Clean Needle Technique (CNT) Review Course: Acupuncture Safety

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# Table of Contents

*Instructions* .................................................................................................................................................. 4  
*Application* .................................................................................................................................................. 5  
*Worksheet* .................................................................................................................................................. 6  
I. Overview .................................................................................................................................................... 7  
II. Literature Review – Adverse Events (AE) .............................................................................................. 7  
   A. Acupuncture ......................................................................................................................................... 7  
      1. Bruising and Bleeding ............................................................................................................... 9  
      2. Needle Site Pain/Sensation ....................................................................................................... 10  
      3. Fainting Due to Needling ......................................................................................................... 11  
      4. Stuck Needle ............................................................................................................................ 11  
      5. Failure to Remove Needles ....................................................................................................... 11  
      6. Pneumothorax ........................................................................................................................... 12  
      7. Accidental Injury to Other Organs .......................................................................................... 12  
      8. Infections .................................................................................................................................... 13  
      9. Broken Needle .......................................................................................................................... 13  
   CCAOM Position Paper: Skin Preparation Prior to Needle Insertion ............................................. 14  
   B. Moxibustion ........................................................................................................................................ 16  
      1. Burns ........................................................................................................................................... 17  
      2. Infections ..................................................................................................................................... 18  
      3. Nausea or Other Reactions to Moxa Smoke ........................................................................... 18  
   C. Other Heat Therapies ......................................................................................................................... 18  
   D. Cupping ............................................................................................................................................ 19  
   E. Bleeding ........................................................................................................................................... 22  
III. Healthcare-Associated Infections (HAIs) ........................................................................................... 23  
   A. Bloodborne Pathogens .................................................................................................................... 24  
      1. Hepatitis A (HAV) ..................................................................................................................... 24  
      2. Hepatitis B (HBV) ..................................................................................................................... 26  
      3. Hepatitis C (HCV) ..................................................................................................................... 31
Instructions

1. Welcome to the CCAOM’s CEU course, entitled “Clean Needle Technique (CNT) Review Course: Acupuncture Safety”. Completion of this course will earn you 4 PDA points toward the NCCAOM safety CEU course requirement (NCCAOM Provider # ACHB 664-001). Completion of this course and worksheet should take approximately 4 hours.

2. After you have read the course material and completed the worksheet, please do one of the following:
   - mail the completed application form (page 5 of this document), along with payment and the completed worksheet (page 5 of this document), to: CCAOM, PO Box 65120, Baltimore, MD, 21209
   - or, fax the information to: 410-464-6042 (if you fax the information, please call the CCAOM national office at 410-464-6040 to confirm receipt, as faxes are not always successfully transmitted)
   - or, email the documents as attachments to: pdiamond@ccaom.org (if you email your documents, please call the office at 410-464-6040 to give us your credit card information, as it is generally not safe to send payment information over the internet)

3. Fill out all sections of the application form and sign where indicated. INCOMPLETE OR ILLEGIBLE APPLICATIONS WILL BE RETURNED.

4. After reading the course content contained in this document, you must answer all questions on the worksheet to the best of your ability.

5. The cost of the CEU course is $50, payable in U.S. dollars to “CCAOM,” by personal or certified check, or by credit card. If you are using a credit card for payment, complete the applicable portion of the application form. If you are paying by check, please note that if your check is returned for insufficient funds, you will be charged an additional $20 fee.

6. Within ten days of receipt of your application, payment and worksheet, we will email you an assessment (a 20-question multiple choice exam) and a course evaluation. Please complete these documents and email them back to us at pdiamond@ccaom.org.

7. Within ten days of receipt of your completed assessment and course evaluation, we will send a certificate of completion to you in the mail, as well as to the NCCAOM. (NOTE: To pass the assessment, you must correctly answer at least 17 of the 20 questions. If you fail the assessment, you will be notified by email.)

8. If you have any questions after reading any of the material, please call the CCAOM national office at 410-464-6040, or email the office at pdiamond@ccaom.org.
Application Form

Send this completed application form, along with payment and completed worksheet, to:

CCAOM
PO Box 65120
Baltimore, MD  21209

- Or, fax application and worksheet with credit card information to:  410-464-6042  (if faxing, call the office at 410-464-6040 to confirm that your fax was received)
- PLEASE TYPE OR PRINT ALL INFORMATION CLEARLY; INCOMPLETE OR ILLEGIBLE APPLICATIONS WILL BE RETURNED
- PLEASE NOTE THAT UPON COMPLETION OF THIS COURSE, YOUR CERTIFICATE WILL AUTOMATICALLY BE SENT TO YOU, AS WELL AS TO THE NCCAOM

CEU Course Title:  Clean Needle Technique (CNT) Review Course: Acupuncture Safety

Name, as it should appear on your certificate: _____________________________________________________________

Date of Birth:  _____/_____/______       Email Address: ________________________________________________
(month)   (day)   (year)

(NOTE: You must provide us with an email address or your application will be considered incomplete.)

Mailing Address: _____________________________________________________________________________________

City:  _______________ State:  _______ Country:  _______ Zip Code:  __________

Phone: ___________________________       Fax: ___________________________

State in which you are licensed to practice acupuncture:  ___________ License #:  ___________

Payment Information:

The cost of the CEU course is $50. Please include either a personal or certified check with this application form, or if paying by credit card, complete the following:

Card Number:  _______________________________       Exp. Date:  __________       Security Code:  ______

Billing Zip Code:  ___________ Signature:  _______________________________       Date:  __________
After reading the course content, complete the questions below and return this worksheet to the CCAOM with your application form and payment. The assessment and an evaluation will be emailed to you upon receipt of these documents.

1. What are the common adverse effects (AEs) of acupuncture, moxibustion, heat lamps, electro-acupuncture and cupping?

2. Name the critical and highly recommended procedures to reduce AE for acupuncture.

3. How are diseases transmitted, including blood borne pathogens and other infections that have been associated with healthcare settings in general and acupuncture specifically?

4. Name the critical features of preventing disease transmission in AOM practice locations.

5. What are the best practices for hand hygiene for AOM procedures?

6. What national safety standards exist, including OSHA BBP standard, that apply to the AOM office?

7. Name the critical elements of preventing practitioner to patient cross infections.
I. Overview

Safety is of critical importance 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, the 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 healthcare providers to be well trained and the practice of acupuncture to be relatively safe.

The following is a review of the risks associated with acupuncture, moxibustion, and heat lamps. Of these risks, infections have seen a significant drop in the last decade. Continued efforts to understand and limit the risk of infection are crucial to advancing optimal public safety in practitioners’ offices. A review of healthcare-associated infections (HAIs) related to acupuncture follows. The last section of this course deals with some of the more common legal requirements of practice.

II. Literature Review – Adverse Events AEs

A. Acupuncture

Acupuncture is the insertion of needles into the skin for a therapeutic effect, expected to come primarily from the act of inserting, manipulating and/or retaining the needles in specific locations. Acupuncture points may be stimulated in a variety of ways by practitioners of Acupuncture and Oriental Medicine (AOM), including needling, moxibustion, cupping, manual pressure, electrical stimulation, laser stimulation, magnets, plum blossom, bleeding, and injection therapies among many others. However, “acupuncture” only occurs when the primary effect of treatment is caused by the insertion of a needle.

White and Lao, in an early review of the literature, conclude that “the risk of serious events occurring in association with acupuncture is very low, below that of many common medical treatments,” (1) and “acupuncture performed by trained practitioners using clean needle techniques is a generally safe procedure.” (2)

In a 2001 study, Ernst and White note that “the most common adverse events were needle pain (1% to 45%) from treatments, tiredness (2% to 41%), and bleeding (0.03% to 38%). Feelings of faintness and syncope were uncommon, with an incidence of 0% to 0.3%. Feelings of relaxation were reported by as many as 86% of patients. Pneumothorax was rare, occurring only twice in
nearly a quarter of a million treatments. . . Those responsible for establishing competence in acupuncture should consider how to reduce these risks.” (1)

Lao et al., in their review of literature covering the years 1965-1999, conclude that “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)

The widespread use of single-use disposable sterile needles began in the late 1980s.

White reviewed a significant body of published evidence regarding AEs associated with acupuncture in 2004, 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, including those by Park et al., (4) and Witt et al., (5) also conclude that the vast majority of AEs are minor and require little or no treatment. Park et al. studied 2,226 patients over 5 weeks of acupuncture treatments, and found only 99 AEs during that time (4.5%). The most common AEs 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 AEs were experienced by any patients during this study. Witt et al. observed 229,230 patients who received, on average, 10 treatments for common complaints such as pain and allergies. Of these, 19,726 reported AEs (8.6%). Common AEs 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 AEs included 2 cases of pneumothorax and 31 cases of nerve injury (0.014%). 31 instances of local infections at acupuncture insertion sites were reported (0.014%). No blood borne or systemic infections were reported. [In the Witt study, 85% of the surveyed acupuncture practitioners had only 140 hours of acupuncture-specific training; only 15% had more than 350 hours of acupuncture training.—Ed.]

A systematic review of the Chinese literature regarding acupuncture adverse effects reported 479 cases of adverse effects following acupuncture reported in the Chinese medical literature between 1980-2009. (6) 296 cases of traumatic events (pneumothorax, injuries to organs, nerves, blood vessels and other tissues). “Nine cases of bacterial infection and two cases of viral infection” were reported during this time frame; all patients recovered. 172 cases involving
other AE were reported ranging from allergic reactions to the needles to fainting. The authors conclude that proper clean technique and limiting needle manipulation in high-risk acupoints would have limited even these few acupuncture AE. (6)

In the most recent comprehensive review of AEs associated with acupuncture, moxibustion, and cupping, Xu et al. find that, between 2000 and 2011, “117 reports of 308 AEs from 25 countries and regions were associated with acupuncture (294 cases), moxibustion (4 cases), or cupping (10 cases).” (7) While the majority of these AEs associated with acupuncture are infections, this is a significant reduction in the number of infections when compared to earlier reports. Also, the most common acupuncture-related infections have changed from hepatitis to infections of the skin and soft tissues such as *Mycobacterium spp.* and *Staphylococcus spp.* The authors suggest this reduction in AEs in the U.S. is likely due to the introduction of the CNT course of the Council of Colleges of Acupuncture and Oriental Medicine (see page 11 of the paper). (7)

1. **Bruising and Bleeding**

Given the nature of acupuncture needling, it is difficult to prevent all bleeding and bruising. In some cases, minimal bleeding may be expected and even beneficial. It is possible, however, to prevent severe bleeding and hematomas. Acupuncture practitioners must be aware of the vascular anatomy of their patients. Needling should be performed so 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 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 it against the scalp or pinna a few seconds longer than when removing needles from other areas. 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.

Acupuncture points which lie over or next to major vessels include:

- **LU 9 Taiyuan** (radial artery)
- **ST 9 Renying** (carotid artery)
- **ST 12 Quepen** (supraclavicular artery and vein)
- **ST 13 Qihu** (subclavian artery)
• ST 42 Chingyang (dorsalis pedis artery)
• SP 11 Jimen (femoral artery)
• HT 1 Jiquan (axillary artery)
• LV 12 Jimai (femoral artery and vein)

There is no evidence that acupuncture needling is limited by patient use of anticoagulants, which are also known as blood thinners. A 2014 systematic review says “acupuncture appears to be safe in anticoagulated patients, assuming appropriate needling location and depth.” (8) This review cites an anticoagulant complication rate of 0.003%, concluding that regular acupuncture is acceptable for patients taking anticoagulant medications, as long as blood vessels are avoided.

2. 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 before 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 are 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.

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) in response to acupuncture. When a patient presents with a chronic pain condition, such as fibromyalgia, he or she may have an increased sense of pain from either hyperalgesia or allodynia. (9, 10)

Caffeine consumption may also affect patients’ pain perceptions. Studies have found that caffeine may lower the perception of pain (10, 11) and enhance muscular strength.
performance. (10) Caffeine consumption may also heighten anxiety, which is associated with the increased perception of pain. (12) One early study found that caffeine could block the electro-acupuncture-induced elevation of the nociceptive thresholds. (13) 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.

3. Fainting Due to Needling

While feeling faint or lightheaded is a possible AE of acupuncture, most studies indicate that, after needle insertion, more people report a sensation of faintness or lightheadedness than actually faint. Witt et al. find that, while 0.72% of patients have some sort of vegetative symptoms, only 0.027% faint. (5) White, in the SAFA study, reports faintness in 93 patients but the fainting of only 6 patients. (15) In the report by McPherson et al., 8 patients had symptoms of faintness, but only 4 fainted. (16)

Patients usually experience lightheadedness or faintness during their first acupuncture treatment, if they are nervous, if there is excessive needle manipulation, or if they are particularly hungry or tired before needle insertion. (17)

Fainting as a result of acupuncture is reported more frequently in a review of the Chinese literature (18). This might be associated with strong needling stimulation in patients who are in a sitting position, which can cause a marked vasodilatation that leads to a decrease of blood pressure. (2)

4. Stuck Needle

Practitioners may find it difficult to rotate, lift, or withdraw a needle after inserting it. 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. If the needle is still difficult to withdraw, ask the patient to lie calmly for a few minutes or perform another needle insertion nearby 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.

5. 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, 19, 20)

This error by practitioners may be related to distractions from patient care. Some basic steps can decrease the occurrence of this mistake. Retained needles may be more common within the hairline; on the chest or back if hair is 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. Practitioners may want to inspect and manually palpate these areas for retained needles at the end of a treatment. 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 also help prevent this AE.

6. Pneumothorax

Pneumothorax is defined as the collection of air in the space around the lungs, which prevents lung expansion. A pneumothorax may be the result of a puncture of the chest wall, such as that from a knife or gunshot wound that allows air into the pleura and lungs. It may also occur spontaneously when a small area in the lung that is filled with air (“bleb”) breaks open. Tall, thin people, smokers, and those suffering from chronic obstructive pulmonary disease (COPD) are more likely to suffer from a pneumothorax. (21)

Pneumothorax is rarely caused by acupuncture because of the pleura and layers of muscle which surround the lungs. An acupuncturist must be aware of the anatomy of the chest and take proper precautions to prevent inserting an acupuncture needle deeply on the chest or back above the diaphragm.

According to a World Health Organization (WHO) review of acupuncture-related AEs (22), the points associated with pneumothorax are: Jianjing (GB21; 30%), Feishu (BL13; 15%), Quepen (ST12; 10%) and Tiantu (CV22; 10%). Infrequent AEs occur at Ganshu (BL18), Jiuwei (CV15), Juque (CV14), Jianzhen (SI9), Quyuan (SI13) and Dingchuan (EX-B1).

7. Accidental Injury to Other Organs

The major prospective studies of AEs associated with acupuncture do not report injury to other organs, but the Chinese literature reports that such AEs are possible (6). In their 2013 review, Xu et al. (7) report 9 cases of central nervous system injury; 5 heart injuries; and 7 cases of injury to other organs or major vascular structures, but no cases of injury to the liver or kidneys.
Before administering acupuncture, 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 such infections 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. (7) 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, pain upon percussion around the kidney region, and bloody urine.

If a needle enters too deeply, or there is inappropriate manipulation in such points as Du 15 (Yamen) or Du 16 (Fengfu) in an adult, or Du 22 (Xinhui) in an infant, there may be bleeding and other severe consequences for the brain and spinal cord. Clinical manifestations may include minor or major neurological changes such as twitching, changes in breathing, convulsions, paralysis, and even coma. (23)

8. Infections

Infections may be local or systemic, due to an autogenous source (the patient), or a cross-infection (from the practitioner, staff or other patients). Infections associated with acupuncture needling are rare. However, any disruption of normal barriers to infection, such as a skin puncture, can allow pathogens 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 significant stress, use of corticosteroids and other immune suppressing drugs, and patients who have such diseases as cancer or 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 can be taken to limit even the rare but measurable risk of infection associated with needling. Clean needle techniques are designed to limit patients’ exposure to autonomous and
cross-infections, and to limit the exposure of practitioners and their staff to infections which are part of any medical practice.

9. Broken Needle

The advent of the single-use disposable sterile acupuncture needle has significantly reduced the incidence of broken needles during acupuncture. Metals are made brittle by the heating and cooling associated with autoclave sterilization procedures, but now that needles are not reheated and not reused, the risk of broken needle is negligible. However, manufacturing errors may still allow for such events, so practitioners must know how to respond to a broken needle. Neither White (14) nor McPherson (15) report any broken needles during their prospective studies. Witt reports 2 broken needles out of 229,230 patients treated. (5)

A broken needle may occur when there are cracks or erosions to a needle’s shaft or handle junction; the needle is of poor quality; the patient has changed position to too great an extent; there is a muscle spasm; excessive force is used in manipulating the needle; the needle has been struck by an external force; or, when a bent needle has been rigidly withdrawn.

CCAOM Position Paper: Skin Preparation Prior to Needle Insertion

The administration of acupuncture should ensure the attainment of maximum benefit with the least possible harm. Acupuncture AEs include bleeding, bruising, needle site pain, (4) aggravation of symptoms, (5) and, rarely, such severe complications as local infections. (7) It is important to reduce the occurrence of these AEs.

There are no studies which compare skin preparation prior to acupuncture needle insertion with no skin preparation, however, studies on skin preparation before insulin injections for and vaccinations yield relevant information. According a 1960s study on diabetic patients by Dann (24) and Koivisto & Felig, (25) skin preparation with alcohol before injection reduces skin bacteria, but skin cleansing at injection sites is not necessary to prevent infection. Additional studies report also no increased infection risk if skin is not cleansed before injecting insulin. (26, 27, 28)

There is similar evidence from reports of infections following vaccination. In 2003, the World Health Organization reported, after a review of the literature, that if the skin is “clean” there is no need to swab an injection site, regardless of its location. (29) Similarly, UK Guidance on Best Practice in Vaccine Administration and the Royal College of Paediatrics and Child Health’s Position Statement on Injection Techniques (March 2002) agree that skin cleansing is not required before injection. (30, 31) The CDC (2002) states that alcohol, soap and water or chemical agents are not needed for preparation of the skin before vaccination, unless the skin is grossly contaminated or dirty. (32)
Some researchers recommend cleaning an injection site to minimize the risk of infection. (33, 34, 35) Many practitioners believe it follows best practice guidelines to clean skin before injection, and the NIH states “since the skin is the body’s first defense against infection, it must be cleansed thoroughly before a needle is inserted.” (35)

The organisms most often responsible for causing skin infections at medication injection sites are *Staphylococcus aureus*, *Streptococcus pyogenes*, and coryneform bacteria. (36) Occasionally, various non-tuberculous mycobacteria may also infect the skin. (36) *Staphylococcus aureus* is found on the skin, including the forehead and nostrils of both children and adults, as resident flora. (37, 38) These same organisms are those most commonly associated with skin infections related to acupuncture practices. (7)

Needles should not be inserted in skin that is inflamed or has lesions, because these conditions indicate a higher risk of infection. According to NIH guidelines, injections should not be given “if the skin is burned, hardened, inflamed, swollen, or damaged.” (35)

There is one case report of a patient who had acupuncture with no skin preparation, which caused a local muscle infection that ultimately led to septicemia. (10) Given the millions of acupuncture insertions that take place every year, a single incidence of infection following an intramuscular acupuncture procedure without skin preparation does not, in itself, resolve differing claims about the necessity of skin preparation.

The NIH, CDC, and WHO all agree that skin must be clean before any type of needle insertion is performed (29, 32), and that practitioners’ hands must be washed prior to needle insertion. There remains the question of how a patient’s skin should be prepared before acupuncture needle insertion.

Scientific evidence supporting the use of soap and water for skin cleansing is limited; however, the physical action of washing to mechanically remove transient flora has long been accepted as good practice. (40, 41, 42) Xu et al. (2013) state that “guidelines such as Clean Needle Technique must be followed in order to minimize acupuncture AEs.” (7)

Currently, the most common practice for cleaning a patient’s skin before injection is to use premedicated 70% alcohol swabs. (43) The perceived advantages of patient skin cleansing with an alcohol swab include a reduction in transient skin bacterial counts, and the fact that using a swab is less time-consuming than soap and water in a clinical setting. The perceived disadvantages of patient skin cleansing with an alcohol swab include the fact that alcohol is rendered inactive as a cleansing agent if skin is soiled with organic matter, (43) and the potential for pain if the skin is not allowed to dry prior to needle insertion. (44)

Some practitioners assert that chlorhexidine products should be used as skin cleansing agents because chlorhexidine may work better than alcohol in reducing microbial load on the skin. A recent meta-analysis says that the “perceived efficacy of chlorhexidine is often in fact based on evidence for the efficacy of the chlorhexidine/alcohol combination. The role of alcohol has
frequently been overlooked in evidence assessments.” (45) That is, alcohol may play as great a role as the chlorhexidine in the reduction of microflora.

The CCAOM’s Clean Needle Technique Manual (6th edition) states that skin should be cleaned with alcohol prior to needle insertion. In a July 2013 letter, the CDC says (46) “the procedures outlined in the CNT Manual are reasonable” regarding skin preparation.

CONCLUSIONS:

- The evidence suggests that both the practitioner’s hands and the patient’s skin at the acupuncture point need to be clean prior to the 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 skin cleansing where required. If a patient’s skin is soiled, it 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 cleansing 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.
- The CCAOM supports the position that the skin should be clean prior to needle insertion, but that skin cleansing immediately prior to needle insertion is not necessarily essential to prevent infections.

B. Moxibustion

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.

There have been few retrospective studies of the safety of direct and indirect moxibustion treatment. In 2010, Park et al. (47) reviewed the medical literature and provided an overview of AEs associated with moxibustion. Using results from clinical trials, they identify “rubefaction, blistering, itching sensations, discomfort due to smoke, general fatigue, stomach upsets, flare-
ups, headaches, and burns” as AEs. They conclude that practitioners should be prepared to deal with burns, allergic reactions, and infections as probable AEs of moxa therapies. In the 2013 report by Xu et al. (7) the primary AEs associated with moxibustion are bruising, burns, and cellulitis. In a 2014 review, the most common AEs of moxibustion are allergies, burns, infection, coughing, nausea, and vomiting. (48)

Prospective studies of moxibustion therapy alone are not available in the English literature. A 1999 Japanese study, (49) fails to differentiate between AEs associated with acupuncture needling and those specifically from moxibustion, concluding that “serious or severe AEs 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. (50) Burns from any therapeutic modality are more common in diabetic patients. (51)

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. (49)

Volatile substances such as borneol in the moxa smoke, or the smoke itself, may cause nausea or allergic reactions, but Mun JH et al. state “under normal operating conditions neither volatile nor carbon monoxide [associated with moxa smoke] would present a safety hazard.” (51) With proper ventilation, the toxicity of moxa smoke is probably minimal. (52, 53)

Effects of moxibustion on the chemical parameters of health are limited, suggesting that except for such AEs as burns, moxibustion is a relatively safe procedure. In a study published in 2011, researchers found that indirect moxibustion is generally considered safe. (54)

There is one case report of hepatitis which was inaccurately identified as being associated with moxa use in the medical literature. This report states 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.” (55)

Contraindications for moxibustion involve the sensitive areas of the body, such as the face, due to the possibility of burns with scarring, and getting smoke directly into the eyes or nose; the nipples and the genitals, due to sensitivity; and within the hair line, as hair can burn. O’Connor and Bensky in Acupuncture: A Comprehensive Text (56) reinforce the need to avoid the head and face for moxibustion by labeling the following points as contraindicated for this therapy:
Shangxing (DU-23), Chengqi (ST-1), Sibai (ST-2), Touwei (ST-8), Jingming (BL-1), Zanzhu (BL-2), Sizhukong (SJ-23), Heliao (LI-19), and Yingxiang (LI-20).

1. 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 patients who have conditions that cause the sensitivity of local nerves to be diminished, such as a neural injury, diabetes mellitus, or a pathology resulting in paralysis, because these patients 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, the practitioner should refer the patient to a physician.

Burns to the practitioner can also happen when proper precautions are not taken. Practitioners should create office practices that limit burns, and include these practices in their OSHA Hazardous Communication materials.

2. Infections

Infections associated with moxibustion are secondary AEs related to burns. 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 to determine if a referral to a physician is necessary.

3. Nausea or Other 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.

C. 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 practitioners carefully monitor TDP lamps when in use, Mechanical failure of the heat lamp itself may occur during treatment, allowing the arm and heating element to descend near or onto a 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 of heat therapies used in cancer treatment reports an AE called “thermal lesions.” (56) Heat can affect skin in a variety of ways, including biological and molecular changes, (57) although these effects appear minimal when heat therapies are applied intermittently in clinical practice. Significant AEs of heat lamps and other heat therapies are most likely limited to burns, the secondary effects of burns (infection), and the possibility of fire.

In one retrospective study of the frequency of burns from therapeutic modalities performed in Korea, hot packs are twice as likely to cause a burn as the application of moxibustion. Other heat therapies that are sources of burns in patient care are electric heating pads and radiant heat/heat lamps. (59)

D. Cupping

Cupping is a therapeutic procedure commonly used by AOM and other healthcare practitioners. Similar techniques are used throughout the world in traditional medicines. Cupping uses a partial vacuum to intentionally create therapeutic petechiae and ecchymosis in the dermis. There are three types of cupping, each with different safety profiles: fire cupping, suction cupping, and cupping after the use of a lancet for blood withdrawal.

One review study of the literature finds that “the diseases in which cupping was commonly employed included pain conditions, herpes zoster, cough or asthma.” (60) This review cites no AEs.

There are no prospective studies of the safety of cupping techniques. One small study (46) of such complications as hemorrhagic bullae, keloids, vasovagal syncope, and panniculitis concludes that AEs induced by cupping are extremely rare. Another report (62) states that skin lesions associated with cupping are likely to be misdiagnosed “as trauma or violence-related lesions.”
The 2013 report by Xu et al. (7) finds ten AEs associated with cupping. Most were minor, such as keloid scarring, burns, and bullae.

Individual case reports of AEs related to cupping include factitial panniculitis, (61) herpes simplex, (64) cervical epidural abscess, (65) and iron-deficiency anemia. (66) [The case for anemia associated with cupping is poorly reviewed and probably represents a misunderstanding of the cupping procedure.—Ed.] These case reports indicate that, while such AEs are rare, practitioners should always be aware of the possibility of AEs.

One review of the Chinese medical literature regarding cupping-associated AEs says they are similar to such acupuncture-related AEs as syncope. Other cupping-related AEs include localized itching following cupping. (67)

Cupping does not require sterile equipment as nothing enters or breaks the skin. Cups must be clean and disinfected, but need not be sterile. After use on a patient, cups must be cleaned of any lubricants or biological materials, disinfected in an appropriate moderate to high level disinfectant, rinsed with filtered or distilled water, and then stored in a closed container to avoid contamination from dust, dust mites, and other common contaminants. Some hospitals, integrated clinics, and other settings may set their own rules about cups and sterilization. (67) Practitioners are advised to discuss this with the appropriate administrator at each hospital or clinic.

**Cupping issues associated with special patient populations:**

**Psoriasis:** Two articles in the literature establish that it is possible to induce Köebner phenomenon in psoriasis patients. (155, 156) 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.

**Chemotherapy:** Because the intended therapeutic goal of chemotherapy for cancer is apoptosis, and because it is theoretically possible to interfere with this process through the cupping’s effects on the local circulation, it is recommended to avoid cupping for 48 hours before and 24 hours after chemotherapy.

**Clean Technique for Wet Cupping**

Practitioners must use gloves and should also utilize eye protection when blood is being expressed into a cup therapeutically. 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 (or traditional tree-edged needles), with a new lancet being
used for each puncture. Apply the cups and retain as needed for the desired effect. Allow the vacuum to be compromised, and then remove the cup. Clean the site of the punctures with an appropriate skin cleanser. Discard the extravasated blood in the biohazard trash. (52) The cup itself can be cleaned with soap and water and disinfected using a high-level disinfectant solution, or may be discarded in the biohazard trash.

Preventing Cupping AEs

**Burns**

Fire cupping carries with it a risk of burning the patient. The burning material must be placed in the deepest part of the cup, not near the rim, and removed prior to placing the cup on the patient’s skin.

- **Critical:** Never retain the burning material inside the cups when the cups are placed onto the skin.
- **Strongly Recommended:** Avoid the use of fire cupping on patients who have a decreased response to pain (e.g., those with diabetes or neuropathies).

**Extensive Bruising**

While petechiae and ecchymosis are expected after cupping, extensive bruising is rare. Patients with bleeding disorders, (54) and those taking anticoagulant medications, are at higher risk for such AEs. Cupping is contraindicated over any area where there is an active lesion.

- **Critical:** Practitioners must take a thorough history, including bleeding disorders and medication history, before applying cups.
- **Critical:** Do not cup over an active skin lesion.
- **Strongly Recommended:** Avoid wet cupping for patients currently taking anti-coagulant medications unless cleared for treatment by a physician.
- **Recommended:** Limit retention time to that of the physical tolerance of the patient.

**Infections**

Blood or fluid may express into cups. As cups are commonly used on multiple patients after they have been cleaned and disinfected, the risk of healthcare-associated infections (HAIs) is low but still present. To limit the risk of cross-contamination from cupping, this procedure is contraindicated where there is an active skin lesion. While there are studies on the use of cupping for herpes zoster and other skin lesions, (55) practitioners should be specifically trained in the use of cupping for active skin lesions before attempting this kind of care.
• Critical: Practitioners must wash hands before starting the procedure and again after removing gloves.
• Critical: Personal protective equipment (PPE) - wear gloves at all times when blood or OPIM may be present when cupping (wet cupping, cupping after needling).
• Critical: Cups used for suction or fire cupping should be cleaned immediately after use and then disinfected with a registered CDC/OSHA approved disinfectant before reuse.
• Strongly Recommended: Lancets used for wet cupping should be used only once, then discarded in a proper sharps container.
• Strongly Recommended: Cups used for wet cupping should be cleaned immediately after use, sterilized or disinfected with a high-grade disinfectant solution, then rinsed with water and dried before reuse.
• Strongly Recommended: When cups are obviously contaminated with blood or OPIM, wear gloves and eye protection when releasing pressure, and when disposing of cup contents.
• Recommended: Practitioners should consider disposing of cups used for wet cupping in the biohazard trash after use.

It is strongly recommended that if bleeding does occur during cupping, practitioners take the following steps:

1. Gather gloves and cleaning materials.
2. Put on gloves. The use of eye protection, such as goggles, is recommended.
3. Remove the cups, taking care to prevent body fluid from spreading or splashing.
4. If necessary, stop the bleeding through the use of appropriate pressure, using cotton or sterile gauze.
5. Clean up any bleeding that has occurred.
6. Immediately isolate the cups.
7. Handle and dispose of all materials used in the cleaning process as biohazardous waste.
8. Clean the cups of any biological material or lubricant using soap and water, then disinfect the cups using a high-level disinfectant solution. Cups may be rinsed in filtered water after disinfecting to remove any residual disinfectant solution. Cups should then be stored in a closed container.

E. Bleeding

In AOM, the bleeding of specific points ("blood-letting") may be used to clear heat and reduce pain or itching. There is only minimal information in the English literature about therapeutic bleeding, and no overviews of safety or AEs. There have been a few case studies and one limited review of the use of lancets for drawing blood from the heels of infants for lab testing, (67) which points out that lancing the heel in infants can lead to localized infections.
A review of the Medline and Cochrane databases with the terms "blood-letting puncture" and "needle pricking" yielded only limited case studies and studies in Chinese, many of which combine bleeding with EA, acupuncture, or cupping. No AEs were reported in any of the studies available in English.

A review of the literature regarding the use of lancets for capillary blood collection also produced limited data. Studies focus on limiting pain and producing enough blood for proper testing, not on any AEs. (70) 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 says that an identical HBV viral strain was discovered among patients who had procedures performed with the same multi-patient lancing device. (71) Devices that hold lancets for uses such as blood sugar monitoring need be new for each new patient. Since blood droplets may collect within a finger stick or lancing device, each new puncture presents a risk for cross-infection. They cannot be used for multiple patients even when the lancets themselves are changed for each new puncture.

According to the CDC, “finger stick 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

Preventing Common AEs of Bleeding

Other than local pain, bleeding and bruising, there are no reported common AEs associated with bleeding techniques. While no AEs associated with bleeding treatments are reported in the literature, this technique is not without risk. Because lancets break the skin surface, blood and OPIM are present on the lancets and may be a source of needle stick injuries. Practitioners must take care to limit the risk of needle stick injuries. Retractable lancets may allow bleeding techniques to be practiced with reduced risk. Retractable devices need to be new for each new patient to prevent cross-contamination with blood borne pathogens.

- Critical: Personal protective equipment (PPE) - wear gloves at all times as blood and OPIM will be present.
- Critical: Lancets should be used only once then discarded in a proper sharps container.
- Critical: Lancing devices must be limited in use to a single 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 active skin lesions.
• Recommended: Utilize eye protection, such as goggles, when performing bleeding techniques.
• Recommended: Utilize lancets engineered to retract after use to significantly reduce the risk of needle stick injuries.

III. Healthcare-Associated Infections

It is essential that practitioners understand the mechanisms of disease transmission and know the characteristics of infectious diseases, particularly blood borne pathogens such as hepatitis and HIV, skin infections from *Staphylococcus* and *Streptococcus*, and other common healthcare-associated infections (HAIs). Knowledge of the mechanisms and characteristics of these diseases underscores the need to use clean needle technique for the protection of patients, practitioners, and staff. Acupuncturists must always consider the safety of patients, clinicians, and other members of the clinic staff, and adherence to clean needle technique will reduce the risk of the spread of blood borne and surface pathogens.

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.

A. Blood borne Pathogens

1. 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 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. (72)

The CDC identifies food transmission and exposure in daycare settings the as top exposure risks in the U.S. (See graph below.)
Unlike hepatitis B (HBV) or C (HCV), HAV infection causes an 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 reinfected.

In the United States, hepatitis A has occurred in large nationwide epidemics approximately every 10 years, with the last increase in cases in 1989. (73) The HAV infection rate has declined steadily since its last peak in 1995, when there were 356,000 cases. (See the CDC graph of reported cases below.) 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 due to routine HAV vaccination beginning in 1999. The incidence of hepatitis A is now similar in all age groups. (74) 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 CDC does not recommend routine HAV vaccination for healthcare workers since they are not at increased risk. (75) Established infection control precautions, particularly handwashing, will prevent transmission.
2. 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 people aged 6 years or older, 0.27% had chronic HBV infection (corresponding to approximately 704,000 people nationwide). (76, 77)

In adults, ongoing HBV transmission occurs primarily among unvaccinated people with behavioral risks for HBV transmission (e.g., heterosexuals with multiple sex partners, injection-drug users (IDUs), men who have sex with men (MSM), and among household contacts and sex partners of people with chronic HBV infection. (78)

An estimated 700,000-1.4 million people are estimated to be infected with HBV. (79) In the U.S., the rate of new infections has declined steadily since 2002. (See graph below.)
Hepatitis B virus (HBV, serum hepatitis, or long-incubation hepatitis) is one of the blood borne pathogens presenting a significant risk of infection in the acupuncture clinic environment. HBV is the second subtype 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 people infected as infants or young children, rates of new infections and acute disease are highest in adults. People with chronic disease then serve as a reservoir for continuing transmission of HBV. (80) Healthcare personnel who have received the HBV vaccine, and developed immunity to the virus are at virtually no risk for HBV infection. (81)

a. Transmission of HBV

HBV is contagious for those susceptible. It 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. An 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 such long-term complications of HBV 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.

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. HCWs such as acupuncturists, physicians, dentists, nurses, blood bank workers, paramedical personnel, and laboratory staff all 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 HBV is associated with contact with infected body fluids such as blood. The risk of a healthcare worker developing hepatitis B following exposure to HBV through exposure to contaminated blood is 22%-31%. The risk of developing serologic evidence of infection is 37%-62%. (82)

One of the most common modes of HBV transmission in a healthcare setting is an unintentional injury of an HCW from a needle stick, or a cut by a contaminated instrument. (See graph below.)
The rate of HBV transmission to susceptible HCWs ranges from 6% to 30% after a single needle stick exposure to an HBV-infected patient, but is virtually zero if that HCW has been immunized against HBV. (82) 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 infections 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, including vaccination, to eliminate HBV transmission in the United States. In 2005 it was noted in follow-up surveillance that 75% of HCWs had been vaccinated. (83)

Other groups at risk include those who live in crowded or unsanitary conditions (including prisoners and certain immigrant populations); have multiple sexual contacts; are 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 patients or workers 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. (80)

b. Exposure to HBV

HBV is transmitted through percutaneous or parenteral contact with infected blood or body fluids, and by sexual intercourse. HBV is only spread when blood, semen or other body fluids (OPIM) enter the body of another person through an orifice, a break in the skin or through mucous 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 intact skin. Some break in this barrier, which can be minimal and insignificant, is required for transmission. (82, 85)

HCWs who are not immune are at a higher risk for HBV infection than the general public due to possible occupational exposure to blood, blood products, and 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 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 recommends that all personnel working in such areas should 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. For an HCW, multiple doses of hepatitis B immune globulin, or the hepatitis B vaccine alone, is 70%-75% effective in preventing sequelae of HBV exposure. (84)

c. HBV Vaccination

A hepatitis B vaccine 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. As there
are a low number of non-responders even after the second series, no further vaccine is recommended for them. 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 HCWs be vaccinated against HBV. OSHA requires all employers to offer HBV vaccination to personnel performing invasive procedures or who clean contaminated equipment. (83) In October 1997, the Advisory Committee on Immunization Practices expanded its hepatitis B vaccination recommendations to include all children aged 0-18 years.

d. HBV Infection Process

The incubation period for HBV is 50 to 180 days. (86) During this period, the infectious virus appears in the blood, and it may appear in the feces and semen. The infection may be spread to other people even though no symptoms are present. Early signs of HBV infection include such mild flu-like symptoms as fever (in 60% of cases), general malaise, chills, nausea, joint pain, rash, diarrhea, abdominal pain, and the insidious onset of anorexia. Typically, these symptoms last from two to six weeks, and are frequently followed by a period of extreme fatigue and depression that can last for several months.

Practitioners should be aware that some individuals infected with the virus only develop mild symptoms or are asymptomatic. Approximately 30% of those infected have no signs or symptoms. 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 3 months or more after symptoms have subsided. Up to 90% of infants who acquire HBV infection from their mothers at birth become chronically infected. The older a person is when infected, the lower the rate of chronic infection. 30%–50% of infections in 1-5 year old children become chronic; among adults, approximately 5% of all acute HBV infections progress to a chronic stage. (85)

If a practitioner becomes infected with HBV, he or she may unknowingly transmit HBV to patients or office staff via 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 transmission among practitioners and patients. A practitioner with acute HBV should not practice during its infectious period. If a provider is found to be infected, he or she should consult with a physician before going back to work. (82)
e. Treatment of HBV Exposure

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.

In the event of exposure, multiple doses of hepatitis B immune globulin, or the hepatitis B vaccine alone is 70%-75% effective. (82-84) Combining these two treatments increases efficacy.

3. Hepatitis C (HCV)

Hepatitis C virus (HCV) infection is the most common chronic blood borne viral infection in the U.S. First identified in 1988, HCV is the causative agent for what was formerly known as non-A non-B hepatitis. HCV 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. In the US there are approximately 3 million people with chronic HCV infection, mostly in those born between 1945-1965 (“baby boomers”).

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. (87)

HCV may be contracted through sexual contact, but the risk of sexually transmitted HCV is believed to be very low. This risk increases for those who have multiple sex partners, have a sexually transmitted disease, engage in “rough sex,” or who are infected with HIV. (88)

In 2012, there were an estimated 2.7–3.9 million people living with HCV infection in the U.S. (88) However, the official number of reported Hepatitis C cases is much lower. Many people who are infected never have symptoms, and therefore never come to the attention of medical or public health officials. (88)
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 declining, there has been an uptick in the number of reported cases in the U.S., which is possibly due to better testing. (See graph below.)

![Figure 4.1. Reported number of acute hepatitis C cases — United States, 2000–2012](http://www.cdc.gov/hepatitis/Statistics/2012Surveillance/Slide4.1.htm)

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 (0.3%) and lower than the risk of seroconversion after percutaneous occupational exposure to HBV seropositive fluids (22-33%). (82)

### a. 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 coinfected with HIV (30-50%). (89) Other risks of HCV infection include transfusions and transplants before 1992, when the screening that is currently in place took effect; 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 perinatally 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, exposure to blood, such procedures 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. (See graph below.)


While the risk of occupational exposure leading to HCV seroconversion may be limited to needles with a lumen, it is important to note, that as with HIV and HBV, exposure following a needle stick 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. (91, 92)

b. Consequences of HCV Infection
About 15-25% of those infected with HCV clear it without further problems. 75-85% will develop chronic infection, and approximately 60-70% will go on to develop chronic hepatitis. A chronic infection is the presence of the agent, HCV, and a patient’s immune response. Chronic hepatitis is an inflammation of the liver that may be caused by long-standing infection. While they often go together, they are defined differently, and are not interchangeable.

Cirrhosis of the liver occurs in at least 20% of HCV patients over a 10-20 year period; 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. Drug treatment is an important adjunct to care for many people 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 20-90 days, with most cases occurring 5 to 10 weeks after exposure. Because up to 70% of patients with acute hepatitis C (HCV) have no specific symptoms and instead only exhibit flu-like symptoms, the exact incubation period is hard to pin down. The CDC references various journal articles that offer incubation periods as short as 6 weeks and as long as 6 months. The period of communicability extends from one week after exposure to HCV through to the chronic stage. The onset is insidious and accompanied by anorexia, nausea, vomiting, and jaundice. HCV’s course is similar to that of 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 the condition of the liver, including the extent to which it is scarred. Treatment may last from 24 weeks to 2 years. Treatment currently consists of newer drug cocktails utilizing SOVALDI® (sofosbuvir) and Harvoni (ledipasvir/sofosbuvir).

4. Hepatitis D

Hepatitis D, also known as "delta hepatitis," is a serious liver disease caused by infection with the hepatitis D virus (HDV), which is an RNA virus structurally unrelated to the hepatitis A, B, or C viruses. Hepatitis D, which can be acute or chronic, is uncommon in the United States. HDV is an incomplete virus that requires the helper function of HBV to replicate and only occurs among people who are infected with the Hepatitis B virus (HBV). HDV is transmitted through percutaneous or mucosal contact with infectious blood, and can be acquired as either as a coinfection with HBV, or as a superinfection in people with HBV infection. There is no vaccine for hepatitis D, but it can be prevented in people who are not already HBV-infected by hepatitis B vaccination.
5. Human Immunodeficiency Virus (HIV/AIDS)

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 Acquired Immunodeficiency 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 global public health issue. Mathers and Loncar estimate that, over the 25 year period from 2006 to 2030, between 89 million and 117 million people will die of HIV/AIDS. (96)

The CDC reports that in 2012, an estimated 47,989 people were diagnosed with HIV infection in the U.S. (98)

**Estimated New HIV Infections in the United States, 2010, for the Most Affected Subpopulations**

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>White MSM</td>
<td>11,200</td>
<td></td>
</tr>
<tr>
<td>Black MSM</td>
<td>10,600</td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino MSM</td>
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<td></td>
</tr>
<tr>
<td>Black Heterosexual Women</td>
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<tr>
<td>Black Heterosexual Men</td>
<td>2,900</td>
<td></td>
</tr>
<tr>
<td>White Heterosexual Women</td>
<td>1,300</td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>Black Male IDUs</td>
<td>1,100</td>
<td></td>
</tr>
</tbody>
</table>

*Subpopulations representing 2% or less are not reflected in this chart. Abbreviations: MSM, men who have sex with men; IDU, injection drug user

http://www.cdc.gov/hiv/statistics/basics/ataglance.html

To date, there are no confirmed cases of occupational HIV transmission following an accidental acupuncture-related needle stick in the United States. In one 2003 case report from Thailand, acupuncture is the only known risk for the seroconversion of a previously HIV seronegative 60-year-old female. (99)

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. HIV-1 is the more virulent virus and is more easily transmitted. It is the cause of the majority of HIV infections globally. 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. HIV-2 is predominantly found in West Africa. Cases are seen infrequently in the U.S. and usually have some association with West Africa. (100)

a. 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, the probability of infection is high, especially for HBV. Prospective studies of HCWs have estimated that the average risk for HIV transmission after a percutaneous exposure is approximately 0.3%, the risk of HBV transmission is up to 30%, and the risk of HCV transmission is approximately 1.8%. (101) The most common mode of HIV transmission is percutaneous exposure that occurs from contaminated instruments (mostly from suturing and needle sticks), 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 a particular healthcare setting, depending on the specific risks involved. (102)

HIV is not 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. It includes shaking hands, touching, hugging, holding hands, or kissing. HIV cannot be transmitted through the use of common objects.

b. Risk of HIV Transmission through Invasive Procedures

In general, the risk for HIV transmission between patients and HCWs is very low. (96, 99) Adherence to CDC-recommended procedures for Standard Precautions reduces this risk significantly. Practitioners should prevent direct blood contact and carry out proper disinfection procedures, as described at the website: http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-gl-standard-precautions.html

c. 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 were infected with HIV yearly. By the early 1990s, the infection rate dropped to about 40,000. As of 2012, more than 1.2 million people in the United States are
living with HIV infection, and almost 1 in 7 (14%) are unaware of their infection. (98) 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 (MSM), injection drug users (IDUs), sex workers, and transfusion recipients. Today, HIV infection is no longer limited to these initial populations. Recently, more cases are associated with unprotected sex between mixed-sex couples. Due to successful protocols for perinatal cases, newborns are acquiring HIV from their mothers far 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) is in danger of contracting HIV.

HIV seroconversion in HCWs is rare, but, as always, Standard Precautions must be maintained. In the CDC’s investigation of HIV-positive HCWs, who had no other identified risk factors, from 1981-2010, 57 had documented seroconversion to HIV following occupational exposures, including 48 that were due to puncture or cut injuries. Additionally, 49 HCWs were exposed to HIV-infected blood; 3 to concentrated virus in a laboratory; 1 to visibly bloody fluid; and 4 to an unspecified fluid. There are an additional 143 possible occupationally-acquired cases of HIV during this period, but these cases were not documented. The total numbers of documented and possible cases in this report are likely to be low due to the nature of pre-1991 non-standardized, voluntary reporting of HCWs exposed to HIV on the job. (103)

There remains a significant risk of HIV infection in the healthcare workplace. In 1996, there were 786,885 percutaneous and mucocutaneous exposures to potentially infectious substances among HCWs in the United States. (104)

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 body 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?”)

d. Testing for HIV/AIDS

Voluntary testing is encouraged. Rapid tests for HIV antibodies can produce results within 30 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. (105) Anyone falling into high-risk categories should continue to be tested regularly as part of routine medical care. Testing is especially important for those in the following categories:

1. People in professions with a high risk of exposure.
2. People 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 intravenously injected drugs.
7. The 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.

e. Reporting of HIV/AIDS

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.

f. HIV Infection Process

HIV targets several cell types, including the CD4 (T4) lymphocyte, which interrupts the cell-mediated response to antigens. 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.
Untreated HIV causes progressive damage to the immune system over a long period, making an individual vulnerable to a host of infections and malignancies. The disease known as Acquired Immunodeficiency Syndrome (AIDS) is the final stage of HIV infection. AIDS is diagnosed when an HIV patient has an absolute CD4 count of less than 200 cells per microliter; or one or more of such AIDS-defining conditions as Pneumocystis carinii pneumonia, Cryptosporidiosis, or Kaposi’s sarcoma. (106)

HIV infection 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 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.

Clinical presentations of AIDS patients vary. 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.

It is not presently known why some people infected with HIV 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, it can be managed as a chronic condition. Today there are many HIV-infected individuals living very long lives. (107)
g. Treatment of HIV

AIDS represents the end stage of the clinical spectrum of HIV infection. 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 its opportunistic infections.

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

h. Additional Risks to Healthcare Workers (HCWs)

An additional risk to practitioners working with people 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. Appropriate infection control precautions should be taken, and may include masks in case of respiratory infection and gloves in case of skin lesions. It is imperative to assume any patient may be HIV-infected and to use Standard Precautions with all patients.

B. Non-Blood borne Pathogens

Healthcare-associated infections (HAIs) are infections that patients develop during the course of receiving treatment for other conditions. They can happen following treatment in healthcare facilities, including hospitals, outpatient centers, and community clinics. HAIs 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.

1. Tuberculosis

Tuberculosis (TB) is caused by the bacterium *Mycobacterium tuberculosis*, an acid-fast bacterium with a waxy coat which is transmitted through the air. *M. tuberculosis* has a long incubation period of up to 12 weeks. (108, 109)

In 2013, a total of 9,588 new TB cases were reported in the United States, with an incidence rate of 3.0 cases per 100,000 population, a decrease of 4.2% from 2012. (110) Both the number of TB cases reported and the case rate decreased; this represents a 3.1% and 3.8% decline,
respectively, compared to 2009. The number of reported TB cases in 2012 was the lowest recorded since national reporting began in 1953. (110)


While TB infection rates are in decline in the United States, TB remains a significant source of risk in the healthcare environment. Jensen et al. (66) list the following populations who are especially at risk for TB:

- Foreign-born people, 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 such high-risk congregate settings as correctional facilities, long-term care facilities (LTCFs), and homeless shelters.

- HCWs who serve patients who are at high risk.

- HCWs who have had 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 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.


People who are infected with TB 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; are infants or children 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 MDR TB cases increased slightly from 1.2% (86 cases) in 2012 to 1.4% (95 cases) in 2013. (111, 112)
While most strains of *M. tuberculosis* can be treated by antitubercular antibiotics, the treatment takes nine months to complete; in the event that 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. You should have an annual skin test for TB. This test should be repeated after two weeks if your 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 (Bacillus 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 acupuncturist’s practice location, there is one case of tuberculosis being caused by an illegal or unqualified acupuncturist, (113) highlighting the need to understand and identify this disease.

Transmission of *M. tuberculosis* is a recognized risk to patients and HCWs. 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 who have not been placed in tuberculosis isolation. Transmission of *M. tuberculosis* in healthcare settings has been associated with close contact with people who have infectious tuberculosis. (114)

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 blood borne pathogens, and other appropriate risk management techniques, prevent harm to the practitioner, his or her family members, and the public. An AE, such as a needle stick incident leading to infection, may result in harm to a practitioner or patient’s health; potential financial harm due to loss of work; a lawsuit if a coworker or patient is harmed; or administrative
sanction by a licensing board. Safe practice remains the most important obligation for the acupuncturist. Clean needle technique is a vital part of safe practice for the acupuncturist.

2. Skin Infections: Staph and Strep

Prospective and retrospective studies of acupuncture safety point to a small number of localized skin infections occurring as a result of acupuncture. (6, 7)

Common resident bacteria of the skin include the *Staphylococcus* and *Streptococcus* species. Impetigo and other localized skin infections can occur when a break in the skin allows Staph or Strep to enter the dermis or lower structures. (115)

   a. *Staphylococcus*

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 bacteria on the skin is passed into the body through the insertion of a needle into the skin. (116)

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. (117)

*Staphylococcus aureus* accounts for more than half of the reported cases of acupuncture-related bacterial infections of the skin. (118)

Individual case reports of Staph infections after acupuncture include cases of pericardial abscess, (119) necrotizing fasciitis, (120) bacteremia, (121) and spinal subdural empyema. (122)

The prevention of Staph infections includes such standard practices as handwashing, and avoiding needling or other procedures in areas with active skin lesions.

   b. Methicillin-Resistant *Staphylococcus aureus* (MRSA)

The bacterium *Staphylococcus aureus* is a gram-positive, coagulase-positive aerobic coccus associated with wounds and other infections. One strain of *S. aureus* is resistant to the antibiotic methicillin. It is known as methicillin-resistant *Staphylococcus aureus*, or MRSA, and it has become a significant source of antibiotic-resistant infections. (123, 124) MRSA is spread by skin-to-skin contact and can be easily transmitted from patients to healthcare providers,
staff, and other patients. Between 25% and 30% of the population may be carriers of MRSA. (125) While the majority of MRSA infections appear to be nosocomial (infections acquired from a healthcare setting), 12% are community-acquired. (124)

**Prevention of MRSA**

It is imperative to prevent the spread of MRSA to patients and co-workers. Good prevention strategies include the following: (125, 126)

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. Avoiding contact with draining wounds, pimple-like lesions, or other skin lesions that may be a site of infection.
5. Meticulous use of suitable disinfectants. This includes disinfecting treatment tables and other surfaces that come in contact with patient skin between each and every patient treatment.
6. Referral of patients that may be infected to a physician for appropriate treatment.

MRSA has been reported after acupuncture treatments. It may cause significant damage. (7, 127) In one case study, the transmission of MRSA was clearly from practitioner to patient. (128) There are significant risks associated with treating a patient who 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 a practitioner has active skin lesions that have not been assessed by a medical professional. An assessment of any active skin lesions in either a patient or a practitioner should be made as soon as possible. It is appropriate to delay AOM treatment until such an assessment is made and antibiotic therapy initiated, if necessary.

The use of clean needle technique, including handwashing, single-use disposable sterile needles, and strict avoidance of the use of needles for which the point or shaft of the needle has come in contact with the practitioner’s skin or other non-sterile objects, is needed to prevent the spread of MRSA in the healthcare setting.
c. *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 noses or throats of people who are infected, or through contact with infected wounds or sores on the skin. (129)

Strep A may cause impetigo or other skin infections. Pyogenic skin infections associated with acupuncture may be Strep infections. While rare (approximately 50 cases reported globally in the 1970s and 1980s), (130) Strep infections may occur as a result of acupuncture.

The prevention of Strep infections involves standard practices of handwashing and avoiding needling or other procedures in areas with active skin lesions. (131)

3. **Mycobacterium Other Than Tuberculosis**

(*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 people with various chronic lung diseases. (132) All MOTT infections have similar life cycles.

Mycobacterium other than tuberculosis (MOTT), including *Mycobacterium abscessus*, *Mycobacterium fortuitum*, and *Mycobacterium haemophilum*, is of special significance to acupuncturists. There have been a number of reports of AOM-associated MOTT infections. The recognition and management of MOTT diseases are in the domain of the dermatologist. (132) MOTT are slow-growing bacteria that can cause disease in both immunocompetent and immunocompromised patients. The most common clinical presentation of MOTT infection is the appearance of suppurative and ulcerated skin nodules. (133)

MOTT is widely distributed in the environment, particularly in wet soil, marshland, streams, rivers, and estuaries. (134)

Acupuncture-related MOTT infections are “probably associated with the inadequate sterilization of the needles or the puncture site,” according to Guevara-Patiño et al. (135) MOTT infections are probably not associated with acupuncture when the practitioner follows all critical components of the CNT protocols. It is also likely that some of these infections are caused by contact with dirt carried in by patients and then left behind on towels used for hot
packs, treatment table linens, or any other cloth that is not changed after each patient visit. (7, 135-139)

Prevention of mycobacterium other than tuberculosis (MOTT):

- Appropriate handwashing and the use of alcohol-based hand cleansers.
- Conscientious use of CNT procedures.
- Proper handling of potentially contaminated materials such as sharps and disposable supplies such as cotton and gauze.
- Diligent use of appropriate disinfectants for the treatment room and treatment tables.
- Referral of patients that may be infected to a physician for appropriate treatment.

4. **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 an infection on the hands of healthcare personnel. 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.

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. (140-143)

Acupuncture and cupping may also be associated with spreading HSV if Standard Precautions are not taken. (143)

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)
5. 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. (146)

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. (147) 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. (148-149) 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: (146)

- 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.

Summary of Prevention of Disease Transmission in AOM Practice Locations

A. Basic Critical Principles

- Follow clean technique for acupuncture and 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, and after contact with any bodily fluids or OPIM
• Always establish a clean field to ensure the cleanliness of the practitioner’s and patient’s skin, and the sterility of the needle shaft 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

B. Preventing Patient-to-Patient Cross-Infections
• 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 (between patient visits) and treatment room surfaces (daily)
• 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 infection.

C. Preventing Patient-to-Practitioner Cross-Infections
• Always immediately isolate used sharps in proper containers
• Avoid touching the shaft or tip of a used needle or other used sharp
• Use a dry cotton ball or gauze to ‘close the point.’ Never use a bare finger to cover the skin where a needle has been removed.
• Keep all skin breaks on practitioners’ hands covered
• Consider vaccination against Hepatitis B

D. Preventing Practitioner-to-Patient Cross-Infections
• Handwashing is critical
• Avoid touching the shaft of a needle before insertion
• Avoid all patient contact if you have an overt 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

E. 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 recommended skin preparation
• Utilizing sterile needles and other devices that enter the skin, and storing them properly
• Clean technique
• Careful management and disposal of used needles and other equipment
• Maintain a clean working environment

INFECTIONOUS WASTE DISPOSAL

<table>
<thead>
<tr>
<th>SHARPS: DISPOSE IN RIGID MARKED SHARPS CONTAINER</th>
<th>INFECTIOUS WASTE: DISPOSE IN REG BAGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needles</td>
<td>Items soaked with blood</td>
</tr>
<tr>
<td>Syringes</td>
<td>Items which would release blood or OPIM* if compressed (soaked cotton balls or gauze)</td>
</tr>
<tr>
<td>Lancets</td>
<td>Items which are caked with dried blood or OPIM* which are capable of releasing these materials during handling</td>
</tr>
<tr>
<td>Scalpels</td>
<td>Coagulated blood removed from cups after wet cupping procedures</td>
</tr>
<tr>
<td>Plum blossom tools</td>
<td></td>
</tr>
<tr>
<td>Broken glass with blood (blood tubes, wet, broken cups)</td>
<td></td>
</tr>
</tbody>
</table>

*Other Potentially Infectious Materials (OPIM) Include:

1. The following body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any other body fluid that is
visibly contaminated with blood such as saliva or vomitus and all body fluids in situations where it is difficult or impossible to differentiate between body fluids such as in an emergency response.

2. Any unfixed tissue or organ (other than intact skin) from a human (living or dead).

3. HIV-containing cell or tissue cultures, organ cultures and HIV or HBV-containing culture medium or other solutions; and blood, organs or other tissues from experimental animals infected with HIV and HBV.

IV. Handwashing

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

The CDC and WHO 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.jointcommission.org/assets/1/18/hh_monograph.pdf](http://www.jointcommission.org/assets/1/18/hh_monograph.pdf)
- [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm](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.

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 the proper amount of antibacterial soap 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 disposable towel to turn off the faucet, not your clean hands

The CDC recommends handwashing under the following circumstances:

1. When hands are visibly dirty or are visibly soiled with blood or other body fluids, wash hands with an antimicrobial soap and water

2. If hands are not visibly soiled, practitioners may use either an alcohol-based hand rub or soap and water for routine decontamination of hands in all other 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, non-intact 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

8. Before eating and after using a restroom, wash hands with an antimicrobial 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 rub. An alcohol-based hand rub can decontaminate hands in less than 30 seconds, without the use of running water, soap, and hand drying.
Studies have shown that clinicians find alcohol-based hand rubs convenient, accessible, and less irritating to the skin. (151) The CDC has also accepted the use of antiseptic hand cleansers or towelettes except when circumstances require the use of soap and water. (152)

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 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.

V. 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. ([http://www.cdc.gov/HAI/prevent/sd_medicalDevices.html](http://www.cdc.gov/HAI/prevent/sd_medicalDevices.html))

**Safety Guidelines for Disinfecting Reusable Medical Equipment**

<table>
<thead>
<tr>
<th>Sterility Category of Equipment:</th>
<th>Acupuncture Practice Examples</th>
<th>Disinfectant Level Required before Reuse</th>
<th>Disinfecting Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Critical</td>
<td>BP cuff, Stethoscope, e-stim clips.</td>
<td>Low or intermediate disinfecting agents acceptable.</td>
<td>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.</td>
</tr>
<tr>
<td>Cups or gua sha tools used over intact skin.</td>
<td>Intermediate disinfecting agents required.</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Sterility Category of Equipment:</td>
<td>Acupuncture Practice Examples</td>
<td>Disinfectant Level Required before Reuse</td>
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</tr>
<tr>
<td>----------------------------------</td>
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</tr>
<tr>
<td>Semi-Critical</td>
<td>All cups used for wet cupping; cups and gua sha spoons used on non-intact skin.</td>
<td>Sterilize before reuse; or high-level disinfectant required.</td>
<td>Step 1: Removal of all biological and foreign material (e.g., soil, organic material, skin cells, lubricants) from objects using soap and water. \nStep 2: \nOption 1: Autoclave. \nOption 2: Soak in high-level disinfectant (e.g., Sporox, Sterrad, Acecide, Endospore, Peract) as per product label instructions.</td>
</tr>
<tr>
<td>Reusable Critical</td>
<td>Equipment that breaks the skin or enters the vascular system; <strong>No AOM equipment falls in this category.</strong></td>
<td>Must be sterilized.</td>
<td>Example: autoclave.</td>
</tr>
</tbody>
</table>

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, Aceicide, Endospore, or Peract), or autoclaved.

Please note that bleach and water solutions are no longer acceptable for use for disinfecting medical equipment. Commercial products, registered with the FDA (for medical tools) or EPA (for surface disinfection) are the only acceptable disinfecting solutions in healthcare facilities.

**VI. Cleaning and Disinfecting Environmental Surfaces in Healthcare Facilities**

- Clean treatment tables and chairs, and areas used as clean fields, between every patient visit and again at the end of every “shift” or work day.
- 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. 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.
VII. Basic Legal Standards

This section addresses the federal and 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 a risk or injury to 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 that causes injury, loss, or a 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 AOM medical practice, 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. Exposure Control Plan

Employers of HCWs are encouraged to participate in the task of controlling risks in the workplace, including the spread of such blood borne pathogens as HBV/HIV, by disseminating preventive information in the workplace through a detailed exposure control plan (ECP). Those employers who have a risk of occupational exposure to their employees must develop such a plan designed to eliminate or minimize employee exposure incidence.

All employees in a clinical practice must be considered in an ECP. HCWs, and other staff members including receptionists or custodians, may be exposed to blood borne pathogens during such tasks as pulling needles, emptying the trash, and assisting patients in dressing and undressing. 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 blood borne pathogens (BBP) as well as a Hazardous Communication Plan for chemical exposures. (153)

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 where 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 work site 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 blood borne 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, which is reviewed as part of the annual program evaluation and maintained for at least five years following the end of the calendar year covered and must include the following:

   • Type and brand of device involved in the needle stick injury
   • Department or work area involved
   • Explanation of how the incident occurred
   • NO employee identification
   • How the office changed policy based on the incident (if applicable)

e. HEPATITIS B VACCINE DECLINATION STATEMENT/POLICY (maintain for the duration of employment plus 5 years)

Sample ECPs for BBP can be found here:


OSHA documents relating to ECPs include:


Practitioners and office managers should keep in mind that your BBP/Exposure Control Plan cannot just be created and then kept in a drawer in the office. The BBP requires annual review by all those employees who are at risk of exposure. At a minimum, the plan should be updated annually based on the experiences of the staff. (For instance, if an incident occurs and the forms do not cover the specific
incident, or if the staff believes the plan should be changed to incorporate a type of incident, the plan must be updated and the new version of the plan must be reviewed by all involved.

Updates to the BBP ECP should also include changes in tasks or positions as needed.

Keep in mind that the BBP ECP must be accessible to all staff when they are working on at-risk tasks. It cannot be kept in a locked drawer in a manager’s office. A copy should be accessible in all work areas.

A note about the annual training for employees:

Many offices choose to use a standard video or online training webinar for their BBP training. While this will meet some of the requirements for training, offices must also offer an opportunity for interactive questions by employees and there must also be training specific to the office or clinic where employees work.

A note about recordkeeping:

The record keeping requirements above are based on OSHA regulations. Your individual state may require additional recordkeeping. Bear in mind that state OSHA regulations trump federal rules.

High-Risk Patients

All patients should be treated the same by following Standard Precautions.

Summary of CDC’s Standard Precaution Recommendations

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.

B. Reporting Communicable Diseases and Abuse

State laws vary with regard to requirements for healthcare providers to report known or suspected communicable diseases, child, or elder abuse. You should be aware of the law in your state.

C. Informed Consent
It is generally recognized that the relationship between a healthcare practitioner and his or her patient comes into being because of the patient’s need and trust in the skill, learning, and experience of the practitioner. A physician may not, under ordinary circumstances, treat a patient without his or her consent.

A full legal explanation of informed consent is beyond the scope of this course. 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 a patient or a person authorized by law to consent on his or her 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 less 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:

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 of signing the form.

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, direct moxibustion, and cupping or *gua sha*, which may leave petechiae/bruises.

Practitioners can use the information contained in this course to develop informed consent forms for acupuncture, moxibustion and heat therapies. Practitioners should also review the risks associated with other AOM practices, and develop necessary consent procedures for all interventions used at their clinics.
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Acupuncture:

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152. 29 CFR 1910.1030(d)(2)(iv), which specifies that “when provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.”


