

# Safety Program for Traditional Chinese Medicine Practitioners and Acupuncturists

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# **Section 1: Overview of Safety Course Content**

### 1.1 Introduction

The College of Traditional Chinese Medicine Practitioners and Acupuncturists of British Columbia (CTCMA-BC) and the College of Traditional Chinese Medicine Practitioners and Acupuncturists of Ontario (CTCMPAO) are mandated by their respective provincial government to protect the public's right to safe, effective and ethical traditional Chinese medicine (TCM) services by regulating the practice of TCM.

On February 18, 2011, the CTCMA-BC and the transitional Council of the CTCMPAO signed an agreement to jointly develop a Safety Program that provides materials and standards for safe practices and tools to assess practitioners' understanding of safe practices. The purposes of the Program are:

- To inform practitioners of traditional Chinese medicine (TCM) the expected safety standards, procedures and processes when offering TCM services;
- To ensure that practitioners registered with CTCMA-BC and/or CTCMPAO engage in safe practices; and
- To provide a base for registered practitioners to reference, to maintain and to upgrade in their professional development efforts.

# 1.2 Overview of the Handbook

This handbook provides an overview of the basic safety standards, procedures and processes that CTCMA-BC and CTCMPAO expect their registered members to comply in their day-to-day practice. Compliance will ensure protection to patients, the general public, members in the health care system, as well as the members themselves.

The content of this handbook was developed over a period of eighteen months with a consultant organization working with over two dozen content experts and reviewers drawn from registered members of CTCMA-BC and practitioners in Ontario.

In developing the content, experts researched and drew extensively from the mandatory safety courses of the CTCMA-BC and the College and Association of Alberta. A significant portion of the Herbology section was adapted from guidelines developed by the Chinese Medicine Registration Board of Victoria, Australia, with their permission.

The handbook contains four major sections:

- Section 2 Infection Prevention and Control
- Section 3 Risk Management of TCM Practice
- Section 4 Safe Procedures & Processes: Acupuncture
- Section 5 Safe Procedures & Processes: Herbology

Sections 2 and 3 are relevant to all practitioners, irrespective of the scopes they practise and the treatment modalities they use.

Section 4 defines the basic procedures and processes necessary for safe practice of acupuncture and moxibustion. Section 5 defines the basic procedures and processes necessary for safe practice using traditional Chinese herbal medicines.

# 1.3 Demonstration of Understanding

After reviewing the information contained in this handbook, practitioners are required to demonstrate that they understand the information and be able to apply them in their daily practice.

The tools developed for assessment of practitioners had been pilot tested and validated by practitioners in both provinces.

However, because of differences in the governing legislation and the practice environment in British Columbia and Ontario, implementation of the assessment and the standards to be expected of individuals applying for registration with CTCMA-BC will not be the same as those applying for registration with CTCMPAO. Where necessary, this handbook specifies the information and the standards relevant to British Columbia or to Ontario.

To obtain detailed information on the assessment requirements and expectations of CTCMA-BC and CTCMPAO, please visit their respective websites:

British Columbia: <a href="http://www.ctcma.bc.ca">http://www.ctcma.bc.ca</a>
Ontario: <a href="http://www.ctcmpao.on.ca">http://www.ctcmpao.on.ca</a>

# 1.4 Acknowledgements

The CTCMA-BC and the CTCMPAO are grateful to their Board/Council members, registered members of CTCMA-BC, volunteer practitioners in Ontario and legal counsel, for contributing time and effort to develop, review and validate the handbook content and the assessment tools. We are thankful to the Ontario Ministry of Health and Long-Term Care for funding a part of the development cost. We extend our grateful thanks to Curriculum Services Canada for their guidance through each stage of the program content and assessment development, the final delivery of the course content and assessment tools.

The CTCMA-BC and the CTCMPAO would also like to extend their appreciation to the staff that supported and coordinated all stages of program development through letters, emails, phone calls, teleconferences and other logistic supports.

# 1.5 Intellectual Property and Copyright

The CTCMA-BC and CTCMPAO jointly own all intellectual property rights and copyright of this Handbook and the Safety Program in its entirety. Any individual or organization wishing to use, reproduce, translate (in any language) or distribute this handbook in whole or in part must obtain prior written permission from the CTCMA-BC and CTCMPAO.

# **Section 2: Infection Prevention and Control**

### 2.1 Introduction

Professional TCM practitioners practise safe and hygienic procedures in clean, well-managed clinical settings.

Infection prevention and control is an essential consideration for TCM practitioners when providing patients with safe health care services. Infection control is an ongoing process that focuses on minimizing the risks of spreading infections to patients, to staff, and to practitioners while performing required routines and procedures.

In a clinical setting, infection prevention and control is the responsibility of all staff. However, the establishment and assignment of effective procedures and the ongoing monitoring and accountability rests with the practitioner.

TCM practitioners are required to not only establish infection prevention and control strategies and procedures, but also regularly evaluate and update these procedures in order to continually address concerns of infectious illnesses and of the spread of blood-borne diseases.

Practitioners have an obligation to remain current on infection and control procedures and to ensure that such practices are implemented in their practices and by their staff. This includes the availability of the necessary supplies and equipment, as well as the personal and staff training that is required to maintain a safe and healthy office setting for both patients and employees.

This document consolidates published guidelines from government agencies, regulatory bodies and professional associations. As such, this document is based on "best practices" established at the time of writing. Many recommendations have been adapted from techniques currently in use by other health care professions. Knowledge of safety issues and clinical risk management should not be limited by the scope of this course. Participants are expected to continually remain knowledgeable by referencing other sources, including their regulating provincial college (CTCMA-BC, CTCMPAO), federal and provincial government health ministries, and other regulatory agencies.

Current information related to Infection Prevention and Control can be obtained from:

- Health Canada (http://www.hc-sc.gc.ca/index-eng.php)
- British Columbia Ministry of Health (http://www.gov.bc.ca/health/)
- Ontario Ministry of Health and Long-Term Care (<a href="http://www.health.gov.on.ca">http://www.health.gov.on.ca</a>)
- British Columbia Centre of Disease Control (http://www.bccdc.ca/default.htm)
- Public Health Ontario (<a href="http://www.oahpp.ca/index.html">http://www.oahpp.ca/index.html</a>)

Both general principles of infection control and universally accepted precautions and procedures are highlighted in this document. More detailed information about infection control specifically related to acupuncture and to herbology is further detailed in their respective sections of the course.

### As a TCM practitioner:

- know and apply the current infection control guidelines to your practice;
- train others under your supervision;
- ensure the ongoing quality of your infection control practices;
- monitor changes to infection control practices and make adjustments to your practice as needed;
- refer or report patients with suspected infectious diseases to the appropriate health care professional or facility.

### Please Note:

Many of the infection control processes and procedures that are included in this document have been derived from regulations and legislation. There will be specific direction on what practitioners should or should not do under described conditions. This document also includes some suggestions and tools that are descriptions of best practices that are intended to minimize the risks related to the spread of infection to patients and practitioners. These suggested best practices are to inform the practitioner's professional judgment and can be applied appropriately and thoughtfully within the context of a diverse range of health care settings.

In the event of a serious infectious outbreak, some practices identified in this course may be supplemented or replaced by directives from your provincial Ministry of Health, by your college, or by other provincial or national regulatory bodies.

## 2.2 Overview of Infection Control

Understanding and practising effective infection prevention and control procedures is an important safety consideration for patients, for staff and for your personal safety. Understanding how diseases are transmitted is the first step for practitioners in establishing and maintaining procedures that can break or interrupt the chain of infectious transmission. Infection control requires attention to interactions with patients and staff, with instruments and equipment, and to the practice environment.

### Infections can occur with or without direct skin penetration.

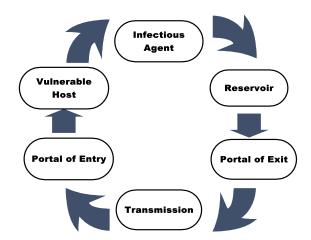
Sharps (e.g., acupuncture needles, dermal needles) are intended to penetrate the skin thereby becoming easily and regularly contaminated by blood or body fluids. The contaminated sharp can infect the practitioner through inadvertent penetration caused by unsafe disposal or handling of the sharps.

Infections may be the result of the use of contaminated equipment or utensils coming in contact with open cuts or contaminated hands inadvertently touching mucous membranes at the eye, nose, or mouth.

As well, potential sources of infection are found through normal contact with the environment including treatment tables, work surfaces, door knobs, and waiting room furniture. The name to such objects is **fomites** (objects that have become contaminated with microorganisms and serve as a vehicle of transmission for infection).

### 2.2.1 Chain of Infection

The infection process can be modelled as a chain of infection.



The chain links the **infectious agent** to the **vulnerable host** through a sequence of connections that allow for the infectious agent to be transmitted. For infection to occur, each link must be present and connected in a sequential order. Understanding the links and how they may be broken provides practitioners with the knowledge that reduces the risk to themselves and to their patients.

Infectious Agent: A pathogenic micro-organism causing the infection or disease. The four types of infectious agents that cause most infectious disease are viruses, bacteria, fungi and parasites. There are many other kinds of infectious agents such as prions (which can cause mad-cow disease) and viroids (which can cause Hepatitis D). Viruses: (e.g., HIV, chicken pox, influenza, hepatitis) are the smallest micro-organism and are made up of the genetic material known as DNA or RNA, which the virus uses to replicate. Viruses require a living host cell to reproduce.

**Bacteria:** (e.g., pulmonary tuberculosis, streptococci) are living organisms that are more complex than viruses. Bacteria have the genetic blueprint to reproduce themselves, whereas viruses must invade other cells to reproduce. Bacteria are normally not more than one single cell but can reproduce very rapidly.

**Fungi:** are single or multi-celled plant-like organisms that can cause a wide variety of fungal infections (e.g., ringworm). Fungi usually appear on the skin, but can infect deeper in the body.

**Parasites:** are organisms that live on or in a host and gets its food from or at the expense of its host (e.g., lice).

Knowing which type of infectious agent is present informs the practitioner of the types of disinfectants, antiseptics, and antimicrobials that are best to use, the severity of the disease it is capable of causing, and the mode of transmission.

The possibility of a micro-organism causing infection is influenced by the organism's *virulence* (ability to grow), *invasiveness* (ability to enter), and *pathogenicity* (ability to cause disease).

**Reservoir:** The reservoir is where the organism lives and grows between outbreaks. This can be food, water source, feces, in the environment, or in a living organism.

**Portal of Exit:** Portal of exit identifies how the infectious agent is able to leave the reservoir (e.g., blood, mucus, secretions, and open wounds).

*Transmission:* Transmission identifies how the agent is able to move from one host to another host (e.g., human-to-human through blood contact, respiratory droplets or other secretions, on the hands of a health care worker, through the air in an unfiltered ventilation system, attached to a living organism like a mosquito). Knowing how the infection is transmitted is essential for deciding the infection control measures that will be the most effective.

In a TCM practice setting, the four main transmission routes that are important to understand are direct contact, indirect contact, droplet, and airborne.

### **Direct Contact Transmission**

This is the physical transfer of the infected organisms by the direct physical contact between an infected person and a vulnerable person. Gastrointestinal infections can be transmitted by contact.

#### **Indirect Contact Transmission**

This is contact through an intermediary such as contaminated equipment or work surfaces. Some organisms are capable of surviving on surfaces for lengthy periods of time. For example, Hepatitis B can remain infectious on equipment for a week or more. In an office setting, inanimate objects such as magazines, toys, door knobs, computer keyboards, and waiting room surfaces are often overlooked as sources of infection.

### Droplet

This is contact due to contaminated splatter or through sneezing or talking when an infected person and a vulnerable person are in close proximity. Infected droplets can often be transferred through contact with the eyes or mouth. Droplets normally are large enough that they remain airborne for only short periods of time and can be controlled with protective equipment such as masks. Influenza, mumps, colds, pertussis, rubella, and SARS are examples of infections that can be transmitted through droplets.

## **Airborne**

Residue from evaporated droplets or infected dust particles can remain suspended in the air for extended periods of time. Airborne micro-organisms can remain suspended for long time periods and can be widely distributed by air currents. Environmental controls such as ventilation systems are often helpful. Diseases such as tuberculosis, measles, and chickenpox are capable of airborne transmissions.

There are other modes of transmission that are not directly relevant to the infection control procedures for a TCM practitioner. For example, *vector-borne transmission* can occur through a bite of vectors such as mosquitoes, rats and dogs, or through contact with the infected surfaces of vectors such as flies. As well *vehicle transmission* relates to

micro-organisms transmitted to multiple hosts through contaminated sources such as water supply, food products, and medications.

**Portal of Entry:** This describes how the agent enters the vulnerable host (e.g., insect bite, inhaling, break in the skin, mouth when eating). The portal of entry (nose, mouth, skin) informs the practitioner on the **personal protective equipment** that may be required.

*Vulnerable Host:* The vulnerable host is the person infected by the agent. The most vulnerable are often the very young and the very old, or those who have their immune systems suppressed. Because of the occupational exposure of health care workers, TCM practitioners and staff have increased opportunities to be exposed to infectious diseases.

### 2.2.2 Contamination and Cross-contamination

Infectious organisms can be spread throughout a clinic by contamination or by cross-contamination.

**Contamination** is the spread of infectious micro-organisms to an object (such as an acupuncture needle or herb storage container).

**Cross-contamination** is the indirect spread of infection from one person to another person via unclean instruments or improper sterilization processes.

Contamination and cross-contamination put both the patient and the practitioner at risk and can be caused by practices such as the following:

- Clean equipment or instruments are placed on unclean surfaces.
- Sterile equipment or instruments are placed on non-sterile surfaces.
- Practitioner hygiene is not sufficient.
- Contaminated instruments and tools are not disposed of promptly and appropriately (used instruments and equipment can be contaminated even without clear visible signs of blood or secretions).
- Linens are not cleaned thoroughly.
- Surfaces and facilities are not satisfactorily and regularly cleaned (viruses can survive on damp, warm work surfaces for just a few hours, e.g., HIV, or for weeks or longer, e.g., Hepatitis A can survive for months).

### 2.2.3 Infections

Infectious micro-organisms in human blood (blood borne pathogens) can cause disease in humans. Use of sharps can expose TCM practitioners to blood borne pathogens. Sharps include objects such as needles, broken glass, and razor blades. The safe handling and disposal of sharps is discussed in more detail in Section 4 of this document.

It is beyond the scope or intent of this course to provide a comprehensive explanation of all pathological conditions. For the purposes of this course, the following diseases and conditions are highlighted for special attention for TCM practitioners.

### Hepatitis A, B, C

Hepatitis is a general term for the medical condition defined by swelling and inflammation of the liver. Hepatitis viruses cause most incidences but hepatitis can also be caused by other means including liver damage from toxins (e.g., alcohol, poisons) and overdoses of medications (acetaminophen).

Many carriers of hepatitis are asymptomatic (show no symptoms) but are still infectious. This requires that safe practices be applied to <u>all</u> patients, and not just patients displaying specific symptoms (see **Routine Practices** below).

Hepatitis B is an irritation and swelling of the liver caused by infection with the Hepatitis B virus (HBV). The swelling of the liver is due to the reaction of the body's immune system to the infection. Hepatitis B can cause acute illness but can become chronic (lifelong). There is no cure for Hepatitis B but there are means to control the infection. Vaccination is an effective means to prevent HBV infection. Health care workers who regularly come in contact with blood and other body fluids are particularly at risk and should be immunized against Hepatitis B. The use of the clean needle technique (see section 4) greatly reduces the risks of infection. (Read Hepatitis B Fact Sheet, Health Canada) <a href="https://www.phac-aspc.gc.ca/hcai-iamss/bbp-pts/hepatitis/hep\_b-eng.php">https://www.phac-aspc.gc.ca/hcai-iamss/bbp-pts/hepatitis/hep\_b-eng.php</a>

**Hepatitis C** is a viral disease that leads to swelling of the liver and is caused by the Hepatitis C virus (HCV). Hepatitis C has an acute and chronic form. There are some treatments, but there is no vaccine. Health care workers who regularly come in contact with blood have an elevated risk. The use of the clean needle technique (see section 4) greatly reduces the risks of infection. (Read *Hepatitis C Fact Sheet*, Health Canada)

http://www.phac-aspc.gc.ca/hcai-iamss/bbp-pts/hepatitis/hep\_c-eng.php

**Hepatitis A** is more frequently evidenced in locations with poor sanitation. Eating food and drinking water that is contaminated by fecal matter containing Hepatitis A is common source of Hepatitis A virus (HAV). Hepatitis A is less severe than Hepatitis B or C. Hepatitis A infected blood presents a smaller risk to practitioners. Like Hepatitis B, there is a vaccine that can be administered for Hepatitis A. Unlike Hepatitis B, there is no unique risk for healthcare workers that would specifically recommend the Hepatitis A vaccine. An effective means of prevention against HAV infection is regular hand washing. (Read *Hepatitis A Fact Sheet*, Health Canada)

http://www.phac-aspc.gc.ca/hcai-iamss/bbp-pts/hepatitis/hep\_a-eng.php

The *Immunization Action Coalition* summarizes and compares Hepatitis A, B, and C. This summary should be examined by practitioners. The document is available online at the following site.

http://www.immunize.org/catg.d/p4075abc.pdf

### **Human Immunodeficiency Virus (HIV)**

HIV impacts the immune system and can result in progressive illnesses and increased vulnerability to infections. HIV is spread through direct blood-to-blood contact and through direct contact with certain body fluids, including blood. Health care workers who regularly come in contact with blood and other body fluids should take appropriate

precautions. HIV can lead to Acquired Immune Deficiency Syndrome (AIDS), which is a collection of diseases that a person can contract when their immune system is weakened. HIV can be diagnosed with a blood test. AIDS is diagnosed through a combination of indicators, including a confirmed HIV infection, and further evidence of certain infections.

In a TCM practice, strict adherence to the routine practices outlined in this document provides effective measures to minimize risks for patients and practitioners. Read information from Health Canada on HIV/AIDS.

http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/diseases-maladies/hiv-vih-eng.php

### **Tuberculosis**

Tuberculosis is contagious bacterial infection that mainly involves the lungs. Tuberculosis can be transmitted by breathing in droplets from a cough or sneeze of an infected person. It is not highly contagious. People with tuberculosis are most likely to spread the bacteria to people that they have prolonged or regular contact. (As required, read Health Canada for additional information)

http://www.phac-aspc.gc.ca/tbpc-latb/index-eng.php

### Influenza

Influenza or the flu affects primarily the respiratory tract and is caused by the influenza virus. Influenza is spread through droplets when someone coughs or sneezes, through the air in enclosed spaces, through direct contact with contaminated hands, and indirect contact with contaminated objects (e.g., door knobs). Influenza often has seasonal strains. The elderly or weak are at greater risk of worsening complications. (Health Canada has additional information on the Canadian Pandemic Influenza Plan for the Health Sector)

http://www.phac-aspc.gc.ca/cpip-pclcpi/pdf-eng.php

### **Pneumonia**

Pneumonia is a respiratory condition caused by an infection of the lungs. Pneumonia may be caused by bacteria, viruses, or fungi. In adults, bacterial infection is the most common cause (e.g., bacteria from the sinuses or mouth may spread to the lungs). In infants and children, viruses can commonly cause pneumonia.

### **Skin Infections**

Skin infections can range in cause (bacterial, fungal), visibility (from small spot to covering large portions of the body) and in seriousness (from harmless to life threatening). The most common types of bacterial skin infections are caused by *Staphylococcus* and *Streptococcus*. Bacteria can invade through broken skin causing a range of discomfort and ulcerations. The nature of TCM practice requires practitioners to be vigilant of skin disorders on themselves and on their patients.

As health care professionals, TCM practitioners have an obligation to report communicable/ reportable diseases. If during the course of treatment, practitioners become aware of a communicable/ reportable disease, they must take the necessary steps to report as required by provincial legislation. The links below provide further information about reportable diseases.

### **British Columbia**

http://www.bccdc.ca/NR/rdonlyres/261E1CF3-7D31-4DEB-AE13-968D330C91BC/0/Epid Guidelines reportable diseases British Columbia July2009.pdf Ontario

http://www.toronto.ca/health/cdc/communicable disease surveillance/monitoring/pdf/reportablediseases.pdf

### 2.3 Routine Practices

Health Canada uses the terminology "Routine Practices" to identify the foundational level of infection control to be used in a healthcare setting, and identifies procedures that apply at all times and with all patients. In the United States, the Centres for Disease Control (CDC) may use the equivalent term "Standard Precautions".

Routine practices are based on the assumption that all patients are potentially sources of infection, even if a person shows no symptoms or illness. As well, all blood, body fluids (except tears and sweat), secretions, excretions, non-intact skin, undiagnosed rashes, and areas such as eye, nose, and mouth are potentially infectious. Routine practices control the transmission of infectious microorganisms in healthcare settings from patient-to-practitioner, patient-to-patient and practitioner-to-patient.

Routine practices for TCM practitioners include:

- 1. Conducting Risk Assessment
- 2. Hand Hygiene
- 3. Use of Personal Protective Equipment
- 4. Safe Handling and Disposal of Sharps

### 2.3.1 Conducting Risk Assessment

A risk assessment approach to infection control requires the practitioner to analyze and assess how risks can be minimized before each interaction with patients, and as an overall strategy for clinical safety.

A patient risk assessment should be performed before each interaction with a patient. The required interventions required to prevent the transmission of infection will vary, and will be dependent on the:

- likelihood of exposure to blood, secretions, and body fluids;
- health of the patient;
- characteristics of the patient, such as level of anxiety;
- clinical environment and resources available;
- immune status of the practitioner.

Higher risk procedures may require the use of appropriate personal protective equipment, while interactions that do not involve physical contact may require less precautions.

The chart below provides examples of infection control strategies that vary by your patient risk assessment. These strategies are for the protection of the practitioner, the patient, and the staff.

Situation	Infection Control Strategy
Routine patient interview with no physical contact	Hand washing Respiratory etiquette* (cover mouth and nose when coughing,
no priysical contact	wash hands)
Physical contact with patient and either you	Hand washing
or the patient has an open wound	Use of medical gloves, proper disposal, followed by hand washing
Contact with patient may involve body fluids	Hand washing
or splattering (droplets)	Professional judgment related to use of medical gloves, mask, eye protection, gowns
	Proper disposal of protective equipment, followed by hand
	washing
Physical contact with patient with	Hand washing
respiratory concerns or symptoms	Respiratory etiquette (cover mouth and nose when coughing, wash
	hands)
	Professional judgment related to use of medical gloves, mask (on
	you and/or patient), eye protection
Physical contact with patient with a fever	Hand washing
and respiratory concerns or symptoms	Respiratory etiquette (cover mouth and nose when coughing, wash hands)
	Professional judgment related to use of medical gloves, mask (on you and/or patient), eye protection
	Health alert observation, as appropriate

# \* Respiratory Etiquette

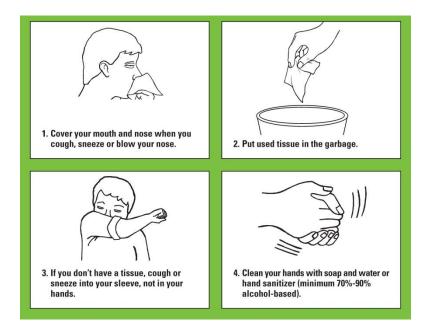
The following measures to contain respiratory secretions are recommended for all individuals with signs and symptoms of a respiratory infection.

- Cover the nose/mouth when coughing or sneezing.
- Use tissues to contain respiratory secretions and dispose of them in the nearest waste receptacle after use.
- Perform hand hygiene (e.g., hand washing with non-antimicrobial soap and water, alcohol-based hand rub, or antiseptic hand wash) after having contact with respiratory secretions and contaminated objects/materials.

The following posters by the Region of Peel Public Health and Toronto Public Health can be useful in a TCM practice setting.

http://www.phac-aspc.gc.ca/amr-ram/ipcbp-pepci/gfx/cough-toux\_large-eng.jpg

http://www.toronto.ca/health/cdc/resources/pdf/english\_cough\_factsheet\_pos\_ter.pdf



The Centre for Disease Control (CDC) has a number of pamphlets and flyers that may be useful in your health care setting.

http://www.cdc.gov/flu/professionals/pdf/resphygiene.pdf http://www.cdc.gov/flu/pdf/protect/cdc\_cough\_nologo.pdf http://www.cdc.gov/flu/protect/covercough.htm

# 2.3.2 Hand Hygiene

Hand hygiene is the most important infection control measure.

Hand washing should be done:

- before and after patient contact or acupuncture treatment;
- before and after preparing, handling, or dispensing herbs or herbal remedies;
- when hands are contaminated during the treatment;
- immediately after inadvertent exposure to blood or body fluids;
- when hands are visibly soiled;
- after contact with environmental surfaces or equipment;
- after removing gloves;
- before preparing, handling, serving or eating food;
- after handling money or other items that may be contaminated;
- after answering the phone or using the computer or other electronic devices and returning to a patient;
- after personal body functions.

### **Hand Washing Procedure**

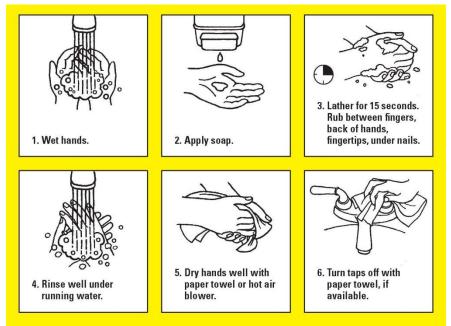
Remove any hand or wrist jewellery and avoid use of artificial (acrylic) nails.

### Follow these 6 steps when hand washing.

- 1. Wet your hands in warm running water.
- 2. Apply sufficient liquid soap to achieve lather. (Bar soap is discouraged and should not be used.)

- 3. Wash all surfaces of your hands including backs of hands, fingertips, between fingers, wrists, base of thumbs, and around and under finger nails. Scrubbing should last approximately 15 seconds.
- 4. Rinse well and leave water running.
- 5. Dry thoroughly with a disposable paper towel or electric hand dryer.
- 6. Turn off the water with the towel, and not with your bare hands. Automatic taps are an effective option.

Toronto Public Health has very useful posters that can be used to educate staff and patients regarding hand washing and hand sanitizing.



The complete poster on hand washing can be obtained at: http://www.toronto.ca/health/cdc/resources/pdf/handwashing\_poster.pdf

### Alcohol-based hand rubs

If hands do not have visible soiling, then the use of an alcohol-based hand rub is an effective addition to (but not a substitute for) hand washing. When using hand rub, apply the product to dry hands and rub hands together, covering all surfaces, for at least 30 seconds. Hands should be allowed to dry thoroughly. Do NOT use paper towels.

### For further details visit:

http://www.health.gov.on.ca/english/public/pub/pubhealth/pdf/handwash\_tech.pdf

A useful poster on hand sanitizing can be obtained from Toronto Public Health at: <a href="http://www.toronto.ca/health/cdc/resources/pdf/handsanitizing\_poster.pdf">http://www.toronto.ca/health/cdc/resources/pdf/handsanitizing\_poster.pdf</a>

There are many additional resources that practitioners can access to educate themselves, patients, and staff on proper hand hygiene.

### **Ontario Ministry of Health and Long-term Care**

• <a href="http://www.health.gov.on.ca/english/public/pub/pubhealth/pdf/handwash\_tec">http://www.health.gov.on.ca/english/public/pub/pubhealth/pdf/handwash\_tec</a> h.pdf

### **British Columbia Centre of Disease Control**

• http://www.bccdc.ca/prevention/HandHygiene/default.htm

### **Centre of Disease Control and Prevention (US)**

http://www.cdc.gov/handhygiene/

# **World Health Organization**

- http://www.who.int/gpsc/en/
- <a href="http://www.who.int/gpsc/5may/How To HandRub Poster.pdf">http://www.who.int/gpsc/5may/How To HandRub Poster.pdf</a>
- http://www.who.int/gpsc/5may/How To HandWash Poster.pdf

Practitioners can visit the site "Clean Hands, Good Health" for an informative video tutorial on hand washing.

http://www.ahsc.health.nb.ca/cleanhandsahsc/cleanhandsworkingahsc.html

### **Hand Care**

Frequent hand washing requires practitioners to gently dry hands to avoid chapping which can cause the skin to break open, providing an entry portal for bacteria. Hand lotion can assist in maintaining soft skin in order to reduce chapping. Lotion should be available to all staff.

Fingernails should be kept short and clean. The use of artificial nails or the wearing of hand or wrist jewellery is strongly discouraged because they can harbour bacteria.

### Hand washing facilities

Because hand hygiene is central to effective infectious control, hand washing facilities in the clinic should be clearly accessible and kept fully equipped and sanitary.

- every sink should have soap dispensers and disposable towels
- alcohol-based rubs should be clearly evident and be easy to access and use
- to reduce contamination, hand washing sinks should not be used for other purposes

If a treatment room does not contain a sink, alcohol-based rubs should be readily accessible. Remember, alcohol-based rubs are not a substitute for hand washing.

### **Antiseptic Agents**

Antiseptics are antimicrobial substances that can be used as skin preps for patients. Using an antiseptic such as isopropyl alcohol (70%) provides effective skin cleansing prior to invasive procedures. Use disposable swabs or forceps with disposable cotton ball with isopropyl (70%) to clean skin.

### 2.3.3 Use of Personal Protective Equipment (PPE)

Practitioners may need to use personal protective equipment to protect themselves from potential infections. PPE's can also protect the patient by preventing the practitioner from becoming the agent of transmission of infectious organism from patient-to-patient.

### **Medical Gloves**

Practitioners should use clean, single-use gloves when the following contacts are anticipated:

contact with blood and body fluids

- contact with mucous membranes, pus, secretions, undiagnosed rashes or nonintact skin
- the practitioner has non-intact skin on her or his hands, or is HIV or HBV positive

Non-sterile examination gloves (latex, vinyl, or nitrile) must meet the requirements of Health Canada. Vinyl gloves tend to be less durable, and some patients report sensitivities and allergic reactions to latex gloves. Gloves must be discarded after each procedure (see additional sections on **Waste Disposal**).

Practitioners should assess the possibility of blood contact during each treatment and consider the use of medical gloves as appropriate.

- The use of medical gloves may not be essential during a routine acupuncture treatment due to the absence of significant bleeding. See Section 4 Safe
   Procedures and Practices: Acupuncture for additional considerations related to the clean needle technique.
- Medical gloves are strongly recommended if "bleeding" is performed for the purpose of treatment or if the patient has open wounds or lesions.
- Medical gloves are highly recommended for palpation or needling in the mouth or genital area.

Note: Medical gloves provide an additional level of protection to the practitioner and to the patient. The use of medical gloves is NOT a replacement for thorough hand hygiene.

### **Protective Clothing**

Gowns and aprons should be worn by practitioners and staff when there is risk of soiling or splatter. If soiled, gowns should be replaced after a patient treatment. Plastic aprons provide additional protection for some procedures (e.g., bleeding). The lab coat is not protective equipment and does not replace an apron or gown when required. The white lab coat might seem clean, but could be harbouring infectious bacteria.

When dealing or disposing soiled linens, the practitioner and staff must use appropriate protective equipment (e.g., non-medical utility rubber gloves) to transport or dispose of soiled linens, gowns or aprons.

### Masks

Masks can provide additional protection for the practitioner or the patient to transmission by droplets or splatter. Masks are effective in minimizing the risks and the spread of droplet-borne organisms (e.g., coughs and sneezing), but are less effective for airborne infections.

### 2.3.4 Safe Handling and Disposal of Sharps

(Note: see further details in Section 4: Safe Procedures and Processes: Acupuncture)

Used needles and sharps are classified as non-anatomical, biohazardous waste, and as such, must be treated with extreme care in order to protect patients and staff from injury as a result of contact from sharp objects.

- The practitioner is responsible for ensuring that acupuncture needles and other sharps are disposed of safely.
- The person using the sharp must dispose of the sharp himself or herself.

- Single-use sharps are opened in front of the patient and disposed of immediately after use in a puncture-resistant, rigid container that cannot be punctured by sharps under normal conditions.
- It is recommended that the container have a handle for safe transport and a lid that fits tightly. As well, the container should allow the practitioner to open it with one hand for ease of disposal.
- The container should be identified with the biohazard label and placed out of reach of children.
- Containers should not be filled to more than three-quarters capacity.
- Containers must <u>not</u> be treated as "general waste" and must be disposed of in compliance with approved local and provincial procedures.

# 2.4 Additional Precautions

The previous section focused on some of the **routine practices** that apply at all times and with all patients.

Additional precautions (or *transmission-based precautions*) may need to be used in conjunction with routine practices when such practices are deemed not to be sufficient to control transmission. Additional precautions focus on the further measures that may need to be employed based on the mode of transmission — contact, droplet, or airborne. They include the physical separation of individuals who are known or are suspected of being infected or colonized by pathogens, and the use of protective barriers to limit or prevent transmission by contact, droplet or airborne transmission.

### 2.4.1 Patient Management

Some patients may arrive at a clinic with communicable diseases that will require additional precautions to keep you, your staff, and other patients safe.

Because of the very nature of the work of TCM practitioners, people who are ill will be seeking your advice and the waiting room of the clinic may be an environment that hosts infectious diseases. It is the responsibility of the practitioner to protect all patients who have come to her or him for health care through vigilant patient management and a clean clinical environment.

### **Additional Precautions for Infectious Patients**

- Try to arrange the waiting room to maximize the separation of possibly infectious patients from other patients (2 metres or more if possible).
- Post signs that patients with respiratory or gastrointestinal symptoms should clearly identify this to the practitioner or to staff.
- Post signs encouraging respiratory etiquette (covering nose and mouth).
- Offer masks to patients, provide tissues, waste containers, and hand sanitizers.

### **Droplet Transmission Precautions**

- Triage the patient from the waiting room as quickly as possible.
- Use a mask and wear medical gloves while working within 2 metres of the patient, and offer a mask and hand sanitizer to the patient.
- At the end of the treatment, wipe all horizontal surfaces and utilized instruments with low-level disinfectant.

### **Contact Transmission Precautions**

- Triage the patient from the waiting room as quickly as possible.
- Wear medical gloves and gown, as appropriate.
- Offer patient hand sanitizer.
- At the end of the treatment, wipe all horizontal surfaces and identified instruments with low-level disinfectant.

### **Airborne Transmission Precautions**

- Triage the patient from the waiting room as quickly as possible.
- Try to see these patients at the end of the day or during low volume times.
- Use a high-efficiency mask (e.g., N95 particulate respirator).
- If treating patients with chickenpox (varicella) or measles (rubeola), the treating practitioner should be immune.
- Provide a mask for the patient to use throughout the treatment; offer hand sanitizer.
- Notify staff of the need for extra care or to use masks if not immune.
- Open a window if possible, or allow time for ventilation to exchange air (ideally, the patient is at the end of the day).

TCM practitioners must ensure that infection prevention and control procedures (including routine practices and additional precautions) are evident in their practice and applied by staff.

This poster by the Region of Peel Public Health can be useful in a TCM practice setting. <a href="http://www.phac-aspc.gc.ca/amr-ram/ipcbp-pepci/gfx/poster-affiche\_large-eng.jpg">http://www.phac-aspc.gc.ca/amr-ram/ipcbp-pepci/gfx/poster-affiche\_large-eng.jpg</a>

**Example of Client/Resident Screening Questionnaire,** developed by Peel Region Public Health and adapted from British Columbia Centre for Disease Control. <a href="http://www.phac-aspc.gc.ca/amr-ram/ipcbp-pepci/appendix\_ii-annexe\_ii-eng.php">http://www.phac-aspc.gc.ca/amr-ram/ipcbp-pepci/appendix\_ii-annexe\_ii-eng.php</a>

# 2.5 Clean Environment, Clean Equipment

### 2.5.1 Environment Cleaning

### **General Housekeeping**

All housekeeping surfaces need routine or periodic cleaning with a solution of diluted detergents. Establish a cleaning schedule to ensure all surfaces are kept clean, and educate your cleaning staff to ensure they understand the importance of their work in a health care setting. High traffic or high touch surfaces should be identified for more frequent cleaning (e.g., door knobs, handles) possibly using a low-level disinfectant, where appropriate. Non-clinical surfaces that are low-risk of contamination should be cleaned first then disinfected using a low-level disinfectant such as:

- quaternary ammonium compounds
- chlorine bleach solution (e.g., 1:500, 1 part chlorine and 499 parts water)
- 3% hydrogen peroxide
- phenols (sometimes called phenolics)

These products come as liquids or as disinfectant wipes. Staff should use household utility gloves for disinfecting.

**Note**: There is a difference between alcohol-based wipes and detergent-based wipes when cleaning. Alcohol wipes do not clean and their use is limited to routine environmental decontamination. Detergent wipes clean but do not disinfect. Detergent wipes are suitable for environmental cleaning, but are not suitable for blood and body fluid spillages.

Floor mops should be cleaned and dried after use, and fresh cleaning solutions should be used each day to prevent creating reservoirs for infectious organisms. Carpets are not recommended for high traffic areas. Carpets are more difficult to clean and disinfect to the standard required in a health care setting.

### **Clinical Contact Surfaces**

Clinical contact surfaces that may be contaminated by spray, splatter, or touch should be cleaned and disinfected after each patient visit. Surfaces should be cleaned (using utility gloves) with a low-level disinfectant. In some instances, an intermediate level disinfectant (e.g., 1:10 household bleach mixed daily or 70-90% isopropyl alcohol) may be necessary. To facilitate clinical cleaning, treatment areas should be uncluttered and well organized.

### Spot Cleaning of Blood Spills

- Wear household utility gloves.
- Blot or wipe up as much as possible using disposable towels. Dispose of the
  paper towels in a plastic lined and covered container (see additional information
  on waste disposal).
- Clean the spill area with a detergent disinfectant. Dry with disposable towels.
- Use an intermediate-level, hospital-grade disinfectant on the area and follow the manufacturer's directions. An alternative is a 1:10 dilution of household bleach and leave for at least 10 minutes before drying with a disposable towel.

### **Laundering Sheets, Towels or Other Linens**

Practitioners may use linens (washed on-site or handled by a linen service) or disposable paper sheets to cover patient treatment areas. All bed linens, used towels, or disposable paper sheets must be changed between patients.

Linens (e.g., sheets, towels, gowns, pillow cases) can be laundered with hot water (70°C to 80°C) and soap if there is no visible soiling (bleach can be added as required by soiling).

Linen that is soiled with blood should be handled, transported and laundered with additional care. Place linen in appropriate impermeable bags and use protective non-medical utility gloves when handling.

### 2.5.2 Cleaning, Disinfecting and Sterilizing

Practitioners are expected to understand the differences among and important features of what is meant by cleaning, disinfecting, and sterilizing in the context of their TCM practice.

**Cleaning** is the removal of visible soil from objects and surfaces and normally is accomplished using water with detergents or enzymatic products. Thorough cleaning is

vital before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments constrain the effectiveness of these processes.

**Sterilization** describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, and liquid chemicals are sterilizing agents often used in health care facilities.

**Disinfection** describes a process used on inanimate objects that kills or destroys many or all infectious microorganisms, except bacterial spores. In health care settings, objects are usually disinfected using liquid chemicals.

**Sterilants** are a unique class of disinfectants. Unlike sterilization, disinfection does not kill spores. A few disinfectants will kill spores with prolonged exposure times (3–12 hours); these are called chemical sterilants. These same chemicals used for *shorter* exposure periods can act as high-level disinfectants.

**Decontamination** removes infectious microorganisms from objects so they are safe to handle or discard.

**Germicide** is an agent that can kill pathogenic organisms or "germs". The term *germicide* includes both **antiseptics** and **disinfectants**.

Antiseptics are germicides that can be applied to skin and tissue; while disinfectants are anti-microbial substances that can be applied only to inanimate objects.

**Fungicide**, **bactericide**, **and sporicide** are examples of terms that indicate by their prefix the type of microorganism that can be destroyed through application. For example, a fungicide is an agent that kills fungus.

### 2.5.3 Cleaning Instruments and Equipment

TCMPA: Safety Course

Cleaning of equipment and reusable patient care items and instruments is an essential step for preventing transmission of infected micro-organisms to patients and to practitioners.

Practitioners can reference a useful *Fact Sheet* from Toronto Public Health titled, *Personal Service Settings: Cleaning Instruments*. http://www.toronto.ca/health/cdc/infection\_control/pdf/cleaning\_instruments.pdf

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Toronto Public Health, January 2009.

**Instruments MUST be properly cleaned, rinsed and dried before disinfection and sterilization.** Cleaning can be considered the most important step since it is required to remove any organic debris that will compromise the process of disinfection or sterilization. The following chart is adapted from "Infection Prevention and Control Best Practices for Personal Services Setting", Ministry of Health and Long-Term Care, Ontario, January 2009.

# Steps to Clean Instruments

	Cleaning Process	Reason and Comments
1.	Soak items that cannot be immediately cleaned in a container of clean warm water (with or without detergent) in a clean sink or in a labelled "dirty instruments" container.	Soaking instruments prevents blood and other organic matter from drying on the item. Do not soak dirty items in hot water or in a disinfectant before cleaning, as this can cause organic matter (dirt) to stick to the surface of the object.
2.	Put on thick rubber utility gloves (non-medical gloves).	Thick rubber utility gloves suitable for cleaning have a wider bib at the wrist to help prevent water from entering the inside of the glove.
3.	Take instruments apart and <b>rinse</b> in a sink filled with <b>lukewarm</b> water.	Hot water may cause organic matter (dirt) to stick to objects.
4.	Prepare cleaning sink by adding warm water and detergent.	To reduce the risk of injury, ensure that sharp objects are visible by using low suds detergent according to directions.
5.	Clean instrument surfaces by using <b>friction</b> (washing and scrubbing motions). Use a brush to clean any crevices or seams in instruments	Scrub below the water surface to prevent splashing into the eyes or onto clothing. An <b>ultrasonic cleaner</b> may be used for cleaning. When using this device, the lid should be closed to prevent aerosolization.
6.	<b>Inspect</b> instruments to ensure removal of all visible organic matter.	Organic matter prevents disinfection from occurring.
7.	Drain dirty water. <b>Rinse</b> cleaned instruments under running water.	Rinsing removes residual detergent and soil that may impair the function of the instrument or interfere with the action of disinfectants
8.	Either air dry or <b>dry</b> with a disposable towel.	If wet items are not dried a film may be left on the surface which may contain pathogens.
9.	Store cleaned instruments in a <b>covered</b> container (can be towel or clean storage area) until disinfected or sterilized, as required.	Uncovered, clean instruments may become contaminated by dust or moisture.
10.	Clean and disinfect the <b>sink</b> .	Sinks become contaminated during use, therefore, cleaning and disinfection is required to reduce microorganisms prior to reuse.
11.	Remove rubber utility <b>gloves</b> and wash, rinse and, hang to dry.	Cleaned rubber utility gloves may be used again as long as the rubber is not torn or punctured.
12.	Perform hand hygiene.	Hand hygiene should be performed after removing gloves.

### **Additional Best Practices: Cleaning**

- Staff must be protected when cleaning instruments. Supply required personal protective equipment.
- Begin the cleaning process as soon as possible after use so that organic material does not dry and harden.
- If staff are used to clean equipment, it is best to assign tasks to a single person who should receive ongoing training related to new instruments or equipment.
- Follow manufacturer's recommendations and keep important procedures near the reprocessing area for reference and reminder.
- The use of automated cleaning equipment can be more efficient, effective and safe for staff by reducing risks of exposure to blood or body fluids. Large debris should be removed before using ultrasonic cleaners. Ultrasonic cleaners do not sterilize or disinfect.

### 2.5.4 Sterilizing, Disinfecting

Specific patient care items must be cleaned and then disinfected or sterilized after each use.

Instruments are categorized based on whether they contact sterile tissue, mucous membranes, or intact skin. Medical instruments are categorized as either critical, semicritical, or non-critical. The categorization is used to determine the reprocessing requirements.

## **Categorization of Medical Instruments**

Category	Definition	Reprocessing (minimum
		requirement)
Critical Item	enters sterile tissue including	cleaning, followed by
	bloodstream (arteries and veins).	sterilization
Semi-critical item	contacts intact mucous	cleaning, followed by high-level
	membranes or non-intact skin	disinfection* (some items may
	(but ordinarily does not	require only intermediate level
	penetrate) the exception being	disinfection)
	needling followed by cupping in	
	which exposure to blood borne	
	pathogens require sterilization of	
	cupping devices.	
	e.g., cupping devices,	
	acupuncturescope.	
Non-critical item	contacts intact skin (but not	cleaning, plus low level
	mucous membranes) or does not	disinfection
	directly contact the patient	
	these items are rarely	
	contaminated	
	e.g., Tuina devices, electrical	
	clips and rubber or silicone	
	electrical pads.	

<sup>\*</sup> Sterilization is preferred for semi-critical items, but especially for items that cannot tolerate sterilization, high-level disinfection can be used

Some of the factors that reduce the effectiveness of disinfection and sterilization include:

- insufficient cleaning as an initial step to remove matter
- nature and level of contamination
- incorrect dilution of disinfectant
- water that is used is too hard
- inadequate exposure time to the germicide
- physical nature of the object (e.g., small crevices, flexible hinges)
- incorrect temperature and pH of the disinfection process
- reduced effectiveness because used passed expiry date
- reactions to rubber or plastic

### Disinfection

*Disinfection* is a process used on inanimate objects to eliminate many or all pathogenic micro-organisms, except bacterial spores.

Disinfectants are all registered in Canada and should come with a DIN number. This means that the manufacturer has to stand behind the claims about which microorganisms it is effective against and the described safe use of the product. You should request the material safety data sheet (MSDS) which provides information about the product and the worker safety procedures. There are three levels of disinfection: high-level, intermediate-level, and low-level.

### **Disinfection Chart**

The following chart is adapted from, "Infection Prevention and Control Best Practices for Personal Services Setting," Ministry of Health and Long-Term Care, Ontario, January 2009. This chart is **NOT** inclusive of all approved high-, intermediate-, and low-level disinfectants but is only to provide guidance to practitioners.

### **High-Level Disinfection**

High-level disinfectants will kill all bacteria and viruses but will not kill large numbers of bacterial spores. These disinfectants may be used for critical items that cannot withstand heat sterilization.

Chemical (examples)	Application	Exposure Time (approximate)	Notes
2% gluteraldehyde* (not recommended for personal service settings)	semi-critical devices	45 minutes (follow manufacturer's instructions)	Toxic, irritating to skin, and limited shelf life Use in well ventilated room NEVER use as a spray Not recommended for personal service settings
6% hydrogen peroxide	semi-critical	45 minutes (follow	Can be corrosive to metals such as
(not the 3% hydrogen	devices	manufacturer's	brass, copper, silver
peroxide found in stores)		instructions)	
Ortho-phthalaldehyde (OPA)	semi-critical	> 10 minutes (follow	Less occupational risk
0.55%	devices	manufacturer's	No mixing and fast acting
		instructions)	Stains proteins and limited shelf life
1:50 chlorine bleach solution	semi-critical	> 20 minutes	Inexpensive, but can corrode and
(using 5.25% chlorine bleach)	devices		destroy adhesives

<sup>\*</sup> can be used as a **sterilant** with increased exposure time (>10 hours) and carefully following manufacturer's instructions.

### Intermediate-Level Disinfection

Intermediate-level disinfectants will kill most bacteria, most fungi, and most viruses but does not kill large numbers of bacterial spores such as *Mycobacterium tuberculosis*.

Chemical (examples)	Application	Exposure Time	Notes
		(approximate)	
70 – 90% isopropyl alcohol	semi-critical ,devices	10 minutes	allow to dry
	environmental surfaces		fast acting
			can damage rubber
1:50 chlorine bleach	semi-critical devices,	≥ 10 minutes	inexpensive, but can
solution	environmental surfaces		corrode and destroy
(using 5.25% chlorine			adhesives
bleach)			

### **Low-Level Disinfection**

Low-level disinfectants will kill some bacteria, some fungi, and some viruses (e.g., HBV, HCV) but it is not effective against *Mycobacterium tuberculosis*, *fungi*, *or spores*.

Chemical (examples)	Application	Exposure Time (approximate)	Notes
Quaternary ammonium compounds	non-critical devices daily cleaning and	follow manufacturer's instructions	Do not use for disinfecting instruments
3% hydrogen peroxide	disinfection of all surfaces		Low risk of irritation to the user
1:500 chlorine bleach			
solution			May corrode or oxidize some metals
Phenolics			For environmental
			surfaces only

### **Sterilization**

Sterilization, when done correctly, destroys all forms of microbial organism (bacteria, viruses, spores, and fungi) including the most resistant forms such as bacterial spores.

All items that are invasive or pierce the skin MUST be sterilized. Single-use, presterilized, acupuncture needles must be used prior to the expiry date and should not be reused or desterilized.

Any sterile instruments that are accidently touched or contaminated, either before or during treatment, should be replaced by another sterile instrument. All items that are reprocessed for sterilization must be pre-cleaned and appropriately packaged and stored after sterilization.

There are two main types of sterilization: steam (autoclave) and dry heat.

### **Steam Autoclave**

Steam sterilization is a practical, economical, and effective means of sterilization and is the most frequently used form used by TCM practitioners. The time required for sterilization will be dependent on whether the instrument is wrapped or unwrapped. For example, packaged items at 121° C may require a

sterilization time of 30 minutes. Others may suggest 133° C for 15 minutes. Unpackaged instruments regularly require less time. Unwrapped instruments should be used immediately to avoid contamination. Some autoclaves may not have a drying cycle, but packages must be dry before being removed to reduce chance of contamination.

Always follow manufacturer's guidelines and instructions when using the autoclave.

### **Dry Heat Sterilizers**

It is recommended that dry heat sterilizers be used for items that cannot be sterilized by steam. It can be effective for use with glass and may be more effective for instruments that cannot be disassembled. Dry heat sterilizers require longer exposure time and higher temperatures (limiting available options for packaging).

Sterilization CANNOT be done by domestic ovens, microwave ovens, boiling water, alcohol, ultraviolet sterilizer, or pressure cookers.

### **Monitoring Sterilization**

Chemically treated bags or tape that alters colour are useful to confirm that items have been processed and have been exposed to the required combination of time, temperature, and steam. These indicators do NOT provide evidence that sterilization has taken place. Only biological indicators (or spore tests) can confirm sterilization. Spore strips or vials should be placed in the centre of the load during a regular sterilizing cycle. For steam sterilization, Bacillus stearothermophilus should be used, and for dry heat, Bacillus subtilis should be used.

Tests should be conducted each month (more frequently for heavy use) and sent to a laboratory to test for spore kill. Your clinic should have a back-up plan for sterilization in case test results are positive and the sterilizer needs to be repaired or replaced.

All items for sterilization must be pre-cleaned. The effectiveness of sterilization is influenced by time, temperature, pressure (in autoclave), and full contact with the item that is being sterilized.

The following chart is adapted from, "Infection Prevention and Control Best Practices for Personal Services Setting," Ministry of Health and Long-Term Care, Ontario, January 2009.

# Steps to Sterilizing Instruments

	Steps	Notes
1	Clean instruments. (See chart: Steps to Clean Instruments)	Instruments that are not clean <b>cannot</b> be sterilized.
2	Perform <b>hand hygiene</b> and apply gloves.	Hands should be as clean as possible to prevent contamination of clean instruments/equipment.
3	Clean instruments must be placed in the appropriate <b>sterilization package</b> and sealed.	Sealed packaged items will maintain sterility after sterilization has been achieved until opened for use. If packaging becomes wet or damaged, sterility cannot be ensured.  Instruments in damaged packages must be re-sterilized or
		discarded. Ensure packaging is appropriate for type of sterilizer used.
4	Temperature sensitive <b>chemical indicators</b> must be used with each package.	Temperature sensitive chemical indicators provide an immediate visual check to ensure package has been processed. Note: The colour change demonstrated by a chemical indicator does not ensure that the processed items have been sterilized. Only an appropriate biological indicator can confirm that the sterilization cycle has been successful.
5	Load the sterilizer evenly and avoid overloading the chamber. Follow manufacturer's directions for loading the chamber.	Overloading the sterilizer will prevent effective sterilization; allow space between the packages.
6	<b>Start</b> the sterilization process.	Sterilizing time, temperature, pressure and cycles may vary depending on the type of sterilizer used. Follow manufacturer's instructions at all times. With dry heat and autoclave sterilization, time does not start until the appropriate temperature has been reached.
7	After the sterilization cycle has been completed, <b>remove</b> instruments when dry.	Ensure items are dry before removing from the unit. Sterilized instruments may become contaminated when wet packaging is handled.
8	Store sterilized items in a clean, dry, place that is protected from dust, dirt, and moisture. Sterile items must be stored off the floor.	Handling increases the chances of punctures of sterilized bags. Sterilized items must be stored separately from dirty equipment/instruments.  Check the following:  • the seal is intact  • package is free of tears, dust, dampness  • chemical indicators have changed to appropriate colour
9	<b>Record</b> information about each sterilization cycle in the log book.	Monitor each load, recording temperature, pressure, cycle length, etc.  Mark the date that the product was sterilized
		Mark the date that the product was sterilized.

# **Additional Reference:**

Best Practice Guidelines for the Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities, British Columbia Ministry of Health (Patient Safety Branch), March 2007. <a href="http://www.health.gov.bc.ca/library/publications/year/2007/BPGuidelines Cleaning Disinfection Sterilization MedicalDevices.pdf">http://www.health.gov.bc.ca/library/publications/year/2007/BPGuidelines Cleaning Disinfection Sterilization MedicalDevices.pdf</a>

*Infection Prevention and Control Best Practices for Personal Services Setting, Ministry of Health and Long-Term Care, Ontario, January 2009.* 

http://www.health.gov.on.ca/english/providers/program/pubhealth/oph\_standards/ophs/progstds/pdf s/pssp\_2008.pdf

# 2.6 Safety Responsibilities of Practitioners and Staff

### 2.6.1 Training

All clinical staff should receive sufficient training about the risks of their assigned tasks and the infection prevention and control strategies that are relevant to their assigned tasks. Risks should be expressed in terms of the office-specific environment. The training should be continually monitored and updated to reflect changes in policies, procedures, staff changes, and equipment. Included in this training is an understanding of the responsibilities of working in a health care facility, and the requirements to manage their personal health and actions that impact the health and safety of patients.

As a TCM practitioner and employer, you are expected to implement reasonable measures to minimize the risk of your staff acquiring or spreading infection. To this end, training for staff should include an understanding of:

- their exposure risks as health care providers;
- infection control and prevention strategies that are relevant and specific to their tasks and responsibilities;
- management of personal illness and injury to reduce exposure to others.

Practitioners have an ethical obligation to remain current on infection and control procedures and to ensure that such practices are implemented in their practices and by their staff. It is expected that TCM practitioners will have written policies and procedures for infection control that are made available to staff and are appropriate and relevant to the practices and duties of staff.

### 2.6.2 Immunization

Immunization is critical for the prevention and control of infections. Health care workers have increased exposure to communicable diseases and should consider vaccinations that provide immunity to preventable illness.

All staff members are strongly encouraged to know their immunization status and to keep their chosen immunizations up-to-date.

Staff members who are not immunized are at increased risk of acquiring infection or suffering severe symptoms from acquiring infectious diseases from patients. Immunocompromised staff may also be more likely to transmit some viruses to staff and patients over longer periods of time. Care should be taken when assigning certain tasks to staff with compromised immunity.

Hepatitis B and tetanus are the most important vaccine-preventable diseases for all TCM practitioners and staff to carefully consider.

It is **strongly recommended** that all TCM practitioners and staff who may have exposure to blood, blood products, body fluids, or sharps be immunized against hepatitis B and tetanus.

It is **recommended** that all TCM practitioners and staff consider being immunized against flu, measles, mumps, diphtheria, and polio. It is also recommended that practitioners have an annual physical that includes testing for TB, hepatitis, and HIV. Pre-employment screening can assist staff and practitioners in identifying conditions that may put individuals at risk.

Practitioners and staff can reference provincial health care websites to get detailed information of the immunization recommendations and schedules. The following booklet "Immunization: Your Best Protection" from the Ministry of Health and Long-Term Care (Ontario) provides detailed information on vaccinations. http://www.health.gov.on.ca/english/public/pub/immun/pdf/immunization.pdf

The following site provides detailed information on the immunization schedule for British Columbia.

http://www.healthlinkbc.ca/immunization.stm

The following site provides detailed information on the immunization schedule for Ontario.

http://www.health.gov.on.ca/en/public/programs/immunization/docs/schedule.pdf

#### Diseases with Available Vaccines

All practitioners and staff members should have an informed understanding of infectious diseases and available vaccines.

The following information is adapted from, "Immunization: Your Best Protection," Ministry of Health and Long-Term Care, Ontario.

**DIPHTHERIA** is a very serious bacterial infection. It can cause breathing problems, heart failure, nerve damage, and death in about 10% of cases.

**HAEMOPHILUS INFLUENZAE B (HIB)** is a bacterium that can infect any part of the body. It can cause middle ear infections, breathing problems, damage to joints, pneumonia (lung infection), inflammation of the brain leading to brain damage and death. This vaccine is recommended for children less than 5 years of age.

**HEPATITIS B** is a virus that can cause serious liver problems that can be fatal, such as liver failure and liver cancer.

**HUMAN PAPILLOMAVIRUS (HPV)** is a very common virus transmitted through sexual activity. HPV has been found to cause cervical cancer, some other rare cancers and genital warts. (About 75 per cent of adults will have at least one HPV infection in their lifetime.)

**INFLUENZA** is a viral infection that causes cough, high fever, chills, headache and muscle pain. It can cause pneumonia (infection of the lungs), middle ear infections, heart failure and death. The danger of this infection varies from year-to-year depending on the strain and can be mild to life threatening.

**MEASLES** causes rash, high fever, cough, runny nose, and watery eyes. It can cause middle ear infection, pneumonia (lung infection), inflammation of the brain, hearing loss, brain damage, and death.

**MENINGOCCAL DISEASE-GROUP C** is a very serious bacterial infection and a common cause of meningitis (infection of the lining of the brain and spinal cord) and meningococcemia (severe infection of the blood) that can cause severe complications and death.

**MUMPS** causes fever, headache, painful swelling of the glands in the mouth and neck, earache, and can cause inflammation of the brain. It can cause temporary or permanent deafness and swelling of the ovaries in women and testes in men, possibly leading to sterility.

**PERTUSSIS** (Whooping Cough) causes severe coughing spells for weeks or months. It can also cause pneumonia (lung infection), middle ear infection, convulsions (seizures), inflammation of the brain, and death. The risk of complications is greatest in children younger than one year of age.

**PNEUMOCOCCAL DISEASE** is a bacterial infection that can cause serious illnesses such as pneumonia, blood infection, and meningitis.

**POLIO** can cause paralysis (loss of control over muscles in the body) inflammation of the brain and death. People get polio from drinking water or eating food with the polio virus in it. It is no longer common in Canada because of high immunization rates, but cases do occur elsewhere in the world and polio may be acquired when traveling if you are not fully immunized.

**RUBELLA** (German measles) causes fever, rash, swelling of the neck glands, and swelling and pain in the joints. It can cause bruising and bleeding. If a pregnant woman gets rubella, it can be very dangerous for the unborn baby.

**TETANUS** (Lockjaw) causes painful muscle spasms, breathing failure, and can lead to death. It is caused by bacteria and spores in the soil that can infect wounds.

**VARICELLA** (Chicken pox) is a highly contagious viral infection. It can cause fever, headache, chills, muscle or joint aches a day or two before the itchy, red rash appears. A pregnant woman with chicken pox can pass it on to her unborn baby. Mothers with chicken pox can also give it to their newborn baby after birth. Chicken pox can be very severe or even life threatening to newborn babies.

### 2.6.3 Illness and Work Restrictions

Practitioners and staff are justifiably concerned about contracting infectious diseases from patients through their regular work-related duties. As previously referenced, procedures such as the following can reduce risk for staff:

- adhering to routine practices with strong emphasis on effective hand hygiene
- using additional precautions when warranted
- triaging or rescheduling patients when appropriate
- regular and effective cleaning and disinfecting of office space and equipment
- encouraging appropriate immunization based on risks and duties

Practitioners and staff who are ill can act as the infectious agent who spreads infections to patients and other staff.

Staff members who are ill or injured need to use good judgment in taking precautions so that patient health is not compromised, either through actions that control and prevent the spread of the disease or by staying at home. Listed below are some of the considerations that should be part of the discussions and training with staff.

### **Common Cold and Upper Respiratory Illnesses**

- continuous and diligent hand hygiene
- practise respiratory etiquette
- wear surgical mask
- avoid contact with immune compromised patients
- stay at home if fevered, vomiting, or diarrhea

### Influenza

- do not work until well
- if you must work then:
  - wear surgical mask
  - o practise continuous and diligent hand hygiene
  - o practise respiratory etiquette
  - avoid contact with high risk patients (e.g., older patients, chronic cardiac)

### Dermatitis (chapped hands or eczema)

- note: areas of broken skin increase the risk of infection transmission
- cover with bandage or glove
- practise good skin care

### **Cuts, Abrasions**

- covered with bandage or protective dressing
- re-evaluate work duties if large or persistent cuts are present

### **Cold Sores**

- cover the lesion if possible
- avoid touching
- practise diligent hand hygiene
- assess the risk to certain patients and take appropriate additional precautions

### **Herpetic Finger Infection**

- avoid all patient contact until the lesion is resolved
- note: medical gloves are not effective in preventing the spread

# **Shingles**

- do not have contact with high risk patients until lesions are crusted
- some duties may still be carried out (except with high risk patients) if all lesions can be covered and diligent hand hygiene is used

# Vomiting, Diarrhea or Fever

do not work until well

### 2.6.4 Blood-borne Pathogens: Precautions, and Exposure Management

### **Blood-Borne Pathogens: Precautions for Staff**

The most effective approaches to reduce exposure to blood-borne pathogens are based on practices that assume all blood and body fluids (except tears and sweat) are potentially infectious. As well, blood and body fluids do not have to be obvious or visible on an instrument or equipment in order to be potential sources of infection. Most exposures are preventable through adherence to practices that include safe handling and disposal of sharps, use of personal protective equipment, appropriate immunization, hand hygiene, and effective cleaning of blood spills.

# **Blood-Borne Pathogens: Exposure Management**

Exposure to blood-borne pathogens such as HBV, HCV and HIV requires practitioners and staff to react in an organized and swift way. This requires attention and preplanning in order to minimize any risk to staff caused by accidental exposure to blood (needle stick) or mucous membrane (splash) accidents. Establishing an effective plan provides an efficient and defensible process that protects staff and patients.

If the exposure is deemed significant, the following steps are recommended.

### 1. Immediately provide first aid

- after sharps injuries
  - o allow the wound to bleed freely for a brief time
  - o gently wash with soap and water
  - o bandage as required
- after exposure to eye, nose, or mouth
  - o flush area with generous amounts of water for at least 10 minutes
- after exposure to broken skin
  - wash with soap and water

### 2. Assess patient's status and seek patient consent for testing

- practitioner should assess the risk by examining patient's medical history and questioning the patient
- patient cooperation should be sought to clarify status
- if HBV, HCV, or HIV status is unknown or uncertain, advise patient to consent to testing of blood-borne pathogens by qualified medical professionals

# 3. Staff member should be referred to an infectious disease specialist or hospital emergency department for further advice and if necessary, post-exposure prophylaxis

• have processes and information readily available so that the staff member can have prophylaxis treatment administered as quickly as possible

### 4. Document the incident

- workplace safety requirements must be adhered to
- record the staff member's name, and status of their immunizations
- date and time of the incident
- what the staff member was doing
- detail the extent of the exposure, the protective measures that were in place, and the actions that were taken immediately afterward

- the name of the source and the known status of the blood-borne pathogen
- identify follow-up procedures and post-exposure counselling and management

# 2.7 Waste Management

This section provides a general overview of waste management for TCM practitioners. In most TCM practices, waste can be categorized as either **general waste** or **biomedical waste**.

**Biomedical wastes** are the solids, liquids, and sharps derived or contaminated from biological sources that are potentially infectious or dangerous. Biomedical waste must be handled and disposed of carefully in order to protect the public and staff from potential infections.

The most common biomedical waste in many TCM clinics are sharps (acupuncture needles, lancets, dermal needles, three-edged needles, intradermal needles, or anything that could potentially pierce the skin) and materials and equipment containing blood or body fluids (e.g., cotton swabs).

The practitioner is responsible for ensuring that acupuncture needles and other sharps are disposed of safely.

- The person using the sharp must dispose of the sharp themselves.
- Single-use sharps are disposed of in a puncture-resistant, rigid container that cannot be punctured by sharps under normal conditions.
- It is recommended that the container have a handle for safe transport and a lid that fits tightly.
- The container should be identified with the biohazard label and placed out of reach of children.
- Containers should not be filled to more than three-quarters capacity. Containers
  must not be treated as general waste and must be disposed of in compliance
  with approved local and provincial procedures.
- Office staff managing biomedical waste should wear protective apparel and be informed of relevant immunizations.
- Licensed medical waste handlers must be used to remove biomedical waste.

TCM often involves the use of botanical material, which is neither irradiated nor sterilized, and can therefore form mould. Although not "contaminated by use", such moulds are potential health hazards and should be disposed of appropriately and in compliance with any local requirements.

Check with local municipal regulations for specific waste handling and segregation requirements.

# 2.8 Other Regulations

As required under **Occupational Health and Safety Act** (OHSA), employers have a duty to have written procedures related to the health and safety of employees. These procedures must include:

- safe work practices
- safe working conditions

- proper hygiene practices
- use of hygienic facilities
- control of infections

Also under the act, employees are required to wear the protective clothing or use protective equipment that the employer has deemed necessary for safety.

**Workplace Hazardous Materials Information System** (WHMIS) is a national system for safe management of hazardous materials legislated by federal and provincial jurisdictions. The WHMIS legislation provides that workers *must be informed* about the hazards in the workplace, and *receive appropriate training* to allow them to work safely.

WHMIS provides the necessary information for:

- cautionary labels on containers of controlled products;
- the provision of material safety data sheets (MSDS) for each controlled product;
- a worker education program.

As such, practitioners who purchase or use controlled products must make sure:

- that hazardous materials are correctly labelled or supply labels for all controlled materials that do not have labels;
- material safety data sheets (MSDS) are available to staff members;
- training programs about hazardous materials are provided to staff.

# 2.9 Breaking the Chain of Infection

The following graphic summarizes some key elements of infection prevention and control from this document. The graphic highlights some strategies for practitioners in breaking the chain of infection in their practices.



#### Vulnerable Host

all are vulnerable, but some groups have higher risk

#### Break the Chain

- wash hands
- immunization
- treatment of primary disease



#### **Portal of Entry**

mucous membranes, broken skin, inhalation, ...

# **Break the Chain**

- hand washing
- protective equipment
- wound care

# Infectious Agent

bacteria, virus, fungi, parasite, ...

#### Break the Chain

- prompt treatment
- clean, disinfect surfaces
- hand washing

# Breaking the Chain of Infection

# Transmission

direct contact, indirect contact, droplet, airborne

#### Break the Chain

- hand washing
- respiratory etiquette
- patient management
- protective equipment
- airflow control
- disinfection/sterilization



#### Reservoir

people, equipment, water, ...

#### Break the Chain

- good health and hygiene
- education
- disinfection/sterilization



#### Portal of Exit

droplets, secretions, ...

#### Break the Chain

- hand washing
- waste management
- aseptic techniques
- protective equipment



# Glossary of Terms for Infection Prevention and Control

- **Additional precautions:** Infection prevention and control interventions that are applied in addition to routine precautions for certain pathogens or clinical practices, based on the method of transmission (e.g., contact, droplet, airborne).
- **Airborne transmission:** Occurs by dissemination of microorganisms (infectious particles < 5mm in diameter) that remain suspended in the air for long periods of time. These microorganisms (or germs) enter the host by inhalation and can survive for long periods and can be widely dispersed by air currents.
- **Alcohol-based hand sanitizer:** An alcohol preparation (usually 70% ethyl alcohol) used for waterless application in order to reduce microorganisms on the hands. It is an effective complement (but not replacement) to hand washing. If hands are physically soiled, hand washing with soap and water must be done.
- **Antimicrobial soap:** Soap containing an antiseptic agent.
- **Antiseptic:** A substance that destroys or stops the growth of micro-organisms on living tissue (e.g., skin). Antiseptics and disinfectants are manufactured for distinct and separate purposes. It is <u>not</u> advisable to use antiseptics on inanimate objects or, to use disinfectants on living tissue.
- **Aseptic technique:** A term used to describe practices that prevent infection during invasive procedures such as needling.
- **Blood-borne pathogens (BBPs):** Viruses found in blood which produce infection, such as hepatitis B virus (HBV), hepatitis C virus (HCV) or human immunodeficiency virus (HIV).
- **Clean field:** The area that has been prepared to contain the equipment necessary for acupuncture in such a way as to protect the sterility of the needles. (Note: A clean field is not the same as a sterile field.)
- **Cleaning:** The physical removal of foreign material (i.e., dust, soil, organic matter) from an object or item using water and mechanical action (e.g., brushing) with or without detergents. Cleaning physically removes rather than kills micro-organisms. Cleaning and then rinsing is performed before further processing. Meticulous cleaning must precede disinfection or sterilization of medical instruments.
- **Communicable:** Infectious organisms which can be transmitted to others.
- **Biomedical Waste**: Also known as infectious waste or clinical waste, biomedical waste includes waste associated with blood, body fluids secretions and excretions, and sharps. Infectious waste is suspected to contain pathogens (bacteria, viruses, parasites, or fungi) capable of causing a disease in a susceptible host. Whether or not they are infected, such items are considered as hazardous health care waste. Licensed medical waste handlers must be used to remove biomedical waste.

- **Contamination:** The introduction of contaminating viruses, bacteria, or other organisms into or onto previously clean or sterile objects rendering them unclean or non-sterile.
- **Contact Transmission:** The physical transfer of an organism between an infected person and a susceptible host involving direct or indirect contact. Indirect contact occurs when a patient comes in contact with equipment contaminated with infectious microorganisms. Direct contact occurs when an infected person transfers the organism directly to a susceptible host.
- **Droplet Transmission:** Inhalation of respiratory pathogenic microorganisms suspended on liquid particles exhaled by someone already infected. For example, a person suffering from an upper respiratory infection sneezes, allowing infectious microorganisms to leave the person's body and infect another person within close proximity.
- **Decontamination:** The process of cleaning, followed by inactivation of pathogenic micro-organisms from objects rendering an object safe for identified use.
- **Disinfectant:** A chemical agent with a drug identification number (DIN) used on inanimate (non-living) objects to kill micro-organisms. Examples include hypochlorite dilutions such as bleach, and commercial disinfectants such as LYSOL®. Disinfectants are used on inanimate objects; antiseptics are used on living tissue.
- **Disinfection:** A process that destroys or kills some, but not all, disease-producing micro-organisms on an object or surface. Disinfection usually involves chemicals, heat or ultraviolet light. Levels of chemical disinfection (high, intermediate, low) vary with the type of product used.
- **Fomites:** These are objects in the inanimate environment that may become contaminated with microorganisms and serve as a vehicle of transmission. Examples include toys or magazines in a waiting room.
- Health Care Facility: An organization that employs health care workers and cares for patients/clients.
- **Health Care Worker**: Any person working in a health care facility (e.g., practitioner, student assistant, receptionist, and cleaner).
- **Infection**: Occurs when bacteria, fungi, viruses, or parasites enter the body and grow and multiply. The progression of the organism may cause symptoms in the infected person. However, people can be infected with an organism but have no symptoms or signs. If the infection begins to cause harm to the person, it is then called a *disease*.
- **Infectious Agent**: A microbial organism with the ability to cause disease. The greater the organism's virulence (ability to grow and multiply), invasiveness (ability to enter tissue), and pathogenicity (ability to cause disease), results in the increased possibility that the organism will cause an infection. Infectious agents are bacteria, viruses, fungi, and parasites.
- Material Safety Data Sheets (MSDS): Material Safety Data Sheets are produced by the manufacturer with details of the substance, including first aid measures if there is exposure. Employers must have MSDS from the manufacturer of controlled products used in the office. For further information, consult the Ministry of Labour.

- **Micro-organism:** Microscopic organisms such as bacteria, virus, or fungus (commonly known as germs), that can cause an infection in humans.
- **Mode of Transmission:** Method of transfer by which the organism moves or is carried from one place to another.
- **Mucous Membrane:** Thin sheets of tissue that line various openings of the body, such as the mouth, nose, and eyes.
- Pathogen: Any disease producing microorganism such as a virus, bacterium, prion, or fungus.
- Personal Protective Equipment (PPE): Specialized clothing or equipment (e.g., medical gloves, masks, plastic apron) worn by staff for protection against infectious hazards. It is the responsibility of the health care worker to put on the appropriate personal protective equipment in any situation that is likely to lead to exposure (either for the health care worker or the patient) of blood, body fluids, excretions and secretions.
- **Portal of Entry:** An opening allowing the microorganism to enter the host. Portals include body orifices, mucus membranes, or breaks in the skin.
- **Portal of Exit:** A place of exit providing a way for the microorganism to leave the reservoir. For example, the microorganism may leave the reservoir through the nose or mouth when someone sneezes or coughs.
- **Reprocessing**: The procedures required to make an instrument or equipment, that has been used (contaminated), ready to be used again.
- **Respiratory Etiquette:** A standard of behaviour and manners established during the SARS outbreak used to minimize transmission of respiratory infections.
- **Routine Practices:** A Health Canada term used to describe basic standards of infection prevention and control that are required for safe patient care. Routine practices are based on the concept that all patients are potentially infective, even when asymptomatic, and that the same safe standards of practice should routinely apply to contact with blood, body fluids and secretions (e.g., saliva) mucous membranes, and non-intact skin. It may also be referred to as *Routine Precautions*.
- **Sanitation:** A process that reduces microorganisms on an inanimate object to a safe level (e.g., dishes and eating utensils are sanitized).
- **Sterilization:** A validated use of procedures that kills all pathogenic micro-organisms, including bacteria, fungi, viruses, and spores. Items must be cleaned thoroughly before effective sterilization can take place. Sterilization is a rigid standard and there is no such thing as partial sterility. In acupuncture, sterilization is required for all instruments that pierce the skin (e.g., needles, plum blossom needles, lancets) and guide tubes.
- Sterilant: A substance or agent used in sterilization.

- **Vulnerable Host:** A person who is unable to resist a microorganism invading the body and resulting in infection. The host is susceptible to the disease, lacking immunity or physical resistance to overcome the invasion by the pathogenic microorganism.
- **Workplace Hazardous Materials Information System (WHMIS):** Federal and provincial legislation enacted to ensure safety in the workplace with respect to hazardous products.
- **Waste Management System**: All the activities related to the creation, handling, storage, transportation and disposal of waste generated by health care establishments.

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# **Section 3: Risk Management of TCM Practice**

#### 3.1 Introduction

The provision of all health care services requires application of professional judgment, and this comes with inherent risks. This risk can be minimized and managed by making informed professional judgments with thorough knowledge and understanding of best practice guidelines and applicable regulations.

TCM practitioners must comply with all local, provincial, and national regulations related to the safe delivery of health care services such as:

- obtaining informed consent to treatment
- creating, using, storing, and disposing of patient records
- maintaining confidentiality of patient information and records
- reporting of communicable disease

As well, the TCM practitioner must adhere to safety requirements, such as:

- building codes and safety codes when establishing or renovating a clinic, or working from a home-based setting
- fire regulations, fire protection and detection requirements, and electrical safety
- provincial and national safety standards and related policies and procedures
- safe handling of chemicals and biohazards in the workplace
- the proper documentation of accidents related to injury or property loss as required
- safety of patients and staff related to abusive or violent behaviour in the workplace

# 3.2 Risk Management: Working Environment

## 3.2.1Principles for Maintaining Safe Working Environments

The premises used for the practice of Traditional Chinese Medicine and Acupuncture must be appropriate and suitable for the safe delivery of professional health care services.

- The premises must allow for safe, clean, and sanitary practices.
- The premises must have hand-washing facilities.
- The treatment room must allow for ease of movement and efficient cleaning.
- The treatment room and work room procedures must reduce the risk of possible cross-contamination.

#### The premises must allow for safe, clean, and sanitary practices.

The premises must:

- be used only for the TCM practice or for delivery of related health care services;
- have convenient and sufficient washroom facilities for clients and staff of the practice;
- comply with current local building, fire, and health and safety regulations;
- be in good repair and properly maintained.

If the practice is in a private home, the treatment room(s) must be entirely separate from any rooms used for living, sleeping, dining or other domestic purposes that are not compatible with the delivery of health services.

The treatment room must be clean and should have a designated working area that sterile equipment can be placed (e.g., a table covered with a clean towel). Sterile equipment should be covered until needed for use (e.g., covered with clean linen). The treatment rooms must have adequate light and ventilation.

It is recommended that a cleaning and maintenance schedule be established and documented in the event that such activity is required for evidence.

#### The premises must have hand washing facilities.

The facility must have a hand sink with a clean running hot and cold water supply. It is preferable to include hand washing facilities that are for the sole use of the practitioner. The hand washing facilities must be located in or in close proximity to the treatment area in order to reduce the risk of cross contamination. It is recommended that faucets be hands-free operated, or with sensor taps. The facility must include a liquid soap dispenser, disposable paper towels and a waste receptacle next to the sink. It is not recommended to use bar soaps or cloth towels in hand washing areas. If the waste receptacle is lidded, it should be equipped with a foot-operated lid.

# The treatment room must allow for ease of movement and efficient cleaning.

The treatment room must:

- have sufficient space to allow for safe practice;
- have sufficient space for the safe and clean storage of instruments and supplies (enclosed storage is recommended to protect from moisture and dust);
- have adequate heating, ventilation, and artificial lighting;
- be constructed of materials that are washable and can be easily cleaned and disinfected, as required.

Countertops, trays and all working surfaces must have smooth, impervious, easily cleaned surfaces (e.g., laminate, stainless steel). Practitioners are reminded that viruses such as Hepatitis B can survive on surfaces at room temperature for one week or more.

Sterilized tools and equipment (e.g., needles) are not to be placed on work surfaces, unless the surface is prepared as a clean field. If the work surface comes into contact with a used needle or blood, it must to be cleaned with a high level disinfectant (see Section 2: Infection Prevention and Control). Low-level disinfectant is sufficient for regular cleaning of work surfaces.

Patient tables, chairs, mats or other furniture used for treatment or that come in direct contact with patient's skin during treatment must have smooth surfaces, be impervious to moisture, and be easily cleaned.

Smooth, nonporous flooring is recommended (e.g., hardwood, tiles, or laminated flooring). Carpets and rugs are not easily washed and are not recommended in treatment areas. If carpets are used in the waiting or reception room, they should be short-piled and easily cleaned. Walls should be painted or paneled. Cloth-type wallpaper is not recommended for the treatment areas.

Treatment rooms should be equipped with a box of disposable medical gloves, disposable paper towels or single-use cloth towels, a waste container (with plastic liners), and a sharps disposal container (if applicable) that is not in reach of patients. As applicable, the room may require a suitable receptacle for soiled linen or a separate receptacle for clinical waste.

Storage jars for such items as cotton balls and tweezers must be cleaned regularly. Never refill the dispenser without first cleaning the container. The container for isopropyl alcohol should be cleaned and its contents replaced regularly. Alcohol can evaporate leaving a solution which can act as a breeding-ground for bacteria.

The level of activity in the practice must guide the frequency of regular and ongoing daily and weekly cleaning that is required. Clinics should have a documented cleaning schedule by staff or outside workers. Cleaning staff must be instructed how to safely handle and dispose of any found sharp that was not disposed of in the sharps container.

The following cleaning schedule may be appropriate for many practices.

# **Daily Cleaning**

- Clean immediately any surface that has been contaminated with blood or body fluids.
- Clean daily all surfaces in the treatment area and instrument reprocessing area with an appropriate detergent/disinfectant.
- Inspect the floors in the treatment areas for sharps that have been mistakenly dropped.
- Wash all floor surfaces in the treatment area and instrument reprocessing area with appropriate cleansers.
- Clean all counters, sinks, and washrooms. Spot-clean walls and doors. Clean and disinfect door handles and other high-touch areas as appropriate.
- Remove all garbage.

#### **Weekly Cleaning**

- Clean with detergent/disinfectant cleanser all tabletops, vertical surfaces on cupboards, door handles, and hard surface equipment and furniture (e.g., desks, carts, vinyl chairs).
- Clean the inside of cupboards weekly or monthly depending on use.

See additional information regarding cleaning in **Section 2: Infection Prevention and Control**.

The treatment room and work room procedures must reduce the risk of possible cross-contamination.

Treatment surfaces must be covered with:

- clean paper roll that is disposed of after treating each patient, or
- fresh, clean towels or linens that have been boiled or machine-washed on hot water setting before being reused.

Work surfaces must be cleaned and dried:

- when visibly soiled;
- after each treatment session;
- after contact with contaminated equipment or materials;

- after instruments are cleaned on the surface;
- at the start or end of the day.

The *reprocessing area* is a designated area of the practice that is used to clean and to sterilize reusable instruments and equipment.

Reprocessing areas should:

- be designed to ensure that equipment can be handled safely to minimize the risk of cross contamination;
- have a separate sink that is only used for reprocessing instruments and not for hand washing. It is recommended that reprocessing sinks are double sinks to allow for cleaning and rinsing as two processes that reduces the risk of cross contamination;
- be well ventilated and free from excessive humidity.

Food preparation areas must be separate from the reprocessing area. Staff must be educated on where food and drinks can be prepared and consumed. Food, drink, cosmetic application, or similar activity must not occur in areas where there is exposure to blood or other potentially infectious materials may occur.

#### 3.2.2 Guidelines specific to the storage and preparation of Chinese herbs

The following guidelines apply to setting in which herbs are prepared, compounded, dispensed or stored.

- All work surfaces, storage facilities floors, floor coverings and furniture should be made of materials that can be easily and thoroughly cleaned.
- There is a supply of hot and cold water that is adequate for the effective operation of the dispensary and for washing utensils and equipment used in the preparation, service, or storage of herbs.
- A refrigerator is available for the exclusive storage of herbs requiring refrigeration.
- Sufficient containers are available for storing waste in a safe and sanitary manner.
- Hand-washing facilities are available for staff and are located in a separate location in the dispensary.

Only a potable water supply should be available and used in any room where herbs are prepared, compounded, dispensed or stored.

All herbs should be stored on or in shelves, drawers or fixtures provided for that purpose. Every room in a dispensary where herbs are prepared, compounded, dispensed, or stored should be kept free from materials and equipment not regularly used in the room.

Herbs are botanical material which can form mould and be a potential health hazard. Enclosed storage is recommended (as appropriate to the type of herb) to protect herbs from moisture. Labelling should indicate expiry date so that herbs can be safely managed and disposed of as required.

The room should be well ventilated and free from excessive moisture and sunshine. The room temperature for safe storage of herbs should not be in excess of 20° Celsius. The use of high speed fans to cool work areas is discouraged in rooms designated for processing and compounding of herbs. The use of fans increases the risk of possible cross-contamination of dry powders caused by rapid movement of air. The use of other means of room cooling, such as air conditioning, is encouraged.

Refrigerators for the storage of herbs in a dispensary should be maintained at a temperature between  $1.3^{\circ}$  Celsius and  $10^{\circ}$  Celsius. Refrigerators should be kept clean and in sanitary condition and be located in an area not accessible to the public.

When cleaning equipment and surfaces where herbs are prepared, care must be taken to ensure residues from the cleaning process itself (e.g., detergents, solvents, etc.) are also removed from surfaces and equipment.

Additional information is available in **Section 5: Safe Procedures and Processes: Herbology**.

# 3.3 Risk Management: Site of Practice

Traditional Chinese Medicine and Acupuncture is practised in a variety of locations and settings including private clinics, hospitals, educational institutions, and multi-disciplinary health care settings. Each site must comply with the appropriate regulatory requirements and jurisdictional bylaws. The following are guidelines for the building and site of the practice.

#### Location:

- Check city bylaws to ensure the premises are zoned for the practice of TCM.
- Make sure that building code requirements are met.

#### Accessibility for disabled patients or employees:

- Wheelchair accessibility to a TCM practice may or may not be a requirement for your jurisdiction. If wheelchair access is not required and not available at your site, try to make arrangements for treatment of those patients who are unable to access your practice.
- Where required, patients and staff may need wheelchair access from the parking area to the office.
- Where required, patients and staff will need access to a restroom with a toilet stall equipped with a transfer bar, and with a sink that is at an accessible height.

#### **Electrical/Heating/Ventilation/Air Conditioning Systems**

The electrical, heating, ventilation and air conditioning systems must be maintained in suitable working condition. Install smoke detectors and carbon monoxide detectors in compliance with local requirements. The use of moxa increases the importance of ongoing monitoring and preventative maintenance. Moxa smoke may set off smoke detectors in the practice or in neighbouring offices.

If you use moxa in your treatment room(s), the ventilation system is of particular importance and must comply with local government requirements.

#### **Air Quality Control:**

The quality of air in the TCM clinical environment is very important. Fumes, odors and vapors can affect the health of the practitioners, staff, and the patients.

- Moxa smoke may require the installation of special ventilation systems (or choosing other options such as smokeless moxa sticks). Moxibustion treatments need to be carefully monitored as a potential fire hazard.
- Ventilation and air filtration systems are important considerations when working with herbs, especially if the air is particularly humid or dusty. Consider installing ventilation and air filtration systems in dusty or vaporous conditions.
- Odors from disinfectants such as bleach and other solvents may cause allergic reactions or illness. Thoughtful selection of a disinfectant is an important risk management consideration.
- Weak air exchange systems and moulds are also important considerations in air quality control.

# 3.4 Risk Management: Emergencies

#### 3.4.1 Emergency Actions

Anticipating and planning for emergency situations is a critical step in risk management in order to protect your patients and staff, and to avoid or reduce the likelihood of possible liability issues.

- Clearly identify and post a list of phone numbers to call in the event of an emergency. These telephone numbers may need to include local hospital, local physician and community health centre, and the poison control centre.
- Develop responses so that staff members know what to do in a power failure.
- Post or have on file guidelines for common mishaps (e.g., burns and scalds, chemical burns, electrical burns, eye injuries, choking).
- Post the locations of emergency items such as first aid boxes and fire extinguishers.
- Establish and post escape plans and routes in case of fire or other emergencies that requires the premises to be evacuated. Check with local authorities on any requirements that require staff training or practise of the evacuation plan.
- Establish procedures in order to account for all individuals after evacuation.

#### Fire Emergency Plans

Health care settings often have flammable items that can start or aggravate the spread of fire. Fire emergencies are a potential risk factor in the practice of TCM and acupuncture, especially in the use or moxa or fire-cupping therapies. Moxa extinguishers or containers with sand are critical when using moxa in the clinic.

It is important that clinics and practices have a documented fire prevention plan that includes:

- information on location of fire alarms and fire extinguishers
- instructions on how to use the fire extinguisher

- how and where to evacuate the building
- guidelines to assist the evacuation of patients or staff with disabilities
- guidelines if people become trapped in the building due to the fire
- lists of flammable chemicals used or stored in the practice

Ensure that you or a staff member is trained on how to use the fire extinguisher. It is strongly recommended that this training be documented. The fire extinguisher must be checked, maintained, and replaced as required by the manufacturer's instructions and local fire regulations. It is recommended that you maintain a list of potential fire hazards or ignition sources for fire, and consider appropriate the safe storage for chemical or flammable items.

Fires may occur in neighbouring facilities and spread to your clinic. Patient medical files and other important documents should be secured in fire proof storage.

Check with your local authorities to ensure proper and regular inspections or approvals as required.

## **Fall Injuries**

- Good housekeeping practices are the best preventative measures that can reduce the likelihood of falls by staff or patients.
- Keep main walkways clear of trip or slip threats.
- Practitioners may be liable for preventable situations that cause falls to staff or
  patients (e.g., dangling electrical cords, slippery or recently washed floors, loose
  rugs, stairways without railings, ice on outdoor sidewalks). If renting or leasing,
  check your agreement on what is required of the landlord and of the
  renter/leaser.
- When in treatment, patients may faint or fall asleep. Ensure proper placement and monitoring of the patients. Ensure the patient is able to safely move onto and off tables.
- All fall or slip incidents must be documented. Staff should have access to forms that allow them to document the who, what, when, where and why of an accident.

# 3.5 Risk Management: Chemicals and Waste

#### 3.5.1 Chemical Hazards and Labelling

Disinfectants, bleach, alcohol and iodine are often used and stored in TCM practices. Most of these items can be safely stored and used as long as containers are properly labelled (with common or chemical name and any hazards clearly indicated) and used as directed. Correct storage and use of chemicals ensures that contamination does not occur.

Precautions do need to be taken with chemicals that are decanted or transferred from bulk containers to other generic containers. These generic containers should be labelled or referenced with important precautions clearly indicated so that chemicals are not improperly used.

#### **Guidelines for Storing Chemicals**

In order to safely store chemicals, attend to the following procedures.

- Store all chemicals in accordance with the manufacturer's instructions.
- All chemicals are to be clearly labelled and are easily read.
- All solutions that have been decanted from bulk containers are to be clearly
  and fully labelled to allow for safe use. Include the date of decanting and
  any applicable expiry date.
- Read the relevant material safety data sheet before decanting any chemical.

See **Section 2.8: Other Regulations** for further elaboration related to WHMIS.

#### 3.5.2 Waste Management

See **Section 2: Infection Prevention and Control** for detailed information on waste management.

Check with local municipal regulations for specific waste handling and segregation requirements.

#### **Important Reminders**

- Single-use sharps must be disposed of immediately after use in a punctureresistant, rigid container that complies with local requirements.
- Sharps must only be disposed of in the approved manner and never disposed of in general waste, recycled waste, or in industrial waste bins.
   Local directories will identify companies that can manage biohazard waste disposal.

# 3.6 Risk Management: Staff

#### 3.6.1 Introduction

There are many aspects of a TCM practice that require staff (and practicing students) to be aware of and trained in order to operate in a safe and professional health care environment. The practitioner has the responsibility of ensuring that staff members will receive the required training, and will have their training refreshed and updated as appropriate and needed. The important nature of the services provided in a TCM practice require staff members to be fully trained in order to support the delivery of safe, responsible, quality health care to patients.

Many of these specific training requirements have been identified previously in the course (e.g., training on infection prevention and control processes, educating and training related to confidential patient records and the protection of private data).

There may be situations that arise that are unforeseen and staff may be unsure of what actions to take. In a health services setting, it is important to establish duties, protocols, and a hierarchy of decision-making rights and responsibilities with staff so that actions are not taken or decisions are not made that unintentionally affect the health and safety of patients.

Establishing a positive working environment in a TCM practice requires staff and student practitioners to understand the scope and limits of their decision-making. Decisions and actions that are beyond their training and qualifications and are related to patient

health, safety and privacy must be directed to the supervising practitioner. Actions that are assigned to student practitioners remain the responsibility of the qualified supervising practitioner. Supervising practitioners are required to provide appropriate monitoring and supervisory processes of students in order to be assured that patients continue to receive safe, high quality, health care experiences.

#### 3.6.2 Managing Abusive or Violent Behaviour of Patients

In health care settings, patients may experience anxiety or stress related to their illness and may target their feelings of anger, fear, frustration, or aggression toward others. As a result, staff members are at potential risk of being abused, harassed, threatened or assaulted in circumstances related to their work. For example, staff may experience verbal abuse (e.g., swearing, insults, condescending language), harassment (e.g., demeaning or humiliating statements, bullying, unwelcome behaviours or acts), threatening behaviours (e.g., shaking fists, throwing objects, verbal or written threats of harm), or physical attacks (e.g., pushing, hitting).

Abusive or violent behaviour of patients can happen in any clinical setting. The following guidelines are to raise awareness for practitioners and staff. The guidelines do not provide all the necessary tools and training that may be required to manage situations safely. It is encouraged that all practitioners receive appropriate training by certified instructors, e.g., Non Violent Crisis Intervention™ (NVCI). Such training is strongly recommended for practitioners and staff who work in settings with a history or increased risk of abusive or violent behaviour by patients.

Guidelines for managing abusive or violent behaviours of patients:

- The primary concern when presented or addressing aggressive behaviours is to ensure personal safety and the safety of others.
- Do not place yourself in physical risk. Assess your personal safety and the safety of others in the vicinity.
- Do not aggravate or escalate the situation. Remain calm. Do not become confrontational.
- Engage the help of others as appropriate or required. Clinics should establish
  protocols so that assistance from others can be signalled for without
  intensifying the situation.
- If the aggressive behaviour is by a patient, the behaviour should be documented in the patient file at some point following resolution of the incident. Further actions may be required based on the nature and severity of the issue.

#### **Verbal Intervention Strategies**

If no immediate physical danger is evident, then the use of verbal intervention strategies may be appropriate. The following provide some suggested strategies and considerations.

- Be an empathetic listener. Give your full attention to what is being said and be non-judgmental. Try to discover the source of the distress.
- If you sense patient anxiety or a noticeable change in behaviour, then speak in tones that let the person know that you care and that you are there to help. Focus the discussions on your efforts to help or resolve the distress.
- If the patient becomes defensive, non-compliant or is starting to lose a logical perspective, then use statements that provide simple directions or set reasonable limits. Providing the patient with choice in other acceptable

behaviours can be very effective.

- Describe the patient's unacceptable behaviour and state the behaviors that are expected. Describe acceptable alternate behaviors or actions (e.g., talking about feelings).
- o Inform the patient of limits and help the patient understand the reason for the limits.
- Be aware of the tone and volume of your voice. Speak in a calm voice that does not further provoke actions.
- Be aware of body language that may be perceived by the patient as threatening (leaning forward with hands on hips) or dismissive (rolling your eyes).
- Do not confront or crowd the individual. Provide them personal space. Your stance should communicate that you are non-challenging or non-threatening.
- Your actions should be focused on calming the situation. Listen carefully and be supportive.
- Do not take what is said by the patient as personal. There may be many unrelated and unknown factors that are provoking their behaviour.
- For patients that are acting out or demonstrating a loss of physical or emotional control, there are **physical interventions** that offer safe means of control that can be used by practitioners or staff <u>who are trained</u> in such strategies.

# 3.6.3 Medical Emergencies and Staff

In the case of emergencies, first aid should be applied as required, and the patient transported to a medical emergency centre for treatment.

- Traditional Chinese Medicine and Acupuncture should not be used to replace a necessary surgical intervention.
- Traditional Chinese Medicine and acupuncture is contraindicated in medical emergencies in which the condition is life-threatening and requires immediate transportation to a medical facility with emergency services.
- TCM practitioners should inquire of patients of any recent medical emergencies and describe steps for post-emergency follow-up with patients so that safe services may continue to be delivered as appropriate.

#### First Aid and First Aid Certification

Every TCM clinic should be equipped with a functional first aid kit. Guidelines for the content and number of first aid kits can be found at the Canadian Red Cross (www.redcross.ca).

#### It is recommended that:

- registered practitioners hold a current Standard First Aid Certificate (or equivalent), <u>or</u>
- a person is present at the TCM clinic that holds a current Standard First Aid Certificate (or equivalent) and has been appointed by the registered practitioner to administer first aid as required.

#### Cardiopulmonary resuscitation (CPR)

CPR is an emergency procedure used to assist an individual who has suffered cardiac arrest. The main purpose of CPR is to at least partially restore the flow of oxygenated blood to the heart and brain. CPR can extend the window of opportunity for a successful resuscitation without permanent damage being done to the brain.

It is recommended that:

- registered practitioners hold a CPR certification (level A), or
- a person is present at the TCM clinic that holds CPR certification (level A) and has been appointed by the registered practitioner to administer CPR as required.

See sections Section 4: Safe Procedures and Processes: Acupuncture and Section 5: Safe Procedures and Processes: Herbology specifically related to adverse reactions and contraindications.

# 3.7 Risk Management: Patients and Their Records

#### 3.7.1 Scope of Practice

Practitioners of TCM offer an important and unique set of diagnostic and treatment skills to their patients. Like all health care professionals, TCM practitioners have a defined scope of practice. Unless training and applicable legislation allows, TCM practitioners must not make a medical diagnosis based on non-TCM modality/therapy. This is important for the safety of patients. If evidence is found in patient case records of practitioners acting beyond their scope of practice, patients could be harmed and practitioners may be subject to legal actions by patients, insurance companies, and/or regulatory bodies or agencies.

The health and best interests of the patients must inform all decisions about suggested treatments. When the situation warrants, TCM practitioners must refer patients to other practitioners, medical or otherwise, who have the required knowledge and skills to deliver the needed services.

TCM practitioners must make referrals to other health care professionals based on:

- limitations of their personal training and skills, or
- limitations of Traditional Chinese Medicine.

Check with appropriate regulatory bodies to ensure your understanding of your scope of practice responsibilities.

#### 3.7.2 Legal Concepts that are Relevant to the Practitioner-Patient Relationship

Risk management is not solely about safety issues, but also includes practices and actions that reduce a practitioner's vulnerability to legal consequences and lawsuits. The following are some of the legal concepts that are relevant to practitioners and are highlighted in this course. It is recommended that these and other legal topics be studied in greater depth by the practitioner through further readings or courses.

- **Confidentiality**: patients have the right to expect that their personal information will remain confidential
- **Defamation**: can relate to disparaging communications that are slanderous (transitory statements) or libelous (written, published or broadcast statements)
- **Informed Consent:** (see section 3.7.7)
- **Standard of Care**: patients can expect a standard of care that a reasonably prudent professional practitioner would provide

#### 3.7.3 Terminating the Practitioner-Patient Relationship

There are a variety of situations where practitioner-patient relationships should or must be terminated. For example, termination may occur if:

- treatment has been completed;
- the passing of either the patient or the practitioner;
- the patient chooses to end the relationship;
- the practitioner chooses to terminate the relationship (this process is further clarified below).

TCM practitioners have an ethical responsibility not to abandon their patients. If there is a situation where the practitioner, using professional judgment, decides to terminate the practitioner-patient relationship, it must be done carefully and thoughtfully in order to ensure the health of the patient and the continuity of care needed for the patient.

The practitioner must provide written notification to the patient, outlining the specific reasons for termination and the date that care will be terminated. If applicable, the practitioner must identify the need for continued care and establish processes to allow for the efficient transfer of records to the new practitioner.

#### 3.7.4 Patient Record Keeping

The following provides general guidelines for the managing and maintaining of patient records. This section will NOT detail all legal requirements or liabilities related to record keeping and management, but will focus on standards and guidelines that support safe delivery of service.

**Note:** Practitioners must refer to the provisions of their College for specific and detailed requirements.

TCM practitioners have a legal and ethical responsibility to keep patient information **confidential**.

Practitioners must comply with all laws and regulations related to:

- collection, use, disclosure, disposal and transfer of information;
- processes that affect the quality and security of the information;
- procedures that grant access to patient information.

Patient case records are the practitioner's or the clinic's memory. Records are the outputs that document the practitioner's activities, and the activities of patients and contacts external to the practice. Records provide evidence of decisions, transactions, and events which may need to be recalled or proven at a later date.

TCM practitioners have the responsibility to ensure that all staff members with access to patient records are properly educated and trained in ensuring patient record confidentiality.

Records build on the foundation of quality patient information gathered through effective clinical interviews during every practitioner-patient consultation. The clinical interview is a critical stage in the consultation/visit process. At every consultation, accurate and appropriate information is gathered during the clinical interview to support the diagnostic, treatment, and planning processes. Patient records document

this critical process and support quality and consistent care.

#### **Purpose of Record Keeping**

Building an adequate record of every patient consultation is a critical element of quality TCM practice.

Patient records are legal documents. Patient case records provide:

- a record of the patient's health history;
- thorough, organized and chronological documentation of important information such as assessments, treatments, significant communications, incident reports, referrals, delegation and supervision, discharge process, and so on;
- guidance that promotes consistency of care among TCM practitioners and among all health care professionals;
- means of legal protection for the practitioner and for the patient;
- potential legal documentation of treatments;
- enhanced quality care by documenting relevant information (both current and historical) that can be efficiently communicated to other treating practitioners and health care professionals;
- the basis for professional development and continuous improvement activities regularly carried out by TCM practitioners;
- foundation for retrieval of treatment details to assist in resolving disagreements or supporting evidence;
- a demonstrable record of accountability by the practitioner for the provision of responsible care.

The patient 'record' includes all written, scanned, digital, photographic, radiological or other forms of chronicled or documented patient information.

- patient health records (either paper documents or electronic documents)
- photographs, images, audio or video tapes
- lab reports, imaging reports
- administrative records (e.g., contact information, complaint or commendation records)
- e-mails, records of telephone conversations or text messages

Actions, observations and discussions need to be documented; otherwise it may be assumed, in a legal context, to have not occurred.

#### 3.7.5 Overview of Recording Requirements

Sound risk management requires the documentation of consent, procedure explanation, patient comments and responses, observations, diagnostic processes, and other clinical recommendations and findings.

TCM practitioners must inform themselves regarding relevant laws and standards and ensure compliance with regulations. The legislative requirements apply to all individuals who handle patient information.

In Ontario, patient records can be initially written in the preferred language of the practitioner. However, patient record information that is mandated must include a translation in one of the official languages in order that relevant health care information can be accurately shared with health care professionals and patients as required. In British Columbia, practitioners must reference the CTCMA regulations for specific standards and practices related to the language requirements for patients' records.

The following provides an overview of requirements. The list is not complete and is not intended to be complete. The list highlights selected requirements that are relevant to the safety course. A more complete list of requirements should be referenced through the College or through courses and training that is focused on legal requirements related to TCM practice.

- Patient records are confidential.
- These records must be legibly handwritten (in ink), typed or in electronic
- Records must be permanent.
- Records must be accurate and concise.
- All entries must be dated.
- All pages of a patient case record must clearly and uniquely identify the patient.
- Financial records must be kept separate from patient records.
- Key information in the records must be understandable to other health care professionals, particularly another TCM practitioner. (See WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region (2007), available in pdf format at:
  - http://www.wpro.who.int/publications/docs/WHOIST 26JUNE FINAL.pdf
- The record is to be made at the time of the consultation or as soon as practically possible following the consultation.
- If there are alterations or amendments made to the records, all original entries must be clearly identifiable. If corrections are necessary at any time, liquid paper or erasable pens are not permitted. The changed words should be circled and struck through with a line, and the revised words written or typed next to the change in a manner that makes it clear that it was added at a later time (this is true for both paper and electronic changes). The changed entry should be signed and dated. If a new document is re-created the original document must be kept and referenced.
- It is highly recommended that the acupuncture points used in the treatment be documented with the numbering detailed in WHO Standard Acupuncture Point **Locations in the Western Pacific Region**, World Health Organization (2008).
- The use of commonly accepted abbreviations that are generally recognizable by professional peers is allowed. Codes and abbreviations that are obscure or personal should be avoided. In an emergency, a non-consulting TCM practitioner should be able to understand the record so that the patient can be aided.
- Best practices recommend that records use factual, objective, and nonjudgmental language.
- Personal information that is collected from patients should be carefully restricted to information that is required for the safe and effective delivery of TCM services to the patient.

- Responsibility for the <u>accuracy</u> of clinical information is solely that of the
  treating TCM practitioner and cannot be delegated to another person (e.g.,
  student trainee, staff member). If an individual under the direct supervision of
  the treating practitioner (e.g., a student trainee) records the information in a
  patient record, the practitioner is still responsible for the <u>content</u>, and must
  countersign the recorded notes at the time of writing by the student.
- A patient or their authorized representative may request access to their personal patient record. There are only limited and prescribed legislated situations in which a practitioner may refuse a patient access to their medical records (e.g., likelihood of significant risk of serious bodily harm to patient or third party).
- Patient access to their records can be provided in a variety of ways (e.g., inspection, provision of a copy, documented explanation or summary of contents). If it can be shown that factual information is inaccurate or incomplete, patients can request to have information corrected or updated.
- Patient records must be safeguarded. Safeguarding includes securing and controlling the access, use, storage, or disposal of the records. In clinical situations where several practitioners require access to the records, the responsibility to safeguard the records can be assigned to an appropriate individual.
- If a practitioner works in a clinic with other practitioners, the responsibility for safeguarding patient records is the shared responsibility of the clinic operator and the treating practitioner.
- The physical file (i.e., paper file and/or product of electronic file) is owned by the treating practitioner. The patient has a right of access to the information, but does not own the documents.
- Confidentiality requirements do not preclude a practitioner from discussing
  patient cases with other practitioners. However, for such discussions to occur,
  patient names and other identifying and private information must not be shared
  as part of that professional dialogue.

#### 3.7.6 Information Contained in Patient Records

Patient records should be accurate and provide an "adequate level of detail". The nature and complexity of the presented condition will influence the type and extent documentation. As well, follow-up consultations may focus on progress details and treatment, while initial consultations may focus on symptoms, health history, and diagnosis.

When deciding on the level of detail in a patient record, the practitioner can apply professional judgment. However, the practitioner must make those professional judgments with an understanding of the legal and medical importance of patient records.

Practitioners may follow standard medical recording methods, such as the use of **SOAP** notes, when documenting information. SOAP notes have four components:

- **Subjective information** (patient description of reason for consultation, medical, family, and social history)
- **Objective information** (obtained by practitioner, such as pulse, tongue)
- Assessment of condition or progress from treatment
- Plan for treatment (TCM diagnosis, pattern differentiations, treatment

principles, treatment including herbs, points, lifestyle advice, etc.)

Patient case records can include the following documentation of care (not necessarily in the described order).

- date and time of consultation
- patient's name, address and contact number (where applicable, include parent or guardian information)
- relevant medical and health history (allergies, prescription and non-prescription medications, past illnesses, pregnancies, etc.)
- relevant family and social history
- other treatments/therapies being used (including herbal, dietary, naturopathic, manipulative, pharmaceutical, psychological)
- allergies with any allergy alerts noted. Though identified in medical history, it is important to make many allergies and allergic reactions very visible and prominent in the record keeping
- document adverse reactions to medications, foods, environmental substances, etc.
- reason(s) for the TCM consultation
- symptoms and signs (identified by the patient and detected and recognized by the practitioner using the four diagnostic methods of Inspection, Auscultation and Olfaction, Inquiry and Palpation)
- assessment findings including tongue and pulse observation/palpation
- TCM diagnosis (with clear evidence of thorough assessment of the patient's condition)
- treatment principles
- options for care if applicable (clearly document that patient had choices identified)
- detailed treatment plan
- evidence of **informed consent** by patient. (e.g. a dated and signed "Consent to Treatment" form.)
- other relevant information (e.g., identification of possible side effects, alternative treatments available)
- evidence of patient's *refusal to consent* to treatment (as appropriate)
- evidence of **non-compliance to treatment** by patient
- treatments performed:
  - acupuncture (include name and number of points and methods of stimulation)
  - herbal (prescribed formulas documented)
  - o other modalities used with additional documented informed consent
- advice provided to patient (e.g., diet, exercise, lifestyle)
- referrals to other services or practices
- discussions/contacts with other health care professionals (as it relates to the patient's condition)
- discussions with family (with patient's consent, if applicable)
- patient response to treatment
- subsequent adjustments to treatment plan (with accompanying consent forms)

To help summarize this list, the initial patient visit to the practice may include some or all of the following information being detailed in the patient record.

- chief complaint and other complaints
- health history
- allergy notation
- medications
- other therapies being utilized
- TCM diagnosis
- treatment principles
- treatment plan
- · consent to treatment
- treatment performed
- advice given

Follow-up visits may include components shown above, as well as:

- progress notes, significant observations during appointment, and clinical findings
- explanations given to the patient
- discussions with the patient or his/her other health care providers
- responses to previous treatment(s)
- documented patient's refusal to follow recommendations
- document missed appointments, cancellations, and late arrivals
- correspondence with the patient and others (e.g., blood tests, e-mail messages)

#### 3.7. 7 Documenting Informed Consent to Treatment

A patient has the right to receive sufficient information in order to make an informed decision on whether to accept treatment. A TCM practitioner may not impose care on a patient. It is the responsibility of the practitioner to inform the patient about the procedure in order to obtain informed consent from the patient (or substituted decision maker) prior to treatment.

Informed consent means that the patient agrees to the treatment and that he or she understands:

- the nature of the procedure that is being proposed;
- alternatives for the treatment;
- consequences of not having treatment;
- possible risks of the treatment;
- expected results of the treatment.

A complete clinical record should contain documentation that informed consent has occurred, whether the consent has been given orally or in writing by the patient. The most defensible form of consent is in writing using a comprehensive and credible *Consent to Treatment* form that is signed and dated by the patient (or legal guardian). Documented consent is especially important with procedures that may be perceived as causing damage or bruising to the patient (e.g., direct moxibustion and cupping, gua sha).

It is important that consent be *informed* by a meaningful dialogue between the practitioner and the patient. A signed form is simply *evidence* of informed consent. The actual consent is the dialogue that occurs between the practitioner and the patient. If a patient is asked to sign a form without having had the discussion with the practitioner,

then the practitioner has <u>not</u> managed risk. Once the dialogue is complete, and the patient has provided informed consent, the practitioner can document this in the record and ask the patient to sign a consent form.

If a patient does not provide informed consent to treatment, then the practitioner should not treat the patient. Obtaining informed consent to treatment is essential for the protection of the patient and the practitioner.

As appropriate for risk management, the practitioner may record a patient's **refusal to consent to treatment** and that the consequences of the refusal have been explained to the patient.

Full requirements and meanings of informed consent are described in the College practice standards.

A more complete description of the requirements for informed consent, including exceptions such as emergencies, is identified in:

- Health Care Consent and Facilities Admissions Act (British Columbia)
- Health Care Consent Act, 1996 (Ontario)

#### **Documenting Noncompliance**

Documenting noncompliance provides best practice evidence, if required.

- Document the recommended treatment.
- Describe the instructions or procedures that the patient was expected to follow.
- Describe the instructions that were not followed by the patient.
- Describe specific patient behaviours that were observed and document specific patient comments in quotation marks.
- Document the discussions that identified consequences of noncompliance for the patient.
- If possible, have the patient sign the form indicating noncompliance.

#### 3.7.8 Records Management

Records management is the process of systematically managing and organizing records and the data, information, and documents that are contained in these clinical records. Effective records management can make better use of physical space and electronic space, promote staff efficiency, improve security and control procedures to protect private information, and ensure evidence of compliance to legislated and regulated requirements.

Traditionally, records were held in paper format but are now held increasingly within electronic systems. Even for small practices, it is a challenging task to establish an effective records management process given the scope, volume, and the wide variety of formats, locations, people, documents and media that are required to create, access, and store records.

The detailed processes and procedures for records management are beyond the scope of this safety course. However, the following points highlight important information for the practitioner that is relevant to the course.

Any record, up until the point that is legally disposed of by the practitioner, may be subject to information requests under the applicable privacy legislation. Staff must be

trained on the secure handing of confidential records. Legal obligations and standards of practice must be described to staff in order that they may fulfill their duties.

Establish in your practice the procedures and protocols that conform to the legal and regulatory requirements for the creation, use, retention, appraisal, and disposal of patient records. It is obligatory that records are closely monitored and managed throughout their life cycle.

It is recommended that practitioners and staff regularly review the privacy policy and consider signing confidentiality agreements to affirm the critical importance of privacy and confidentiality by all who manage patient records.

The following summary identifies important considerations for the TCM practitioner, but full description of the regulations is outside the scope of this course and must be the responsibility of the practitioner to seek further information, training, or legal advice.

#### Creation

- The treating practitioner is solely responsible for the creation and accuracy of the clinical records.
- Record management systems should allow for the creation of credible and useful records that are easy to retrieve but securely stored.

#### Use, Disclosure and Transfer

- Records must be handled and accessed in compliance with provincial personal information and protection of privacy acts. Establish procedures and controls to the movement and location of records.
- There are a range of statutory provisions that may limit the disclosure of records, even to the police, other health care professionals, relatives of patients, etc. Such regulations are sourced or practitioners are advised to obtain advice.
- Patient records, or any other patient-related information, should not be sent by email unless there is protection, such as encryption, from potential unauthorised access.
- No individual should be permitted to access or use the practice's computer(s), other than the TCM practitioner and authorised staff.
- Authorized staff must be trained so that they are aware of who can and cannot have access to the records and who can and cannot request information from records (e.g., patients may request information from their own file, parents may not have access to records of a child who is capable of making their own treatment and privacy decisions).
- Individuals can complain to the Privacy Commissioner in their province if they believe their privacy rights have been violated.
- If in doubt, all staff must be trained and obligated to seek direction of the treating practitioner before any confidential information is released in any form.
- Practitioners are responsible for the records of your patients. If a practitioner leaves a practice, she or he must provide a safe arrangement for the transfer of those records. Either you designate a new practitioner for your practice or you store the records for future use by another practitioner or agency as required for continuous patient care.

#### **Retention and Storage**

- Patient records have a life cycle, and must be retained for a stated number of
  years after the records are closed. Currently patient records must be retained
  for ten (10) years (or longer if the patient is under 18 years of age), but
  practitioners should reference the College regulations for any details or changes
  to the requirements.
- The storage area for current records should prevent or limit damage to records (e.g., fire, water).
- Storage areas should be secure to restrict unlawful or unauthorized access.
- Electronic files are subject to technical failure (power failure, computer breakdown). Backup files and establish restore protocols and processes. Adequate backup systems to protect patient records are essential.
- Paper records may be placed in a secondary storage area (off-site) or scanned and saved electronically if they need to be retained but are no longer required for current use.

#### Disposal

- Disposal of patient records (following the end of treatment plus the recommended periods of retention) must be conducted in a managed and confidential way. Practitioners should obtain their own legal advice.
- Practitioners must comply with all regulations and requirements related to the legal disposal of patient records.
- Records must be destroyed or shredded in a secure environment.
- Contractors who are used must agree and adhere to confidentiality requirements and agreements.
- Keep a register of the records that have been destroyed.

# 3.8 Patient Privacy and Duties to Report

As a health care provider, practitioners have a legal and professional duty to keep information about their patients private and confidential. However, there is a responsibility and a need to report particular events or conditions to the appropriate government or regulatory agency. Requirements for mandatory reporting include, but are not limited to, the following:

- suspected child abuse and neglect
- suspected elder abuse
- certain communicable and reportable diseases (Health Protection and Promotion Act, report to Health Canada or equivalent provincial offices such as British Columbia Centre for Disease Control, Ontario Agency for Health Protection and Promotion)

Strong patient and practitioner relationships are built on trust and good communication. When it is possible to do so without putting themselves, their patients, or others at risk, practitioners should inform their patients when they are required to make a mandatory report. Practitioners have a legal obligation to report, but are expected to apply sound professional judgment in deciding how best to communicate with patients or their guardians in the process.

# 3.9 Relevant Regulations

# **British Columbia's Privacy Acts**

The Office of the Information and Privacy Commissioner (http://www.oipc.bc.ca) is independent from government and monitors and enforces British Columbia's Freedom of Information and Protection of Privacy Act (FIPPA) and Personal Information Protection Act (PIPA).

• Freedom of Information and Protection of Privacy Act (FIPPA)

<a href="http://www.bclaws.ca/EPLibraries/bclaws">http://www.bclaws.ca/EPLibraries/bclaws</a> new/document/ID/freeside/96165 00

Personal Information Protection Act (PIPA)

http://www.bclaws.ca/EPLibraries/bclaws\_new/document/ID/freeside/00\_03063\_01

• Personal Health Information Access and Protection of Privacy Act <a href="http://www.leg.bc.ca/38th4th/3rd">http://www.leg.bc.ca/38th4th/3rd</a> read/gov24-3.htm

#### **Ontario's Privacy Acts**

The Information and Privacy Commissioner oversees FIPPA, MFIPPA and PHIPA:

- Freedom of Information and Protection of Privacy Act (FIPPA)
- Municipal Freedom of Information and Protection of Privacy Act (MFIPPA)
- <u>Personal Health Information Protection Act</u> (PHIPA)

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# Section 4: Safe Procedures & Processes: Acupuncture

The information in this course is <u>not</u> a comprehensive instruction manual. The course materials are only a *selective summary* of important information related to the safe practice of acupuncture within a TCM practice.

It is expected that practitioners will continue to remain informed and current with current research and literature related to the safe and effective practice of acupuncture.

# **4.1 Required Course Materials**

As part of the course, practitioners are expected to know and reference the following document.

• Table of Points: CTCMA-BC Dangerous/Cautionary Points (Draft) (in Appendix 1).

The document (currently in draft form) will be used as a reference for the course content and the course assessment in the identification of dangerous and cautionary points. As a draft document, it is not intended as a complete reference for a practitioner's practice. For example, at this time contraindications and cautions for extraordinary "extra" points are not identified.

Extra points and Ashi points carry risks similar to points on meridians. Knowledge of the local anatomy, depth and angle for points in the immediate area, as well as indications and contraindications of the points is important to prevent needling accidents.

The depth and angle of needling is critically important, requiring deliberate and careful attention by the practitioner. In practical situations, the precise depth and angle must be based on an informed foundation of knowledge, and applied with a professional interpretation and understanding of the variables (e.g., body shape and size). Practitioners are expected at all times to remain informed and vigilant, and practice with thorough understanding of the requirements for safe and knowledgeable attention to depth and angle. As required in their practice, practitioners are expected to reference reputable professional texts as sources for specific information related to depth and angle.

# 4.2 Clean Needle Technique

#### 4.2.1 Introduction to Clean Needle Technique

The Clean Needle Technique (or sterile needle technique) was established in order to reduce the risk of Hepatitis B transmission in the clinical setting of acupuncture. The technique has proven to be successful and continued adherence is expected and critical to the offering of safe acupuncture services.

The basis for the effective use of the clean needle technique is practitioner understanding of infectious diseases and the means of transmission. See **Section 2: Infection Prevention and Control**.

For TCM practitioners who administer acupuncture, there are two main sources of infectious agents that inform the need for the clean needle technique: **autogenous infections** and **cross-infections**.

**Autogenous infections** are self-produced infections that occur if an infectious agent natural to one location gets carried to another area that doesn't have the same natural defense, causing an autogenous infection. For example, a needle can be infected by being inserted too deeply in the abdominal area, and this infection can be transferred if the needle is reused at another location on the patient's body. Single-use disposable needles provide an effective means of controlling autogenous infections.

**Cross-infections** are not self-produced, but are transferred from another person or from the environment. The risks of cross-infections establish many of the procedures and requirements of the clean needle technique. Cross-infections were examined in detail in **Section 2 Infection Prevention and Control**.

#### 4.2.2 Clean Needle Technique Principles

The clean needle technique includes the following basic principles:

- 1. Always wash hands between patients, before needling, and after needling.
- 2. Always use sterile single-use needles and other instruments that may break the skin (e.g., lancets, sevenstar or plum blossom needle).
- 3. Always establish a clean field before performing acupuncture.
- 4. Always immediately and safely isolate used needles and swabs.

#### **Washing Hands**

- See Section 2.3.2 for general information on hand hygiene.
- Hands should be properly washed between patients and before and after conducting acupuncture. As well, hand washing should be done if there is a possibility that hands have been contaminated by materials that are potentially infectious.
- Alcohol-based sanitizers are not a substitute for hand washing, but may be used in instances where hand washing is not possible.
- Medical gloves are not a substitute for hand washing, but may be used in instances where hand washing is not possible.
- Medical gloves should be used when a practitioner has a hand wound (e.g., cuts or abrasions).
- A practitioner with a significant infected lesion on hands (e.g. herpes or staphylococcus) should not practice until hands are healed. In such cases gloves are not acceptable protection.
- It is highly recommended that a practitioner with a significant infected lesion on hands should not practise until hands are healed.

#### Use of Sterile, Single-Use Needles

- Disposable needles reduce risks to patients.
- Disposable needles must be in appropriate packaging and be approved by Health Canada: Medical Devices, subject to all Federal Legislation. Needles in

- packages that have the seal broken or show evidence of moisture or other damage should not be used.
- Single use sterile needles should not be used past their expiry date.
- Disposable needles must be removed from the packaging without becoming contaminated.
- The needle shaft must remain sterile before and during insertion. (see section 4.4: aseptic technique)
- Each sterile filiform needle should be used for puncturing once, and once only.
- Disposable sterile lancets and three-edged needles are strongly recommended in all instances.

#### Establish a Clean Field

- Set up the area without any instruments contacting clothes or other possibly contaminated materials.
- Lay out the clean field without contaminating it. Set out needles, cotton balls, alcohol swabs, and sterile gauze pads without contaminating the field and for ease of access. Do not let alcohol swabs make the clean field damp.
- Lay out an appropriate number of needles for the procedure without contaminating the site or the needles. Sterile needles must not be placed on a non-sterile environment (e.g., tray, cotton).
- The waste bag and sharps container must be established in an area away from the clean field.

#### Safe Disposal of Needles

- Immediately dispose of the needle in the designated sharps container without touching the container. Contaminated needles pose a real risk to the patient and practitioner.
- Dispose of used cotton or other waste in the waste bag without touching the bag.
- Wash hands.

# 4.3 Preparing the Site

The following should be considered when preparing the site prior to needle insertion.

- Wash hands.
- Inspect the site for lesions or other contraindications. The skin at the needle site should be clean and free from cuts, wounds or infections.
- Areas that are noticeably dirty (e.g., feet, neck) should be washed first then swabbed with 70 % ethyl or isopropyl alcohol.
- Swab the point to be needled with 70 % ethyl or isopropyl alcohol.
- Swab the point from the centre to the surrounding area using an outward rotary motion. In this way, the point has less risk of recontamination.
- Allow the alcohol to dry.
- If palpating the acupuncture point after cleaning, then hands must be clean. Wash or use hand sanitizer as required.

# 4.4 Aseptic Technique

The aseptic technique details the necessary procedures for the hygienic and safe insertion and removal of needles, and is summarized below.

#### 4.4.1 Hygienic and Safe Insertion of the Needle

- Open all single-use needles and instruments just before use in the presence of the patient.
- Patients should be placed in a comfortable position that allows safe access to the selected points.
- After being removed from the packaging, the shaft of the needle is never touched with bare fingers or with non-sterile materials.
- Do not place a needle on a non-sterile surface before use.
- If the needle shaft becomes contaminated before insertion, it must not be used. It must be disposed of in the sharps container.
- Use sterile material (e.g., sterile gauze pad) to support the shaft of the needle once it has been inserted or if it is inserted without a guide tube.
- Guide tubes should be sterile at the start of the treatment.
- Hands must be cleaned if they become contaminated during the treatment (e.g., touch non-sterile surfaces or materials, touches saliva when needling near the mouth).

The use of disposable medical gloves is recommended in situations such as:

- the patient begins bleeding during the treatment
- the patient has open lesions or is known to have a contagious disease
- the practitioner has a skin infection, or hand wounds, cuts, hangnails that are not properly bandaged
- where exposure to blood borne pathogens are likely i.e. use of lancets, three- edged needle, plum blossom and seven star needle or lancet for blood-letting.

#### 4.4.2 Hygienic and Safe Removal of the Needle

- Wash hands immediately before the removal of needles.
- Remove the needle without touching the shaft or the insertion site with bare fingers.
- Dispose of each needle immediately into the properly labelled sharps container.
- On withdrawing a needle, a sterile cotton ball (from the clean field) can be used to
  press the skin at the insertion site. All compresses or cotton balls that are
  contaminated by blood or body fluids must be disposed of appropriately. Do not
  touch the waste bag.
- If blood is drawn, apply light pressure with clean swab. Dispose of the swab immediately.
- After needling, do not immediately re-palpate the point with a bare finger unless it has been washed or sanitized.
- Following treatment, thoroughly wash hands to reduce the risk of cross-infection with subsequent patients.

# 4.5 Acupuncture Instruments and Equipment Overview

#### 4.5.1 Needling Specifications

• Single-Use Pre-Sterilised Disposable Needles

Needles must be disposed of immediately after use in the sharps container. If the seal is broken and not used during treatment of the patient, the needles must be discarded. Any needle with a damaged packaging seal must not be used. Needles must not be used

past their sterility expiry date. Contamination must be avoided once the needle is removed from the sterile packaging by the practitioner.

#### Guide Tubes

Needle guide tubes must be sterile. The guide tubes must be pre-sterilised and come packaged with each individual needle or set of needles. They must not be used past the treatment session in which the seal on the package is broken. The guide tube is disposed of immediately after use.

#### Plum Blossom Needles/Seven Star Hammers

Pre-sterilized disposable needles <u>must</u> be used. The disposable heads of the plum blossom equipment must be disposed of immediately after use. Detachable needle heads should be handled carefully since they may pose an increased risk for needlestick injury.

- All seven-star/plum blossom needle handles must be cleaned with a high-level disinfectant:
  - the handle with new needle head may be used on the same patient;
  - the handle is cleaned and disinfected (high-level disinfectant) between same client sessions:
  - once all needle head packs are used on the same patient, the handle must be thrown out.

Needles should be stored in a safe, clean, well-ventilated area that is free from excessive humidity (to control for condensation and mould growth). Improper storage conditions can give rise to lose sterility well before the expiry date.

#### 4.5.2 Other Equipment

- Cupping is not a sterile procedure. However, cups must be cleaned and disinfected after each patient use.
  - Cups used on intact skin is a non-critical item and should be cleaned and disinfected with a low-level disinfectant between patients.
  - Cups used on **non-intact** skin (e.g., used with needling) is a semi-critical item and should be cleaned and disinfected with an intermediate-level disinfectant between patients.
  - o If bleeding occurs, cupping devices must be autoclaved, or otherwise sterilized.
  - Bamboo cups should not be used because of the difficulty in disinfecting.
- Lancets or three-edged needles used for blood-letting must be sterile (disposable lancets or three-edged needles are recommended).
- Based on use, disinfect or sterilize moxa equipment as required.
- When an electro-stimulation machine is used, the clippers that attach to the handle of the needle must be cleaned and disinfected between patients.
- Re-useable needle trays should be sterilized after each patient.
- Any item that is used to handle or manipulate the sterile needle <u>before</u> insertion must also be sterile.
- Instruments that contact the needle <u>after</u> insertion (forceps, tweezers) must be cleaned and disinfected between patients. Sterilization may be required based on use.

## 4.6 Managing Needlestick Accidents

Needlestick accidents are injuries caused by needles that unintentionally puncture the skin. Needlestick injuries can transmit infectious diseases, especially blood-borne infections such as Hepatitis B and HIV.

Safe needle management is essential to reduce the risk of needlestick accidents. Needle management requires the practitioner to account for every needle that is inserted, removed, and disposed of during treatment.

#### 4.6.1 Routines to Reduce Risks of Needlestick Accidents

Establish routines and procedures that will reduce the risks of stray or lost needles. For example:

- Thoroughly check the patient for needles that have been left in after treatment.
- Be vigilant during treatment knowing that needles can accidentally fall out of the patient's body before removal, or can drop to the ground during removal.
- Check the bed, linens and surrounding areas for dropped needles before, during and especially after a treatment.
- Be especially carefully when changing bed linen. Do not sweep your hands over the area, but rather hold the sheet up by the edges and allow any needles to drop to the floor, and disposed of safely.

Needlestick injuries are an important concern for the practitioner, not only for personal health, but also the health and safety of patients and staff. The risk of developing an infection after a needlestick injury will depend on the infectious status of the source, the immune status of the injured person, the severity of the injury, and the availability and use of proper post-exposure treatment following exposure to the pathogen. Thoughtful and informed procedures to reduce the likelihood of needlestick injuries are essential for all acupuncture clinics. It is recommended that medical gloves, mask and goggles be used when using three-edged needle or lancet for blood-letting.

See Canadian Centre for Occupational Health and Safety <a href="http://www.ccohs.ca/oshanswers/diseases/needlestick\_injuries.html">http://www.ccohs.ca/oshanswers/diseases/needlestick\_injuries.html</a>

- Because of the risks associated with needlestick accidents, it is strongly recommended that all TCM practitioners and staff are immunized against Hepatitis B, as well as having an annual blood test to check for HIV, Hepatitis C, and other blood-borne diseases.
- The patient source of the contamination should be asked to consent to testing for blood-borne pathogens. The patient is not required to undergo such testing.
- If the practitioner or staff member suffers a needlestick accident, the individual must seek immediate medical attention from a physician.

#### 4.6.2 Recommended Actions following Needlestick Accident

If the exposure is deemed significant, the following steps are recommended. If you suffer a needlestick injury, act quickly for your own safety.

#### 1. Immediately provide first aid

after sharps injuries

- allow the wound to bleed freely for a brief time
- gently wash with soap and water
- apply skin antiseptic and cover with a clean dressing or bandage after exposure to eye, nose, or mouth
  - flush area with generous amounts of water for at least 10 minutes

#### after exposure to broken skin

wash with soap and water

## 2. Assess patient's status and obtain patient consent for testing

- practitioner should assess the risk by examining patient's medical history and questioning the patient
- patient cooperation should be sought to clarify status
- if HBV, HCV, or HIV status is unknown or uncertain, seek patient consent for testing of blood-borne pathogens
- keep records of the consent process

# 3. Staff member should be referred to an infectious disease specialist or hospital emergency department for further advice and, if necessary, post-exposure prophylaxis

- have processes and information readily available so that the staff member can have prophylaxis treatment administered as quickly as possible
- it is strongly recommended that practitioners keep a list of emergency numbers readily available in their practice

#### 4. Document the incident

- workplace safety requirements must be adhered to
- record the staff member's name, and their immunization status
- date and time of the incident
- what the staff member was doing
- detail the extent of the exposure, the protective measures that were in place, and the actions that were taken immediately afterward
- the name of the source and the known status of the blood-borne pathogen
- Keep records according to the requirements of the provincial regulatory body. In Ontario patient records must be kept for ten years.

Similar to needlestick injuries, the above guidelines apply to other accidents related to blood-borne pathogens that can occur during treatment procedures such as:

- suffering a cut on contaminated equipment (e.g., from a broken cup)
- blood splashed on broken or cracked skin
- blood splashed on mucous membranes (e.g., a practitioner's eyes or mouth)

#### 4.7 Contraindications and Precautions for Acupuncture

With practitioner skill and training, many acupuncture points have little or no inherent risk to patients. However, some points carry particular potential risk and have an increased possibility of serious injury to the patient if the practitioner lacks the specific experience and training.

The selection of points by the practitioner can be adapted to their knowledge, experience and skills. For some practitioners, the selection of acupuncture points should be carefully limited. With increased experience and skill, the range of acupuncture points and techniques may expand, but there are points and manipulations that should not be undertaken except in very extraordinary circumstances by very skilled professionals.

Because of varied interpretations and regulatory requirements for acupuncture, it is challenging to establish absolute contraindications for the practice of acupuncture. Based on offering safe and professional patient care, acupuncture should be applied with great caution or avoided in the following situations.

#### **During Pregnancy**

Acupuncture should be performed with great caution during pregnancy. Points on the upper abdomen and lumbosacral region, and points which cause strong sensations should be needled with extreme caution and only by experienced and skilled practitioners. Some ear acupuncture points may also induce labour. Reference **Appendix 1** and reputable texts for more detailed direction related to acupuncture during pregnancy.

#### **Medical Emergencies**

In emergency situations, practitioners are expected to use sound judgment within their defined scope of practice. A medical emergency may require trained use of first aid or CPR techniques. Other situations may require practitioners to terminate treatment and seek medical and first aid assistance from emergency responders and other health care professionals, or to have the patient expeditiously sent to a medical site.

The nature of the emergency is an important factor in guiding practitioner actions. A stroke or heart attack is an emergency situation that warrants immediate action and calling 911, since acupuncture should not be the sole form of treatment. There are situations that acupuncture or other treatments may aid or resuscitate a patient while waiting for first responders to arrive.

#### As a Replacement for Surgical Procedures

Acupuncture may assist patients in the preparation for and recovery from surgery, but should <u>not</u> be used to replace a required surgical procedure.

#### **Malignant Tumours**

Acupuncture should not be used alone to treat malignant tumours. Needling at the site of the tumour should only be performed by an experienced TCM practitioner who has advanced training.

Acupuncture may be used as a complementary measure for the relief of pain or other symptoms, to alleviate side-effects of chemotherapy and radiotherapy, and to improve the quality of life.

#### Specific Areas of the Body

Specific areas of the body should not be punctured:

- fontanelle (or fontanel) area of an infant's skull
- external genitalia
- nipples
- eyeball

#### **Patients with Bleeding Disorders**

Needling should be applied with great caution or avoided on patients with bleeding and clotting disorders. These cautions extend to patients who are on anticoagulant therapy or taking medications with an anticoagulant effect (with the exception of aspirin).

#### **Broken or Infected Skin**

Additional precautions need to be considered if needles are required to be inserted through sites that are inflamed, irritated, or have skin lesions or broken skin.

#### **Deep Puncturing near Vital Organs or Sensitive Areas**

Points located near large blood vessels or vital organs are contraindicated for deep insertion or should not be punctured.

#### **Additional Precautions**

Acupuncture should not be conducted, or conducted only with additional precautions, on patients who:

- are intoxicated or under the influence of drugs;
- have a very empty stomach, fatigued or weak because of possible reactions to treatment;
- have just completed vigorous physical activity;
- are suffering uncontrolled movements;
- are confused, emotionally unstable, non-cooperative, or have a needle phobia;
- are unstable diabetics for which extra care is required because of possible effects on blood sugar levels and blood circulation at the extremities (peripheral circulation);
- are on steroids that may impede healing;
- have a pacemaker or other electronic implants (if using electroacupuncture).

Certain patients are at greater than normal risk for infection from acupuncture: these include patients with:

- recent heart valve surgery;
- diabetes;
- myocardial damage from previous infection of the heart muscle;
- suppressed immune systems from previous infections, or from use of antirejection medications or high-doses of steroids.

Reference the **Table of Points: CTCMA-BC Dangerous/Cautionary Points** (CTCMA-BC) in Appendix 1 for a more complete examination of precautions.

# 4.8 Managing Adverse Reactions to Acupuncture Treatment

Acupuncture is a safe procedure when conducted by trained and skilled practitioners who have taken informed and thoughtful precautions and are prepared to respond to accidents or adverse reactions of patients in their care.

Practitioners are expected to identify symptoms, causes and management strategies related to the adverse reactions and accidents such as:

- fainting
- bent needle
- stuck needle
- broken needle

The following sections provide summary information related to these adverse reactions as required for the course but is not intended to be comprehensive. Practitioners are expected to continually expand their professional learning to effectively identify and manage adverse reactions or side effects to acupuncture treatment.

#### **Terminology**

**Side Effects** are *undesirable* effects which occurs in addition to the desired therapeutic effect of treatment. Side effects are unwanted, but are often unavoidable because they are predictable reactions to the treatment in many patients.

**Adverse reactions** are *unexpected and undesirable* effects that were not predicted or foreseen. The reasons for adverse reaction vary greatly based on the current mental, emotional, and physical status of the patient.

#### 4.8.1 Fainting

A patient may feel faint during acupuncture treatment. Especially for patients that have not had previous treatments, patients should be informed of this possibility and treatment should be done gently while the patient is lying down.

Fainting can be the result of the patient being nervous, weak, fatigued, or overly hungry. It may also be the result of uncomfortable positioning, overly forceful needle manipulation, or over stimulation.

Patients should be monitored for symptoms that may indicate that a fainting spell may be approaching. Symptoms during treatment of potential fainting include:

- feeling ill, nausea, possible vomiting
- dizziness, vertigo, giddiness
- seeing movements or swaying of nearby objects
- oppressive sensation in the chest, palpitations
- complexion or lips turn pale

More severe cases may be shown by weakened pulse, cold hands or feet, cold sweating, lowered blood pressure or loss of consciousness.

If the practitioner identifies symptoms of pending fainting, carefully remove needles and ensure the patient is lying flat on their back with head down and feet elevated. The patient should be offered sips of warm water or water with sugar. In most instances, patients will recover following rest, but if symptoms persist, seek medical assistance.

The practitioner can reduce the likelihood of fainting by attending to gentle needle manipulation, and monitoring early warning signs (such as changes to complexion colour and signs of disorientation). Patients that may be predisposed to fainting should be treated while lying down or firmly supported while sitting up for treatment.

# 4.8.2 Stuck Needle

Following insertion of the needle, it may be difficult to rotate, lift and thrust, or withdraw. The cause of a stuck needle is often the result of a patient muscle spasm or sudden movement, but can also be the result of rotation with too wide an amplitude or rotating in only one direction causing the needle shaft to tangle with muscle fibres.

The key to resolving a stuck needle is to reassure the patient and ask him or her to relax. It may be necessary to leave the needle in for a while to allow for relaxation, or to tap or massage around the point. It is often helpful to needle a nearby point to help relax the muscle. If needles are still entangled in fibrous tissue, needles can be slightly and gently rotated in the opposite direction to loosen and allow for withdrawal.

#### 4.8.3 Broken or Bent Needle

There are many factors that may cause a needle to break or bend, including:

- poor needle quality
- erosion or cracks between the shaft and the handle
- sudden movement or strong muscle spasm by the patient
- improper withdrawal of a stuck needle or bent needle
- excessive force manipulating the needle
- needle is struck by external force (e.g., practitioner extends to reach another point and accidentally leans against an existing insertion)

A needle that is bent during insertion should be withdrawn and replaced by another. Excessive force should not be used when manipulating needles, especially when lifting and thrusting. The most common part of the needle that is prone to breaking is at the junction of the handle and the shaft. For this reason, it is strongly recommended that needles never be inserted up to the handle, and at least one-quarter (1/4) of the shaft is always being kept above the skin. Risks of broken needles can be further reduced by carefully examining needles prior to treatment, and not using excessive force to manipulate needles. It is recommended to always remind patients to remain still during acupuncture treatment.

If a needle breaks, ask the patient to stay still and calm so that any movements do not cause the broken part of the needle to sink deeper into the tissues.

If a portion of the broken needle can be seen above the skin, remove it gently with forceps.

If the needle is at skin level, gently press around the site until the broken end is exposed, and then remove it with forceps.

If the broken needle shaft is completely under the skin, seek medical assistance. Do not cut the skin to allow access to the needle. Surgical intervention may be required.

#### **Properly Positioning the Patient**

Practitioners must be aware that the proper positioning of patients can reduce the likelihood of fainting or of causing sudden movements that can result in bent or stuck needles.

Depending on the area to be needled, the practitioner should carefully consider both the comfort of the patient as well as the requirements for effective and safe insertion and manipulation of the needle. Both the patient and the practitioner should feel comfortable.

# 4.9 Injury to Vital Organs

Accidents may occur near vital organs or very sensitive areas as a result of the site chosen, the needle depth, the needle direction or angle, the manipulation technique used, the stimulation provided, and other factors. Injuries can be avoided if additional precautions are taken by the practitioner when treating points near vital organs.

Accidents must be managed effectively but any injury to vital organs may be serious and may require the practitioner to act urgently to arrange medical assistance.

#### **Lung and Pleura**

- Attend very carefully to the depth and angle of inserted needles on the chest, back, or immediately above the clavicle (supraclavicular fossa).
- Deep insertion may cause collapsed lung (traumatic pneumothorax). Attend to symptoms such as cough, chest pain, and difficult or laboured breath (dyspnoea) that happen immediately or gradually develop in the next few hours following treatment.
- Pneumothorax is one of the most frequently reported complications (point Jianjing GB 21 is the most commonly reported point).

#### Points on the Chest, Back and Abdomen

• Attend carefully to the depth and direction of inserted needles.

#### Liver, Spleen and Kidney

- Attend carefully to the depth and direction of inserted needles.
- A liver or spleen puncture may cause pain or tenderness that is localized, a tear with associated bleeding, or stiffness of the abdominal muscles.
- A kidney puncture may cause pain in the lumbar region and the patient may see evidence of blood in the urine (haematuria). If bleeding continues, the patient may suffer shock due to dropping blood pressure.

#### **Circulatory System**

- Attend carefully to the depth and direction of inserted needles. Feel for the pulse to locate artery.
- Bleeding caused by penetration of shallow blood vessels can often be stopped by applying direct pressure.
- Additional precautions should be taken in needling areas of poor circulation where there is a risk of infection (e.g. varicose veins).
- Avoid puncturing of arteries.

#### **Central Nervous System**

- Exercise caution at points between or beside the upper cervical vertebrae (Yamen GV 15, Fengfu GV 16). Needling the lower half of the brainstem (medulla oblongata) may cause headaches, nausea, vomiting, and slowed respiration. This can be followed by convulsions, paralysis or coma. Seek immediate medical assistance.
- Exercise extreme caution near the spinal cord. Deep insertions may cause lightening pain for the patient or more serious complications such as loss of sensation or movement.

#### **Other Points**

Other points that require significant precautions and specialized training include:

- near the carotid artery (Renying ST 9)
- near the femoral artery (Jimen SP 11, Chongmen SP 12)
- on the radial artery (Taiyuan LU 9, Jinggu LU 8)
- points near the eyes (Jingming BL 1, Chengqi ST 1)
- front of the trachea (Tiantu CV 22)

#### 4.10 Other Possible Side Effects and Adverse Reactions

The following side effects and adverse reactions can be experienced by patients as a result of treatment.

#### **Acupuncture**

- De-Qi (acupuncture sensation) a commonly experienced sensation of warmth, tingling or tightness.
  - (**Note:** Other sensations include numbness, mild electrical shooting sensation that last for seconds, distension, soreness, pulsation like waves. These are all good sensations (or good pain) of de qi. There is also sharp, excruciating and uncomfortable pain (or bad pain) that can be experienced. Practitioners should stop the insertion or manipulation and slightly withdraw the needle to relieve the bad pain.)
- common reactions are feelings of light-headedness, or slight disorientation or euphoria
- feelings of cold if needles are retained for longer periods
- minor bleeding or bruising due to penetration of small blood vessels
- minor swelling or bruising from hematoma
- fatigue caused by the temporary lowering of blood pressure (may also cause fainting)
  - (**Note:** It is common for patient to feel fatigued or relaxed during or after treatment. It is highly recommended that the patient experience no intensive stimulation for the rest of the day. Going to sleep early is also recommended after acupuncture treatments.)
- dizziness, light-headedness, vertigo may occur if too many needles are used or if the patient has a weak constitution
   (Note: caution should be taken and needles should be immediately removed if symptoms do not subside.)
- rashes, itching, discomfort at site of insertion caused by allergic reactions to metals against their skin

#### **Moxibustion**

 blisters and 2<sup>nd</sup> degree burns if burning herbs are too close to the skin or left too long.

#### Cupping and gua sha

- the suction action of cupping, to reduce the stagnation of qi and blood, draws blood close to the skin surface and may cause mild bruising, redness and some local tenderness for several days. Patients are advised to stay warm and avoid chills for 1 or 2 days.
- like cupping, the scraping action of gua sha to stimulate circulation of qi and blood may cause mild bruising, redness and some local tenderness for several days. Patients are advised to stay warm and avoid chills for 1 or 2 days.

#### Tapping, Plum Blossom, Bleeding, Pricking

 bruising or bleeding caused by the intentional drawing of blood, or using multiple needles that may rupture small blood vessels.

#### **Electrical Stimulation (PENS, TENS)**

temporary tingling due to electrical stimulation.

 electro-stimulator, if not used properly (on for too long, setting is too high) or poorly maintained, can cause nerve damage.

#### Tuina

- Tuina therapy may cause soreness Tuina and other manual therapies often
  make muscles and tendons sore from various techniques such as pressing,
  stretching, and tapping on the meridians system. De-Qi sensation may be more
  pronounced.
- Tuina therapy may cause bruising in patients who are prone to bruising.

#### **Blood-letting**

• slight bruising may occur at the site where the lancet is inserted.

# 4.11 Specific Considerations Related to Other Techniques

All ancillary techniques and therapies must be conducted in a safe manner, and practitioners must be properly trained in their use.

#### 4.11.1 Electrical Stimulation

#### **Contraindications to Electrical Stimulations**

- Do not use with patients with pacemakers or other electronic implants.
- Do not use with patients with a history of seizures.
- Due to risks of interference with the heart muscle, two branches of the same electrode should always be on the same side of the patient's body. The circuit should never cross from one side of the back or the chest to the other side (i.e., current does not cross the midsagittal or median plane).
- Do not apply stimulation in regions close to the heart.

#### **Precautions and Considerations**

- Carefully examine the equipment before each treatment. Clean and disinfect required surfaces prior to treatment.
- Ensure that all dials are set to zero before applying current or attaching the clips to the needles.
- Increase intensity gradually.
- Throughout the treatment, make sure that the patient is not in discomfort. Stimulation should never become painful.
- Carefully monitor the patient to prevent neural injury.
- Carefully consider the time requirements of treatment.
- All dials must be set to zero before switching off power and removing connections.
- Use additional precautions with older patients or with frail patients.
- Ensure that all electrical stimulators, acupuncture scope, probes and hand held devices, if using 110 voltages, are plugged into a surge protection bar, not directly to the outlet. The consequence in a power surge could transfer extra current to the patient. For portability, many of these electrical devices provide optional battery back-up. Inspection of medical devices on a regular basis is important to ensure effective treatment and safety of the patient.

#### 4.11.2 Moxibustion

Accidents may occur using moxibustion. Practitioners must be fully trained and competent in the procedure and must consider the contraindications/ precautions.

The patient should never be left unattended at any point during the treatment.

#### **Contraindications to Moxibustion**

Do not use moxibustion:

- near mucous membranes.
- on the lower back or abdomen during pregnancy.
- **Scarring or direct moxibustion** should not be applied to the face, head, sensory organs or the area in the vicinity of large blood vessels.
- See also Table of Points CTCMA- BC Dangerous Cautionary Points, draft 2012.

#### **Precautions and Considerations**

- Do not leave the patient unattended at any point during the treatment.
- Be cautious of using the treatment on hypo-sensitive or hyper-sensitive patients.
- Be cautious of using the treatment over main arteries or organs and on the face or sensitive areas (due to increased vulnerability to burns)
- Use with extreme precautions on patients with decreased sensitivity to heat Needling after moxa requires the skin to be swabbed.
- Moxibustion is a fire hazard. Practitioners need increased awareness about the use of fire extinguishers and emergency procedures in the clinic.
- Practitioners using moxibustion (particularly direct moxibustion) are encouraged to be very clear and explicit with patients. Ensure that signed consent to treatment forms identify possible risks of the procedure.
- The use of scarring moxibustion should be evaluated carefully to determine if it is a required method for treatment as it causes scarring.
- Heated needle methods require increased attention to risk management procedures. Use a disposable heat shield under the needle and when burnt moxa is being removed from the needle.

#### **Managing Burns**

- Moxibustion carries a risk of burns which requires practitioners to carefully attend to risk management procedures and legal actions as a result of burns and scars.
- Small blisters should be protected and may be allowed to heal without the need of puncturing.
- Severe burns or large blister may need to be seen by a physician.
- A large blister may need to be treated as follows:
  - Wash hands thoroughly.
  - Disinfect the blister area.
  - o Puncture the blister with a sterilized needle and drain hygienically.
  - Apply an appropriate dressing of sterile gauze.
  - See a physician as required.

As appropriate, it is highly recommended that treatment rooms have a wireless call button or alert button to notify the practitioner or staff of any situations that require swift response (e.g., strong electro-acupuncture stimulation, overly hot moxa/heat

lamp, patient feeling discomfort or in an uncomfortable position, patient needing to use the washroom during the treatment). The call button also assures more sensitive or anxious patients that they can call the practitioner without the embarrassment of having to call out loudly. If a call button is not used, the practitioner should stay in the treatment room or regularly check on the patient at frequent intervals.

# 4.11.3 Heat Lamps

For patient safety and carefully managed risk, the use of heat lamps requires the practitioner to cautiously attend to the operation and maintenance of the equipment. Heat lamps must be used and maintained in strict accordance to manufacturer's instructions. It is essential that practitioner frequently and regularly monitor the heat lamps to confirm and ensure that the lamps are operating as intended and maintained in safe working order.

# 4.12 Acupuncture Treatment in Unfamiliar Settings

Practitioners that make home visits are expected to meet the health and safety standards that are equivalent to working in a clinic.

- The clinic, home, or business premises of the practitioner must have the facilities to establish a clean and sterile setting for the establishment of a travel kit. The practitioner will require at least one room where equipment can be adequately disinfected and sterilized (as required), instruments and materials that will be required can be stored in a clean environment; and clinical waste, used sharps, and soiled equipment and linens can be stored temporarily but safely.
- The setting for the off-site treatment (e.g., a patient's home) should allow for safe treatment. The room should have adequate lighting, be clean, and have easy access to sanitary hand washing facilities.
- It must not be assumed that any needed clean supplies are available on site. Pack
  the travel pack with all required supplies and equipment required for treatment.
  Include supplies to allow for sanitary hand washing, creating sanitary work and
  treatment surfaces, and to establish a clean field. (See Travel Kit Contents.)
- Following treatment, all used sharps must be disposed of in a portable sharps container, all clinical waste appropriately collected for removal and disposal, and all other waste must be disposed of consistent with local requirements.
- Allow adequate time in the schedule of visitations to confirm that the patient is not suffering adverse reactions before leaving.

If you carry out treatment at a patient's home, you must ensure that, as much as possible, the treatment is carried out in a clean room with sufficient lighting and convenient access to hand washing facilities. As well as required instruments and materials, the practitioner should bring supplies to ensure appropriate hand washing (liquid soap, sanitizer, paper towels, etc.) and to establish a clean field.

#### **Travel Kit Contents**

Sterile equipment and materials can be placed in an easily disinfected portable container that can be sealed for easy, sanitary transport.

The following sterile items can be carried in this container:

single-use disposable needles in a separate sealed plastic bag

- supplies to establish a clean field, each in separate sealed plastic bags (e.g., sterile gauze, cotton ball, sterile linen or equivalent). Use sterile tongs to aid packaging
- disposable medical gloves as required
- sterile, packaged equipment such as tweezers or forceps (package should indicate date of sterilization)
- package 70% isopropyl alcohol swabs (or equivalent) in a separate container.

#### Packaged separately from sterile items:

- a plastic lined bag to receive clinical waste
- portable sharps container appropriately labelled.

#### **Additional Items**

- liquid soap for hand washing, hand sanitizer, sealed and clean paper towels or equivalent (paper towels should transferred immediately in aplastic sealed bag to keep clean)
- clean paper rolls (or equivalent) to cover work surfaces or patient's bed or couch where treatment will be conducted
- required documents (e.g., consent to treatment forms), record keeping notes to document consultation.

# Preparing the Clean Field

- Wash your hands.
- Select the area for the clean field and clean and dry the area thoroughly.
- Wash your hands.
- Cover the chosen area with your clean field linen or equivalent.
- Arrange materials and instruments on the clean field. Open the storage bags and remove items in such a way as to minimize handling.
- The sharps container and waste bags are placed away from the clean field.

### Safe Insertion and Removal of Needle

The hygienic safe insertion and removal of the needle should follow the same procedures (aseptic technique) as outlined for on-site needling (see Section 4.4).

# 4.13 Patient Privacy and Draping

Practitioners must be in compliance with all regulations related to proper draping of patients, including the applicable College's Practice Standards. Establishing and maintaining ethical draping procedures is an essential element of risk management for the acupuncturist.

Practitioners have a professional and moral responsibility to ensure that a patient's dignity and privacy is maintained in the conduct of consented treatments.

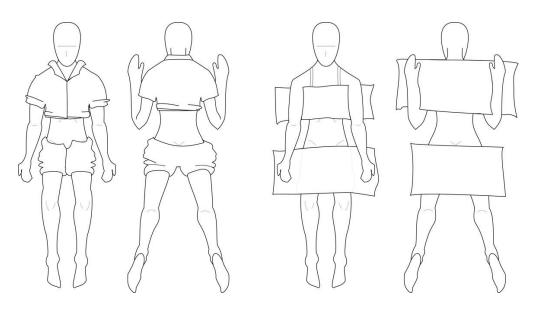
For some treatments, draping may not be required. If the patient has loose fitting clothing, it may be possible for the patient to remain fully clothed during treatment by rolling sleeves above the elbow, pant legs to above the knees, and allowing full exposure to the abdomen or back. It can also be suggested that patients bring loose fitting clothes or shorts that they can change into for treatment.

For other procedures, draping may be necessary. It should be explained fully to the patient why draping is necessary as it relates to their personal safety making needling safer. Draping significantly reduces the opportunity for clothing to inadvertently cover needles or to having needles left in after treatment. The patient must be given the opportunity to consent to undressing and draping. The patient must be provided with adequate and appropriate draping materials. The practitioner must not be present during undressing and the dignity of the patient must be maintained at all times.

The degree of undress must be based on the treatment requirements. It is recommended that if draping is necessary, unless specific procedures cannot be conducted safely and effectively, females remain clothed in a bra (preferably with a hook at the back) and all patients remain clothed in underwear. If full undress is needed, a female's breasts and a client's genitalia and gluteal cleft must remain properly draped at all times except for the safe, comfortable and effective application of treatment requirements.

Every effort must be made by the practitioner to ensure the dignity and modesty of the patient is respected and maintained by the use of maximum proper draping. The use of gowns may be more comfortable in addition to site specific draping of private areas involving woman's breast, genitalia and gluteal cleft of all patients. Patients should be informed to express any concerns whenever he or she is uncomfortable or unsure of any aspect of the treatment. If the patient is comfortable with <u>not</u> being draped or clothed, it is the duty of the practitioner to insist, for the practitioner's protection, that the patient be properly draped. At all times, the practitioner must establish an uncompromised professional environment of treatment.

The following graphic is a visual guide to draping that is useful for many common situations. The graphic is for reference only and is not meant to be comprehensive for all procedures or point selections.



Reference your College's Practice Standards for additional details related to draping.

Page deliberately inserted

# **Section 5 - Safe Procedures and Processes: Herbology**

The information in this course is <u>not</u> a comprehensive instruction manual. The course materials are only a *selective summary* of important information related to the safe practice of herbology within a TCM practice.

It is expected that practitioners will continue to remain informed and current with current research and literature related to the safe and effective prescribing and dispensing of herbal medications.

# **5.1 Required Course Materials**

As part of the course, practitioners are expected to know and reference the following documents included in the Appendices.

- Index of Materia Medica ( Pin-yin, Chinese and Botanical or Pharmaceutical Name) See Appendix 2.
- Animal and Plant Ingredients in Traditional Medicine (Environment Canada, 2011) See Appendix 3.

# 5.2 Overview of Safety Issues related to Herbal Medications

Herbal medicine is very complex in its nature, and practitioners have a responsibility to continue their professional learning related to the safe prescribing and dispensing of herbal medications.

Research continues to enrich practitioner's knowledge of adverse reactions and contraindications related to the effective use of herbs. Every herb can *potentially* cause problems when not used properly. Knowing the potential adverse reactions of individual herbs is important but not sufficient, since reactions may change when used in combination or in formulas. Many factors must be considered and the studies of herbal interactions continued.

#### **Terminology**

**Intolerance** means a lowered threshold to what is seen as normal reactions to the herbal medicine. Though not prevalent with herbal medications, some patients may have less (or more) tolerance requiring appropriate adjustments to the dosage.

**Side Effects** are an undesirable effect which occurs in addition to the desired therapeutic effect of the medication. Side effects are unwanted, but are often unavoidable because they are predictable reactions to the therapeutic effects of the medication (e.g., some herbs contain compounds that can act as mild stimulants that may cause incidents of insomnia). Practitioners should advise their patients of any common side effects when prescribing herbal medications.

**Adverse reactions** are unexpected and undesirable effects that were not predicted or foreseen. The reasons for adverse reaction vary greatly (e.g., caused by unwanted interactions with pharmaceutical medications, incorrect identification of herb, incorrect diagnosis, incorrect use of herb, and contamination of herb).

Allergic reactions are "overreactions" by a person's immune system to normally harmless substance (i.e., allergen). Allergens include dust, food, insect bites, animal dander, etc. Some herbs can cause food allergy reactions in select individuals (rash, nausea, indigestion).

#### 5.2.1 Allergic Reactions to Herbal Medications

It is beyond the scope of the safety course to provide for a complete discussion of the very important and dynamic information related to allergic reactions. Practitioners at all times need to be aware and vigilant of the potential for allergic reactions. Through professional learning and quality assurance programs, CTCMA-BC and CTCMPAO will continue to further support practitioners in the recognition and understanding of allergic symptoms.

It is strongly recommended that all practitioners subscribe to Health Canada's **Canadian Adverse Reactions Newsletter** or to regularly monitor the newsletter's summaries.

<a href="http://www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/index-eng.php">http://www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/index-eng.php</a>

#### 5.2.2 Adverse Reactions to Herbal Medications

Human metabolism varies widely across the population, so it is understandable that patients will not react uniformly when using TCM herbal remedies. The uniqueness of patients presents professional challenges to TCM practitioners as it does to all health care providers whether they are is prescribing herbal remedies or drugs.

Adverse effects may or may not be a reaction to the herbal medication. For example, some herbs may have mild effects that can interact with prescription drugs resulting in inflated or reduced effects. However, practitioner reporting any adverse effects is important for the patient in that it provides relevant clinical data for the practitioner providing the patient fully informed treatment options and modifications.

As research continually expands related to interactions of TCM herbs (e.g., herb-to-herb interactions, herb-to-food interactions, herb-to-natural health product interactions, herb-to-pharmaceutical drug interactions) new information and legislation is continually evolving related to the knowledge requirements for the safe practice of prescribing and dispensing herbal medications. Practitioners have a responsibility to remain current on such information through updates, readings and courses offered by the Colleges (CTCMA-BC, CTCMPAO) and by other governmental, professional and private organizations and associations.

#### **Minor Adverse Reactions**

With trained TCM practitioners and the skilled use of herbs prepared in accordance with TCM methods, the bulk of the adverse effects will be minor in nature and short in duration. The practitioner should openly welcome the patient describing adverse effects so that possible causes can be examined and appropriate adjustments made to treatment. Adverse events are an important source of clinical data, so they should not be ignored.

Care should be exercised when using TCM herb concentrates and extracts. Practitioners should inquire about the concentration/extract ratio in order to avoid potential overdosing.

#### **Severe Adverse Reactions**

Severe adverse reactions herbal medications are rare, but patients should be advised how to seek medical assistance as needed (i.e., information about the local poison control centre, contacting physician, seeking emergency care).

Severe reaction to an herbal medicine should be reported to the *Canada Vigilance Regional Offices* and *Canada Vigilance Nation Office*. Reporting can be done by the practitioner or directly by the client. Information on how to report such adverse effects is at the following website:

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php#a1

The practitioner should provide positive encouragement to patients to report such adverse reactions and to professionally manage such reports so appropriate follow-up is provided to the patient, the practitioner, and to the profession as required. Reporting severe adverse reactions is a measure that may support practitioners in any associated malpractice complaint.

Canada Vigilance Adverse Reaction Reporting Form: <a href="http://www.hc-sc.gc.ca/dhp-mps/alt\_formats/pdf/medeff/report-declaration/ar-ei\_form-eng.pdf">http://www.hc-sc.gc.ca/dhp-mps/alt\_formats/pdf/medeff/report-declaration/ar-ei\_form-eng.pdf</a>

#### **5.2.3 Herbal Remedies Contraindications and Precautions**

Herbal medications are contraindicated or used with great caution in specific situations. These situations include:

- patient is taking many different drugs
- after using herbs, liver-function test indicates abnormality
- symptoms of liver or renal failure are clearly evident or patients are on medications to treat the condition (cautionary use may be appropriate)
- patient has suffered allergic reaction to herbs in the past
- during the first three months of pregnancy (used with great caution)
- babies under one year of age (used with great caution).

#### 5.2.4 Dosage and Duration

Traditional dosages are well known to practitioners, but the multitude of client-dependent variables can impact finding the optimum dosage for each individual patient. It is recommended that starting doses should be relatively low, allowing increases to occur as required by the treatment and supported by positive reactions to treatment. Starting with full dosage may be warranted if the situation is predictable and uncomplicated, or may be necessary if treating severe symptoms.

Dosage for patients must be carefully considered and analyzed by the practitioner, and be given thoughtful consideration to such factors as:

- body weight or body surface area
- character of the illness condition
- general health of the patient
- severity of the symptoms (for acute or serious conditions, larger dosage may be appropriate, and for chronic or mild conditions, small dosages are preferred)

- form of the medication (herbs in the form of decoction may be given in a higher dosage than herbs given in powder form)
- previous experiences and use of herbs
- gender of the patient (e.g., during menstrual period, dosage may be smaller)
- climate and seasonal differences (e.g., cold or hot temperatures can affect the skin pores and the amount of sweating, pungent and bitter herbs that dry damp are less used in dry climates)
- age of the patient (older patients and children may require lower doses).

The following guidelines can be referenced to assist in deciding on **dosage for children** based on age.

•	1-6 months	1/18-1/10 of adult dose
•	6-12 months	1/10-1/8 of adult dose
•	1-2 years	1/8-1/6 of adult dose
•	2-4 years	1/6-1/3 of adult dose
•	4-6 years	1/3-2/5 of adult dose
•	6-9 years	2/5-1/2 of adult dose
•	9-14 years	1/2-2/3 of adult dose

The following guidelines can be referenced to assist in deciding **on dosage based on weight for children**, the elderly, and small adults.

•	30-40 lbs	20-27% of adult dose
•	40-50 lbs	27-33% of adult dose
•	50-60 lbs	33-40% of adult dose
•	60-70 lbs	40-47% of adult dose
•	70-80 lbs	47-53% of adult dose
•	80-100 lbs	53-67% of adult dose
•	100-120 lbs	67-80% of adult dose
•	120-150 lbs	80-100%

Other considerations effecting dosage include:

- quality (e.g., herbs that are wild may require smaller doses than farmed herbs)
- texture(flowers and leaves may require smaller doses; non-toxic plant herbs commonly use 3-10 grams; non-toxic mineral herbs commonly use 10-30 grams)
- flavour (e.g., stronger flavour may require small doses)
- toxicity (e.g., dosage of toxic herbs need cautioned consideration).

Herbs that eliminate a pathogen (promote urination, promote bowel movement, promote sweating) or increase blood/Qi movement, should be closely monitored and reduced in dosage or stopped when the condition improves.

Some herbs, if the dosage is too large, or if used for too long a time, may cause harm to the patient's kidney, liver, heart, stomach, or nervous system. The list that follows includes *some* of the herbs that require careful attention to dosage.

- Ma Huang, Ephedra, (Herba Ephedra)
- Tian Hua Fen (Trichosanthes Root) Radix Trichosanthis
- Fen Fang Ji (Stephania Root) Radix Stephaniae Tetandrae
- Guang Fang Ji (Aristolochia Fanchi Root) Radix Aristolochiae Fangchi

- Guan Mu Tong (Aristolochia Manshuriensis Stem) Caulis Aristolochiae Manshuriensis
- Xi Xin, Asarum, (Herba Asari)
- Chuan Mu Tong (Clematis Armandi Stem)Caulis Clematidis Armandii
- Fu Zi (Aconitum) Radix Aconiti Lateralis Praeparata
- Zao Jiao (or Zao Jia) (Gleditsia Fruit) Fructus Gleditsiae Sinensis
- Ting Li Zi (Lepidium Seed) Semen Descurainiae Seu Lepidii
- Bai Guo (Ginkgo Seed) Semen Ginko
- Zhu Sha (Cinnabaris), Cinnabaris

Aside from dosage, another important consideration is the number of days that the herbal medication may be prescribed.

Duration of the prescription will be influenced by many factors including the patient's condition, experience and understanding of herbal medications, and severity of symptoms. Prescriptions of longer than 1 week should be limited to situations where the practitioner is very familiar with patient's history and condition, and is knowledgeable about the formula to know that it can be taken for a longer duration without risk of adverse effects.

#### **5.2.5 Safety of Raw Herbs**

Practitioners should strive to ensure that herbal products are of high quality. Quality controls for Chinese herbs should include provisions for:

- correct identification of each herb;
- manufacturing in hygienic conditions with clear identification of each production batch;
- stringent processes to ensure no microbial contamination as well as contamination from heavy metals, pesticides, aflatoxins, residual solvents, and other foreign substances.

In order that practitioners work within their scope of practice and within the law, practitioners must be fully aware of TCM herbs and formulas that are banned or restricted, or herbs that have legislated controls and requirements due to their derivation from endangered animals or plants.

The Natural Health Products Directorate (NHPD) is the regulating authority for natural health products for sale in Canada. The role of NHPD is to ensure that Canadians have ready access to natural health products that are safe, effective, and of high quality while respecting freedom of choice and philosophical and cultural diversity.

 The Natural Health Products Directorate (NHPD) can be found online at: <a href="http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/nhpd-dpsn/index-eng.php">http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/nhpd-dpsn/index-eng.php</a>

The importing and use of herbs must comply with Health Canada regulations through the Natural Health Products Directorate, and Canada's Wildlife Trade Law through the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Environment Canada is the lead agency responsible for implementing CITES on behalf of the federal government. The regulation act is the Wild Animal and Plant Protection and Regulation of International and Interprovincial Trade Act (WAPPRIITA).

NHPD in their regulations prevent the use of specific TCM herbs that are identified as extremely toxic. NHPD regulations relate to herbs in their end products or manufactured substances but do not prevent the importation of these toxic herbs in raw form. Requirements for the importation of raw herbs is under the jurisdiction of Health Canada's Food Directorate and CITES. TCM practitioners who operate their own herbal dispensary and use raw herbs need to be vigilant and aware of serious safety and legal issues related to agriculture and quality control, and use a reliable distributor.

Practitioners must be fully aware of the following:

 The restrictions and requirements related to the importation or use of specific animal or plant parts or derivatives based on the classifications identified under CITES.

An electronic copy of the brochure *Animal and Plant Ingredients in Traditional Medicine* found in **Appendix 3** is available at:

http://www.ec.gc.ca/Publications/default.asp?lang=En&xml=91DC8C3C
 -F3F7-4545-973D-C9F48EF641CA

This document identifies *some* toxic herbs (pages 87-88) that require careful attention to dosage. All TCM practitioners in prescribing highly toxic herbs should do so cautiously and within their area of expertise.

# **5.3 Safety Considerations: TCM Prescriptions**

Significant portions of Section 5.3 have been adapted from: Guideline for the Practice of Chinese Herbal Medicine, Chinese Medicine Registration Board of Victoria, Australia (2006).

Safety considerations apply to the following kinds of prescriptions for Chinese herbal medicine:

- individual raw herbs
- single herbs in the form of granules, powders, liquids and extracts
- manufactured formulas (i.e., formulas that have been manufactured into pills, tablets or granules).

These considerations do not apply to TCM Natural Health Products sold over-the-counter (OTC) without prescription.

Practitioners who are engaged in the over-the-counter distribution of such products must meet all provisions of the *Natural Health Product Regulations*, 2004.

Additional information specific to OTC is clearly identified in this document.

#### **5.3.1 General Overall Requirement of Prescriptions**

The prescribing practitioner has responsibility for the completeness, accuracy and comprehensiveness of information that is provided on the prescription. Clarity of prescription information is the guiding principle for practitioners.

The accuracy and clarity of the herbal prescription is important in all situations, but has increased importance when the prescribing practitioner uses an external dispensary to fill the prescription.

TCM prescriptions should be legible and should contain all necessary information to allow the prescription to be accurately and safely dispensed, used, and tracked. For the safety of the public, the information in the prescription must be useful to and understandable by other health professionals, especially in emergency situations.

#### **Language Requirements for Writing Prescriptions**

In Ontario:

A practitioner may choose their preferred language to initially record the prescription. However, they <u>must</u> include a record that other health professionals who use the official languages (English or French) will understand.

#### In British Columbia:

The language requirements are currently under review by CTCMA-BC and official policy will be stated at a later date.

#### 5.3.2 Guidelines for Writing a Prescription

The information required on a TCM herbal prescription includes:

- name, address and contact telephone number of the practitioner
- name of the patient (and patient's parent or guardian where required)
- date the prescription was written
- name of each herb included in the prescription
- part of the herb (when relevant to avoid confusion)
- method of preparation (e.g., whole, powdered, granule, tincture)
- form of processing (when relevant to avoid confusion)
- quantity of each herb
- preparation instructions
- number of packets or dosage as applicable
- instructions on how to use the medication as required for safe usage

#### **Requirements for Naming Herbs**

In general, the name of the herb may initially be written in Chinese characters or in Chinese using Pinyin (see further explanation below) but it is expected that the botanical or Latinate medicinal name will also be provided. The guiding principle is that information be communicated in an effective and understandable way so that patient safety is best ensured.

The use of **Chinese characters** (traditional or simplified) or the Latinate medicinal name provides the most unambiguous herbal names. Standard names, as per the *Chinese pharmacopoeia*, are recommended.

The use of **Chinese using Pinyin** may be included but should not be used alone since this may result in confusion. The botanical name or Latinate medicinal name should always be provided along with Pinyin.

The use of the **botanical name or the Latinate medicinal name** is required, but may not be sufficient for all situations. The Chinese characters (traditional or simplified) or Chinese using Pinyin name should always be provided along with botanical name or the Latinate medicinal name in order to meet the safety requirement. Care should be taken to accurately specify the herb required. In cases where a number of species may share the same Chinese name, specific nomenclature is needed to provide clarity. It is not sufficient to use only an English name if that could lead to confusion.

To assist practitioners, Appendix 2 contains a reference table with Chinese, Pinyin, botanical name and Latinate medicinal name.

#### **Abbreviations**

Unclear abbreviations can result in dispensing errors and uneven and unintended interpretation of the prescription by the dispensary. When writing the names of herbs, shortened forms of the names may be acceptable only if such abbreviations are consistently interpreted by dispensers.

#### **Part of Herb**

In some cases, various parts of a plant may be used to obtain different effects. When there is a possibility of confusion or inconsistent interpretation, the part of the herb must be specified.

#### **Amount of Herb**

The amount of each herb should be specified on the prescription. This amount may be stated in grams or in numbers as applicable. For safety, the measurement unit should be specified clearly.

#### Form of Processing

The form of processing of the herb should be specified if a dispenser is required to do processing. If more than one form of processing is commonly used, then identification of the type of processing is required so that the dispensary acts accordingly.

When there is only one common kind of processing used for the particular herb, then use of 'preparata' or 'processed' is sufficient when using the botanical name, Latinate medicinal or commonly used TCM herbal name.

#### **Preparation Instructions**

Special preparation instructions should be provided.

If a herb is expected to be handled, treated or used differently from other herbs in the prescription (e.g., specific requirements when to add herb, steeping, etc.), these

instructions should be provided clearly on the prescription adjacent to the relevant herb or herbs.

#### **Number of Packets**

The number of packets or bags to be dispensed should be evident on the prescription.

#### **Administration Instructions**

Specific or special instructions for the patient on how to use the herbal medication (e.g., use only after meals, do not take within 1 hour of other medications, do not consume caffeinated drinks or alcohol while on this medication) should be provided to the patient on the prescription or alternatively on supplementary information provided to the patient.

#### Warnings

Warnings related to the use or storage of the TCM herbal medication should be clearly written on the prescription (e.g., keep out of reach of children).

# 5.3.3 Prescribing Granulated or Powdered Herbs

When prescribing granulated or powdered herbs, the previous guidelines are applicable (**Guidelines for Writing a Prescription**). However, there will be directives that may no longer be relevant (e.g., special preparation instructions).

Additional requirements for granulated or powdered herbs include:

- **Prescribing single herb extracts**: specify the weight of each herb, the total weight of the prescription and the dosage
- Prescribing a formula extract: specify the name of the formula, weight and dosage
- Prescribing a formula with additional single extracts: specify the weight of the formula, the weight of each addition, the total weight of the prescription, and the dosage

If relevant to ensure quality and safety, the manufacturer of the granulated or powdered herbs should be specified on the prescription.

#### 5.3.4 Prescribing a Manufactured Herbal Medicine

If manufactured herbal formulas are prescribed, the information is kept on file by the practitioner. The prescription documentation supplied to the patient should allow clear identification of:

- specific medication being prescribed
- ingredients
- manufacturer of the medication
- medication batch number

#### **Over-The-Counter Products**

Over-the-counter (OTC) herbal medications should already have the necessary prescription information printed on the packet (or included inside), and this should be sufficient. However, if the information is not provided, the practitioner should make the required information available to the patient in written form.

#### **Dosage and Administration**

The dosage and patient use instructions must be provided in written form to the patient (e.g., one pill three times per day).

# **Repackaging Over-The-Counter Medicines**

In many circumstances, OTC medicine will be supplied with the manufacturer's packaging intact allowing compliance with packaging information requirements established by Health Canada and Natural Health Products Directorate.

If the herbal medication is no longer in the original manufacturer's packaging (i.e., dispensed in a loose form) the practitioner must ensure that the patient receives the required information when the medication is dispensed. The information must include the name of the herbal formula, manufacturer, and identification of the individual ingredients (using clear and acceptable terminology).

In order to ensure the herbal formula can be readily identified, the name of the formula may initially be written in the practitioner's preferred language or style (e.g., Chinese characters or Pinyin) but should also include:

- anglicised formula name as used in reputable texts, and
- the name of the manufacturer

Practitioners must check their respective college (CTCMA-BC, CTCMPAO) for further guidance and requirements for naming herbs.

If a manufacturer's packaged product uses non-standard names, the practitioner should use the names as used by the manufacturer, and clearly specify the name of the manufacturer so that dispensing can be accurate.

Herbal medications that are unlabelled must not be prescribed or dispensed.

#### 5.3.5 Providing Prescriptions to the Patient

The patient should be provided with a copy of the prescription. The patient copy should provide the following additional information:

- Number of allowed refills
  - One-time use prescriptions should be clearly indicated (e.g., indicate "no repeats"). Herbal medicine are most often one-time use, then monitored to adjust the herbal formula.
- Expiry date
  - If no expiry date is indicated, the prescription is assumed to expire one week following the date of writing.
- Dosage and use
  - The dosage, frequency and timing of use of the medication (e.g., 100 ml, three times a day, one hour after a meal).
- Warnings
   Include any applicable warnings on the use of the prescription.

#### **5.3.6 Providing Instructions to Patients**

Clear instructions should be provided to the patient (or the patient's parent or guardian as required) both verbally and in writing, to allow the patient to safely:

- use and fill the herbal prescription;
- prepare the herbal medication as required (see below);

consume or use the herbal medication.

The method of preparing an herbal decoction should be explained verbally and in writing. The instruction sheet should be in a language that is understandable to the patient or designate.

The verbal instructions should provide the patient with information related to:

- frequency, timing, and duration of the prescription;
- expected factors or normal reactions related to the medication (e.g., unexpected taste, likely aroma, common sensations that may be experienced after use);
- possible adverse reactions, and specific guidance on what the patient is to do if adverse effects are experienced;
- when to stop taking the prescription (e.g., nausea, significant change in bowel movements, having a menstrual period, in the event of pregnancy);
- what to do after completion of the medication (e.g., what repeats may be utilized, or if further consultation may be required to continue medication).

If the patient is required to fill a prescription at a separate herbal dispensary, instructions should be given regarding how to find a dispensary and what to tell the dispenser to do.

# **5.4 Dispensing Chinese Herbal Medications**

This guideline applies to the dispensing of the following kinds of prescriptions for Chinese herbal medicine:

- individual raw herbs
- single herbs in the form of granules, powders and extracts
- manufactured formulas (i.e., formulas that have been manufactured into pills, tablets or granules)

This guideline does <u>not</u> apply to TCM Natural Health Products sold over-the-counter (OTC) without prescription or to the supply of individual herbs or combination of herbs requested by a client.

# 5.4.1 Accurate Dispensing of the Components of a Prescription

The dispensing TCM practitioner has the responsibility for patient safety by ensuring that the formula the patient receives is identical to that recorded on the prescription.

If individual herbs are specified, all herbs indicated on the prescription are included in the formula in the same form and in the same dosage as specified on the prescription.

If manufactured formulas are specified, the dispensed formula will have the same name as indicated on the prescription and contain the same individual herbs.

Substituting Herbs

When an herb or formula is unavailable, or the dispenser is unsure of what is written on the prescription, the dispenser should obtain further advice from the practitioner who wrote the prescription before dispensing the prescription.

The need to contact the practitioner may be waived if:

- the difference in the individual herb specified and the herb available has no significant therapeutic implications. Thorough knowledge of comparable therapeutic effect of different forms of herbs is an expected competency of dispensers who make the substitution.
- the specified formula is not available and a formula of the <u>same name and composition</u> can be substituted from a different manufacturer. The substitution should be done with care and the patient and the practitioner should be advised of this change.

If the dispenser is at all uncertain about the appropriateness of a substitution, the dispenser has the professional responsibility to consult with the TCM practitioner before the prescription is dispensed. Patient safety must guide these decisions.

In Canada, dispensers cannot prescribe TCM herbal formulas to patients but may sell the OTC products or individual raw herb. If a prescription needs a substitute herb, the dispenser should consult with the prescribing practitioner. If another practitioner changes the formula (e.g., substitution of individual raw herb or single herb in powder), the revising practitioner will have assumed some or all of the responsibilities for patient safety.

#### **Providing Herbs in the Form Specified**

The dispenser should provide herbs in the form specified on the prescription.

#### Accuracy in Weighing

Each herb in the prescription should be weighed independently.

- Raw herbs should be weighed with a level of accuracy of ± 1 g. Toxic herbs may require greater accuracy.
- Granulated herbs or herbal extracts should be weighed with a level of accuracy of  $\pm$  0.5 g. Toxic herbs may require greater accuracy.

#### **Checking Prescriptions**

The dispensing TCM practitioner should carefully examine the prescription and check that there are no inadvertent errors evident (e.g., herbs correctly identified, appropriate dosages). If the dispenser suspects that an error was made, the dispenser should contact the prescribing practitioner for clarification or confirmation.

If contact cannot be made with the prescribing practitioner and the nature of the error is clearly evident to the trained dispenser, the dispenser may correct the error, and dispense the prescription and contact the practitioner at a later time. The correction or alteration should be clearly noted on the prescription. The patient is informed of the change at the time of dispensing and the practitioner should be informed of the change in a prompt manner.

# 5.4.2 Accurate Identification of Herbs and Quality of Herbs

The dispensing TCM practitioner should ensure that herbs are accurately identified and of good quality upon receipt in the dispensary and at the time of dispensing.

- If the dispenser is uncertain of the provided identification or labelling of an herb by the supplier, it is expected that the dispenser will seek further information and clarification from the supplier before dispensing the herb. The herb should not be dispensed if there is uncertainty.
- Herbs of poor quality or significant deterioration should not be dispensed. Herbs, being natural materials, may have minor evidence of deterioration that can be suitably handled.
- If readily removable contaminants are evident (e.g., other plant matter, grit) they should be removed by the dispenser.

#### 5.4.3 Accurate Dispensing of Amount of the Prescription

The dispenser should provide the client with the same number of packets of herbs specified on the prescription.

- If no number is specified, at most three packets should be dispensed.
- The dispenser should provide the client with the same number of packets/bottles of pre-packaged manufactured formulas specified on the prescription.
   If no number is specified, the dispenser should dispense one bottle or packet (or up to one week supply).
- The dispenser should not fulfill requests by the client for an increase in the amount of the prescription without first consulting the prescribing practitioner.

#### 5.4.4 Labelling of the Medicine Dispensed

Dispensers are expected to adhere to the following labelling guidelines:

- Each packet or container is labelled with the name of patient and dispensing date.
- If multiple packages are bagged together, the identifying name should be written on the outside bag.
- If several packages are supplied and the patient is required to use them or prepare them in a certain sequence, the dispenser should label the packages appropriately so that instructions are easily followed (e.g., packages are labelled as 1, 2, 3, etc., with appropriate supporting instructions).
- Pre-packaged manufactured medications that are properly labelled require no additional labelling.
- Include appropriate cautionary labels (e.g., related to safe storage or kept out of reach of children).

#### 5.4.5 Record Keeping

The following procedures are recommended in order to keep accurate dispensing records.

- After dispensing the herbal medication, the dispensing practitioner should provide
  the following information on the client's prescription (or on a separate form and
  attach it to the prescription):
  - date that the prescription was dispensed
  - the dispenser's name (or name of the dispensing outlet)
- Return the prescription to the client. For risk management purposes, the dispensing
  practitioner is strongly encouraged to make a copy of the prescription to keep in the
  dispensary files.

• If the dispenser is also the patient's prescriber and practitioner, the comparable information should be recorded in the patient record.

# 5.4.6 Provision of Repeat Prescriptions

The dispensing practitioner should only provide the client with the number of repeats specified on the prescription.

- If the number of repeats is not specified, the dispenser should fill the prescription only once.
- If a client requests repeats not specified on the prescription, the dispenser should either:
  - consult with the prescribing practitioner to determine whether added repeats should be dispensed, or
  - refer the client back to their prescribing practitioner for further consultation.

#### **5.4.7 Expired and Undated Prescriptions**

An expired or undated prescription should not be dispensed without seeking further direction from the TCM practitioner who wrote the prescription.

- If no expiry date is evident on the prescription, the dispenser should assume the prescription expiry date is no more than one week after the prescription was written, or should check number of packets of herbs specified on the prescription (e.g., 3 packets means the expiry date is after three days).
- Dispensers should not fill prescriptions that have not been prescribed by a TCM practitioner.

#### **5.4.8 Providing Instructions**

The dispensing practitioner should provide the client with instructions about the correct preparation of the prescription.

- These instructions are not required if provided previously by the prescribing practitioner.
- The dispensing practitioner should provide verbal instructions of what the patient should do if experiencing adverse reactions.

# 5.5 Safe Management of a TCM Herbal Dispensary

These guidelines are not applicable to retailers of over-the-counter TCM herbal products.

#### **5.5.1 General Requirements for Dispensaries**

The following general specifications apply to all Chinese herbal dispensaries:

- The dispensary should be clean and orderly.
- Medicinal substances should be stored and handled in a hygienic manner.
- The facility should be able to monitor humidity, temperature, and air flow.
- The dispensary should be organised to allow for effective and safe preparation and dispensing of medications.
- Staff should be trained for the tasks required and demonstrate competence in carrying out duties.
- Facilities for hand washing should be readily available.
- Facilities for cleaning of utensils should be readily available.

- Proper records should be kept including batch identification and supplier identity.
- Expiry date should be monitored as applicable.
- Procedures should be established to ensure the accurate dispensing of prescriptions.
- Procedures should be established to prevent prescriptions from being confused, mishandled, or mislabelled.

## **5.5.2 Labelling of Herbs**

Herbs should be clearly identified and labelled to avoid confusion.

- Containers and/or dispensary drawers and packets of herbs in storage should be clearly labelled.
- Purchased herbs should be inspected to confirm that the herb is correctly identified and labelled. Incorrectly labelled herbs should be referred to the wholesaler. If an herb's identity cannot be confirmed, it should be returned to the wholesaler.
- Packets of herbs supplied to clients should be accurately labelled.

#### **5.5.3 Storage of Herbs**

It is expected that herbs will be stored using safe procedures and appropriate containers that ensure that the herb can be kept free from contamination and that herb quality can be maintained.

- Herbs should be stored in clean, dry containers. The containers should provide protection from insect and rodent infestation.
- Herbs that show signs of deterioration (mould, discoloration, insect attack) should be discarded.
- When herbs are transferred from storage into dispensing containers, they should be checked for deterioration and any extraneous matter.
- Herb storage containers should be properly managed. Do not top-up containers leaving older herbs at the bottom of the container. Empty containers should be properly cleaned before re-filling.
- Keep herbs out of reach of children.
- The optimal method of storage will vary based on the herb. (e.g., some herbs do
  best in air-tight containers, some others do best with regular exposure to air to keep
  them mould free).

#### 5.5.4 Handling Herbs

A clean and hygienic environment must be established and maintained for the handling and dispensing of herbal prescriptions. Procedures to avoid contamination and prevent cross-infection are further detailed in **Section 2: Infection Prevention and Control**.

- Dispensing practitioners should wash and dry their hands prior to dispensing a prescription.
- The surfaces on which herbs are dispensed should be clean and free from extraneous matter.
- Medical gloves, tongs or other means of hygienic handling may be used to reduce risks of cross-infection.
- Scales used for weighing herbs should be accurate and regularly and thoroughly cleaned.
- Utensils used in the processing of herbs should be regularly and thoroughly cleaned.
- Prescriptions must be packaged using clean materials (commonly paper or plastic).

#### **5.5.5 Supervising Dispensary Assistants**

It is the responsibility of practitioner to ensure that the dispensary is properly managed and prescriptions are safely and accurately dispensed.

- The dispensing practitioner is responsible for all aspects of the TCM herbal dispensary.
- Dispensary assistants must be provided with sufficient training to enable them to perform all assigned tasks.
- Practitioners and dispensers must provide dispensary assistants with training in relevant regulations and practice guidelines such as labelling and dispensing, dispensary management, controlled substances, patient privacy requirements, and infection control procedures.
- The dispensing practitioner in charge of the dispensary must not assign or delegate duties to dispensary assistants for which the assistants are not sufficiently trained.
- It is expected that the dispensing practitioner will use sound professional judgment delegating appropriate tasks and not exposing dispensary assistants to any task or activity which may exceed their level of knowledge, training, skills, or competence.
- Duties that a TCM dispensing practitioner may allocate to dispensary assistants include:
  - preparation of herbal medicines to be dispensed (e.g., identification, weighing, pao zhi/a method used for preparing herbs utilizing heat: Pao translated means quick frying a substance until it becomes dark brown while Zhi means frying with liquids.)
  - managing inventories (e.g., ordering, stocking, repackaging, storage)
  - attaching dispensing labels, advisory labels, and collating prescriptions
  - infection control tasks
- The dispensing practitioner must not delegate any activity that is required by regulation, or by standards of professional practice. Duties that cannot be delegated include:
  - dispensing herbal medications
  - presenting opinions to the client on the safety, effectiveness, or appropriateness of any prescription herbal medications
  - providing patient health counselling
- A TCM dispensing practitioner should be in attendance and actively supervising dispensary assistants in order to monitor and advise their work.
- Prescriptions should first be examined and confirmed by a TCM dispensing practitioner before being given to a dispensary assistant.

#### 5.5.6 Record Keeping

When a prescription is dispensed, a record (or copy) of the prescription should be kept on file. This record should include:

- ingredients of the prescription and amounts (should be on the copy of the prescription if it was made)
- date the prescription was dispensed
- number of packets dispensed
- name and contact details of the prescribing practitioner (should be on the copy of the prescription if it was made)
- name of the dispenser

A record should be kept of the inventory of herbs that includes:

• identity of the herbs purchased

- name of the wholesaler
- country of origin (to manage any recalls due to adulteration of specific species)
- date purchased

# **5.6 Additional References**

Natural Health Products Directorate (regulator of natural health products) <a href="http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/nhpd-dpsn/index-eng.php">http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/nhpd-dpsn/index-eng.php</a>

Natural Health Products Regulations <a href="http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/index-eng.php">http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/index-eng.php</a>

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# **Appendices**

# **Appendix 1**

# Table of Points: CTCMA-BC Dangerous/Cautionary Points (Draft Nov 2012)

This draft document will be used as a reference for the course content and the course assessment in the identification of dangerous and cautionary points. The information in the table is based on references to the following journal articles and texts.

- The Safe Use Of Difficult & Dangerous Acupuncture Points (Journal of Chinese Medicine #72 June 2003) The Use Of Acupuncture As A Routine Pre-Birth Treatment (Journal of Chinese Medicine #76 October 2004)
- A Manual of Acupuncture, 2<sup>nd</sup> Edition (2007) by Peter Deadman, Kevin Baker et al. Published by Journal of Chinese Medicine. ISBN: 0-9510546-5-1
- Chinese Acupuncture and Moxibustion (1993) by Qiu Mao-Liang, Zang Shanchen, et al. Published by Longman Singapore Publishers Ltd. Distributed by Churchill Livingstone Inc., 650 Avenue of the Americans, New York, New York.
- Chinese Acupuncture and Moxibustion (1990) by Foreign Language Press, Beijing. 1SBN: 0-8351-2109-7 1SBN:7-119-00378-X.

The points highlighted "yellow" in the table refer to dangerous and cautionary points identified in two or more reference texts. They correspond with the dangerous points identified in the referenced journal articles. Some points are considered "dangerous" because they are contraindicated in pregnancy. For course purposes these are referred to as "cautionary" as related to use in pregnant patients.

Extra points are not included in the review of dangerous points in this draft.

Point	Point name	Pg.#	P. Deadman	PG#	САМ	Pg. #	Qiu Mao-Liang
LU -1	Zhongfu	76	Deep perpendicular or oblique insertion carries a substantial risk of causing pneumothorax.	127	To avoid injuring the lungs, never puncture deeply towards the medial aspect.	63	Never puncture deeply towards the medial aspect.
LU-2	Yunmen	77	Deep perpendicular or oblique insertion carries a <b>substantial</b> risk of causing pneumothorax.	128	To avoid injuring the lungs, never puncture deeply towards the medial aspect.	63	Never puncture deeply towards medial aspect of chest.
LU-8	Jingqu			130	Avoid puncturing the radial artery.	65	No moxa
LU-9	Taiyuan			130	Avoid puncturing the radial artery.		
LI-4	Hegu	103	Contraindicated in pregnancy	132	Acupuncture and moxibustion are contraindicated in pregnant women.	68	Contraindicated for pregnant women.
LI-13	Shouwuli			134	Avoid injuring the artery.		
LI-16	Jugu	117	Deep medial insertion carries a risk of causing pneumothorax, particularly in thin patients.				
LI-17	Tianding	118	Deeper needling may puncture the carotid artery or jugular vein.				
LI-18	Futu	118	Deeper needling may puncture the carotid artery or jugular vein.				
LI-20	Yingxiang					72	Contraindicated in moxibustion.
ST-1	Chengqi	130	- Needle should be inserted slowly without lifting, thrusting or rotating; - Immediately on withdrawal of the needle, press firmly with a cotton wool ball for about a minute to prevent haematoma; - This needling method should not be attempted by those who have not had appropriate clinical supervision.	136	It is not advisable to manipulate the needle with large amplitude.	74	Avoid injuring blood vessels and causing haematoma, not advisable to lift and thrust needle.
ST-2	Sibai	131	- Deep insertion along the foramen may injure the eyeball;  - Manipulation by lifting and thrusting is contraindicated due to risk of damaging the infraorbital nerve which emerges from foramen.	137	It is not advisable to puncture deeply.	75	Deep needling is contraindicated.

Point	Point name	Pg.#	P. Deadman	PG#	CAM	Pg. #	Qiu Mao-Liang
ST-5	Daying	133	Vigorous manipulation is contraindicated to avoid the risk of damaging the facial artery and vein.	137	Avoid puncturing the artery.	75	Avoid the artery.
ST-8	Touwei	135				76	Contraindicated for moxibustion.
ST-9	Renying	138	Care should be taken to avoid puncturing carotid artery which must be palpated and then held laterally during needling, by using the index finger and thumb of one hand, above and below the point. This needling method should not be attempted by those who have not had appropriate clinical supervision.	139	Avoid puncturing the common carotid artery.	76	Avoid common carotid artery. Contraindicated for moxibustion.
ST-10	Shuitu	138	Care should be taken to avoid puncturing carotid artery which must be palpated and then held laterally during needling, using the index finger and thumb of one hand, above and below the point. This needling method should not be attempted by those who have not had appropriate clinical supervision.				
ST-11	Qishe	139	Deep insertion may puncture the lung.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-12	Quepen	140	Deep or posterior insertion may injure the subclavian vessels or puncture the lung.	139	- Avoid puncturing the artery.     - Deep puncture is not advisable.	77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-13	Qihu	140	Deep or perpendicular insertion carries a substantial risk of puncturing the lung or injuring the subclavian vessels.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.

Point	Point name	Pg.#	P. Deadman	PG#	САМ	Pg. #	Qiu Mao-Liang
ST-14	Kufang	141	Deep or perpendicular insertion carries a substantial risk of puncturing the lung.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-15	Wuyi	142	Deep or perpendicular insertion carries a substantial risk of puncturing the lung.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-16	Yingchuang	142	Deep or perpendicular insertion carries a substantial risk of puncturing the lung.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated
ST-17	Ruzhong	142	This point is contraindicated to both needling and moxibustion, and is used simply as a reference point.	140	Acupuncture and moxibustion on this point are contraindicated. This point serves only as a landmark for locating points on the chest and abdomen.	77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-18	Rugen	143	Deep or perpendicular insertion carries a substantial risk of puncturing the lung.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-19	Burong	144	Deep insertion may injure the heart on the left or the liver on the right if either of these organs is enlarged.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-20	Chengman	144	<ul> <li>In this subject, deep needling may penetrate the peritoneal cavity.</li> <li>Deep needling at right Chengman ST-20 may penetrate an enlarged liver.</li> </ul>			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-21	Liangmen	145	<ul> <li>In this subject, deep needling may penetrate the peritoneal cavity.</li> <li>Deep needling at right Liangmen ST-21 may penetrate an enlarged liver.</li> </ul>			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-22	Guanmen	146	In this subject, deep needling may penetrate the peritoneal cavity.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.

Point	Point name	Pg.#	P. Deadman	PG#	САМ	Pg. #	Qiu Mao-Liang
ST-23	Taiyi	146	In this subject, deep needling may penetrate the peritoneal cavity.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-24	Huaroumen	147	In this subject, deep needling may penetrate the peritoneal cavity.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-25	Tianshu	148	In this subject, deep needling may penetrate the peritoneal cavity.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated; moxibustion is contraindicated on this point for pregnant women.
ST-26	Wailing	149	In this subject, deep needling may penetrate the peritoneal cavity.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-27	Daju	150	In this subject, deep needling may penetrate the peritoneal cavity.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-28	Shuidao	150	Deep needling may penetrate the peritoneal cavity in thin patients or may penetrate a full bladder; the patient should therefore be asked to empty the bladder before needling.			77	Deep underneath from ST-11 to ST-28 are large arteries and important viscera such as lung, liver, so deep puncture is contraindicated.
ST-29	Guilai	151	Deep needling may penetrate the peritoneal cavity in thin patients or may penetrate a full bladder; the patient should therefore be asked to empty the bladder before needling.				

Point	Point name	Pg.#	P. Deadman	PG#	САМ	Pg. #	Qiu Mao-Liang
ST-30	Qichong	152	In thin patients:  - deep insertion in superior direction may penetrate the peritoneal cavity or a full bladder (the patient should therefore be asked to empty the bladder before needling);  - Deep insertion in an inferior direction in the male may penetrate the spermatic cord.				
ST-41	Jiexi	167	The anterior tibial vessels and nerve lie deep to this point.				
ST-42	Chongyang	169	Care should be taken not to puncture the dorsalis pedis artery which lies beneath this point.	147	Avoid puncturing the artery.	83	Avoid artery.
SP-6	Sanyinjiao	189	Contraindicated in pregnancy.	150	Acupuncture on this point is contraindicated in pregnant women.	87	Contraindicated in pregnant women.
SP-11	Jimen	198	Deep needling may puncture the femoral artery.			89	Avoid artery.
SP-12	Chongmen	198	Deep needling in medial direction may puncture the femoral artery, and in lateral direction, the femoral nerve.	152	Avoid puncturing the artery.	89	Avoid artery.
SP-13	Fushe	199	In thin patients deep needling may penetrate the peritoneal cavity.				
SP-14	Fujie	199	In thin patients deep needling may penetrate the peritoneal cavity.				
SP-15	Daheng	200	<ul> <li>In thin patients deep needling may penetrate the peritoneal cavity.</li> <li>Deep needling at this point may penetrate a substantially enlarged spleen or liver.</li> </ul>				
SP-16	Fuai	201	- In thin patients deep needling may penetrate the peritoneal cavity Deep needling at this point may penetrate a substantially enlarged spleen.				

Point	Point name	Pg.#	P. Deadman	PG#	САМ	Pg. #	Qiu Mao-Liang
SP-17	Shidou	201	Perpendicular insertion, especially in thin patients, carries a substantial risk of inducing pneumothorax.			90	Underneath points from SP-17 to SP-21 lies the lung; deep needling is contraindicated.
SP-18	Tianxi	202	Perpendicular insertion, especially in thin patients, carries a substantial risk of inducing pneumothorax.			90	Underneath points from SP-17 to SP-21 lies the lung; deep needling is contraindicated.
SP-19	Xiongxiang	203	Perpendicular insertion, especially in thin patients, carries a substantial risk of inducing pneumothorax.			90	Underneath points from SP-17 to SP-21 lies the lung; deep needling is contraindicated.
SP-20	Zhourong	204	Perpendicular insertion, especially in thin patients, carries a substantial risk of inducing pneumothorax.			90	Underneath points from SP-17 to SP-21 lies the lung; deep needling is contraindicated.
SP-21	Dabao	204	Perpendicular insertion, especially in thin patients, carries a substantial risk of inducing pneumothorax.			90	Underneath points from SP-17 to SP-21 lies the lung; deep needling is contraindicated.
HT-1	Jiquan	212	Medial insertion toward the chest may puncture the lung.	155	Avoid puncturing the axillary artery.	92	Avoid axillary artery.
HT-7	Shenmen	219	The ulnar artery and ulnar nerve lie adjacent to this point.				
SI-8	Xiaohai	239	The ulnar nerve lies deep to this point.				
SI-12	Bingfeng	242	Deep perpendicular insertion, especially in thin patients, carries a substantial risk of inducing pneumothorax.				
SI-13	Quyuan	243	This point is located close to the medial border of the scapula. Too medial an insertion or deep medial oblique needling may puncture the lung.				
SI-14	Jianwaishu	244	Perpendicular insertion, especially in thin patients, carries a substantial risk of inducing pneumothorax.				

Point	Point name	Pg.#	P. Deadman	PG#	САМ	Pg. #	Qiu Mao-Liang
SI-15	Jianzhongzhu	244	Deep insertion inferiorly, especially in thin patients, carries a substantial risk of inducing pneumothorax.				
SI-18	QuanLiao					100	Contraindicated for moxibustion.
BL-1	Jingming	256	- Needling at this point should not be attempted by those who have not had appropriate clinical supervision.	164	Moxibustion is forbidden	102	Not advisable to rotate or lift and thrust needle. To avoid bleeding, press the puncture for a while; moxibustion is contraindicated on this point.
BL-10	Tianzhu					104	Puncture in a medial or upward direction is forbidden, to avoid injuring medulla.
BL-11	Dazhu	264	Perpendicular needling carries a <b>substantial</b> risk of causing pneumothorax.			105	Deep puncture is contraindicated for the points on the back along this meridian, to avoid injuring important viscera beneath.
BL-12	Fengmen	266	Perpendicular or oblique needling away from spine carries a substantial risk of causing pneumothorax.				See BL-11
BL-13	Feishu	267	Perpendicular or oblique needling away from spine carries a substantial risk of causing pneumothorax.				See BL-11
BL-14	Jueyinshu	269	Perpendicular or oblique needling away from spine carries a substantial risk of causing pneumothorax.				See BL-11
BL-15	Xinshu	270	Perpendicular or oblique needling away from spine carries a substantial risk of causing pneumothorax.				See BL-11
BL-16	Dushu	272	Perpendicular or oblique needling away from spine carries a substantial risk of causing pneumothorax.				See BL-11
BL-17	Geshu	273	Perpendicular or oblique needling away from spine carries a substantial risk of causing pneumothorax.				See BL-11

Point	Point name	Pg.#	P. Deadman	PG#	CAM	Pg. #	Qiu Mao-Liang
BL-18	Ganshu	275	Perpendicular or				See BL-11
			oblique needling away				
			from spine carries a				
			substantial risk of				
			causing pneumothorax.				
BL-19	Danshu	277	Perpendicular or				See BL-11
			oblique needling away				
			from spine carries a				
			substantial risk of				
			causing pneumothorax.				
BL-20	Pishu	278	Perpendicular or				See BL-11
			oblique needling away				
			from spine carries a				
			substantial risk of				
DI 24	347 * 1	200	causing pneumothorax.				6 81 44
BL-21	Weishu	280	Perpendicular or				See BL-11
			oblique needling away from spine carries a				
			substantial risk of				
			causing pneumothorax.				
BL-22	Sanjiaoshu	281	Deep perpendicular				See BL-11
DL-22	Sanjiaosnu	201	needling carries a risk				366 PF-11
			of injuring the kidneys.				
BL-23	Shenshu	283	Deep perpendicular				See BL-11
DL-23	Silensila	203	needling carries a risk				See BL-11
			of injuring the kidneys.				
BL-40	Weizhong	300	The tibial nerve and the				
B2 10	Weizhong	300	popliteal artery lie deep				
			to this point.				
BL-41	Fufen	301	Deep perpendicular or				See BL-11
			oblique needling in a				
			medial direction carries				
			a <b>substantial</b> risk of				
			causing pneumothorax.				
BL-42	Pohu	302	Deep perpendicular or				See BL-11
			oblique needling in a				
			medial direction carries				
			a <b>substantial</b> risk of				
			causing pneumothorax.				
BL-43	Gaohuangshu	303	Deep perpendicular or				See BL-11
			oblique needling in a				
			medial direction carries				
			a <b>substantial</b> risk of				
DI 44	CI I	204	causing pneumothorax.				6 81 44
BL-44	Shentang	304	Deep perpendicular or				See BL-11
			oblique needling in a medial direction carries				
			a <b>substantial</b> risk of				
			causing pneumothorax.				
BL-45	Yixi	305	Deep perpendicular or			+	See BL-11
DL-43	1141	303	oblique needling in a				2CC DF-11
			medial direction carries			1	
			a <b>substantial</b> risk of				
			causing pneumothorax.				
BL-46	Geguan	306	Deep perpendicular or			1	See BL-11
	0		oblique needling in a			1	
			medial direction carries			1	
			a <b>substantial</b> risk of				
			causing pneumothorax.				

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Point	Point name	Pg.#	P. Deadman	PG#	CAM	Pg. #	Qiu Mao-Liang
KI-18	Shiguan	357	Deep needling may penetrate the peritoneal cavity.				
KI-19	Yindu	357	Deep needling may penetrate the peritoneal cavity.				
KI-20	Futonggu	358	Deep needling may penetrate the peritoneal cavity.				
KI-21	Youmen	358	Deep needling, especially in thin subjects, will puncture the liver on the right side and the peritoneum on the left.	186	To avoid injuring the liver, deep insertion is not advisable.	122	Deep needling is forbidden, to avoid injuring the liver
KI-22	Bulang	360	Deep perpendicular or oblique needling may puncture the lung and/or the liver.		To avoid injuring the heart, deep insertion is not advisable.	123	For points along this meridian on the chest, Deep needling is contraindicated so as not to injure the heart and lung
KI-23	Shenfeng	360	Deep perpendicular or oblique needling may puncture the lung.				See KI-22
KI-24	Lingxu	361	Deep perpendicular or oblique needling may puncture the lung.				See KI-22
KI-25	Shencang	361	Deep perpendicular or oblique needling may puncture the lung.				See KI-22
KI-26	Yuzhong	362	Deep perpendicular or oblique needling may puncture the lung.				See KI-22
KI-27	Shufu	362	Deep perpendicular or oblique needling may puncture the lung.				See KI-22
PC-1	Tianchi	370	Deep needling carries a substantial risk of causing a pneumothorax.	189	Deep puncture is not advisable.	125	Deep needling is contraindicated so as not to injure the lung.
PC-3	Quze	372	The brachial artery and veins lie deeply, just medial to this point.				
P-6	Neiguan	376	The median nerve lies directly under this point and needling commonly induces a significant electric sensation. This is an acceptable manifestation of deqi, but once elicited, further manipulation is inappropriate and may damage the nerve.				

Point	Point name	Pg.#	P. Deadman	PG#	САМ	Pg. #	Qiu Mao-Liang
PC-7	Daling	379	The median nerve lies directly under this point and needling commonly induces a significant electric sensation. This is an acceptable manifestation of deqi, but once elicited, further manipulation is inappropriate and may damage the nerve.				
TE-5	Waiguan	396	Movement of the patient's arm or hand after needling this point can result in a bent needle.				
TE-6	Zhigou	398	Movement of the patient's arm or hand after needling this point can result in a bent needle.				
TE-15	Tianliao	406	Perpendicular insertion, especially in thin patients, carries a substantial risk of inducing a pneumothorax.				
TE-22	Erheliao		,			134	Avoid artery.
GB-3	Shangguan	424	It is traditionally emphasized that deep needling should be avoided at this point.				
GB-20	Fengchi	436	Deeper needling may damage the spinal cord.			140	In the centre of the deep portion is the medulla; correct angle and depth of needling are strictly demanded.
GB-21	Jianjing	438	- Perpendicular insertion, especially in thin patients, carries a substantial risk of inducing a pneumothorax - Contraindicated in pregnancy.			140	Underneath is the apex of the lung and deep needling is contraindicated; contraindicated for pregnant women.
GB-22	Yuanye	440	Deep or perpendicular insertion may induce pneumothorax.			140	For points of this meridian from GB-22 to GB-25, deep needling is contraindicated so as not to injure the important viscera underneath.
GB-23	Zhejin	441	Deep or perpendicular insertion may induce pneumothorax.				See GB-22

Point	Point name	Pg.#	P. Deadman	PG#	CAM	Pg. #	Qiu Mao-Liang
GB-24	Riyue	441	Deep or perpendicular insertion may induce pneumothorax.				See GB-22
GB-25	Jingmen	442	In thin subjects, deep needling may penetrate the peritoneal cavity.				See GB-22
GB-26	Daimai	444	In thin subjects, deep needling may penetrate the peritoneal cavity.				
LR-1	Dadun					148	Contraindicated for pregnant women (before and after labour) when treated with moxibustion.
LR-12	Jimai	488	Care should be taken to avoid penetrating femoral vein.			151	The Plain Questions states that moxibustion is applicable but needling contraindicated at this point.
LR-13	Zhangmen	489	Deep perpendicular needling may damage an enlarged liver or spleen.				
LR-14	Qimen	490	Deep perpendicular or oblique insertion carries a substantial risk of causing pneumothorax.				
CV-1	Huiyin	497	Contraindicated in pregnancy.				
CV-2	Qugu	498	Deep insertion will penetrate a full bladder which therefore should be emptied before treatment.			161	Points from CV-2 to CV- 13 can only be used with special caution for acupuncture or moxibustion treatment in pregnant women
CV-3	Zhongji	499	Deep insertion will penetrate a full bladder which therefore should be emptied before treatment.				See CV-2
CV-4	Guanyuan	501	Deep insertion will penetrate a full bladder which therefore should be emptied before treatment.				See CV-2
CV-5	Shimen	503	Deep needling may penetrate the peritoneal cavity.				See CV-2
CV-6	Qihai	504	Deep needling may penetrate the peritoneal cavity.				See CV-2
CV-7	Yinjiao	507	Deep needling may penetrate the peritoneal cavity.				See CV-2
CV-8	Shenque	507	Needling is contraindicated at this point				Generally needling is not applied in this point. See CV-2

Point	Point name	Pg.#	P. Deadman	PG#	CAM	Pg. #	Qiu Mao-Liang
CV-9	Shuifen	508	In thin patients, deep needling may penetrate the peritoneal cavity.				See CV-2
CV-10	Xiawan	510	In thin patients, deep needling may penetrate the peritoneal cavity.				See CV-2
CV-11	Jianli	510	In thin patients, deep needling may penetrate the peritoneal cavity.				See CV-2
CV-12	Zhongwan	511	In thin patients, deep needling may penetrate the peritoneal cavity.				See CV-2
CV-13	Shangwan	512	In thin patients, deep needling may penetrate the peritoneal cavity.				See CV-2
CV-14	Juque	514	- Deep insertion, especially in thin patients, may damage the left lobe of the liver or the heart if either is enlarged - Oblique superior insertion towards the heart is contraindicated in all cases.				
CV-15	Jiuwei	516	- Deep insertion, especially in thin patients, may damage the left lobe of the liver or the heart if either is enlarged - Oblique superior insertion towards the heart is contraindicated in all cases.				
CV-22	Tiantu	522	Needling this point should not be attempted by practitioners who have not had appropriate clinical experience under supervision.			165	Correct angle and depth of needling should be stressed so as not to injure the lung and related arteries and veins.
GV-1	Changqiang		·			153	Perpendicular puncture easily injuries the rectum.
GV-3	Yaoyangguan	536	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				
GV-4	Mingmen	536	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				

Point	Point name	Pg.#	P. Deadman	PG#	САМ	Pg. #	Qiu Mao-Liang
GV-5	Xuanshu	538	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				
GV-6	Jizhong	539	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				
GV-7	Zhongshu	540	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				
GV-8	Jinsuo	540	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				
GV-9	Zhiyang	541	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				
GV-10	Lingtai	541	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				
GV-11	Shendao	542	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				
GV-12	Shenzhu	543	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				
GV-13	Taodao	544	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				
GV-14	Dazhui	545	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build.				

Point	Point name	Pg.#	P. Deadman	PG#	САМ	Pg. #	Qiu Mao-Liang
GV-15	Yamen	547	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build. Deep perpendicular insertion is therefore strictly contraindicated, as is superior oblique insertion towards the brain.	221	Neither upward obliquely nor deep puncture is advisable. It is near the medullar bulb in the deep layer, and the depth and angle of the puncture should be paid strict attention to.	156	Upward oblique or deep puncture is forbidden. The point is near the medulla in its deep portion, and the correct angle and depth of needling should be strictly enforced.
GV-16	Fengfu	548	The spinal canal lies between 1.25 and 1.75 cun deep to the skin surface, varying according to body build. Deep perpendicular or superior oblique insertion is therefore strictly contraindicated.	222	Deep puncture is not advisable. Medullar bulb is in the deep layer, special attention should be paid in acupuncture.	156	Deep puncture is forbidden. Deep underneath is the medulla, and caution is needed while needling this point.
GV-21	Qianding	554	This point should not be needled in infants whose fontanelle has not yet closed.				
GV-22	Xinhui	555	This point should not be needled in infants whose fontanelle has not yet closed.	223	This point is prohibited in infants with metopism.	157	This point is prohibited in infants with a patent frontal suture.
GV-23	Shangxing			224	This point is prohibited in infants with metopism.		

#### **Appendix 2**

### Index of Materia Medica (Pin-yin, Chinese and Botanical or Pharmaceutical Name)

中藥名稱對照表(含漢語拼音、中文名及植物學名)

Name list of Materia Medica (listed by the alphabetical order of pin-yin name)

$\mathbf{A}$			
Ai Ye	艾葉	艾叶	Folium Artemisiae Argyi
В			
Ba Ji Tian	巴戟天	巴戟天	Radix Morindae Officinalis
Bai Bian Dou	白扁豆	白扁豆	Semen Dolichoris Album
Bai Bu	百部	百部	Radix Stemonae
Bai Dou Kou	白豆蔻	白豆蔻	Fructus Amomi Rotundus
Bai Fu Zi	白附子	白附子	Rhizoma Typhonii
Bai Guo	白果	白果	Semen Ginkgo
Bai He	百合	百合	Bulbus Lilli
Bai Hua She She Cao	白花蛇舌草	白花蛇舌草	Herba Hedyotis Diffusae
Bai Ji	白芨	白芨	Rhizoma Bletillae
Bai Ji Li/Ci Ji Li	白蒺藜/刺蒺藜	白蒺藜/刺蒺藜	Fructus Tribuli
Bai Jiang Cao	敗醬草	败酱草	Herba Patriniae
Bai Jie Zi	白芥子	白芥子	Semen Sinapis Albae
Bai Mao Gen	白茅根	白茅根	Rhizoma Imperatae
Bai Qian	白前	白前	Rhizoma Cynanchi Stauntonii
Bai Shao	白芍	白芍	Radix Paeoniae Alba
Bai Tou Weng	白頭翁	白头翁	Radix Pulsatillae
Bai Wei	白薇	白薇	Radix Cynanchi Atrati
Bai Xian Pi	白蘚皮	白藓皮	Cortex Dictamni Radicis
Bai Zhi	白芷	白芷	Radix Angelicae Dahuricae
Bai Zhu	白术	白术	Rhizoma Atractylodis Macrocephala
Ban Lan Gen	板藍根	板蓝根	Radix Isatidis
Ban Mao	班蟊	班蟊	Mylabris
Ban Xia	半夏	半夏	Rhizoma Pinelliae
Bei Xie	萆薢	萆薢	Rhizoma Dioscoreae Hypoglaucae
Bian Xu	萹蓄	萹蓄	Herba Polygoni Avicularis
Bie Jia	幣甲	鳖甲	Carapax Trionycis

Bin Lang	檳榔	槟榔	Semen Arecae
Bing Pian	冰片	冰片	Borneolum Syntheticum
Bo He	薄荷	薄荷	Herba Menthae
Bo/Bai Zi Ren	柏子仁	柏子仁	Semen Biotae
Bu Gu Zhi	補骨脂	补骨脂	Fructus Psoraleae
C	100 74 74	11 74 774	
Can Sha	蠶砂	蚕砂	Faeces Bombycis
Cang Er Zi	蒼耳子	苍耳子	Fructus Xanthii
Cang Zhu	蒼朮	苍术	Rhizoma Atractylodis
Cao Dou Kou	草豆蔻	草豆蔻	Semen Alpiniae Katsumadai
Cao Guo	草果	草果	Fructus Tsaoko
Се Во Үе	側柏葉	侧柏叶	Cacumen Biotae
Chai Hu	柴胡	柴胡	Radix Bupleuri
Chan Tui	蟬蛻	蝉蜕	Periostracum Cicadae
Che Qian Zi	車前子	车前子	Semen Plantaginis
Chen Xiang	沈香	沉香	Lignum Aquilariae Resinatum
Chi Shao Yao	赤芍藥	赤芍药	Radix Paeoniae Rubra
Chi Shi Zhi	赤石脂	赤石脂	Halloysitum Rubrum
Chi Xiao Dou	赤小豆	赤小豆	Semen Phaseoli
Chuan Bei Mu	川貝母	川贝母	Bulbus Fritillariae Cirrhosae
Chuan Lian Zi	川楝子	川楝子	Fructus Meliae Toosendan
Chuan Xiong	川芎	川芎	Rhizoma Ligustici Chuanxiong
Ci Shi	磁石	磁石	Magnetitum
D			
Da Fu Pi	大腹皮	大腹皮	Pericarpium Arecae
Da Huang	大黄	大黄	Radix et Rhizoma Rhei
Da Ji	大戟	大戟	Radix Euphorbiae Pekinensis
Da Jing	大薊	大蓟	Radix Cirsii Japonici
Da Qing Ye	大青葉	大青叶	Folium Isatidis
Da Zao	大棗	大枣	Fructus Ziziphi Jujibae
Dai Zhe Shi	代赭石	代赭石	Haematitum
Dan Dou Shi/Chi	淡豆豉	淡豆豉	Semen Sojae Praeparatum
Dan Shen	丹參	丹参	Radix Salviae Miltiorrhizae
Dan Zhu Ye	淡竹葉	淡竹叶	Herba Lophatheri
Dang Gui	當歸	当归	Radix Angelicae Sinensis
Dang Shen	黨參	党参	Radix Condonopsis Pilosulae
Di Fu Zi	地膚子	地肤子	Fructus Kochiae
Di Gu Pi	地骨皮	地骨皮	Cortex Lycii Radicis
Di Long	地龍	地龙	Lumbricus
Di Yu	地榆	地榆	Radix Sanguisorbae

Ding Xiang	丁香	丁香	Flos Caryophylli	
Dong Chong Xia Cao	冬蟲夏草	冬虫夏草	Cordyceps	
Dong Gua Pi	冬瓜皮	冬瓜皮	Exocarpium Benincasae	
Du Huo	獨活	独活	Radix Angelicae Pubescentis	
Du Zhong	杜仲	杜仲	Cortex Eucommiae	
E				
E Jiao	阿膠	阿胶	Colla Corii Asini	
E Zhu	莪朮	莪术	Rhizoma Zedoariae	
F				
Fan Xie Ye	番瀉葉	番泻叶	Folium Sennae	
Fang Feng	防風	防风	Radix Ledebouriellae	
Fen Fang Ji	粉防己	粉防己	Radix Stephaniae Tetrandrae	
Feng Mi	蜂蜜	蜂蜜	Mel	
Fo Shou	佛手	佛手	Fructus Citri Sarcodactylis	
Fu Ling	茯苓	茯苓	Poria	
Fu Pen Zi	覆盆子	覆盆子	Fructus Rubi	
Fu Xiao Mai	浮小麥	浮小麦	Fructus Tritici Levis	
Fu Zi	附子	附子	Radix Aconiti Praeparata	
G				
Gan Cao	甘草	甘草	Radix Glycyrrhizae	
Gan Jiang	乾薑	干姜	Rhizoma Zingiberis	
Gan Sui	甘遂	甘遂	Radix Euphorbiae Kansui	
Gao Ben	藁本	藁本	Rhizoma Ligustici	
Gao Liang Jiang	高良薑	高良姜	Rhizoma Alpiniae Officinarum	
Ge Gen	葛根	葛根	Radix Puerariae	
Ge Jie	蛤蚧	蛤蚧	Gecko	
Gou Ji	狗脊	狗脊	Rhizoma Cibotii	
Gou Qi Zi	枸杞子	枸杞子	Fructus Lycii	
Gou Teng	鉤藤	钩藤	Ramulus Uncariae cum Uncis	
Gu Sui Bu	骨碎補	骨碎补	Rhizoma Drynariae	
Gua Lou	瓜萋	瓜蒌	Fructus Trichosanthis	
Guang Fang Ji	廣防己	广防己	Radix Aristolochiae Fangchi	
Gui Ban	龜板	龟板	Plastrum Testudinis	
Gui Zhi	桂枝	桂枝	Ramulus Cinnamomi	
Н				
Hai Er Cha	孩兒茶	孩儿茶	Catechu	
Hai Fu Shi	海浮石	海浮石	Pumex	
Hai Ge Ke	海蛤殼	海蛤壳	Concha Cyclinae	
Hai Jin Sha	海金沙	海金沙	Spora Lygodii	
Hai Zao	海藻	海藻	Sargassum	

	日北北	日廿廿		
Han Lian Cao	早蓮草	旱莲草	Herba Ecliptae	
He Huan Pi	合歡皮	合欢皮	Cortex Albizziae	
He Shou Wu	何首烏	何首乌	Radix Polygoni Multiflori	
He Zi	訶子	诃子	Fructus Chebulae	
Hei Zhi Ma	黑芝麻	黑芝麻	Semen Sesami Nigrum	
Hong Hua	紅花	红花	Flos Carthami	
Hong Teng	紅藤	红藤	Caulis Sargentodoxae	
Hou Po	厚朴	厚朴	Cortex Magnoliae Officinalis	
Hu Huang Lian	胡黃連	胡黄连	Rhizoma Picrorhizae	
Hu Jiao	胡椒	胡椒	Fructus Piperis Nigri	
Hu Po	琥珀	琥珀	Succinum	
Hu Tao Rou	胡桃肉	胡桃肉	Semen Juglandis	
Hua Jiao	花椒	花椒	Pericarpium Zanthoxyli	
Hua Shi	滑石	滑石	Talcum	
Huai Hua	槐花	槐花	Flos Sophorae	
Huang Bo/Bai	黄柏	黄柏	Cortex Phellodendri	
Huang Jing	黄精	黄精	Rhizoma Polygonati	
Huang Lian	黄連	黄连	Rhizoma Coptidis	
Huang Qi	黄耆	黄耆	Radix Astragali seu Hedysari	
Huang Qin	黄芩	黄芩	Radix Scutellariae	
Huo Ma Ren	火麻仁	火麻仁	Fructus Cannabis	
Huo Xiang	藿香	藿香	Herba Pogostemonis	
J				
Ji Nei Jin	雞內金	鸡内金	Endothelium Corneum Gigeriae Galli	
Ji Xue Teng	雞血藤	鸡血藤	Caulis Spatholobi	
Jiang Can	僵蠶	僵蚕	Bombyx Batryticatus	
Jiang Huang	薑黃	姜黄	Rhizoma Curcumae Longae	
Jiang Xiang	降香	降香	Lignum Dalbergiae Odoriferae	
Jie Geng	桔梗	桔梗	Radix Platycodi	
Jin Qian Cao	金錢草	金钱草	Herba Lysimachiae	
Jin Yin Hua	金銀花	金银花	Flos Lonicerae	
Jin Ying Zi	金櫻子	金樱子	Fructus Rosae Laevigatae	
Jing Jie	荊芥	荆芥	Herba Schizonepetae	
Ju Hua	菊花	菊花	Flos Chrysanthemi	
Ju Pi/Chen Pi	橘皮/陳皮	橘皮/陈皮	Pericarpium Citri Reticulatae	
Jue Ming Zi	決明子	决明子	Semen Cassiae	
K				
Ku Lian Pi	苦楝皮	苦楝皮	Cortex Meliae	
Ku Shen	苦參	苦参	Radix Sophorae Flavescentis	
Kuan Dong Hua	款冬花	款冬花	Flos Farfarae	

Kun Bu	昆布	昆布	Thallus Laminariae Eckloniae	
L	せせつ	4t 4t 7		
Lai Fu Zi	萊菔子	莱菔子	Semen Raphani	
Li Zhi He	荔枝核	荔枝核	Semen Litchi	
Lian Qiao	連翹	连翘	Fructus Forsythiae	
Lian Zi	蓮子	莲子	Semen Nelumbinis	
Liu Huang	硫黄	硫黄	Sulfur	
Liu Ji Nu	劉寄奴	刘寄奴	Herba Artemisiae Anomalae	
Long Dan Cao	龍膽草	龙胆草	Radix Gentianae	
Long Gu	龍骨	龙骨	Os Draconis	
Long Yan Rou	龍眼肉	龙眼肉	Arillus Longan	
Lu Feng Fang	露蜂房	露蜂房	Nidus Vespae	
Lu Gan Shi	爐甘石	炉甘石	Calamina	
Lu Gen	蘆根	芦根	Rhizoma Phargmitis	
Lu Hui	蘆薈	芦荟	Aloe	
Lu Rong	鹿茸	鹿茸	Cornu Cervi Pantotrichum	
M				
Ma Dou Ling	馬兜鈴	马兜铃	Fructus Aristolochiae	
Ma Huang	麻黄	麻黄	Herba Ephedrae	
Ma Huang Gen	麻黃根	麻黄根	Radix Ephedrae	
Ma Qian Zi	馬錢子	马钱子	Semen Strychni	
Mai Men Dong	麥門冬	麦门冬	Radix Ophiopogonis	
Mai Ya	麥芽	麦芽	Fructus Hordei Germinatus	
Man Jing Zi	蔓荊子	蔓荆子	Fructus Viticis	
Mang Xiao	芒硝	芒硝	Natrii Sulfas	
Meng Chong	牤蟲	牤虫	Tabanus	
Ming Fan	明礬	明矾	Alumen	
Mo Yao	沒藥	没药	Myrrha	
Mu Dan Pi	牡丹皮	牡丹皮	Cortex Moutan Radicis	
Mu Gua	木瓜	木瓜	Fructus Chaenomelis	
Mu Li	牡蠣	牡蛎	Concha Ostreae	
Mu Tong	木通	木通	Caulis Akebiae	
Mu Xiang	木香	木香	Radix Aucklandiae	
N				
Nan Gua Zi	南瓜子	南瓜子	Semen Cucurbitae	
Niu Bang Zi	牛蒡子	牛蒡子	Fructus Arctii	
Niu Xi	牛膝	牛膝	Radix Achyranthis Bidentatae	
Nu Zhen Zi	女貞子	女贞子	Fructus Ligustri Lucidi	
0				
Ou Jie		藕节		

	和为以		TTO GGO TTO GGG TO GGG	
P				
Pei Lan	佩蘭	佩兰	Herba Eupatorii	
Pi Pa Ye	枇杷葉	枇杷叶	Folium Eruobotryae	
Pu Gong Ying	蒲公英	蒲公英	Herba Taraxaci	
Pu Huang	蒲黄	蒲黄	Pollen Typhae	
Q				
Qian Cao	茜草	茜草	Radix Rubiae	
Qian Hu	前胡	前胡	Radix Peucedani	
Qian Shi	芡實	芡实	Semen Euryales	
Qiang Huo	羌活	羌活	Rhizoma seu Radix Notopterygii	
Qin Jiao	秦艽	秦艽	Radix Gentianae Macrophyllae	
Qin Pi	秦皮	秦皮	Cortex Fraxini	
Qing Dai	青黛	青黛	Indigo Naturalis	
Qing Hao	青蒿	青蒿	Herba Artemisiae Annuae	
Qing Pi	青皮	青皮	Pericarppium Citri Reticulatae Viride	
Qu Mai	瞿麥	瞿麦	Herba Dianthi	
Quan Xie	全蠍	全蝎	Scorpio	
R				
Ren Shen	人參	人参	Radix Ginseng	
Rou Cong Rong	肉蓯蓉	肉苁蓉	Herba Cistanches	
Rou Dou Kou	肉豆蔻	肉豆蔻	Semen Myristicae	
Rou Gui	肉桂	肉桂	Cortex Cinnamomi	
Ru Xiang	乳香	乳香	Olibanum	
S				
San Leng	三棱	三棱	Rhizoma Sparganii	
San Qi	三七	三七	Radix Notoginseng	
Sang Bai Pi	桑白皮	桑白皮	Cortex Mori Radicis	
Sang Ji Sheng	桑寄生	桑寄生	Ramulus Taxilli	
Sang Piao Xiao	桑螵蛸	桑螵蛸	Ootheca Mantidis	
Sang Shen	桑椹	桑椹	Fructus Mori	
Sang Ye	桑葉	桑叶	Folium Mori	
Sang Zhi	桑枝	桑枝	Ramulus Mori	
Sha Ren	砂仁	砂仁	Fructus Amomi	
Sha Shen	沙參	沙参	Radix Glehniae	
Sha Yuan Zi/Tong Ji Li	沙苑子/潼蒺藜	沙苑子/潼蒺藜	Semen Astragali Complanati	
Shan Yao	山藥	山药	Rhizoma Dioscoreae	
Shan Zha	山楂	山楂	Fructus Crataegi	
Shan Zhu Yu	山茱萸	山茱萸	Fructus Corni	
She Chuang Zi	蛇床子	蛇床子	Fructus Cnidii	

She Gan / Ye Gan	射干	射干	Rhizoma Belamcandae	
Shen Qu	神麴	神麴	Massa Medicara Fermentata	
Sheng Di Huang	生地黄	生地黄	Radix Rehmanniae	
Sheng Jiang	生薑	生姜	Rhizoma Zingiberis Recens	
Sheng Ma	升麻	升麻	Rhizoma Cimicifugae	
Shi Chang Pu	石菖蒲	石菖蒲	Rhizoma Acori Graminei	
Shi Di	柿蒂	柿蒂	Calyx Kaki	
Shi Gao	石膏	石膏	Gypsum Fibrosum	
Shi Hu	石斛	石斛	Herba Dendrobii	
Shi Jue Ming	石決明	石决明	Concha Haliotidis	
Shi Jun Zi	使君子	使君子	Fructus Quisqualis	
Shi Liu Pi	石榴皮	石榴皮	Pericarpium Granati	
Shi Wei	石葦	石苇	Folium Pyrrosiae	
Shu Di Huang	熟地黃	熟地黄	Radix Rehmanniae Praeparata	
Shui Zhi	水蛭	水蛭	Hirudo	
Si Gua Luo	絲瓜絡	丝瓜络	Vascularis Luffae Fasciculus	
Su Mu	蘇木	苏木	Ligum Sappan	
Su Zi	蘇子	苏子	Fructus Perillae	
Suan Zao Ren	酸棗仁	酸枣仁	Semen Ziziphi Spinosae	
Suo Yang	鎖陽	锁阳	Herba Cynomorii	
_		- ·	•	
T			<u> </u>	
T Tai Zi Shen	太子參	太子参	Radix Pseudostellariae	
	太子参檀香	太子参檀香		
Tai Zi Shen	檀香 桃仁		Radix Pseudostellariae	
Tai Zi Shen Tan Xiang	檀香	檀香	Radix Pseudostellariae Lignum Santali Albi	
Tai Zi Shen Tan Xiang Tao Ren	檀香 桃仁 天花粉 天麻	檀香 桃仁	Radix Pseudostellariae Lignum Santali Albi Semen Persicae	
Tai Zi Shen Tan Xiang Tao Ren Tian Hua Fen	檀香 桃仁 天花粉	檀香 桃仁 天花粉	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis	
Tai Zi Shen Tan Xiang Tao Ren Tian Hua Fen Tian Ma	檀香 桃仁 天花粉 天麻	檀香 桃仁 天花粉 天麻	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae	
Tai Zi Shen Tan Xiang Tao Ren Tian Hua Fen Tian Ma Tian Men Dong	檀桃天天天天季香仁称《冬星子	檀桃天天天天葶香仁花麻门南苈	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae Radix Asparagi	
Tai Zi Shen Tan Xiang Tao Ren Tian Hua Fen Tian Ma Tian Men Dong Tian Nan Xing	檀桃天天天天葶通香仁花麻門南蘑草	檀桃天天天天葶通香仁花麻门南苈草	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae Radix Asparagi Rhizoma Arisaematis	
Tai Zi Shen Tan Xiang Tao Ren Tian Hua Fen Tian Ma Tian Men Dong Tian Nan Xing Ting Li Zi	檀桃天天天天季香仁称《冬星子	檀桃天天天天葶香仁花麻门南苈	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae Radix Asparagi Rhizoma Arisaematis Semen Lepidii seu Descurainiae	
Tai Zi Shen Tan Xiang Tao Ren Tian Hua Fen Tian Ma Tian Men Dong Tian Nan Xing Ting Li Zi Tong Cao Tu Si Zi	檀桃天天天天夢通菟香仁花麻門南藍草蘇子	檀桃天天天天葶通菟香仁花麻门南苈草蕬子	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae Radix Asparagi Rhizoma Arisaematis Semen Lepidii seu Descurainiae Medulla Tetrapanacis Semen Cuscutae	
Tai Zi Shen Tan Xiang Tao Ren Tian Hua Fen Tian Ma Tian Men Dong Tian Nan Xing Ting Li Zi Tong Cao Tu Si Zi  W Wa Leng Zi	檀桃天天天天葶通菟 瓦香仁花麻門南蘑草蘇 楞子星子 子子	檀桃天天天天葶通菟 瓦香仁花麻门南苈草蒸 楞 冬星子 子	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae Radix Asparagi Rhizoma Arisaematis Semen Lepidii seu Descurainiae Medulla Tetrapanacis Semen Cuscutae  Concha Arcae	
Tai Zi Shen Tan Xiang Tao Ren Tian Hua Fen Tian Ma Tian Men Dong Tian Nan Xing Ting Li Zi Tong Cao Tu Si Zi  W Wa Leng Zi Wang Bu Liu Xing	檀桃天天天天葶通菟 瓦王香仁花麻門南蘑草蘇 楞不子星子 子 子留	檀桃天天天天等通菟 瓦王香仁花麻门南苈草蒸 楞不子星子 子 子留	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae Radix Asparagi Rhizoma Arisaematis Semen Lepidii seu Descurainiae Medulla Tetrapanacis Semen Cuscutae  Concha Arcae Semen Vaccariae	
Tai Zi Shen Tan Xiang Tao Ren Tian Hua Fen Tian Ma Tian Men Dong Tian Nan Xing Ting Li Zi Tong Cao Tu Si Zi  W Wa Leng Zi Wang Bu Liu Xing Wei Ling Xian	檀桃天天天天夢通菟 瓦王威香仁花麻門南蘑草蘇 楞不靈子 子留仙	檀桃天天天天葶通菟 瓦王威香仁花麻门南苈草蘇 楞不灵子 子 子留仙	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae Radix Asparagi Rhizoma Arisaematis Semen Lepidii seu Descurainiae Medulla Tetrapanacis Semen Cuscutae  Concha Arcae Semen Vaccariae Radix Clematidis	
Tai Zi Shen Tan Xiang Tao Ren Tian Hua Fen Tian Ma Tian Men Dong Tian Nan Xing Ting Li Zi Tong Cao Tu Si Zi  W Wa Leng Zi Wang Bu Liu Xing Wei Ling Xian Wu Bei Zi	檀桃天天天天葶通菟 瓦王威五香仁花麻門南藶草蘇 楞不靈倍子 子 子留仙子	檀桃天天天天葶通菟 瓦王威五香仁花麻门南苈草蒸 楞不灵倍香星子 子 子留仙子	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae Radix Asparagi Rhizoma Arisaematis Semen Lepidii seu Descurainiae Medulla Tetrapanacis Semen Cuscutae  Concha Arcae Semen Vaccariae Radix Clematidis Galla Chinensis	
Tai Zi Shen  Tan Xiang  Tao Ren  Tian Hua Fen  Tian Ma  Tian Men Dong  Tian Nan Xing  Ting Li Zi  Tong Cao  Tu Si Zi  W  Wa Leng Zi  Wang Bu Liu Xing  Wei Ling Xian  Wu Bei Zi  Wu Gong	檀桃天天天天葶通菟 瓦王威五蜈香仁花麻門南藶草蒸 楞不靈倍蚣公留仙子	檀桃天天天天葶通菟 瓦王威五蜈香仁花麻门南苈草蒸 楞不灵倍蚣公星子 子 子留仙子	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae Radix Asparagi Rhizoma Arisaematis Semen Lepidii seu Descurainiae Medulla Tetrapanacis Semen Cuscutae  Concha Arcae Semen Vaccariae Radix Clematidis Galla Chinensis Scolopendra	
Tai Zi Shen Tan Xiang Tao Ren Tian Hua Fen Tian Ma Tian Men Dong Tian Nan Xing Ting Li Zi Tong Cao Tu Si Zi  W Wa Leng Zi Wang Bu Liu Xing Wei Ling Xian Wu Bei Zi Wu Gong Wu Jia Pi	檀桃天天天天葶通菟 瓦王威五蜈五香仁花麻門南蘼草蘇 楞不靈倍蚣加杏屋子 子 子留仙子 皮	檀桃天天天天夢通菟 瓦王威五蜈五香仁花麻门南苈草蘇 楞不灵倍蚣加香星子 子 子留仙子 皮	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae Radix Asparagi Rhizoma Arisaematis Semen Lepidii seu Descurainiae Medulla Tetrapanacis Semen Cuscutae  Concha Arcae Semen Vaccariae Radix Clematidis Galla Chinensis Scolopendra Cortex Acanthopanacis Radicis	
Tai Zi Shen  Tan Xiang  Tao Ren  Tian Hua Fen  Tian Ma  Tian Men Dong  Tian Nan Xing  Ting Li Zi  Tong Cao  Tu Si Zi  W  Wa Leng Zi  Wang Bu Liu Xing  Wei Ling Xian  Wu Bei Zi  Wu Gong	檀桃天天天天葶通菟 瓦王威五蜈香仁花麻門南藶草蒸 楞不靈倍蚣公留仙子	檀桃天天天天葶通菟 瓦王威五蜈香仁花麻门南苈草蒸 楞不灵倍蚣公星子 子 子留仙子	Radix Pseudostellariae Lignum Santali Albi Semen Persicae Radix Trichosanthis Rhizoma Gastrodiae Radix Asparagi Rhizoma Arisaematis Semen Lepidii seu Descurainiae Medulla Tetrapanacis Semen Cuscutae  Concha Arcae Semen Vaccariae Radix Clematidis Galla Chinensis Scolopendra	

Wu Wei Zi	五味子	五味子	Fructus Schisandrae
Wu Yao	烏藥	乌药	Radix Linderae
Wu Zei Gu/Hai Piao Xiao	烏賊骨/海螵蛸	乌贼骨/海螵蛸	Os Sepiellae seu Sepiae
Wu Zhu Yu	吳茱萸	吴茱萸	Fructus Evodiae
X			
Xi Xin	細辛	细辛	Herba Asari
Xi Yang Shen	西洋參	西洋参	Radix Panacis Quinquefolii
Xia Ku Cao	夏枯草	夏枯草	Spica Prunellae
Xian He Cao	仙鶴草	仙鹤草	Herba Agrimoniae
Xian Mao	仙茅	仙茅	Rhizoma Curculiginis
Xiang Fu	香附	香附	Rhizoma Cyperi
Xiang Ru	香薷	香薷	Herba Elsholtziae seu Moslae
Xiao Hui Xiang	小茴香	小茴香	Frictus Foeniculi
Xiao Ji	小薊	小蓟	Herba Cephalanoplos
Xie Bai	薤白	薤白	Bulbus Allii Macrostemi
Xie/Xue Jie	血竭	血竭	Resina Draconis
Xin Yi	辛夷	辛夷	Flos Magnoliae
Xing Ren	杏仁	杏仁	Semen Armeniacae Amarum
Xiong Huang	雄黄	雄黄	Realgar
Xu Duan	續斷	续断	Radix Dipsaci
Xuan Fu Hua	旋覆花	旋覆花	Flos Inulae
Xuan Shen	玄參	玄参	Radix Scrophulari
Xue Yu Tan	血餘炭	血余炭	Crinis Carbonisatus
Y			
Yan Hu Suo	延胡索	延胡索	Rhizoma Corydalis
Ye Jiao Teng	夜交藤	夜交藤	Caulis Polygoni Multiflori
Yi Mu Cao	益母草	益母草	Herba Leonuri
Yi Yi Ren	薏苡仁	薏苡仁	Semen Coicis
Yi Zhi Ren	益智仁	益智仁	Fructus Alpiniae Oxyphyllae
Yin Chai Hu	銀柴胡	银柴胡	Radix Stellariae
Yin Chen Hao	茵陳蒿	茵陈蒿	Herba Artemisiae Scopariae
Yin Yang Huo	淫羊藿	淫羊藿	Herba Epimedii
Yu Jin	郁金	郁金	Radix Curcumae
Yu Li Ren	郁李仁	郁李仁	Semen Pruni
Yu Mi Xu	玉米鬚	玉米须	Stigma Maydis
Yu Xing Cao	魚腥草	鱼腥草	Herba Houttuyniae
Yu Zhu	玉竹	玉竹	Rhizoma Polygonati Odorati
Yuan Hua	芫花	芫花	Flos Genkwa
Yuan Zhi	遠志	远志	Radix Polygalae
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Z			
Zao Jiao Ci	皂角刺	皂角刺	Spina Gleditsiae
Ze Lan	澤蘭	泽兰	Herba Lycopi
Ze Xie	澤瀉	泽泻	Rhizoma Alismatis
Zhe Bei Mu	浙貝母	浙贝母	Bulbus Fritillariae Thunbergii
Zhe Chong/ Ji Di Bie	蟅蟲	蟅虫	Eupolyphaga seu Steleophaga
Zhen Zhu Mu	珍珠母	珍珠母	Concha Margartifera Usta
Zhi Ke	枳殼	枳壳	Fructus Aurantii
Zhi Mu	知母	知母	Rhizoma Anemarrhenae
Zhi Shi	枳實	枳实	Fructus Aurantii Immaturus
Zhi Zi	梔子	栀子	Fructus Gardeniae
Zhu Ling	豬苓	猪苓	Polyporus Umbellatus
Zhu Ru	竹茹	竹茹	Caulis Bambusae in Taeniam
Zi Cao	紫草	紫草	Radix Arnebiae seu Lithospermi
Zi Hua Di Ding	紫花地丁	紫花地丁	Herba Violae
Zi Su Ye	紫蘇葉	紫苏叶	Folium Perillae
Zi Wan	紫菀	紫菀	Radix Asteris
Zong Lu Tan/ Pi	棕櫚炭	棕榈炭	Traachycarpi Carbonisatus

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#### **Appendix 3**

Animal and Plant Ingredients in Traditional Medicine (Environment Canada, 2011)

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# Animal and Plant Ingredients in TRADITIONAL MEDICINE

This brochure is intended to inform practitioners, pharmacists, importers/exporters, and users of medicinal formulas or packaged medicines that list or contain wildlife ingredients about Canada's wildlife trade law, and how it may affect them.









#### CANADA'S WILDLIFE TRADE LAW

CITES – Convention on International Trade in Endangered Species of Wild Fauna and Flora

To prevent over-exploitation of wildlife species through international trade and illegal poaching, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) was formed on July 1, 1975. CITES is an international agreement to ensure that international trade in wild animals and plants does not threaten their survival.

Over 5 000 animal species, subspecies and populations and over 29 000 plant species, subspecies and populations are listed under CITES.

All imports and exports of species listed under CITES have to be authorized through a permit system, as described in the table to the right. It is illegal to trade a CITES listed species or its parts and derivatives without the appropriate CITES permits. Depending on the species' severity of endangerment, CITES animals and plants are classified into one of three appendices.

Appendix	Classification	Permit Requirements
Appendix I	Species are threatened with extinction.	CITES Export Permit from country of export/ re-export AND a CITES Import Permit from country of import. NOTE: Trade in wild specimens for commercial purposes is prohibited (with few exceptions).
Appendix II	Species not considered threatened with extinction but may become so if their trade is not regulated.	CITES Export Permit OR a CITES Re-Export Certificate from country of export/re-export.
Appendix III	Species not considered threatened with extinction, but are under special management in certain countries.	CITES Export Permit OR a CITES Certificate of Origin from country of export/re-export.



**Appendix I** species are threatened with extinction, therefore require strict trade control. Commercial trade in these species is prohibited. The only exceptions are plants that have been artificially propagated or animals that have been produced in CITES Registered captive breeding operations. Possession of Appendix I specimens is allowed if the specimens were removed from the wild prior to July 1975 when CITES was created, or if they were legally imported with permits. For the Register of operations that breed and/or artificially propagate Appendix-I species for commercial purposes please go to: http://cites.org/eng/resources/registers.shtml.

**Appendix II** species are not considered threatened with extinction at present but they may become so if their trade is not regulated. Appendix II also includes species whose parts or derivatives may resemble endangered species (e.g., the American black bear parts may resemble parts from endangered bear species).

When an animal or plant is listed under CITES, it includes not only live specimens, but also any part, derivative or by-product of that species, including herbs and medicines. Plants are not exempt just because they are cultivated, rather than taken from the wild.

#### WAPPRIITA – THE WILD ANIMAL AND PLANT PROTECTION AND REGULATION OF INTERNATIONAL AND INTERPROVINCIAL TRADE ACT

In Canada, CITES is administered by Environment Canada and is implemented under the *Wild Animal and Plant Protection* and Regulation of International and Interprovincial Trade Act (WAPPRIITA).



Under WAPPRIITA, it is unlawful, among other offences to:

- Import or possess any wild species of the animal or plant kingdoms, including their parts and derivatives, that were obtained or exported in violation of a foreign state's law. This is not restricted to CITES-listed species.
- 2. Import or export CITES-listed species without the appropriate permits.
- 3. Offer for sale, or possess, Appendix I CITES species, in most cases.

If a thing is labelled as containing CITES-listed plant or animal ingredients, it will be deemed to contain those ingredients unless proven to the contrary.

Importing and exporting include shipping by air, sea and rail, by mail and courier, and in personal luggage.

**To legally import Appendix I species**, a CITES Export Permit is required from the country of export AND a CITES Import Permit is required from the country of import.

**To legally import Appendix II species**, a CITES Export Permit or a CITES Re-Export Certificate is required from the country of export/re-export.

**To legally import Appendix III species**, a CITES Export Permit or a CITES Certificate of Origin is required from the country of export/re-export.









### Examples of CITES Appendix I, II or III Species Parts and Derivatives in Medicines

"Ingredients" = 成分 / 主要成分 / 處(处)方 / 配料

Note: Characters in "()" are simplified variants of the characters to their immediate left.

Chinese	Pin Yin	Pharmaceutical	Scientific	English	Appendix
穿山甲	Chuān Shān Jiā	Squama manitis	Manis pentadactyla	Pangolin Scales	11
麝香	Shè Xiāng	Moschus	Moschus spp.	Musk Deer	1/11
猴棗(猴枣)	Hóu Zǎo	Macacae mulattae Caculus	Primates spp.	Macaque Gall Stone	1/11
老虎骨	Lǎo hǔ Gǔ	Os Tigris	Panthera tigris	Tiger Bone	1
豹骨	Bào Gǔ	Os Pardus	Panthera pardus	Leopard Bone	1
犀角	Xī Jiǎo	Cornu Rhinoceri	Rhinocerotidae spp.	Rhinoceros Horn	1/11
羚羊角	Líng Yáng Jiǎo	Cornu Saigae Tatarica	Saiga tatarica	Saiga Antelope Horn	II
熊膽(熊胆)	Xióng Dǎn	Fel Ursi	Ursidae spp.	Bear Gall (Bile)	1/11
玳瑁	Dài Mào	Eretmochelydis Carapax	Eretmochelys imbricata	Hawksbill Sea Turtle Shell	I
龜板(龟板) 龜甲(龟甲)	Guī Bǎn Guī Jiǎ	Testudinis Plastrum	Testudinidae spp.	Tortoise (Turtle) Shell	1/11/111
海馬(海马)	Hǎi Mǎ	Hippocampus	Hippocampus spp.	Seahorses	II
鱷魚肉(鳄鱼肉)	È Yú Ròu	Crocodylia spp.	Crocodylia spp.	Alligator / Crocodile Meat	1/11
木香	Mù Xiāng	Radix Saussurea	Saussurea lappa	Aucklandia / Costus Root	I
沉香	Chén Xiāng	Lignum Aquilariae Resinatum	Aquilaria spp.	Aquilaria / Eagle Wood / Agarwood	II
狗脊	Gŏu Jī	Rhizoma Cibotii	Cibotium barometz	Cibotium / Golden Haired Dog Fern	II
石斛	Shí Hú	Herba Dendrobii	Dendrobium spp.	Dendrobium Orchid	II
天麻	Tiān Má	Rhizoma Gastrodiae	Gastrodia spp.	Gastrodia Orchid	11
白芨	Bái Jí	Rhizoma Bletillae	Bletilla spp.	Bletilla Orchid	II
山慈姑	Shān Cí Gū	Pseudobulbus Cremastrae seu Pleiones	Cremastra spp.	Cremastra Orchid	II
甘松	Gān Sōng	Radix Seu Rhizoma Nardostchys	Nardostachys grandiflora	Indian Nard / Spike Nard	II
豬籠草(猪笼草)	Zhū Lóng Cǎo	Herba Nepenthes	Nepenthes spp.	Nepenthes / Pitcher Plant	1/11

#### Understanding the Law

#### Do you own or operate a pharmacy, or sell herbal plant or animal parts, or medicines that contain wildlife derivatives?

You must ensure that there are no Appendix I species animal or plant parts, or derivatives, listed in the ingredients in any of the medicines in your store. If any part or derivative of an Appendix I species is found in your store, it may be confiscated and you could be charged. You may sell Appendix II species parts or derivatives in your store, but only if the necessary permits were obtained when the items were imported. Ask the importer to give you a copy of the permits. Inspections of your store by wildlife officers can be made at any time, so keep a record to prove that the items were legally imported.

### Are you an importer or exporter of herbal plant or animal parts, or medicines that contain wildlife derivatives?

If you import or export herbs or medicines that contain wildlife parts or derivatives, be sure that none of the parts are from Appendix I species and that none of the medicines list Appendix I derivatives. If you import medicines that contain wildlife parts or derivatives containing Appendix II species, you must first obtain the necessary CITES permits and present them to the Canada Border Services Agency upon entry into Canada. Otherwise, your goods may be confiscated and you could be charged.

#### What happens if you do not comply with the law?

The goods will be seized, and you may receive a warning or a ticket, or fines of up to \$150,000 and/or up to **five** years in jail for individuals, and fines up to \$300,000 for businesses. A separate fine can be imposed for every illegal item. For instance, an individual could be charged for every box of a product containing endangered species parts or derivatives. As of 2012, Administrative Monetary Penalties (AMPS) will be in place, which allows for penalties to be laid outside of the court system.







### What can a customer or user of herbs and medicines do to ensure wildlife laws have been met?

You must only buy parts or products that have been imported legally. Ask the store owner for proof of legal import. If you travel with medicines, make sure they do not list Appendix I species as ingredients. Ginseng that is native to Canada, even if it is returned after being shipped to Asia, is not exempt.

### Are there exemptions from requiring CITES permits to import/export wildlife parts or derivatives?

Yes. There are non-commercial exemptions for tourist souvenirs, and personal and household goods, but restrictions apply. You are legally responsible to know what these exemptions are before you travel.

## FOR MORE INFORMATION ON CITES AND WAPPRIITA, PLEASE VISIT: www.ec.gc.ca/CITES

For information on how and where to apply for a CITES permit, contact one of the following Environment Canada offices:

cites@ec.gc.ca (general information)
cites-science@ec.gc.ca (scientific advice)

Management Authority
Convention on International Trade
in Endangered Species (CITES)
Canadian Wildlife Service
Environment Canada
Ottawa ON K1A 0H3

Telephone: **1-800-668-6767** (toll-free number) or **819-997-1840** (National Capital Region)

Fax: 819-953-6283

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#### **Appendix 4**

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