that a reader can visibly see what was changed, who changed it, and when the correction was made. When utilizing Electronic Health Records (EHR) the system should be one that similarly identifies changes (and clearly marks when the chart was changed and by whom).
- Excess empty space on the page should be avoided. If a paper chart is being utilized, a line should be drawn through any unused space and initialed with the time and date included.
- All events involving an individual should be described as objectively as possible, i.e., describe a patient's demeanor by simply stating the facts such as what the person said or did and surrounding circumstances or response of staff, without using derogatory or judgmental language.

- Any occurrence that might affect the person should be documented. Documented information is considered credible in court. Undocumented information is considered questionable since there is no written record of its occurrence.
- If a note is added after the completion of a visit, it should be labeled as an addendum and inserted in correct chronological order rather than trying to insert the information on the date of the actual occurrence.
- Actual statements of people should be recorded in quotes.
- The chart should not be left in an unprotected environment where unauthorized individuals may read or alter the contents.

It is recommended that acupuncturists follow standard medical charting procedures such as the SOAP notes:

1. Subjective (information reported by the patient).
2. Objective (information gathered by the practitioner, i.e., tongue, pulse, palpation).
3. Assessment (of the patient's condition and treatment progress).
4. Plan (treatment record for the day, including points, herbs, dietary and lifestyle recommendations, new diagnosis and referral, if any).

Standard Requirements for AOM charting

A. Subjective:

1. Record personal profile information such as demographics, self-care knowledge, skills and attitudes.
2. Record current and past supplements (herbal and vitamins), prescriptions and OTC medications.
3. Collection of health history data including some or all of the "10 questions"
    a. Energy and Sleep
    b. Head, Eyes & Ears
    c. Chest & Abdomen
    d. Stool & Urine
    e. Thirst, Appetite & Taste Preferences
    f. Menses
    g. Pain (OPPQRST)
    h. Hot & Cold Preference
    i. Perspiration
    j. Emotional Issues/Stressors
4. Record recent consultations with other healthcare providers

B. **Objective**: Perform a clinical evaluation which includes:

1. BP, pulse rate
2. TCM Pulse dx

3. Tongue
4. Palpations of areas of pain/dysfunction
5. May also add:
    i. point palpation, Mu point palpation, joint ROM, reflexes
    ii. information related to the listening and smelling exams
    iii. constitution assessment/eye diagnosis/facial diagnosis, skin, hair, nail diagnosis
    iv. abdominal diagnosis
    v. organ-specific findings
    vi. neuromuscular exam findings
    vii. other biomedical exam findings

Example: *BP 110/76, P 68, R 12.Tongue long, wide, red with a thin white coat and distended sublingual veins. Pulse: regular rate and rhythm, full, thin and wiry. Shoulder ROM decreased in abduction to 110 degrees on the right; 175 degrees on the left. Specific point tenderness noted at GB 21, SJ 14, 15 on the right only.*

C. Assessment:

1. Analyze and interpret all assessment data to evaluate findings from a TCM perspective.
2. Depending on the local and state acupuncture statutes, this may also include a biomedical differential diagnosis (ICD coding as appropriate).
3. Determine whether patient needs can be improved through the delivery of AOM modalities.

Example: *Qi and Blood stagnation in the GB and SJ channels. Shoulder pain previously diagnosed as a rotator cuff strain/sprain (ICD 9 840.4).Improvement from a combination of acupuncture/moxibustion and cupping likely after 4-6 treatments.*

D. **Plan**: Planning is the establishment of goals and outcomes based on patient needs, expectations, values, historical texts, current scientific evidence and other sources of evidence. Treatment record should include the specific points stimulated, modalities applied to points (needle, moxa, gua sha, electrical stimulation, cupping, etc.), dietary and lifestyle recommendations, and any need for referral or consultations. It may include information about home care/self-care. It may include prognosis or treatment planning for a series of the same or similar treatment. If billing insurance, include CPT codes.

Daily treatment records should include the treatment principle(s), points and treatment procedures for each visit, for example: Relieve stagnation of qi in the GB and SJ channels of the right shoulder. Needle and indirect pole moxa on GB 21, 34; electrical stimulation SJ 14-15 (bilaterally). CPT Codes: 99212, 97813.

Implementation: Review and implement the AOM plan with the patient. Modify the plan as necessary and obtain written consent. Confirm the plan for continuing care.

Example: Treatment to be repeated weekly for 4 weeks then reassess and reevaluate progress before additional treatments offered.

Daily Appointment Schedules

Treatment records must be maintained as per state law. In an investigation of an outbreak, particularly of healthcare associated diseases such as HBV, nothing is more important than keeping an accurate record of names and addresses of all patients and dates of treatments. Since hepatitis B has a long and varied incubation period, lack of recorded information about a patient's treatment at relevant times may prevent the proper investigation of any cross-infection related to HBV.

4. Patient Confidentiality

Practitioners should be aware that as a general rule they may not release information regarding a patient, either verbally or in writing, without the patient's consent. Practitioners may, however, discuss cases with other healthcare professionals so long as there is no identifying information provided. In addition to state confidentially statutes, most acupuncturists must now comply with the Health Insurance Portability and Accountability Act (HIPAA). The reader is referred to this act for more details; see information below.

HIPAA Health Information

HIPAA information can be located at: http://www.hhs.gov/ocr/privacy/

HIPAA includes the confidentiality provisions which apply to many health providers. The HIPAA Security Rule establishes national standards to protect a patient's personally identifiable information. "The Security Rule specifies a series of administrative, physical, and technical safeguards for covered entities to use to assure the confidentiality, integrity, and availability of electronic protected health information."

Many acupuncturists are covered by HIPAA. You are a "covered entity" if you conduct certain business electronically, such as sending emails to other health practitioners, electronically billing health insurance companies, or faxing information to others who are covered by HIPAA.

To find out if you are a HIPAA "covered entity" refer to http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/HIPAAGenInfo/AreYouaCoveredEntity.html.

A summary of the HIPAA privacy rules that apply can be found here: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf.

Additional compliance information can be accessed at the following sites:

HIPAA and You: Building a Culture of Compliance
http://www.medscape.org/viewarticle/762170.

HHS Information: http://www.hhs.gov/ocr/privacy/.

And: http://www.wedi.org/workgroups/security-privacy.

Protected Health Information. The HIPAA Privacy Rule (http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/) protects all "individually identifiable health information" held or transmitted by a practitioner or its business associate, in any form or media, whether electronic, paper, or oral. The Privacy Rule calls this information "protected health information (PHI)."Protected information includes: the information healthcare providers put in a medical record; conversations about patient care or treatment with other health professionals; specific health insurer information; and personal billing information.

The Privacy Rule provides that an individual has a right to adequate notice of how a practitioner may use and disclose protected health information about the individual, as well as his or her rights and the practitioner's obligations with respect to that information. Most clinical practitioners must develop and provide individuals with this notice of their privacy practices (NOPP).

Content of a NOPP: Practitioners are required to provide a notice in plain language that describes:

- How the practitioner may use and disclose protected health information about an individual.
- The individual's rights with respect to the information and how the individual may exercise these rights, including how the individual may complain to the practitioner.
- The practitioner's legal duties with respect to the information, including a statement that the practitioner is required by law to maintain the privacy of protected health information.
- Whom individuals can contact for further information about the practitioner's privacy policies.
- The notice must include an effective date. See 45 CFR 164.520(b) for the specific requirements for developing the content of the notice.

http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/notice.html

Some sample NOPPs may be found at the following sites:

http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/model-notices-privacy-practices/index.html

http://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/npp_fullpage_hc_provider.pdf

http://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/npp-layered-provider-spanish.pdf

Reporting of Communicable Disease and Abuse

State laws vary with regard to requirements for healthcare providers to report known or suspected communicable diseases, or child or elder abuse. You should be aware of the law in your state. Check with your local public health office about the requirements about requirements regarding reporting specific diseases for your practice location.

5. Informed Consent

It is generally recognized that the relationship between a clinician and his or her patient comes into being because of the patient's need and trust in the skill, learning, and experience of the clinician. The clinician may not, under ordinary circumstances, impose services upon another without that person's consent.

A full legal explanation of informed consent is beyond the scope of this manual. However, in general, the courts have ruled that every adult has a right to determine what is to be done with his or her own body (referred to as "autonomy").Many states have specific informed consent statutes. Generally, all diagnostic and medical procedures require the consent of the patient or in the case of a child or someone who has certain mental illnesses or communication limitations, his or her legal representative.

Informed consent is authorization by the patient or a person authorized by law to consent on the patient's behalf. This authorization changes a treatment from nonconsensual to consensual. Although most consent cases involve physicians, the principles of law concerning the nature of consent are equally applicable to acupuncturists.

An acupuncturist may be held liable for malpractice if, in rendering treatment to a patient, he or she does not make a proper disclosure to the patient of the risks involved in the procedure.

Required Elements: there are five basic elements that must be disclosed to patients in language that a lay individual reasonably can be expected to understand:

1. The diagnosis, including the disclosure of any reservations the provider has concerning the diagnosis.
2. The nature and purpose of the proposed procedure or treatment.

3. The probable risks and consequences of the proposed procedure or treatment. This includes only those risks and consequences of which the provider has, or reasonably should have, knowledge. It is not necessary to disclose every potential minor risk or side effect. Usually, it is appropriate to disclose those risks which occur more than 1% of the time for a given procedure.
4. Reasonable treatment alternatives. This includes other treatment modalities that are considered to be appropriate for the situation, even though they may not be the personal preference of the disclosing provider.
5. Prognosis without treatment. The patient must be informed of the potential consequences, if he or she elects not to have the recommended procedure.

Written consent provides material proof of consent. A valid, written consent must include the following elements:

1. It must be signed.
2. It must show that the procedure was the one consented to.
3. It must address the nature of the procedure, alternatives, the risks involved, the probable consequences, and demonstrate that the patient understood these concerns.
4. The patient must fill in the date on which the form was signed.

Oral consent, if proven, is just as binding as written consent. However, oral consent may be difficult to prove in court.

Informed consent is particularly important when using techniques that might be interpreted as causing damage to the body; this includes acupuncture as well as direct moxibustion, and cupping or gua sha, which may leave petechiae/bruises.

6. High-Risk Patients

All patients should be treated the same by following Standard Precautions.

7. Other Important Safety Practices

Preventing Trips and Falls

According to OSHA: “Slips, trips, and falls constitute the majority of general industry accidents. They cause 15% of all accidental deaths, and are second only to motor vehicles as a cause of fatalities. The OSHA standards for walking/working surfaces apply to all permanent places of employment, except where only domestic, mining, or agricultural work is performed.” (12)

Slips: Slips occur where there is too little friction or traction between the footwear and the walking surface. These are commonly related to wet or oily surfaces, weather hazards, loose or

unanchored rugs or mats, and flooring or other walking surfaces that do not have same degree of traction in all areas.

Trips: Trips occur when your foot collides (strikes, hits) an object causing you to lose your balance and fall. Common causes of tripping include poor lighting, clutter, wrinkled carpeting, uncovered cables, and uneven walking surfaces.

How to Prevent Falls Due to Slips and Trips

Both slips and trips result from some a kind of unintended or unexpected change in the contact between the feet and the ground or walking surface. This shows that good housekeeping, quality of walking surfaces (flooring), selection of proper footwear, and appropriate pace of walking are critical for preventing fall accidents.

In healthcare practice settings, slips, trips, and falls may be related to any of the above, plus the hazards of walking without shoes to and from treatment tables. Consider creating housekeeping and patient care policies that minimize the risks of slips, trips, and falls.

A guide to small business and safety can be found here:

http://www.osha.gov/Publications/smallbusiness/small-business.pdf

Response to a Bodily Fluid Spill

For a spill of a significant amount of blood or OPIM, use the following guidelines:

- Evacuate personnel from the immediate area, including patients.
- Block off area so no unauthorized person may enter the area.
- Don 2 sets of utility gloves.
- Surround spill with paper towels.
- Put absorbent material on the spill.
- If glass is involved remove the glass with forceps and/or tweezers, or use a broom and dustpan to pick up any biohazardous spill with glass imbedded in it.
- Dispose of absorbent material in hazard waste trash. Double bag.
- Change gloves if contaminated.
- Clean area with detergent and water.
- Disinfect area with an EPA-approved disinfectant appropriate for use on the surface being cleaned, following manufacturer's guidelines for the clean-up if a spill.
- Wash hands after removing gloves.

First Aid

Acupuncture practitioners should be prepared to deal with both minor and major health issues in any treatment setting. It is strongly recommended that all practitioners maintain active CPR

certification. It is recommended that offices have access to an AED if financially possible. In addition, practitioners should have policies in place and training for dealing with:

- Minor cuts
- Bleeding, bruising
- Allergic reactions
- First and second degree burns

It is strongly recommended that every AOM practice location have a simple first aid kit available for employee use. Furthermore, it is strongly recommended that every practitioner maintain a list of emergency numbers for fire, ambulance, and poison control directly next to the phone.

Mental Health Issues/Suicide

Practitioners may also want to evaluate other healthcare situations for which they want to be prepared. This may include mental health issues including suicidal ideation and suicide declarations. There are legal reporting requirements in some states regarding these issues. If a patient threatens harm against him or herself, there can be ethical and legal justification for disclosing that information to a third party (e.g., a spouse or parent) if that disclosure will help prevent that harm. While this may feel like you are violating the rule of confidentiality, having a plan and policy in place will help you deal with these circumstances. See the following for more information

- http://www.dhcs.ca.gov/services/MH/Pages/SuicidePrevention.aspx
- http://healthinformatics.uic.edu/resources/articles/confidentiality-privacy-and-security-of-health-information-balancing-interests/
- http://www.who.int/mental_health/media/en/59.pdf

8. Summary of Recommendations – Part VII

- Critical: Every AOM office must have a written Bloodborne Pathogens Exposure Control Plan.
- Critical: Every AOM office must have a written Hazardous Communication document.
- Critical: All AOM office personnel must follow Standard Precautions. Standard Precautions include: 1) hand hygiene, 2) use of personal protective equipment (e.g., gloves, gowns, masks), 3) safe injection practices, 4) safe handling of potentially contaminated equipment or surfaces in the patient environment, and 5) respiratory hygiene/cough etiquette.
- Critical: Every AOM office must comply with fire department regulations with respect to fire protection and electrical safety.
- Critical: Every AOM office must comply with Building and Safety codes.

- Critical: Every AOM office must comply with State and Federal standards with respect to documenting safety-related policies and procedures.
- Critical: All AOM offices must create, maintain, update and train all personnel (including the owner/acupuncturist) on possible exposures to infectious agents and other hazards annually.
- Critical: All AOM offices must prepare, maintain, and implement a written plan to identify and handle biohazardous waste.
- Critical: All biohazardous waste must be disposed of by removal by a medical waste disposal company. Practitioners must not throw medical waste into the trash for removal.
- Critical: Patient records should be kept of all patient visits and treatments performed. The medical record should be a complete, accurate, up-to-date report of the medical history, condition, and treatment of each patient.
- Critical: Practitioners must not, under ordinary circumstances, impose services upon another without that person's consent.
- Strongly Recommended: Practitioners should require written consent before instituting any clinical procedures.
- Strongly Recommended: Every AOM office should have a simple first aid kit available for employee use.
- Strongly Recommended: Every AOM office should post a list of emergency numbers for fire, ambulance, poison control, and other emergency personnel in a prominent place such as directly next to the office phone.
- Strongly Recommended: Acupuncture practitioners should have written policies in place regarding the release of patient information; and as a general rule they may not release information regarding a patient, either verbally or in writing, without the patient's consent.
- Strongly Recommended: All acupuncture practitioners should maintain active CPR certification.
- Recommended: Acupuncturists should follow standard medical charting procedures such as the SOAP notes.
- Recommended: Acupuncture practitioners should repeat the request for consent either verbally or in written form before performing procedures that leave marks on the body (gua sha, cupping), or that may cause burns (moxa, heat lamps).
- Recommended: AOM offices should have access to an AED.

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Part VIII – Appendices

Appendix A: Glossary/Abbreviations

The following is a list of definitions of terms and abbreviations that are used in this manual.

Acupuncture: Acupuncture is the insertion of needles into the skin where the therapeutic effect is expected to come primarily from the act of inserting, manipulating and/or retaining the needles in specific locations.

AE: Adverse event.

AOM: Acupuncture and oriental medicine.

Antimicrobial agent: Any agent that kills or suppresses the growth of microorganisms.

Antiseptic: Substance that prevents or arrests the growth or action of microorganisms by inhibiting their activity or by destroying them. The term is used especially for preparations applied topically to living tissue.

Aseptic techniques: Techniques for preventing infection during invasive procedures such as surgical operations, dressing wounds, or some laboratory procedures. Acupuncture is not an aseptic procedure because it is not performed in a manner that preserves the sterility of the acupuncturist's hands or the skin of the patient. Acupuncture is a clean rather than sterile procedure. Nevertheless, acupuncture needles must be kept in a sterile condition for use in CNT.

Asepsis: Prevention of contact with microorganisms.

Bacterial count: Method of estimating the number of bacteria per unit sample. The term also refers to the estimated number of bacteria per unit sample, usually expressed as the number of colony-forming units.

Bactericide: Agent that kills bacteria.

BBP: Bloodborne pathogens.

Best practices: Activities, disciplines and methods that are available to identify, implement, and monitor the available evidence in healthcare, such as those practices meant to enhance patient care or limit risks.

Bleach: Household bleach (5.25% or 6.00%–6.15% sodium hypochlorite depending on manufacturer) usually diluted in water at 1:10 or 1:100. Approximate dilutions are 1.5 cups of bleach in a gallon of water for a 1:10 dilution (~6,000 ppm) and 0.25 cup of bleach in a gallon of water for a 1:100 dilution (~600 ppm).

Contact time: For surface disinfection, this period is framed from the moment the disinfectant is applied to the surface until complete drying has occurred.

Clean field: The area that has been prepared to contain the equipment necessary for acupuncture in such a way as to protect the sterility of the needles. By extension, this includes not only the clean surface on which equipment will be placed, but also the patient's skin around prepared acupuncture points, and anything that touches the skin. (Note: A clean field is not the same as a sterile field.)

Clean technique: The use of techniques (such as antisepsis, disinfection, sterilization, handwashing, and isolation of sharps) designed to reduce the risk of infection of patients, practitioners, and office personnel by reducing the number of pathogens, thereby reducing the chances for contact between the pathogens and the patients and personnel.

Cleaning: The removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms and other debris from the surfaces and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

Contamination: The introduction of contaminating viruses, bacteria, or other organisms into or onto previously clean or sterile objects, rendering them unclean or non-sterile.

Cupping (ba guan fa): The application of a partial vacuum to intentionally create therapeutic petechiae and ecchymosis in the dermis.

Decontamination: According to OSHA, "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal." [29 CFR 1910.1030] In health-care facilities, the term generally refers to all pathogenic organisms.

Detergent: A cleaning agent that makes no antimicrobial claims on the label. Such agents comprise a hydrophilic component and a lipophilic component and can be divided into four types: anionic, cationic, amphoteric, and non-ionic detergents.

Disinfectant: Usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms, but might not kill bacterial spores. It

refers to substances applied to inanimate objects. EPA groups disinfectants by product label claims of "limited," "general," or "hospital" disinfection.

Disinfection: Thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

Dx: Diagnosis

ECP: Exposure control plan

Electroacupuncture (EA): The application of 0.5 to 6 mA electrical stimulation to acupuncture needles.

Efficacy/efficacious: The (possible) effect of the application of a formulation when tested in laboratory or in vivo situations.

Effectiveness/effective: The clinical conditions under which a product has been tested for its potential to act as per claims, e.g., field trials.

GCP: Good clinical practice.

Germicide: An agent that destroys microorganisms, especially pathogenic organisms.

Gua sha: A healing technique where the body surface is “press-stroked” with a smooth-edged instrument.

HAI: Healthcare associated infections.

HCP: Healthcare provider.

HCW: Healthcare worker.

High-level disinfectant: An agent capable of killing when used in sufficient concentration under suitable conditions. It therefore is expected to kill all other microorganisms.

Inanimate surface: A nonliving surface (e.g., floors, walls, furniture).

Infectious microorganisms: Microorganisms capable of producing disease in appropriate hosts.

Intermediate-level disinfectant: An agent that destroys all vegetative bacteria, including tubercle bacilli, lipid and some nonlipid viruses, and fungi, but not bacterial spores.

Low-level disinfectant: An agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores.

Medical device: Any instrument, apparatus, material, or other article, whether used alone or in combination, including software necessary for its application, intended by the manufacturer to be used for human beings for:

- diagnosis, prevention, monitoring treatment, or alleviation of disease
- diagnosis, monitoring, treatment, or alleviation of or compensation for an injury or handicap
- investigation, replacement, or modification of the anatomy or of a physiologic process
- control of conception
- and that does not achieve its primary intended action in or on the human body by pharmacologic, immunologic, or metabolic means but might be assisted in its function by such means.

Microbicide: Any substance or mixture of substances that effectively kills microorganisms.

Microorganisms: Animals or plants of microscopic size. As used in healthcare, generally refers to bacteria, fungi, viruses, and bacterial spores.

Moxibustion: The heating of an acupuncture point utilizing moxa (*Artemesia vulagaris*) in various forms.

Mycobacteria: Bacteria with a thick, waxy coat that makes them more resistant to chemical germicides than other types of vegetative bacteria.

Nosocomial infection: An infection that is acquired from healthcare-associated facilities and procedures, including hospitals and other than acute-care facilities; and infections acquired through outpatient care.

OPIM: Other potentially infectious material. OPIM includes synovial fluid, amniotic fluid, cerebrospinal fluid, pleural fluid, semen and vaginal secretions, peritoneal fluid, pericardial fluid, saliva (in dental procedures only), and any fluids visibly contaminated with blood or stool. OPIM includes all body fluids where it may be difficult to differentiate between contaminated and non-contaminated fluids.

Personal protective equipment (PPE): Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts) not intended to function as protection against a hazard are not considered to be PPE.

Parts per million (ppm): Common measurement for concentrations by volume of trace contaminant gases in the air (or chemicals in a liquid); 1 volume of contaminated gas per 1 million volumes of contaminated air or 1¢ in $10,000 both equal 1 ppm. Parts per million = µg/mL or mg/L.

Plum blossom needle: A hammer-like object with multiple needle projections.

Prions: Transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including sheep and goats, bovine spongiform encephalopathy in cattle, and Creutzfeldt-Jakob disease in humans. They are unlike any other infectious pathogens because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (PrP). Prions are extremely resistant to inactivation by sterilization processes and disinfecting agents.

RCT: Randomized controlled trial.

Resident flora (resident microbiota): Microorganisms residing under the superficial cells of the stratum corneum and also found on the surface of the skin.

SAE: Serious adverse event.

Sanitizer: An agent that reduces the number of bacterial contaminants to safe levels as judged by public health requirements, that is commonly used with substances applied to inanimate objects. According to the protocol for the official sanitizer test, a sanitizer is a chemical that kills 99.999% of the specific test bacteria in 30 seconds under the conditions of the test.

Shelf life: The length of time an undiluted or dilution of a product can remain active and effective. It also refers to the length of time a sterilized product (e.g., sterile instrument set) is expected to remain sterile.

SOP: Standard operating procedures.

Spore: A relatively water-poor round or elliptical resting cell consisting of condensed cytoplasm and nucleus surrounded by an impervious cell wall or coat. Spores are relatively resistant to disinfectant and sterilant activity and drying conditions (specifically in the genera Bacillus and Clostridium).

Standard practice: Often synonymous with "customary practice." It is a legal term that is commonly defined as what a minimally competent healthcare provider in the same field would do in the same situation, with the same resources.

Standard Precautions: Standard Precautions are a set of basic infection prevention practices intended to prevent transmission of infectious diseases from one person to another. See http://www.cdc.gov/HAI/settings/outpatient/basic-infection-control-prevention-plan-2011/standard-precautions.html

Sterile or sterility: The state of being free from all living microorganisms. In practice, usually described as a probability function, e.g., as the probability of a microorganism surviving sterilization being one in one million.

Sterilization: A validated process used to render a product free of all forms of viable microorganisms. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

Sterilization for AOM: The use of procedures that destroy all microbial life, including viruses. This is a rigid, uncompromising term. There is no such thing as partial sterility. In acupuncture, sterilization is required for all instruments that pierce the skin: needles, plum blossom needles, seven-star hammers, lancets, and insertion tubes.

Surfactant: An agent that reduces the surface tension of water or the tension at the interface between water and another liquid; a wetting agent found in many sterilants and disinfectants.

Tabletop steam sterilizer: A compact gravity-displacement steam sterilizer that has a chamber volume of not more than 2 cubic feet and that generates its own steam when distilled or deionized water is added.

TCM: Traditional Chinese Medicine.

Transient flora (transient microbiota): Microorganisms that colonize the superficial layers of the skin and are more amenable to removal by routine handwashing.

Tui na: A Chinese system of massage and manipulation using manual maneuvers, including pushing, rolling, kneading, rubbing, and grasping.

Use-life: the length of time a diluted product can remain active and effective. The stability of the chemical and the storage conditions (e.g., temperature and presence of air, light, organic matter, or metals) determine the use-life of antimicrobial products.

Vegetative bacteria: bacteria that are devoid of spores and usually can be readily inactivated by many types of germicides.

Virucide: an agent that kills viruses to make them noninfective.

Appendix B: Where to Find More Information

Federal CDC, state OSHA offices, and local health departments are available to give practitioners specific help regarding infectious diseases, toxins, or suspicious injuries. You should keep your local health department's phone number easily available and contact the department with any questions about specific diseases or regulations regarding the practice of healthcare.

World Health Organization (WHO) – Acupuncture Related Information

WHO: Adverse Events Related to Acupuncture:
http://www.who.int/bulletin/volumes/88/12/10-076737/en/

Guidelines on Basic Training in Acupuncture:
http://apps.who.int/medicinedocs/en/d/Jwhozip56e/4.html

Selected Points for Basic Training in Acupuncture:
http://apps.who.int/medicinedocs/en/d/Jwhozip56e/3.10.html#Jwhozip56e.3.10

Skin Preparation: http://whqlibdoc.who.int/publications/2010/9789241599252_eng.pdf.

Healthcare Associated Infections

CDC Guidelines: Healthcare Associated Infections
http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-gl-standared-precautions.html

National Clinicians' Post-Exposure Prophylaxis Hotline:
http://nccc.ucsf.edu/clinical-resources/pep-resources/pep-quick-guide/

CDC National STD Hotline http://www.usa.gov/directory/federal/cdc-national-std-hotline.shtml

- **Email:** cdcinfo@cdc.gov
- **Toll-free:** 1-800-232-4636

CDC National Prevention Information Network: http://www.cdcnpin.org/

CDC/Specific Pathogens

Hepatitis

- http://www.cdc.gov/hepatitis/PDFs/disease_burden.pdf
- http://www.cdc.gov/hepatitis/Statistics/index.htm
- http://www.cdc.gov/hepatitis/resources/professionals/pdfs/abctable.pdf
- http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepa.pdf
- http://www.vaccineinformation.org/hepa/qandavax.asp

- http://www.who.int/csr/disease/hepatitis/whocdscsrlyo20022/en/index3.html
- http://www.cdc.gov/HAI/pdfs/bbp/Exp_to_Blood.pdf
- http://www.cdc.gov/niosh/docs/2000-108/pdfs/2000-108.pdf
- http://www.hepb.org/professionals/high-risk_groups.htm
- http://www.cdc.gov/hepatitis/HBV/PDFs/HepBGeneralFactSheet.pdf
- http://www.who.int/csr/disease/hepatitis/whocdscsrlyo20022/en/index1.html
- http://www.osha.gov/OshDoc/data_BloodborneFacts/bbfact05.pdf
- http://www.cdc.gov/hepatitis/Resources/Professionals/PDFs/ABCTable.pdf
- http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6103a1.htm

Updated CDC Recommendations for the Management of Hepatitis B Virus–Infected Health-Care Providers and Students

- http://www.cdc.gov/hepatitis/Statistics/2010Surveillance/Commentary.htm
- http://www.cdc.gov/hepatitis/C/cFAQ.htm
- http://www.cdc.gov/hepatitis/PDFs/disease_burden.pdf
- http://www.cdc.gov/hepatitis/HDV/index.htm
- http://wwwnc.cdc.gov/travel/yellowbook/2012/chapter-3-infectious-diseases-related-to-travel/hepatitis-e.htm

HIV

- http://www.cdc.gov/hiv/az.htm
- http://www.cdc.gov/hiv/surveillance/resources/reports/2010report/index.htm
- http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm
- http://www.cdc.gov/HAI/organisms/hiv/Surveillance-Occupationally-Acquired-HIV-AIDS.html
- http://aids.gov/federal-resources/national-hiv-aids-strategy/nhas.pdf

TB

- http://www.cdc.gov/tb/publications/guidelines/infectioncontrol.htm
- http://www.cdc.gov/tb/publications/factsheets/statistics/TBTrends.htm
- http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf
- http://www.cdc.gov/tb/publications/factsheets/statistics/TBTrends.htm
- http://www.cdc.gov/HAI/organisms/tb.html

Other Diseases

- http://www.cdc.gov/bloodsafety/bbp/diseases_organisms.html
- http://www.cdc.gov/features/mrsainfections/
- http://www2.cdc.gov/ncidod/dbmd/abcs/calc/calc_new/intro.htm

- http://www.cdc.gov/hai/organisms/organisms.html
- http://www.cdc.gov/flu/professionals/infectioncontrol/index.htm
- http://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm
- http://www.cdc.gov/HAI/organisms/norovirus.html

Handwashing information and details

- http://www.cdc.gov/handhygiene/download/hand_hygiene_core.pdf
- http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf
- http://www.jointcommission.org/assets/1/18/hh_monograph.pdf
- http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm
- http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_hcf_03.pdf
- http://www.cdc.gov/features/handwashing/
- http://www.cdc.gov/handwashing/
- http://www.cdc.gov/handhygiene/index.html

Standard Precautions

- http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-gl-standared-precautions.html

OSHA Documents and Training Requirements

OSHA Bloodborne Pathogen Standards

- http://www.osha.gov/SLTC/bloodbornepathogens/standards.html
- http://www.osha.gov/OshDoc/data_BloodborneFacts/bbfact03.pdf
- http://www.osha.gov/Publications/osha3151.html

Exposure Control Plan (ECP) Samples

- http://www.osha.gov/Publications/osha3186.pdf (pdf version)
- http://www.osha.gov/Publications/osha3186.html (html version)
- http://www.osha.gov/OshDoc/Directive_pdf/CPL_2-2_69_APPD.pdf (specific small business plan version)

OSHA Documents Relating to ECPs

- http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=1574&p_table=DIRECTIVES
- http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051

Hazardous Communication

- A sample Hazardous Communication policy can be found here: http://www.osha.gov/Publications/osha3186.html

HIPAA

To find out if you are a HIPAA "covered entity" refer to: http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/HIPAAGenInfo/AreYouaCoveredEntity.html

A summary of the HIPAA privacy rules that apply can be found here: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf

Basic HIPAA information: http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/notice.html

Sample NOPP:www.nahu.org/members/hipaa/7_Sample_Employer_Notice.doc

Appendix C: Acupuncture Points that Require Special Skill

Acupuncture has traditionally trained practitioners using an oral tradition. Only relatively recently have comprehensive texts on acupuncture points been produced in English. Research on the limited efficacy of acupuncture points for specific conditions or times of life is not readily available in English. The following chart is meant to bring together information from sources such as the World Health Organization, (1) *Chinese Acupuncture and Moxibustion*, (2) *A Manual of Acupuncture*, (3) and some oral traditions to identify points that, in some traditions, may require more practice or skill to utilize safely. Not all texts agree on the same list of such acupuncture points.

Some of the following listed points are based on risk reduction rather than ideal care considerations. For instance, modern acumoxa practices in the U.S., where scarring may create a malpractice concern, may create a longer list of points requiring special skill than traditional Asian practices utilizing acumoxa in the same areas.

There is no consistent comprehensive list of points that may be contraindicated for acupuncture, moxa or other techniques during pregnancy. Traditionally, students have been cautioned to avoid utilizing points that can be used to stimulate labor (e.g., SP 6, LI 4), points on the sacrum which may stimulate nerves that also innervate the uterus (e.g., BL 31, 32, 33), or points on the foot that may have a reflex action on the uterus (e.g., BL 67). Based upon animal research, some researchers have questioned whether points that are often identified as being contraindicated in pregnancy by traditional texts or oral traditions really need to be avoided in modern practice. (4-6) Practitioners are urged to fully understand the anatomical changes that take place during pregnancy when needling between the pubis and the umbilicus. They are also cautioned to use good clinical judgment when needling bladder points on the foot during pregnancy (except to use BL 67 for breach presentations); and if they plan to use points that act strongly to cause the qi to descend during pregnancy. Students are urged to study standard point function texts such as *Chinese Acupuncture and Moxibustion*, (2) and *A Manual of Acupuncture* (3) to understand which points are considered to need special skill if used during pregnancy.

Acupuncture practitioners need to stay abreast of information in the field about risks associated with acupuncture practice, as well as research re-assessing those same reports of risks, and make care decisions based on evidence-informed practices and clinical judgment.

General AOM Procedure Contraindications: No direct, scarring moxa on the face or in the hairline. No use of AOM procedures over active skin lesions or around areas of acute trauma without special training or supervision. No deep needling on the thorax; use extra caution on points the WHO indicates have been associated with pneumothorax.

Categories of Points*:

A. Due to anatomical considerations, limit needling of point for critical circumstances when other options are not available; or when point function/use outweighs the risks.
B. Due to anatomical considerations or according to historical texts, limit use of moxibustion techniques for limited circumstances when function/use outweighs the risks.
C. Direct, scarring moxibustion should be avoided; the risks of damage outweigh the benefits (e.g., on the face).
D. Apply E-Stim only with special care or for limited circumstances.
E. Point is at or over a major vessel; use care when needling.
F. Point has been associated with pneumothorax by WHO or other authority; limit depth and consider proper angle for needling.

*Note that there is a wide variety of types and styles of acupuncture. Therefore, there is also a wide variance in culture and tradition regarding any risks associated with specific point uses. Even the precautions associated with anatomical locations may be more or less critical depending upon the style of acupuncture or moxibustion being utilized.

Point:	**A**	**B**	**C**	**D**	**E**	**F**
LU 2	X					
LU 3		X				
LU 9					X	
LU 10		X				
LU 11		X				
LI 15		X				
LI 19			X			
LI 20			X			
ST 1	X		X			
ST 2, 3, 4, 5, 6, 7			X			
ST 8			X	X		
ST 9				X	X	
ST 12				X	X	X
ST 13					X	
ST 17	X		X			
SP 7		X				
SP 11	X				X	
HT 1	X				X	
HT 2	X					
SI 10		X				
SI 18			X			

Point:	A	B	C	D	E	F
BL 1	X		X			
BL 2, 3, 4, 5, 6, 7, 8, 9, 10			X	X		
BL 13						X
BL 51		X				
BL 60, 61						
BL 62		X				
KI 11	X					
SJ 16-23			X			
GB 1 TO 19			X			
GB 21						X
LR 12					X	
REN 5	X (*)					
REN 8	X	X				
REN 14	X			X		X
REN 15	X			X		X
REN 17, 18				X		
REN 22	X					X
DU 4		X (**)				
DU 6		X				
DU 11	X					
DU 15	X			X		
DU 16	X		X	X		
DU 17	X		X	X		
DU 18, 19, 20, 21, 22, 23, 24, 25			X	X		
DU 27, 28		X				

*FEMALE PATIENTS (historical reference)
**MALES UNDER 21 only (historical reference)

References

1. WHO, Guidelines on Basic Training and Safety in Acupuncture. World Health Organization. http://apps.who.int/medicinedocs/en/d/Jwhozip56e/4.html Accessed November 2012. Published 1996. Accessed December 2012.

2. Cheng Xinnong (chief editor). *Chinese Acupuncture and Moxibustion*. Foreign Languages Press, Beijing; 1987

3. Deadman, P., Al-Khafaji, M. *A Manual of Acupuncture*. Journal of Chinese Medicine Publications; 2001

Clean Needle Technique 7th Edition FAQ

Should pressure be applied before and during needle removal?	No. Because applying pressure next to a needle that is being removed increases the risk for inadvertent needlestick injuries, best practice techniques would be to apply pressure to an acupuncture point only after the needle has been completely removed from the site.
Does strong thrusting, twisting, inserting and lifting cause an increase in bleeding and bruising?	Unknown/untested. While it makes sense that the more a needle is manipulated the more bruising and bleeding will take place, there have been no studies to support this theory.
Does the size or width of needle make for a stronger or less strong needle sensation?	Unknown/untested. Generally, practitioner expertise has more to do with the amount of needle sensation than does the size or width of an acupuncture needle.
In making sure there are no needles left in a patient at the end of a treatment, does palpating the site where a needle was inserted follow best practices?	Palpating areas looking for forgotten needles may increase the risk of needlestick injuries. Use counting and proper documentation to check for missing needles. However, if needle counts do not match, palpation may be necessary but should be done with extreme caution.
Should warm water or water with sugar be given to patients who have fainted during acupuncture?	Variable. If the patient just feels faint, some water, tea or other liquids may be helpful. If the patient has fainted, then do not force liquids into the mouth until the patient regains consciousness and clarity of thought.
How often do I need to wipe down a treatment table with appropriate disinfecting solution?	Wipe down each treatment chair or table with a solution or disinfectant cloth between every patient visit and at the end of the day. As with handwashing, disinfecting treatment surfaces must be done between each patient visit to prevent cross contamination.
When using a multi-needle pack of sterilized needles, once the packaging is opened for one patient visit, can the unused needles be used for another patient? What if I am seeing the patients back-to-back?	No. Once a multi pack of needles has been opened, the needles are no longer sterile. Since you must use needles that are sterile at the start of every treatment, unused multi-pack needles must be discarded in a sharps container at the end of each patient visit.

If I use table paper over a sheet or other cloth to cover the treatment surface, can I change the paper only for each patient and change the sheet at the end of the day?	No. Table paper does not completely cover the area that a patient may touch. All treatment surfaces must be cleaned between each patient visit. If using sheets or other cloth coverings, these must be changed for each and every patient visit. Note that the incidence of mycobacterium outbreaks in some cases may have been associated with practices of reusing towels and sheets.
Can patients leave the clinic with the press tacks/intradermal needles still inserted on the skin?	Yes. If proper instructions have been given regarding the care of the skin around the intradermal needle, then current studies suggest that they may be retained after the patient leaves the treatment office. Written instructions for returning to the clinic for removal and/or a sharps container and instructions for removal of the intradermal needles at home must be fully explained by the practitioner.
Can practitioners' hands be sterilized?	No. Sterilization is defined as "the complete destruction of all living tissue." Since practitioners are living, breathing individuals, their hands can be clean but not sterile.
Must a different guide tube be used for different areas on the patient's body?	No. Guide tubes must be sterile at the start of a treatment but a guide tube may be used for multiple needle insertions at various areas of the patient's body.
Is the best way to clean skin prior to needle or lancet insertion to use 70% alcohol?	Unclear. The literature is clear about the skin being clean but there have been no comparison studies of soap and water vs. alcohol vs. other products, such as those containing chlorhexidine.
How do I use an alcohol swab to clean the skin – one direction only or back and forth "cleaning"?	Unclear. The alcohol is being used to be sure the skin is clean. Since the needles do not enter the vascular tree, specific directionality of swabbing has not been studied.
When doing wet cupping should the cup be left in place for approximately 30 seconds after "breaking the seal" so as to avoid an aerosol effect of the drawn blood?	No. Some blood will be released during the loss of suction no matter how long the cup is retained. Use of proper PPE is needed to protect the practitioner from blood and OPIM.

Should a new alcohol swab be used for different body regions?	No. Alcohol swabs can be used for multiple points in multiple parts of the body as long as the swab remains moist and is not visibly dirty. New swabs are needed when cleaning areas that are covered with make-up or other products, or for areas with high bacteria counts such as the groin or axilla.
Can I use reusable needles for treatments?	No. The standard of care for U.S. CCAOM CNT course graduates is to use single-use sterile disposable needles only. Reusing needles is not permitted legally in many states. The cost saved by autoclaving needles is negligible when compared to the cost of even one patient contracting a disease from needle reuse.
When cleaning a cup or gua sha device, do I disinfect first, then clean the cup or device?	No. You must remove all biological material for the disinfectant to work properly. Clean the device with soap and water first, then disinfect, then rinse the device (if it is desired to remove any remaining disinfectant) before using on the next patient.
When cleaning a cup or gua sha device, does it need to be sterilized?	A cup or gua sha device needs to be cleaned of any biological material and then disinfected using an EPA-approved disinfecting solution or autoclaved. If the cup has or will be used for wet cupping, there will be a break in the skin. In this case, you must follow the CDC directives for cleaning, disinfecting, storing and using semi-critical devices. PPE is also required. If the cup or gua sha device has or will be used on intact skin, you must follow CDC directives for cleaning, disinfecting, storing and using noncritical devices. The CNT Manual advises when these tools are used over intact skin, you must use at least intermediate-level disinfectants. Because you cannot always anticipate that the skin will remain intact during cupping or gua sha, taking the extra precaution to consider all cups and gua sha tools as semicritical devices that require high-level disinfectants or autoclaving is strongly recommended.
How do I decide whether to use high- or intermediate-level disinfection solution for my cups and gua sha tools?	It is easiest to use one method for all cups and gua sha tools. If you ever use wet cupping, cupping or gua sha over areas where the skin is not intact, the best practice is to use a high-level disinfecting solution (after cleaning with soap and water) following package directions for semi-critical reusable medical equipment. Otherwise, you have to segregate your equipment between those used on intact skin and those used over non-intact skin, which is an unnecessary complication.
What options do I have for holding the shaft of a needle, if necessary, during needle insertion?	The shaft of the needle can be touched with sterile gauze, sterile cotton or a sterile glove. Anything that touches the shaft of the needle before insertion into the skin must be sterile.

When removing needles, do I need to remove acupuncture needles one at a time?	Unclear. While it makes sense for optimal safety purposes to remove needles one at a time, no studies have been done to determine if removing a couple needles located close together is riskier than single needle removal. What is critical is that used needles be immediately isolated in an appropriate sharps container. Practitioners removing needles should never demonstrate or gesticulate while holding used needles as this greatly increases the risk of a needlestick incident.
What does it mean: "Immediate isolation of used needles and lancets"?	When removing needles, used lancet devices, or other used sharps, these items need to be placed in a proper sharps container as soon as possible. Practitioners need to develop practices that limit the amount of movement required to move the sharp to the sharps container. Walking around with used sharps, holding them while talking to the patient or others, and moving from one location to another with used sharps increases the risk of a needlestick injury.
Specifically what fluids are considered potentially infectious?	Blood and OPIM. OPIM include: synovial fluid, amniotic fluid, cerebrospinal fluid, pleural fluid, semen and vaginal secretions, peritoneal fluid, pericardial fluid, saliva (in dental procedures only), any fluids visibly contaminated with blood, stool, and all body fluids where it may be difficult to differentiate between contaminated and non-contaminated fluids.
What bodily fluids are known to be a source for HIV infections?	Blood, any body fluid contaminated with blood, semen, vaginal secretions, synovial fluid, amniotic fluid, cerebrospinal fluid, and breast milk. Sweat and urine are not sources for HIV infections.
What are the standard procedures to follow after an exposure incident such as a needlestick?	1. Treat the exposure site as soon as possible after the exposure incident. 2. Use soap and water to wash and clean areas exposed to blood or OPIM as soon as possible after exposure occurs. DO NOT "milk" a puncture site to draw out some blood first. 3. Flush exposed mucus membranes with water. 4. Flush eyes with running water or saline solution. 5. Do not inject antiseptics or disinfectants into the wound. 6. Report the incident to your supervisor. 7. Note the incident in the incident log. 8. Utilize follow-up procedures as specified in the clinic's BBP manual.

If I can reach into the clean field to pick up needles, why has it been taught that I cannot reach across the clean field when disposing of unclean items?	Unclear. It is important to avoid contaminating the clean field with dirty items by dropping them on the clean field, brushing clothing across the clean field, or dripping unclean liquids on the clean field. Reaching across the clean field may not be a problem as long as practitioners remember not to contaminate the clean items. The historical avoidance of reaching across the clean field helps remind practitioners of the importance of maintaining cleanliness.
What procedures require consent? Does consent for acupuncture treatment cover cupping, bleeding, moxa, and gua sha as well as needle insertion?	Informed consent requires that all patients should understand and agree to the potential consequences of the entirety of their care. Consent must include a number of features, including the nature and purpose of a proposed treatment or procedure and the risks and benefits of proposed treatment or procedures. If your acupuncture consent includes this for ALL procedures you perform, then that probably covers you. But if your consent form only discusses acupuncture, then you probably need to obtain additional or separate consent for all planned procedures. See http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage5.html
Why does this edition of the manual offer opposing views for some traditionally restricted procedures, such as electrical stim on someone with a pacemaker, or points that require special skill?	Practitioners are encouraged to read the manual with a critical eye, reviewing the evidence provided and using their personal knowledge and practitioner judgment to minimize risks for their specific practice. This manual is a teaching tool. Information about risks and benefits of specific procedures continues to grow. Practitioners are encouraged to compare their standard of care with the evidence from research studies and case studies to create their own best practices.
Why are the techniques described in the manual called "clean technique" rather than "sterile techniques?"	While the needles and lancets used as described in this manual are sterile before use, other devices are clean but not sterile and the entire field being prepared for patient treatments is clean, not sterile. Clean technique is a better designation than sterile technique which would require surgical-level cleanliness and sterility.
Can you use of alcohol pump dispensers in clinic setting rather than alcohol wipes?	Alcohol pump dispensers can themselves be source of contamination. If such dispensers used, they should be disinfected daily with appropriate EPA approved disinfecting solution.
Why is there no reference to "needle retention time" even though the CNT Manual references "cupping retention time?"	No available research on needle retention time suggests any adverse effects of longer retention. This is not the same issue as cupping as cupping compresses the skin and has proven adverse effects from excessive retention.

The Manual permits removal of multiple needles at same time, but not clear if needles can be placed in intermediate container for counting purposes before being put in sharps container.	If a practitioner wishes to take out needles near each other before those 2 or 3 needles are put in the sharps container, and can remove them without the sharp end of any needle coming back in contact with the patient's skin, then that is permissible. But needles cannot be put in a secondary container/receptacle between removal from a body and disposal in the sharps container. All needles need to go immediately into a sharps container after removal.
Why is there inconsistency in the Manual as to whether sweat and tears are sources of infection?	Sweat and tears are not sources of bloodborne pathogens. Sweat can carry skin bacteria so can be a source of contamination and cross infection of skin infections between patients, or patients and practitioner. Tears are normally not a source of infection except when a person has a current conjunctival disease. So this is about context. We don't expect that normal handshakes and hugs or touching face-to-face will spread bloodborne pathogens. However, people with conjunctivitis or impetigo or HSV may spread those illness through sweat or tears.
Do used/contaminated cups need to be isolated after use?	Disinfected, not isolated. If bleeding occurs, inadvertently or as a result of wet cupping, those cups need to be handled carefully as blood and OPIM will be present on the inside of the cup. Personal protective equipment, in this case primarily gloves, should be used when handling such contaminated cups. Strict isolation procedures are not necessary. All such cups must be cleaned and disinfected as defined in this text. All surfaces that the contaminated cups come in contact with must be disinfected as well.
Do all lab coats need to be laundered by the healthcare facility?	No. If the use of lab coats is as a form of uniform rather than for the purposes of PPE, then it is OK for clinicians working at healthcare facilities to purchase their own uniforms and launder those at home.

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