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Safety In Acupuncture #4

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Introduction

Preventable medical errors is one of the biggest concerns presently affecting US healthcare. Preventable Medical Errors include such things as adverse events (AEs), adverse drug events (ADEs), fatal drug events, misdiagnosis, incorrect treatment or surgery, failure to treat, treating the wrong patient, and preventable infections and deaths. These outcomes occur in clinics and institutions due to error and neglect. According HealthGrades, a leading third party evaluator of hospitals and resource for health professionals, nearly 1 million patient-safety incidents occurred in US hospitals between 2006-2008. The cost of preventable medical errors in hospitals is about \$9 billion annually. Adverse drug events are the most common health problem with as many as 1.5 million ADEs occurring in the US annually.

All healthcare providers, whether they are allopathic or complementary, are responsible for providing a safe environment for patients to heal. Whether the provider is an acupuncturist, therapist, physician, or nurse, the basic tenet of do no harm governs our work. As acupuncturists, we particularly need to be aware of potential risks and seek to avoid them because many of our patients seek complementary medicine when they feel allopathic medicine failed to meet their needs. Consider this story:

A female patient in her early-fifties was suffering from metrorrhagia, uterine bleeding at irregular intervals. She had been bleeding daily for 6 months. During that time, she was seeing an acupuncturist and receiving herbs as well as acupuncture and Tuina massage treatments. She also had been researching natural hormonal remedies on her own but not taking any other products besides the herbs. During the six month period, her condition worsened. She became pale, had memory problems, and low energy and fatigue. Also, during the six month period, she fell and broke her arm. Needless to say, she was also emotionally distraught.

One day she went to the airport to pick up a friend, who was a physical therapist. The friend noticed how pale and fatigued the patient appeared and that “something” just did not seem right. The

friend suggested the patient to go to the doctor that day if possible. The patient went to the emergency room after leaving her friend. The emergency doctor order lab tests and completed a physical examination. The lab results indicated her hemoglobin count was significantly below 7 g/DL. The patient had lost so much blood from the metrorrhagia that a blood transfusion was necessary. The attending emergency room physician said at the rate the patient was going, she could have died within a matter of days.

This patient was concerned her acupuncturist had not realized how bad her condition had progressed. Only one day prior to the emergency room visit, she had seen her acupuncturist.

Fortunately, this is not a common story. However, it does illustrate as healthcare practitioners, acupuncturists need to be timely in applying the proper intervention and making referrals. Negligence can occur due to failure to act as well as committing an inappropriate action.

The most important maxim of Western medicine comes from the ancient Greeks: “Primum non nocere”- first do no harm. The ancient Chinese also subscribed to a similar view. So how can modern healers adhere to this commitment?

As a caregiver, some important questions we must first consider include:

- What are the clinical risks?
- In what ways are patients harmed?
- How can practitioners prevent mistakes?
- How frequently are patients harmed in the acupuncture setting?
- How do we prevent the spread of disease and infections, which is a major concern in conventional healthcare?
- What are the privacy requirements and the ethical concerns?
- Most importantly, how can practitioners learn from mistakes?

Awareness and proactive action are primary tools in minimizing medical mistakes. In this section of the course, we will cover legal issues, regulatory

requirements, and research issues. We will also learn some important legal terminology.

In the second part of this course, we will look at how an acupuncturist can be proactive in the clinical setting in communicating, referring patients, preventing infections, and avoiding clinical errors. In comparison to other medical practices, acupuncture risks are low. Nonetheless, acupuncturists still need to be aware of safe practices and standards of care to protect themselves and their patients. Additionally, the issue of minimizing and preventing medical errors is not just about safety in the acupuncture setting but also about the quality of care. In this course, we will point out heuristics (rules of thumb) to serve as memory aids for you after completing this course.

One main issue in the profession is that many acupuncturists work in small single practitioner offices and some of the concerns larger clinics and hospitals experience are irrelevant. However, as the profession continues to expand, the issues larger institutions face may increase for the profession.



Hua Tuo

Infectious Disease Awareness

Acupuncturists must be aware of the transmission risks of pathogens and exercise caution to prevent cross-infection and transmission. During a new patient intake, be certain to conduct a thorough health history. The best method to prevent nosocomial infections is to practice hand hygiene and to clean work surfaces. The following summarizes basic information on HIV and Hepatitis transmission and incubation periods.

Hepatitis and HIV

1. Hepatitis A (HAV)

- 15 – 45 days Incubation
- Bloodborne, fecal contaminated food and water
- Abrupt Onset
- Vaccine Available
- Not Chronic, common with children and young adults

2. Hepatitis B (HBV)

- 50 – 180 days Incubation
- Bloodborne
- Insidious (slow) Onset
- Vaccine Available
- Chronic 5 – 10% of cases

3. Hepatitis C (HCV)

- 20 -90 days Incubation
- Bloodborne
- Insidious Onset
- No Vaccine
- Chronic: 50% of cases

4. Hepatitis E (HEV)

- 30 – 40 days Incubation
- Waterborne
- Abrupt Onset
- No Vaccine
- Not Chronic, more prevalent in developing countries

5. Human Immunodeficiency Virus (HIV)

- 2 weeks – 10 years Incubation (50% of cases develop within 10 years; some occur in as much as 20 years from initial exposure)
- Bloodborne
- Asymptomatic or symptomatic; symptoms can resemble other common diseases like mononucleosis or a common cold
- No Vaccine (in development)
- Chronic can lead to Acquired Immune Deficiency Syndrome (AIDS)



Legal & Regulatory

Whether a large or small clinic, there are some general legal and regulatory requirements for safe practice in the acupuncture setting. Safe medical practice in any setting begins with the management of the organization. It requires a systems approach and attitude of safety first.

Legal Duty of Care

It is important to understand that the legal relationship between an acupuncturist and patient is contractual and voluntary. The acupuncturist can determine whom he or she will enter into an agreement with to provide care. Once an agreement has been established, the acupuncturist also has a legal duty to act with the due care and skill of a responsible healthcare provider in similar circumstances.

With respect to duty of care, all practitioners are subject to both criminal and civil law; however, few practitioners are charged with criminal intent. Most medical-related legal cases involve civil suits, and most of these claims are for trespassing or negligence.

Trespassing

A practitioner might be held liable for trespassing for any of the following:

- **Touching the patient without any prior consent**
- **Failing to provide an explanation of the treatment**
- **Misrepresenting or making fraudulent claims to the patient about treatments**
- **Going beyond what the patient has consented or agreed to**

Negligence

Negligence claims are more common in the acupuncture setting and are more likely to result in error than trespassing claims. Negligent acts are those mistakes a practitioner makes outside the standard expected of a reasonable practitioner under similar circumstances. All mistakes are not necessarily negligent. Moreover, negligent acts involve unintended mistakes while criminal acts involve intent.

In a negligent claim, the burden of proof lies with the patient to prove the:

- **Practitioner owed the patient a duty of care**
- **Practitioner breached the duty**
- **Breach of duty caused the patient harm**

Practitioners can be held negligent by either commission or omission. Omission means failing to act in a circumstance when a reasonable practitioner would have acted. For instance, the practitioner in the story at the beginning of this course could have been held liable for failing to act. In the acupuncture setting, it may be easier for a patient to prove a case of negligence by omission rather than commission. For this reason, it is essential for acupuncturists to be diligent in making referrals when circumstances require such action.

An essential point to remember is that the acupuncturist should stay up-to-date and comply with clinical practice guidelines as outlined by the National Acupuncture Foundation, the National Certification Commission for Acupuncture and Oriental Medicine, the State Medical Boards, and other authorities in the field. Many medical mistakes occur when practitioners are unaware of the standards of care or become forgetful and negligent to apply standard guidelines. Compliance with guidelines is not just a legal duty it is also an ethical duty to patients.

Malpractice and Liability

Malpractice claims against acupuncturist are significantly lower than for other healthcare providers. A 1998 report indicated alternative medicine malpractice accounted for 5% of total medical malpractice claims in the US. This number includes all forms of complementary and alternative medicine, not just acupuncture. In the event a malpractice claim is made against an acupuncturist, the patient again bears the burden of proof and must prove malpractice by the acupuncturist. Malpractice is the improper or negligent treatment of a patient, which causes loss, harm or injury. Maleficence means to act with harmful intent.

Informed Consent

Informed consent is when a fully informed patient participates in healthcare decisions. Informed consent is also known as the Right to Know Law and is a legal requirement that systematically addresses the patient's ethical right to understanding and consenting to medical treatment before such treatment is delivered in a non-emergency situation. The major elements of informed consent involve:

1. The patient's right to receive full disclosure of information receiving the treatment or intervention from the provider.
2. The patient's right to understanding the information disclosed. The information disclosed should include:
 - a. Benefits of the treatment
 - b. Alternatives to the treatment
 - c. Risks
 - d. Consequences of the treatment
3. The patient's right to decide whether to accept treatment without coercion.

In no case may an acupuncturist impose services on a patient without prior consent. Informed consent in the acupuncture setting is particularly important when a procedure can cause or be interpreted as causing physical damage, such as with gua sha, moxibustion, cupping, electro-stimulation, and even needling.

Consent can be oral or written consent. However, **written consent provides visible proof of the patient's comprehension and agreement.** Additionally, legal consent is legally binding in court. An acupuncturist may be held liable for malpractice if the acupuncturist renders treatment to a patient without first providing full disclosure of the risks involved.

An important criteria with informed consent is that consent should be obtained from the patient or a person authorized by law to represent the patient. Informed consent is required of an adult patient or parent of the patient. Individuals who can provide consent include:

- 1) The legal guardian of a minor
- 2) Any individual who has given legal authorization (power of attorney)
- 3) A married minor (in some states)

One of the best places to get a sample of a consent to treat form for your clinic is from your malpractice insurance carrier. You may also check with your state board to see if there is any recommended language for your clinic's form.

Infrared Lamps and Burns

At the Healthcare Medicine Institute, we contacted malpractice insurance companies and asked them about preventable law suits against acupuncturists. Uniformly, insurance carriers voiced a concern regarding burns. Heat lamps and moxibustion were the primary concern.

If a burn occurs, it is legally important that the patient had been aware of this possibility. This goes to the issue of informed consent. The American Acupuncture Council includes the following informed consent item in their recommended *Acupuncture Informed Consent to Treat* form:

I have been informed that acupuncture is a generally safe method of treatment, but that it may have some side effects, including bruising, numbness or tingling near the needling sites that may last a few days, and dizziness or fainting. Burns and/or scarring are a potential risk of moxibustion and cupping, or when treatment involves the use of heat lamps. Bruising is a common side effect of cupping.¹

Direct moxa is expressly forbidden by law in some US states, while indirect moxa is allowed in most states and countries. Check your scope of practice regulations or confer with your state acupuncture board to find out what types of moxibustion are legal in your state. Indirect moxa may leave scars or welts. Practitioners are advised to ensure that no scarring or welts occur to avoid legal ramifications. Although scarring moxibustion is historically used, in today's legal environment, it is either inappropriate or illegal in most regions. Heat shields are important at the base of a needle when moxa is attached to the handle.

TDP (Teding Diancibo Pu) heat lamps and other types of infrared lamps are of great concern to insurance carriers. One of the most important concerns to carriers is awareness of patients with numbness or any impairment of sensory capacity for heat. For example, diabetics often have decreased sensitivity in their extremities. These patients are unable to tell the acupuncturist that the lamp is too hot because they are unable to feel the area receiving the heat.

1. AAC-FED, A2004. OPTIONAL Arbitration Information Packet. American Acupuncture Council.

The Medical Insurance Exchange of California (MIEC) reports that 17% of all claims against acupuncturists in 2005 – 2014 were for patients sustaining a burn injury. Out of the 17% total, 11% of burns were caused by infrared heat lamps, 4% due to indirect moxibustion, and 2% were due to hot stone massage.² The MIEC recommends that placement of a heat lamp should be such that, in case of a malfunction, the lamp will not come into contact with the patient. Consider some of the following issues with heat lamps:

- **unstable base or stand**
- **overextended heat lamp adjustment arm**
- **inadequate screen (protective guard) between heating element or bulb and the patient**
- **a power cord that may be tripped over**
- **heat source too close to patient's skin**

The Council of Colleges of Acupuncture and Oriental Medicine (CCAOM) notes “It is imperative that a TDP lamp be monitored carefully when in use and that unexpected movements of the heating element be prevented. Some lamps may slowly lower during the course of a treatment, resulting in a burn over the area being warmed. Mechanical failure of the heat lamp itself may occur during treatment allowing the arm and heating element to rapidly descend near or onto the patient's skin.”³

One of the best legal protections in the case of an accident or injury in an acupuncturist clinic is the acupuncturist's good relations with the patient. Insurance companies note that, even in the case of severe burns, cases have a higher tendency to settle out of court when there is a good relationship between the acupuncturist and the patient.

If an accident or injury occurs, take appropriate steps to provide care to the patient to help remedy the medical issue. The Council of Colleges of Acupuncture and Oriental Medicine recommends, “If the burn is a very

2. MIEC, Point of Exchange, July 2015. Burn injury claims resulting from indirect moxibustion and TDP lamps.

3. Council of Colleges of Acupuncture and Oriental Medicine (CCAOM), 2014.

small, first-degree burn, provide treatment such as cool water, sterile gauze and over-the-counter burn creams. If the burn is severe, or there is concern with infection, refer the patient to a physician.”⁴

Steps to take:

- for minor burns: apply a burn cream, cool water, or other appropriate treatments to alleviate inflammation and skin damage
- refer to an appropriate outside medical source when needed
- express genuine concern and care for the patient’s health and well-being
- document the issue
- document follow-ups with patient on their health status
- advise the patient on steps they may take to relieve a burn



4. Council of Colleges of Acupuncture and Oriental Medicine (CCAOM), 2014.

HIPAA

HIPAA regulations comprise two parts. The Health Insurance Portability and Accountability Act of 1996 is a federal law that says employees belonging to group health plans must be allowed to purchase insurance for a period of time after they leave their jobs or change employment status. This law also created standards regarding how healthcare providers and third party entities handle patient health information. The standards specify who has authorization to view patient information and how private information, such as a patient's name or date of birth should be stored.

As part of their healthcare responsibilities, acupuncturists are legally bound to maintain the confidentiality of patient information and records. Acupuncturists should provide all patients a Health Information and Privacy Notice prior to treatment. Additionally, patient files should be kept up to date and indicate:

- Basic patient information
- Insurance information
- Clinic's cancellation policy
- Patient's health history
- Informed Consent
- SOAP Notes or Patient Intake Forms with patient name, date, examination, diagnosis, treatment plan, and herbal prescriptions
- ICD-10 and CPT codes as applicable

Records should be maintained according to your state's requirements. In an acupuncture setting, HIPAA noncompliance may not directly lead to a clinical error. However, inaccurate information can lead to mistakes in the treatment room. Acupuncturists, or any staff handling patient records, should comply with all federal and state requirements for handling patient information and records.

Media Coverage and HIPAA

Use care when using outside media representatives to ensure compliance with HIPAA. HIPAA protections apply to using media coverage. The press may want to do a highlight of your practice. Be sure to obtain authorizations

from the patients involved in any media gathered or released. HHS (U.S. Department of Health & Human Services) notes of protected health information (PHI):

Can health care providers invite or arrange for members of the media, including film crews, to enter treatment areas of their facilities without prior written authorization?

Answer:

Health care providers cannot invite or allow media personnel, including film crews, into treatment or other areas of their facilities where patients' PHI will be accessible in written, electronic, oral, or other visual or audio form, or otherwise make PHI accessible to the media, without prior written authorization from each individual who is or will be in the area or whose PHI otherwise will be accessible to the media. Only in very limited circumstances, as set forth below, does the HIPAA Privacy Rule permit health care providers to disclose protected health information to members of the media without a prior authorization signed by the individual.

A covered entity, including a health care provider, may not use or disclose protected health information (PHI), except either: (1) as the HIPAA Privacy Rule permits or requires; or (2) as the individual who is the subject of the information (or the individual's personal representative) authorizes in writing. Generally, the HIPAA Privacy Rule does not permit health care providers to disclose PHI to media personnel, including film crews, without having previously obtained a HIPAA-compliant authorization signed by the patient or his or her personal representative. In other words, health care providers may not allow members of the media, including film crews, into treatment areas of their facilities or other areas where PHI will be accessible in written, electronic, oral or other visual or audio form, without prior authorization from the patients who are or will be in the area or whose PHI will be accessible to the media. It is not sufficient for a health care provider to request or require media personnel to mask the identities of patients (using techniques such as blurring, pixelation, or voice alteration software) for whom an authorization was not obtained, because the HIPAA Privacy Rule does not allow media access to the patients' PHI, absent an authorization, in the first place.

In addition, the health care provider must ensure that reasonable safeguards are in place to protect against impermissible disclosures or to limit incidental disclosures of other PHI that may be in the area but for which an authorization has not been obtained.

There are very limited situations in which the HIPAA Privacy Rule permits a covered entity to disclose limited PHI to the media without obtaining a HIPAA authorization. For example, a covered entity may seek to have the media help identify or locate the family of an unidentified and incapacitated patient in its

care. In that case, the covered entity may disclose limited PHI about the incapacitated patient to the media if, in the hospital's professional judgment, doing so is in the patient's best interest. See 45 C.F.R. 164.510(b)(1)(ii). In addition, a covered entity may disclose a patient's location in the facility and condition in general terms that do not communicate specific medical information about the individual to any person, including the media, without obtaining a HIPAA authorization where the individual has not objected to his information being included in the facility directory, and the media representative or other person asks for the individual by name. See 45 C.F.R. 164.510(a).

The HIPAA Privacy Rule does not require health care providers to prevent members of the media from entering areas of their facilities that are otherwise generally accessible to the public, which may include public waiting areas or areas where the public enters or exits the facility.

A health care provider may utilize the services of a contract film crew to produce training videos or public relations materials on the provider's behalf if certain protections are in place. If patients are to be identified by the provider and interviewed by a film crew, or if PHI might be accessible during filming or otherwise disclosed, the provider must enter into a HIPAA business associate agreement with the film crew acting as a business associate. Among other requirements, the business associate agreement must ensure that the film crew will safeguard the PHI it obtains, only use or disclose the PHI for the purposes provided in the agreement, and return or destroy any PHI after the work for the health care provider has been completed. See 45 C.F.R. 164.504(e)(2). As a business associate, the film crew must comply with the HIPAA Security Rule and a number of provisions in the Privacy Rule, including the Rule's restrictions on the use and disclosure of PHI. In addition, authorizations from patients whose PHI is included in any materials would be required before such materials are posted online, printed in brochures for the public, or otherwise publicly disseminated.

Finally, covered entities can continue to inform the media of their treatment services and programs so that the media can better inform the public, provided that, in doing so, the covered entity does not share PHI with the media without the prior authorization of the individuals who are the subject of the PHI.

Legal Authorization For Release

Acupuncturists are advised to seek legal counsel to obtain the appropriate authorization paperwork for purposes of marketing and media coverage. The same applies to information about patients supplied to research projects. In addition, it is advisable to consult with your comprehensive liability insurance carrier (malpractice insurance company) to ensure compliance. It may seem harmless to interview a patient about the benefits of acupuncture and to post it on Youtube or a website. However, prior

authorization is necessary. Care must be used when engaging in community outreach, advertising, and social media. Although informal verbal consent from a patient may seem ethical, it is not the required legal protection required by HIPAA. The following is an example of what a simple release form may look like. This is only a sample and is not for legal use. (Check with legal counsel to ensure that a form that is used fits federal, state, local, and carrier requirements.)

AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

I, (Name of patient), hereby authorize (Name of person or facility which has information) to release the following health information: _____

To: (Name and title or facility name to receive health information)

(Street address, city, state, ZIP code, Telephone number, Fax number)

For the following purposes:

This authorization is in effect until (date or event), when it expires.

I understand that by signing this authorization:

- authorize the use or disclosure of my individually identifiable health information as
- described above for the purpose listed.
- I have the right to withdraw permission for the release of my information. If I sign this
- authorization to use or disclose information, I can revoke that authorization at any time.
- revocation must be made in writing and will not affect information that has already
- been used or disclosed.
- I have the right to receive a copy of this authorization.
- I am signing this authorization voluntarily and treatment, payment, or my eligibility for
- benefits will not be affected if I do not sign this authorization.

- I further understand that a person to whom records and information are disclosed pursuant
- to this authorization may not further use or disclose the medical information unless another
- authorization is obtained from me or unless such disclosure is specifically required or
- permitted by law.

Signed by Patient: _____ Date:

Or Signed by Personal Representative: _____ Date:

On Behalf of: (Name of Patient)

Copy of Identification Attached (Drivers License, Birth Certificate, State or Federal ID Card) If no identification is provided, a notarized signature is required for this document.

The HHS stipulates:

An authorization must specify a number of elements, including a description of the protected health information to be used and disclosed, the person authorized to make the use or disclosure, the person to whom the covered entity may make the disclosure, an expiration date, and, in some cases, the purpose for which the information may be used or disclosed. With limited exceptions, covered entities may not condition treatment or coverage on the individual providing an authorization.



OSHA

A discussion of patient safety would be remiss without a brief overview of occupational safety. The Occupational Safety and Health Administration is the enforcement agency for workplace safety and health. OSHA and the National Acupuncture Foundation (NCCA) outline specific risk management procedures for acupuncturists as related to:

- Safe disposal of needles
- Prevention and control of infectious diseases, including bloodborne and airborne pathogens
- Personal protective equipment, e.g., gloves
- Hygiene, e.g., frequent hand washing
- Clean needling techniques

Acupuncturists certified by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) must comply with clean needle guidelines. These guidelines protect not only the patient but also the provider and clinic staff from accidents and transmission of diseases. In any case, acupuncturists should keep and review copies of clean needle guidelines and maintain an infection control plan for their facilities.

In addition to OSHA requirements, each state has specific licensing requirements and reporting for providers who contract a communicable disease or who have a health condition that impacts their ability to treat patients. Acupuncturists should stay current on their state's requirements.

Research

Evidence-based medicine has transformed modern medical practice. Evidence-based practices are a blend of research and practical application that evaluates therapeutic interventions and assesses them based on levels of evidence. The push for validation of acupuncture protocols will continue to push the profession forward with more scientific research and evidence-based practices. Research will provide evidence for the efficacy of treatments and will provide evidence and support for historical anecdotal and experiential practices. However, the concern for modern practitioners is whether reliable methodologies are used during these studies.

Research can provide essential information in terms of helping to manage risks as well as validate treatments—both new and traditional. Consider the following abstract which illustrates an evidence-based research abstract entitled, “Safety and Efficacy of Acupuncture in Children: A Review of the Evidence” by Jindal V, Ge A, Mansky PJ.

“Acupuncture has been used therapeutically in China for thousands of years and is growing in prominence in Europe and the United States. In a recent review of complementary and alternative medicine use in the US population, an estimated 2.1 million people or 1.1% of the population sought acupuncture care during the past 12 months. Four percent of the US population used acupuncture at any time in their lives. We reviewed 31 different published journal articles, including 23 randomized controlled clinical trials and 8 meta-analysis/systematic reviews. We found evidence of some efficacy and low risk associated with acupuncture in pediatrics. From all the conditions we reviewed, the most extensive research has looked into acupuncture's role in managing postoperative and chemotherapy-induced nausea/vomiting... Through our review of pediatric adverse events, we found a 1.55 risk of adverse events occurring in 100 treatments of acupuncture that coincides with the low risk detailed in the studies mentioned previously. The actual risk to an individual patient is hard to determine because certain patients, such as an immunosuppressed patient, can be predisposed to an increased risk, acupuncturist's qualifications differ, and practices vary in certain parts

of the world. Nevertheless, it seems acupuncture is a safe complementary/alternative medicine modality for pediatric patients on the basis of the data we reviewed.”⁵

Meta-analysis and systematic reviews support evidence-based clinical practices and help practitioners stay abreast of quality research. When evaluating research, be certain methodologies include meta-analysis/systematic reviews, the “gold standard for clinical trials,” or at the least randomized clinical trials. Systematic reviews involve summing up the best available research data for a specific issue by making a comparative review of a number of studies. This process is more reliable than basing practices on one or two research findings.



⁵ Division of Intramural Research, National Center for Complementary Medicine, National Institutes of Health, DHHS, Bethesda, MD, USA. ncbi.nlm.nih.gov/pubmed/18525459

Case Study 1

A patient recently contacted you by telephone regarding treatment for pulmonary hypertension. The patient said he also has been diagnosed with congestive heart failure. The patient wishes to get off of his medication and is wondering if acupuncture will help him. Over the phone, you answer general questions regarding acupuncture and Oriental Medicine. You provide the patient a brief overview of a treatment session. You explain that due to the nature of his illnesses, you wish to work with his primary care physician and cardiologist using an integrated approach to treating his condition rather than having him discontinue medications abruptly and without his physician's awareness. The patient is still hopeful that acupuncture will help him reduce his medication and schedules an appointment. For his first visit, you request the patient to bring with him a list of medications with dosages and his physician's contact information.

On his first visit, you take a detailed patient history. You discover that the patient had an episode of congestive heart failure 3 years ago. The patient says he currently has difficulty breathing with severe fatigue, and today the breathlessness is his chief concern. **What other information should you obtain from this patient?**

Discussion

Before proceeding with needling, discuss the treatment. Ensure the patient understands the risks, alternatives, and expected outcomes to the treatment. Most of all, be certain to obtain his written informed consent.

Section Review Exercises

(Answers on the page following these questions.)

1. Legal duty of care is to:

- a. Act with the due care and skill of a responsible healthcare provider in similar circumstances
- b. Provide patients care in unusual circumstances
- c. Act in an emergency situation
- d. Provide unsolicited healthcare to victims of accidents or trauma

2. Negligence is defined as:

- a. All mistakes which occur in the medical setting
- b. Mistakes a practitioner makes *outside* the standard expected of a reasonable practitioner under similar circumstances
- c. Mistakes a practitioner makes *within* the standard expected of a reasonable practitioner under similar circumstances
- d. Malicious Intent to cause death, harm or injury

3. Maleficence means to:

- a. Cause no harm
- b. Act with a harmful intention
- c. Make unintended mistakes
- d. Provide due care

4. Malpractice is

- a. Care performed under normal circumstances resulting in intended mistakes
 - b. Standard duty of care performed under unusual circumstances
 - c. The correct treatment of a patient, which causes loss, harm or injury
 - d. The improper or negligent treatment of a patient, which causes loss, harm, or injury
5. Informed Consent must include all of the following except for:
- a. An explanation of the treatment to be performed, risks, expected outcomes and possible alternatives
 - b. The patient's understanding of the treatment
 - c. The patient's consent to treatment and signature
 - d. The provider must provide a technically detailed explanation of the treatment
6. HIPAA regulations specify how healthcare providers should:
- a. Provide duty of care
 - b. Store and handle patient records
 - c. Obtain informed consent
 - d. Report incidents
7. OSHA regulations are primarily designed to protect:
- a. Workers
 - b. Patients
 - c. Hospitals
 - d. Clinics

8. OSHA regulations requires all of the following for healthcare workers except for:
- a. Malpractice insurance coverage
 - b. Personal protective equipment
 - c. Training to prevent the spread of bloodborne pathogens
 - d. That employers offer Hepatitis B vaccine to employees
9. All of the following are characteristics of systematic reviews except they:
- a. Combine a number of studies
 - b. Are based on one or two findings
 - c. Support evidence-based practices
 - d. Help practitioners stay current on research

Answers to Self-Help Review Exercises

1. Legal duty of care is to:

Correct answer:

a. Act with the due care and skill of a responsible healthcare provider in similar circumstances

All healthcare practitioners have a legal duty of care to provide their patients. The legal duty of care is to act with the due care and skill of a responsible healthcare provider in similar circumstances.

2. Negligence is defined as:

Correct answer:

b. Mistakes a practitioner makes outside the standard expected of a reasonable practitioner under similar circumstances

Negligence occurs when a practitioner makes mistakes outside of the standards expected of a reasonable practitioner under similar circumstances. Negligence is not intentional harm.

3. Maleficence means to:

Correct answer:

b. Act with a harmful intention

Maleficence is the opposite of non-maleficence or beneficence. Maleficence means to act with a harmful intention.

4. Malpractice is:

Correct answer:

d. The improper or negligent treatment of a patient, which causes loss, harm, or injury

Malpractice is the improper or negligent treatment of a patient. Malpractice causes loss, harm, or injury.

5. Informed Consent must include all of the following except for:

Correct answer:

d. The provider must provide a technically detailed explanation of the treatment

Providers must explain intended treatments to patients. However, the explanation does not need to be, or should be, highly detailed and technical. Patients should be able to easily understand what is being said.

6. HIPAA regulations specify how healthcare providers should:

Correct answer:

b. Store and handle patient records

HIPAA regulations govern how healthcare providers should store and handle patient records. There is also a section of the act that deals with insurance coverage for employees.

7. OSHA regulations are primarily designed to protect:

Correct answer:

a. Workers

OSHA regulations are primarily designed to protect workers. However, they impact everyone.

8. OSHA regulations requires all of the following for healthcare workers except for:

Correct answer:

a. Malpractice insurance coverage

OSHA does not govern malpractice insurance coverage. However, practitioners should carry policies and comply with their state, local government, and employer requirements.

9. All of the following are characteristics of systematic reviews except they:

Correct answer:

b. Are based on one or two findings

Systematic reviews help practitioners stay current on research and promote evidence-based practices. Systematic reviews are generally not based on just one or two findings.

Clinical Practice – Part 1

In the book *To Do No Harm*, by Julianne M. Morath and Joanne E. Turnbull, the authors identify error “as a symptom of a larger problem.” Medical authorities are now beginning to study clinical error with the same rigor they use to study diseases.

Within the scope of clinical practice, some basic requirements are necessary to provide quality care and to prevent error. More and more states are requiring licensure, which is an important step in making acupuncture safe and accessible to patients. While licensure requirements may vary from state to state, training for acupuncturist in the United States is becoming more consistent since US practitioners meet board certification requirements of the National Certification Commission for Acupuncture and Oriental Medicine.

Research shows safety can be linked to qualifications and training of professionals. Studies show the occurrence of serious adverse events in the acupuncture clinic, reduces with the more training a practitioner receives. Licensure and training requirements ensure more qualified practitioners.

The subject of minimizing error in the acupuncture setting, however, is still new. So, acupuncturists must rely on skills they learn during training to form the basis of safe clinical practice. These skills include, but are not limited to:

- Listening, observational, and communication skills
- Documentation skills
- Ability to determine a differential diagnosis and appropriate treatment plan
- Ability to apply theoretical and experiential knowledge to clinical cases
- Ability to administer safe and effective needling, moxibustion, cupping, gua sha, electro-stimulation and other related therapies
- Ability to prevent the transmission of infection

- Ability to appropriately manage emergency situations or accidents
- Ability to safely prescribe herbal medicine

Listening and Communication Skills

We have all heard it before that the best communicators are good listeners. Good listening skills basically translate into active listening. What does it mean to practice active listening? Active listening means the listener is completely engaged in what the speaker is communicating. The listener is not judging what is being said, formulating his thoughts or responses to the speaker, or even worse thinking, about something else totally unrelated.

*“Nature has given men one tongue, but two ears
That we may hear others twice as much as we speak.” - Epictetus*

In general, acupuncturists are trained to be in-tune with their patients and their patients' energy. As a discipline, acupuncture is an intuitive practice, so for the most part acupuncturists already are likely already keen in listening and paying attention to their patient's spoken and unspoken needs. Many patients actually turn to complementary medicine such as acupuncture because they feel traditional doctors do not listen to them.

Communication is built into the Traditional Chinese Medicine diagnosis. If you recall, the four aspects of diagnosis are:

- Asking (10 questions)
- Observing (appearance, signs, smells)
- Listening (spoken and unspoken communication, auscultating)
- Feeling (Palpating, pulse diagnosis)

These guidelines promote active listening and provide a framework for acupuncturists to practice safely. Mistakes from poor communication can be avoided by remembering those guidelines—especially in a fast paced clinic environment. As a heuristic, acupuncturists can practice active

listening by remembering these four pillars and applying their critical thinking skills.

RULE OF THUMB—MISTAKES FROM POOR COMMUNICATION CAN BE AVOIDED BY REMEMBERING THE FOUR DIAGNOSTIC GUIDELINES OF TCM

Critical Thinking Skills

Active listening is a component of critical thinking. Critical thinking as well as intuition is important in the acupuncture setting. Critical thinking helps us to discriminate and make decisions--use our better judgment. Critical thinking involves the use of logic and is a tool that healthcare providers can use to reduce their vulnerability and error.

Critical thinking is not only about how we take action but also when we take action. As previously noted, negligence can occur due to omission or commission. A major area of concern in the acupuncture setting is when to make referrals. When we are presented with unfamiliar, ambiguous or conflicting information, it can sometimes be difficult to determine "Is this a case I should refer?" Our critical thinking skills can help us glean through information and make an informed decision.

Winston Churchill once said that "True genius resides in the capacity for evaluation of uncertain, hazardous, and conflicting information." Factors to help us effectively evaluate information include:

- Being objective
- Making assumptions based on the evidence
- Asking clarifying questions

Consider this example, an acupuncturist receives a call from an individual's adult daughter that her father is having severe heart burn and would like to schedule an appointment. The acupuncturist should also ask does the father have any radiating chest pain, irregular heart beat, or profuse

sweating (signs of cardiac arrest). If so, the appropriate action would be to refer the patient to an emergency room rather than schedule an appointment for acupuncture treatment.

Clinical Warning Signs for Referral

The acupuncturist can use clarifying questions to help decide when to refer a patient. However, the best measure the acupuncturist can take is to actively MONITOR patients for medical red flags. Some situations when an acupuncturist should refer patients include:

- Sudden chest pain (coronary occlusion, pneumothorax, or aneurysm)
- Excessive hemorrhaging (shock risk)
- Recent head trauma (concussion, brain injuries)
- Persistent cough (pleural effusion, lung cancer)
- Severe abdominal pains (appendicitis, ruptured abscess)
- Gastro-intestinal bleeding from upper or lower GI tract
- New onset of severe headache (aneurysms, brain tumor)
- Seriously Infected wounds (any infected foot ulcers in diabetic patients should be referred)
- Persistently swollen lymph nodes, difficulty swallowing, breast lumps, abdominal masses, unexplained weight loss (cancer)
- Unexplained weight loss, thirst, frequent urination (Diabetes Type II)
- Persistent tenderness and swelling in lower leg or thigh (thrombophlebitis, peripheral vascular disorder)
- Visual disturbances or severe redness in eyes (glaucoma)
- Altered levels of consciousness (stroke or impending coma)
- Broken bones or dislocated joints that need immobilizing
- Suicide risks
- Severe depression or emotional disturbance which may require behavioral therapy or counseling

- Children with neurological deficits, developmental delays, or learning disabilities
- Sudden onset of new neurological problems
- Sudden respiratory distress
- Signs of an undiagnosed highly infectious disease (Hepatitis, HIV, tuberculosis)
- Spotting during pregnancy or patients with pre-eclampsia who develop severe headaches and blurred vision (miscarriage risk)
- Post-menopausal vaginal bleeding
- Fever of unknown origin
- Frequent syncope or light-headedness (brain tumor)
- Anaphylaxis (anaphylactic shock)
- New occurrence of exophthalmos/enlarged eyes or goiter (Grave's disease)
- Elder or child abuse (needs to be reported to the proper authorities)

RULE OF THUMB: WHEN A SITUATION IS URGENT, THE ACUPUNCTURIST SHOULD TALK TO THE REFERRED TO PROVIDER OR AUTHORITY DIRECTLY VIA TELEPHONE OR IN PERSON.

Medical Errors

As healers our basic oath is to do no harm. As humans, however, we are subject to err. Understanding this situation, we need to be as objective as possible when treating patients who may be at risk for possible complications, serious illness, or death. We need to stay current on training in our field and to use our critical thinking skills to apply the knowledge we have learned. Additionally, it's helpful to remember that failing to act when needed is the same as acting in error. In healthcare, three terms are used to describe the types of active failure:

- Slips – occur in skilled-based activities that we do automatically, such as picking up the wrong formula bottle when reaching for two bottles with similar labels. ***Slips usually occur when we are distracted or fatigued.***
- Lapses – are readily evident and usually happen with rule-based activities, such as missing a step in the clean needle technique. ***Lapses happen when our memory fails us or we leave out a step because of time constraints and stress.***
- Mistakes – are deficits of knowledge or failed judgment. Mistakes are knowledge-based and can go unnoticed for a long time. ***Mistakes are the easiest of the three types of failure to intervene and correct, though. Mistakes can be prevented by proper training and practice.***

Another more critical medical error is "failure to rescue." Failure to rescue happens when a practitioner withholds treatment or does not act in a timely manner to prevent serious injury or death. Failure to provide timely intervention can be due to negligence, to not being unaware of the all factors affecting a patient, or as a result of misdiagnosis and miscommunication. Failure to rescue is critical because it can result in death or severe disability.

Documentation and Reporting

Accurate documentation is also another important step in preventing mistakes. In the event of litigation, your documentation may be your best witness. Clinical notes should be clear, comprehensive, and coherent. Indicate all referrals and the reason for referring a patient.

Insurance requirements may vary from state to state, so the acupuncturist may need to use specific documentation to meet those requirements. More and more insurance companies are beginning to provide coverage for acupuncture. So, acupuncturists who do choose to bill insurance should be

familiar with the appropriate ICD and CDT codes. At a minimum, treatment records should contain at least the following information:

- Clinical observations, both subjective and objective
- Assessment which includes a TCM and when possible Western diagnosis
- Treatment plan
- Methods used, such as acupuncture, gua sha, cupping, electro-stimulation, qi gong, etc.
- Herbal recommendations
- Follow-up and home care instructions

Each state specifies how long acupuncture records should be retained, so practitioners should check their individual State guidelines.



Case Study 2

A 22 year old male college student came to see an acupuncturist for insomnia, difficulty concentrating, depression, and anxiety. During the first visit, he indicated he was depressed due to emotional strain with his father and a recent break up with his girlfriend. He indicated no history of substance abuse. Further, he said he did not smoke and only drank a few beers occasionally. He said he was conscientious about eating healthy foods since as a youth he had some food allergies. The patient appeared physically healthy. The acupuncturist decided to initially treat him with acupuncture and herbs. On the first visit, the acupuncturist needled ear Shenmen, PC 6, Yin tang, Anmian, LV 3, LI 4, St 36, GB 34, and Ren 12. Xiao Yao San was given for herbal supplementation. The patient continued with weekly acupuncture sessions once a week, for several months. After 4 months, the patient's father passed away and the patient became even more depressed. During a treatment, the patient mentioned to the acupuncturist that he felt fatigued and almost like he couldn't "go on." At the end of that treatment, the acupuncturist strongly recommended the patient contact a mental health counselor for further assistance with his signs of depression and grief. The acupuncturist documented the referral and the patient's comments about not feeling like he could "go on." **Should this practitioner have given the patient the suicide prevention number?**

Discussion

Suicide is a preventable health problem and is the 10th leading cause of death in the US. The patient in this case is at possible risk for suicide. For every 11 suicide attempts, one victim will be successful. Risks for suicide include depression, mental disorders, history of family abuse, drug abuse, firearms in the house, and family history of suicide. Males are four times more likely to die from suicide than females. Additionally, suicide is the third leading cause of deaths for young people ages 15 to 24.

In this situation, the acupuncturist should ask more clarifying questions to see if suicide is a definite risk. Ask: Why does he feel he cannot go on? What support system does he currently have to help with grief? Is he

seeing a counselor? Is the patient taking any drugs or using alcohol to cope?

The patient should not be left alone if suicide is an imminent risk. It is out of the acupuncturist's scope of practice to provide mental health counseling. If the acupuncturist determines in fact that this patient might attempt suicide, the acupuncturist should:

- Call 911, or
- Refer the patient to the emergency room of a hospital, or
- Call the suicide prevention line at 1-800-273-TALK (8255) and provide the patient with this number to keep, as well



Case Study 3

A 50 year old female patient contacted Sally, an acupuncturist, for swelling, pain and redness in her left foot. She had seen an acupuncturist years ago and had experienced good results. She said a family member suggested the swelling might be rheumatoid arthritis and that she should see a rheumatologist. However, the patient wanted to try acupuncture first. During the health intake, the patient indicated she did not have any other health problems. She was not diabetic and usually experienced good health. Additionally, she had gone through menopause without any difficulties. She indicated the swelling had just recently occurred within the past week.

Sally assessed the patient to determine if the possible cause of swelling was rheumatoid arthritis. The patient did not have any bilateral swelling, pain, or redness, fever, or swollen lymph nodes. Additionally, the patient did not have any other signs of joint immobility. After more clarifying questions, the patient mentioned as an aside she liked gardening and had lots of ants. Sally asked the patient if she were allergic to any insects. The patient confirmed severe reactions to bee and ant stings in the past. Sally and the patient then determined it was possible the patient had been bitten by ants while gardening.

In this instance, Sally decided to not refer the patient and to treat her with acupuncture using LI 11, SP 10, SP 6, Bafeng, and local points. The patient was also given a popular topical for insect bites to apply directly on the foot and ankle. After three days, Sally had the patient follow-up. The swelling, redness, and pain had completely disappeared in the patient's affected foot. No further action was necessary besides documenting the patient's records and suggesting a natural repellent when gardening. **Was this acupuncturist's course of action appropriate?**

Discussion

In this case, Sally, the acupuncturist, did not refer the patient to another healthcare provider (i.e., a rheumatologist). Sally asked many clarifying questions to determine the best course of action. This acupuncturist was

thorough in both her evaluation and follow-through. Her decision to treat the patient for indication of an insect bite was effective, and appropriate.

Section Review Exercises

(Answers on the page following these questions.)

1. What is active listening?
 - a. Developing responses while listening to a speaker
 - b. Thinking about other what you want to say while someone else is speaking
 - c. Being engaged with the speaker and listening without distractions
 - d. Being distracted with other thoughts when someone is speaking

2. Critical thinking helps us:
 - a. Make decisions
 - b. Express thoughts
 - c. Store information
 - d. Report findings

3. All of the following are factors to help us effectively evaluate information except for:
 - a. Asking clarifying questions
 - b. Being objective
 - c. Basing decisions on opinion
 - d. Making assumptions based on the evidence

4. With regards to identifying red flags, the acupuncturist should actively:
 - a. Refer
 - b. Communicate
 - c. Monitor
 - d. Report

5. All of the following are clinical red flags except for:
 - a. Unexplained weight loss
 - b. Rhinitis
 - c. Abdominal masses
 - d. Fever of unknown origin

6. The period for retaining acupuncture records:
 - a. Is 1 year
 - b. Is 2 years
 - c. Is 5 years
 - d. Varies state to state

Answers to Review Exercises

1. What is active listening?

Correct answer: d.

Being engaged with the speaker and listening without distractions Active listening is being engaged with your speaker. It means giving a speaker your undivided attention.

2. Critical thinking helps us:

Correct answer: a. Make decisions

Critical thinking helps use or judgment and make decisions. Critical thinking also helps us evaluate information.

3. All of the following are factors to help us effectively evaluate information except for:

Correct answer: c.

Basing decisions on opinion Factors to help us effectively evaluate information include asking clarifying questions, being objective, and using the evidence. Basing decisions on opinion is not a factor.

4. With regards to identifying red flags, the acupuncturist should actively:

Correct answer: c.

Monitor Acupuncturist should actively monitor patients for clinical red flags. They should also ask clarifying questions in addition to active monitoring.

5. All of the following are clinical red flags except for:

Correct answer: b. Rhinitis

The list of clinical red flags is quite extensive. Rhinitis or allergic rhinitis would not be a cause for referral in most cases.

6. The period for retaining acupuncture records:

Correct answer: d.

Varies state to state Each state has its own specific requirements for retaining clinical and employee records. Acupuncturists should be familiar with their state guidelines.

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