

Benchmarks for Training in Traditional Chinese Medicine

Benchmarks for training
in traditional/complementary
and alternative medicine



Traditional Chinese Medicine

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基本知识，是告诉针就具体点
的位置，值得在不同的阵列很
特别的地方替代医学，由非常
事实上，它是唯一的药，有一



World Health
Organization

**Benchmarks for training
in traditional / complementary and
alternative medicine**

**Benchmarks for Training in
Traditional Chinese Medicine**



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Foreword

The oldest existing therapeutic systems used by humanity for health and well-being are called Traditional Medicine or Complementary and Alternative Medicine (TM/CAM).

Increasingly, TM/CAM is being formally used within existing health-care systems. When practised correctly, TM/CAM can help protect and improve citizens' health and well-being. The appropriate use of TM/CAM therapies and products, however, requires consideration of issues of safety, efficacy and quality. This is the basis of consumer protection and is no different, in principle, from what underpins modern medical practice. Upholding basic requirements for the modern practice of TM/CAM therapies can support national health authorities in the establishment of adequate laws, rules, and licensing practices.

These considerations have guided the work of the Regional Government of Lombardy in TM/CAM which was first included in the Regional Health Plan 2002-2004. Clinical and observational studies in the region of Lombardy have provided a crucial step in the evaluation of TM/CAM. With the help of data from these studies, a series of governmental provisions have been used to create a framework for the protection of consumers and providers. The cornerstone of this process was the first Memorandum of Understanding (MOU) for the Quadrennial Cooperation Plan which was signed between the Regional Government of Lombardy and the World Health Organization. The MOU highlighted the need for certain criteria to be met including: the rational use of TM/CAM by consumers; good practice; quality; safety; and the promotion of clinical and observational studies of TM/CAM. When they were published in 2004, the *WHO guidelines for developing consumer information on proper use of traditional, complementary, and alternative medicine* were incorporated into this first MOU.

In the region of Lombardy, citizens currently play an active role in their health-care choices. The awareness of the advantages as well as of the risks of every type of care is therefore critical, also when a citizen actively chooses to use TM/CAM. Consumers have begun to raise new questions related to the safe and effective treatment by all providers of TM/CAM. For this reason, the Regional Government of Lombardy closely follows WHO guidelines on qualified practice of TM/CAM in order to guarantee appropriate use through the creation of laws and regulations on skills, quality control, and safety and efficacy of products, and clear guidelines about practitioner qualifications. The Regional Government of Lombardy has also provided support and cooperated with WHO in developing this series of benchmark documents for selected popularly used TM/CAM therapies including Ayurveda, naturopathy, Nuad Thai, osteopathy, traditional Chinese medicine, Tuina, and Unani medicine.

Modern scientific practice requires a product or a therapeutic technique to be safe and effective, meaning that it has specific indications and evidence for care supported by appropriate research. Practitioners, policy-makers and planners,

both within and outside ministries of health, are responsible for adhering to this, in order to guarantee the safety and the efficacy of medicines and practices for their citizens. Furthermore, safety not only relates to products or practices per se, but also to how they are used by practitioners. Therefore it is important that policy-makers are increasingly able to standardize the training of practitioners for it is another fundamental aspect of protecting both the providers and the consumers.

Since 2002, the Social-Health Plan of the Lombardy Region has supported the principle of freedom of choice among different health-care options based on evidence and scientific data. By referring to the benchmarks in this present series of documents, it is possible to build a strong foundation of health-care options which will support citizens in exercising their right to make informed choices about different styles of care and selected practices and products.

The aim of this series of benchmark documents is to ensure that TM/CAM practices meet minimum levels of adequate knowledge, skills and awareness of indications and contraindications. These documents may also be used to facilitate establishing the regulation and registration of providers of TM/CAM.

Step by step we are establishing the building blocks that will ensure consumer safety in the use of TM/CAM. The Regional Government of Lombardy hopes that the current series will be a useful reference for health authorities worldwide, and that these documents will support countries to establish appropriate legal and regulatory frameworks for the practice of TM/CAM.

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Preface

There has been a dramatic surge in popularity of the various disciplines collectively known as traditional medicine (TM) over the past thirty years. For example, 75% of the population in Mali and 70% in Myanmar depend on TM and TM practitioners for primary care,¹ while use has also greatly increased in many developed countries where it is considered a part of complementary and alternative medicine (CAM). For instance, 70% of the population in Canada² and 80% in Germany³ have used, in their lifetime, traditional medicine under the title complementary and alternative medicine.

Integration of traditional medicine into national health systems

Traditional medicine has strong historical and cultural roots. Particularly in developing countries, traditional healers or practitioners would often be well-known and respected in the local community. However, more recently, the increasing use of traditional medicines combined with increased international mobility means that the practice of traditional medicines therapies and treatments is, in many cases, no longer limited to the countries of origin. This can make it difficult to identify qualified practitioners of traditional medicine in some countries.

One of the four main objectives of the WHO traditional medicine strategy 2002-2005 was to support countries to integrate traditional medicine into their own health systems. In 2003, a WHO resolution (WHA56.31) on traditional medicine urged Member States, where appropriate, to formulate and implement national policies and regulations on traditional and complementary and alternative medicine to support their proper use. Further, Member States were urged to integrate TM/CAM into their national health-care systems, depending on their relevant national situations.

Later in 2003, the results of a global survey on policies for TM/CAM conducted by WHO showed that the implementation of the strategy is making headway. For example, the number of Member States reporting that they have a national policy on traditional medicine rose from five in 1990, to 39 in 2003, and to 48 in 2007. Member States with regulations on herbal medicines rose from 14 in 1986, to 80 in 2003, and to 110 in 2007. Member States with national research institutes of traditional medicine or herbal medicines rose from 12 in 1970, to 56 in 2003, and to 62 in 2007.⁴

¹ Presentation by the Governments of Mali and Myanmar at the Congress on Traditional Medicine, Beijing, People's Republic of China, 7-9 November 2008.

² Perspectives on Complementary and Alternative Health Care, a collection of papers prepared for Health Canada, Ottawa, Health Canada, 2001.

³ Annette Tuffs Heidelberg. Three out of four Germans have used complementary or natural remedies, *British Medical Journal* 2002, 325:990 (2 November).

⁴ WHO medicines strategy 2008-2013 and Report from a WHO global survey on national policy on traditional medicine and regulation of herbal medicines, 2005.

Ideally, countries would blend traditional and conventional ways of providing care in ways that make the most of the best features of each system and allow each to compensate for weaknesses in the other. Therefore, the 2009 WHO resolution (WHA62.13) on traditional medicine further urged Member States to consider, where appropriate, inclusion of traditional medicine in their national health systems. How this takes place would depend on national capacities, priorities, legislation and circumstances. It would have to consider evidence of safety, efficacy and quality.

Resolution WHA62.13 also urged Member States to consider, where appropriate, establishing systems for the qualification, accreditation or licensing of practitioners of traditional medicine. It urged Member States to assist practitioners in upgrading their knowledge and skills in collaboration with relevant providers of conventional care. The present series of benchmarks for basic training for selected types of TM/CAM care is part of the implementation of the WHO resolution. It concerns forms of TM/CAM that enjoy increasing popularity (Ayurveda, naturopathy, Nuad Thai, osteopathy, traditional Chinese medicine, Tuina, and Unani medicine)

These benchmarks reflect what the community of practitioners in each of these disciplines considers to be reasonable practice in training professionals to practice the respective discipline, considering consumer protection and patient safety as core to professional practice. They provide a reference point to which actual practice can be compared and evaluated. The series of seven documents is intended to:

- support countries to establish systems for the qualification, accreditation or licensing of practitioners of traditional medicine;
- assist practitioners in upgrading their knowledge and skills in collaboration with providers of conventional care;
- allow better communication between providers of conventional and traditional care as well as other health professionals, medical students and relevant researchers through appropriate training programmes;
- support integration of traditional medicine into the national health system.

The documents describe models of training for trainees with different backgrounds. They list contraindications identified by the community of practitioners, so as to promote safe practice and minimize the risk of accidents.

Drafting and Consultation Process

The most elaborated material to establish benchmarks comes from the countries where the various forms of traditional medicine under consideration originated. These countries have established formal education or national requirements for licensure or qualified practice. Any relevant benchmarks must refer to these national standards and requirements.

The first stage of drafting of this series of documents was delegated to the national authorities in the countries of origin of each of the respective forms of traditional, complementary or alternative medicine discussed. These drafts were then, in a second stage, distributed to more than 300 reviewers in more than 140 countries. These reviewers included experts and national health authorities,

WHO collaborating centres for traditional medicine, and relevant international and regional professional nongovernmental organizations. The documents were then revised based on the comments and suggestions received. Finally, WHO organized consultations for further final review, prior to editing.

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Introduction

Traditional Chinese medicine (TCM) has been in use in China for over two thousand years. It has its own unique theories for treating disease and to enhance health. There are many modalities included in TCM, such as Chinese herbal medicine, moxibustion, acupuncture, or Tuina.¹ TCM uses traditional Chinese medicines; these include herbs, herbal materials, herbal preparations and finished herbal products which have been documented in classical and modern literature on TCM. These Chinese Materia Medica may contain non-plant substances, such as animal and mineral materials.

Treatment with TCM involves practitioners who may be called TCM practitioner, TCM doctor, TCM therapist or TCM physician. There are also other categories of professionals: distributors and dispensers for whom training is relevant to the safety and quality of the materials used in TCM medicines.

Traditional Chinese medicine is used widely and increasingly practiced outside China (1-3). However, many countries have not yet developed specific training or established legislation to regulate its practice. In countries where no regulatory framework currently exists, there may be no educational, professional or legal framework governing the practice. Moreover, with the rapid growth in demand for TCM, other types of health-care professionals may wish to gain additional qualifications in order to practice TCM.

This document presents what the community of TCM practitioners, experts and regulators considers to be adequate levels and models for training TCM practitioners, as well as for dispensers and distributors. It provides training benchmarks for trainees with different backgrounds, as well as what the community of TCM practitioners considers to be contraindications for safe practice of TCM and for minimizing the risk of accidents. Together, these can serve as a reference for national authorities wishing to establish systems of training, examination and licensure that support the qualified practice of TCM.

¹ Benchmarks for training in acupuncture and Tuina are published separately.

1. The origin and principles of traditional Chinese medicine

1.1 The development of Traditional Chinese medicine

Traditional Chinese medicine has been practiced in China for over 2,000 years. TCM was developed empirically from clinical experience, and documented in many classical texts (4). During the period of 221–207 BC, literature already included comprehensive records from doctors of internal medicine (*Ji Yi*) and doctors of external medicine and traumatology (*Yang Yi*). The *Yellow Emperor's Internal Classic* (*Huang Di Nei Jing*: 475–221 BC) systematically documented human structure, physiology, pathology, diagnosis, treatment and preservation. The *Treatise on Cold Diseases and Miscellaneous Disorders* (*Shang Han Za Bing Lun*) (196–204 AD) described the therapeutic principles of rendering treatment according to differentiation of syndromes. Thus, the theoretical basis of TCM was further strengthened. The first official TCM school, the Imperial Medical School (*Tai Yi Shu*), was founded in China in 624 AD. Over time, various departments of TCM clinical practice were developed, namely, internal medicine (*Ti Liao*), paediatrics (*Shao Xiao*), external medicine (*Chuang Zhong*), ear, eye, stomatology (*Er Mu Kou Chi*), and physiotherapy (*Jiao Fa*). During the Jin and Tang Dynasties (265 – 907 AD), clinical specialisations were also reflected by the publication of monographs in gynaecology and obstetrics, paediatrics, external medicine, emergency medicine and traumatology.

There is also abundant literature relating to the general practice of TCM. This includes Shennong's *Classic of Materia Medica* (*Shen Nong Ben Cao Jing*) (220 AD), which was the first book completely devoted to the description of Chinese Materia Medica. The *Newly Revised Materia Medica* (*Xin Xiu Ben Cao*) was the first official monograph compiled and issued by the government during the Tang Dynasty (659 AD). The *Compendium of Materia Medica* (*Ben Cao Gang Mu*) is one of the classics compiled in the Ming Dynasty (1368 – 1644 AD). Over the past 50 years, a number of textbooks and monographs on TCM have been compiled and published. Higher education on TCM is now available in a substantial number of TCM universities and colleges throughout China, as well as in some other countries, such as Australia. Education and research on TCM in these countries have been well documented, and to a degree, standardized (5).

There is today a sophisticated body of knowledge built over centuries, including basic theory, diagnostic procedures and treatment approaches. TCM is commonly used for chronic diseases, but also for some acute conditions. It has been used in such areas as internal medicine, gynaecology, paediatrics, traumatology, external medicine, dermatology, emergency medicine, and eye, ear, nose and throat. According to TCM theory it is used to treat not only the secondary manifestations (*Biao*) but also the primary causes (*Ben*) of various conditions.

Traditional Chinese medicine philosophy differs significantly from other health-care modalities and this strongly influences the attitude and approach of TCM in health care. Traditional Chinese medicine is guided by a unique theoretical paradigm with key concepts such as the *yin* and *yang* theory,¹ the five elements theory,² the *qi*, blood and body fluids theory,³ and the differential diagnosis of syndromes. Traditional Chinese medicine relies on contemporary diagnostic methods, such as laboratory tests and diagnostic imaging, as well as on traditional diagnostic techniques. Traditional Chinese medicine treatment aims to promote and regulate the flow of *qi* and blood, to regulate the functions of the *zang-fu* organs⁴ and to balance *yin* and *yang*. In order to maximize therapeutic outcomes, patient management relies on Chinese Materia Medica and TCM formulae used in conjunction with dietary therapy, rehabilitative exercises, supportive measures, and patient education and counselling and may, when required, refer to other types of health professionals.

1.2 Chinese Materia Medica

The *Yellow Emperor's Internal Classic (Huang Di Nei Jing)* (475 – 221 BC) recorded details on herbal processing, such as *Rhizoma Pinelliae (Ban Xia)* and *Crinis Carbonisatus (Xue Yu Tan)*. Shennong's *Classic of Materia Medica (Shen Nong Ben Cao Jing)* (220 AD) was the first book that provided the theoretical framework for the practice of TCM while also documenting details of processing methods for toxic Chinese Materia Medica and explaining the rationale of these methods. Alchemy, which is considered to be the precursor of the development of modern medicinal chemistry, was particularly popular during Jin Dynasty (265 – 420 AD). Grandfather Lei's *Discussion of Processing of Materia Medica (Lei Gong Pao Zhi Lun)* (420 – 479 AD) was the earliest complete treatise on processing techniques such as various methods of cleaning, cutting, drying, stir-baking, boiling and calcination. These methods still guide current practice. The *Collection of Commentaries on the Classic of Materia Medica (Ben Cao Jing Ji Zhu)* (500 AD) documented properties, sources, harvesting and collection practices, and identification of Chinese Materia Medica. In 659 AD, the Government issued their first official text, the *Newly Revised Materia Medica (Xin Xiu Ben Cao)*. Processing techniques were further systematically compiled and introduced as guidelines for herbal processing during the Song Dynasty (960 – 1279 AD). The *Compendium of Materia Medica (Ben Cao Gang Mu)* is the most recognized relevant classic text and was compiled in the Ming Dynasty (1368 – 1644 AD) (6-8).

¹ The theory of *yin* and *yang* originated in antiquity in China. It is a theory dealing with the origins of the universe as well as the motion and variation of all things in the natural world.

² The five elements are wood, fire, earth, metal and water. People in ancient China believed that these elements are indispensable to daily life and productive labour and that these five elements were key to the normal variations in the natural world.

³ According to classic Chinese philosophy, *qi* is the primary state of the universe. *Qi*, blood and body fluids, the essential substances for life activities, flow constantly inside the body and all originate from the viscera.

⁴ *Zang-fu* is a collective term for internal organs which are divided into two major categories, namely the five *zang*-organs - the heart, liver, spleen, lungs and kidneys; and the six *fu*-organs - the gallbladder, stomach, small intestine, large intestine, urinary bladder and *sanjiao* (the triple energizer).

The first official TCM school, the Imperial Medical School (*Tai Yi Shu*), was founded in China in 624 AD. The school consisted of eight dispensers (*Zhu Yao*) and 24 assistant dispensers (*Yao Tong*) of TCM who were responsible for Chinese Materia Medica processing and dispensing. From the Song to Yuan Dynasties (960 – 1368 AD), the specific pharmaceutical affairs agencies were set up and an “Exchange Act” (*Shi Yi Fa*) was developed to regulate the Chinese Materia Medica trade and national patents/registrations. According to this Act, the national pharmaceutical administration developed regulations for quality testing, distribution, and the application of TCM (6).

Over the last 100 years, a number of TCM textbooks and monographs on processing, preparation, identification, pharmacology and toxicology have been compiled and published. Higher education is now available in TCM universities/colleges throughout China. Education and research on TCM in China has been well documented.

Traditional Chinese medicines include not only medicinal plants, but also minerals and animal products. Their dispensing and distribution are guided by TCM theory and many require preparing and processing prior to clinical application. The processing and preparation procedures may influence the therapeutic properties and reduce toxicity.

2. Training traditional Chinese medicine practitioners

2.1 Categories of training programmes

Regulating the practice of TCM and preventing practice by unqualified practitioners require a proper system of training, examination and licensing. Benchmarks for training have to take into consideration the following:

- content of the training;
- method of the training;
- to whom the training is to be provided and by whom;
- the roles and responsibilities of the future practitioner;
- the level of education required in order to undertake training.

Experts in TCM distinguish three types of TCM training depending on prior training and clinical experience of trainees.

Type I training programmes are aimed at those who have completed high-school education or equivalent, but have no prior medical or other health-care training or experience. These trainees are required to study a full TCM programme. Type I training programmes cover the basic theories of traditional Chinese and allopathic medicine, as well as the knowledge and skills required for the qualified and safe practice of TCM and relevant research. These programmes are typically three- or four-year, full-time or equivalent programmes offered by an appropriately equipped institution (college or university). The duration is a minimum of 2460 hours, consisting of at least 1560 hours of theory and laboratory/clinical practice and 900 hours of supervised clinical practicum. The programmes are designed to produce TCM practitioners who are qualified to practise as primary-contact health-care professionals, independently or as members of a health-care team, at the community level or within health-care centres or hospitals.

Type II training programmes are conversion programmes aimed at those with medical or other health-care training who wish to become recognized TCM practitioners. Trainees are to study the entire theory of traditional Chinese medicine. These programmes may be structured to provide for either full-time or part-time study, but they should satisfy all requirements included in Type I training, and have flexible curricula to offer appropriate training for health professionals with different training backgrounds. Type II training programmes will generally require two to three years of study, full time or equivalent, and will cover all areas of the Type I curriculum not otherwise addressed in the individual's prior training. Other health-care professionals may complete the requirements for training as a TCM practitioner over a reduced period of time due to credits granted from their prior education.

Type III training programmes are aimed at practising TCM practitioners with either no prior medical or other health-care training, or inadequate training. These programmes are designed to upgrade skills and to allow trainees to obtain formal qualifications for the qualified and safe practice of TCM. Type III programmes may include all of the components of Type I programmes, but the length and components of this programme may vary substantially, depending upon the clinical experience of the trainee. The learning outcomes should be comparable to those of a Type I programme. Type III programmes may be offered on a full-time or part-time basis.

2.2 Benchmark learning outcomes

TCM training is expected to provide trainees with technical, communication, practice and information management skills and competencies (5,9).

Technical skills

The TCM practitioner should be able to:

- describe normal human structures and functions and their relevance to the prescription of TCM;
- apply knowledge of TCM principles to the diagnosis of diseases;
- identify clinical conditions and refer to other health-care professionals when required, and in a timely manner;
- formulate an appropriate TCM prescription based on an understanding of the components and indications and contraindications of a number of commonly used Chinese Materia Medica and TCM formulae;
- develop specific treatment plans, including time-lines for treatment and review, based on individual patient signs and symptoms;
- diagnose and differentiate diseases/disorders of internal medicine, gynaecology, paediatrics, ear, nose, throat and ophthalmology, traumatology and dermatology according to TCM principles and techniques, and formulate an appropriate treatment plan;
- interpret clinical laboratory findings;
- give nutritional, dietary and preventive medical advice in terms of TCM knowledge;
- modify TCM formulae and/or treatment plans based on an understanding of the components, indications and contraindications of currently used western medications and potential interaction among these therapies;
- review and monitor the health of the patient and modify treatment accordingly;
- prepare and dispense TCM prescriptions;
- report adverse drug reactions as per regulatory requirements;
- independently acquire technical knowledge about diseases not necessarily covered in the training.

Communication capabilities

The TCM practitioner should be able to:

- appropriately apply TCM and western medical terminologies in practice;

- communicate effectively with patients, other health professionals, regulatory bodies, herbal instrument suppliers and the general public.

Responsible and sustainable practice capabilities

The TCM practitioner should be able to:

- practise within regulatory and ethical frameworks;
- identify key business issues and draw on appropriate professional resources.

Research and information management capabilities

The TCM practitioner should be able to:

- understand and acquire new knowledge from clinical research;
- remain informed about TCM and apply advances in knowledge where appropriate;
- critically review research publications relevant to prescription in TCM;
- describe the steps involved in TCM research within an ethical framework;
- disseminate or communicate research processes and findings to peers, other professionals, the public and the government in an ethical manner.

2.3 A benchmark curriculum for training TCM practitioners

2.3.1 Elements of TCM

Basic theories or principles of TCM

- Characteristics and key concepts of TCM theory, including: *yin* and *yang*, five elements, *zang-fu*, *qi*, blood and body fluids, meridians,¹ aetiology and pathogenesis;
- Diagnosis in TCM, including: the four diagnostic methods (inspection, auscultation and olfaction, enquiring and palpation);
- Differentiation of syndromes (identification of syndromes according to the eight guiding principles² and *zang-fu*);
- Principles of treatment.

Upon completion of this subject, students are expected to be able to describe concepts of TCM and apply these concepts in diagnosis and prescription; they are also expected to demonstrate competency in diagnosis and differentiation of syndromes guided by the TCM theoretical framework, which reflects the uniqueness of TCM.

¹ The meridians and collaterals are important components of the body. They are linear in form and subdivided into several levels of branches which are interconnected with each other and form into a network.

² The eight guiding principles are *yin* and *yang*, internal and external aspects, cold and heat, and asthenia and sthenia.

Chinese Materia Medica

- Basic theory and concepts;
- Classification, actions, indications, and clinical applications.

Upon completion of this subject, students are expected to be able to describe 350 commonly used Chinese Materia Medica, properly apply them according to TCM theory, particularly as it relates to differential diagnosis and describe methods of decoction and basic knowledge and skills for identifying raw and processed Chinese Materia Medica.

TCM formulae

- Basic theory, concept, therapeutic principles, and methods of prescription and modification;
- Composition, modification, actions, combinations, and clinical application of commonly used formulae.

Upon completion of this subject, students are expected to be able to explain the principles of construction of TCM formulae, describe approximately 120 commonly used formulae and demonstrate knowledge and skills in analysing and applying the formulae in the prescription of TCM. In addition, they are expected to be able to formulate appropriate TCM prescriptions independently according to differentiation of syndromes and therapeutic methods for individual patients.

TCM Internal medicine

- Basic concepts, theories and skills;
- Aetiology, pathogenesis, clinical manifestations, syndrome differentiation, treatment principles and methods, and appropriate formulae for common diseases.

Upon completion of this subject, students are expected to be able to describe the basic methods of differentiation of diseases and syndromes and to manage common conditions of internal medicine using TCM.

TCM Gynaecology

- Theory and basic concepts;
- Aetiology, pathogenesis, clinical manifestations, syndrome differentiation, treatment principles and methods, and appropriate formulae for common diseases.

Upon completion of this subject, students are expected to apply the knowledge and skills for comprehensive diagnosis and TCM management of common gynaecological conditions.

TCM external medicine

- Theory and basic concepts;
- Aetiology, pathogenesis, diagnosis and treatment;
- Basic concepts and common diseases in dermatology.

Upon completion of this subject, students are expected to be able to demonstrate the basic practical skills of sterilization and disinfection and to apply basic

knowledge and methods for diagnosis and clinical management of common external and dermatological diseases.

Introduction to acupuncture

- Historical development;
- Theory, including meridians and acupoints.

Upon completion of this subject, students are expected to be able to demonstrate basic knowledge of acupuncture and its relevance to the prescription of TCM.

TCM dietary therapy

- Origin and history;
- Concepts and principles;
- Commonly used therapeutic approaches.

Upon completion of this subject, students are expected to be able to demonstrate an understanding of the properties, therapeutic effects and compatibilities of foods, the various categories of food and commonly used dietary therapeutic approaches of TCM and their clinical application.

Disease prevention and health promotion

- Concepts and principles;
- Commonly used approaches.

Upon completion of this subject, students are expected to be able to demonstrate an understanding of the concepts, principles and commonly used approaches for disease prevention and health promotion.

2.3.2 Elements of western medicine

Anatomy

- Basic theory;
- Normal anatomical structure and components of body systems, including the names, forms and locations of the structures and their physiological functions;
- Location and morphological structure of every organ;
- Surface anatomy and landmarks of bones, muscles and skin, as well as the underlying structures.

Upon completion of this subject, students are expected to be able to demonstrate an understanding of the terminology of anatomy and the body structure and describe the normal morphological structure of organs.

Physiology

- Basic concepts and theory;
- Major functions of human organs and systems;
- Homeostasis, normal physiological parameters, factors influencing them and their regulation.

Upon completion of this subject, students are expected to be able to demonstrate a basic ability to measure physiological functions and perform basic practical

skills, as well as demonstrate an ability to observe, analyse and summarize problems by applying theoretical knowledge.

Pharmacology

- Basic concepts, theory and terminology;
- Pharmacological actions, indications, contraindications, adverse drug reactions, drug interactions and the clinical application of the main drugs in each category.

Upon completion of this subject, students are expected to be able to demonstrate an understanding of pharmaceutical mechanisms, the practical skills of basic laboratory methods and the sound application of drugs, and to formulate a prescription in the proper format.

Pathology and diagnosis

- Concepts and aetiological factors of diseases;
- Basic theory, concept and skills of diagnosis;
- Chemical pathology, radiology and diagnostic imaging;
- Clinical decision making through comprehensive analysis of data gathered through physical examination and laboratory tests.

Upon completion of this subject, students are expected to be able to identify a range of clinical disease entities.

Biochemistry

- Basic concepts and principles;
- Routine clinical biochemistry investigations and their interpretation;
- Role of clinical biochemistry in diagnosis;
- Literature in clinical biochemistry.

Upon completion of this subject, students are expected to be able to interpret the results of routine clinical biochemistry, understand the results in clinical diagnosis, and extract and present relevant literature in clinical biochemistry.

Clinical Medicine

- Basic knowledge and theory;
- Aetiology, pathogenesis, clinical manifestation, diagnosis and treatment principles of common diseases.

Upon completion of this subject, students are expected to be able to describe and apply basic methods for diagnosis and clinical management of common conditions. They should be able to refer patients to other health-care professionals when required.

2.3.3 Other relevant subjects

Medical ethics and introduction to research

- Basic knowledge of medical ethics and professional code of ethics;
- Professional behaviour expected of health-care professionals;
- Introduction to concept and methods of research;
- Basic knowledge and skills of critical literature review and evidence-based health-care practice.

Upon completion of this subject, students are expected to be able to identify and explain the ethical principles of TCM practice. In addition, graduates are expected to be able to apply evidence-based health-care practice principles in clinic.

Health regulations

- Health regulations within the context of prescribing in TCM.

Upon completion of this subject, students are expected to be able to explain the legal requirements relating to TCM practice, including the relevant local health acts, legal responsibilities, standards of practice and related regulations, such as endangered species, and the protection and management of toxic Chinese Materia Medica.

Medical psychology

- Theory and practice;
- Psychological factors and their relevance to mental health, psychological counselling, diagnosis and health promotion.

Upon completion of this subject, students are expected to be able to explain the need for effective communication and outline key aspects of communicating with patients, with particular focus on patients with psychological disorders. They should be able to refer patients to other health-care professionals when required.

Documentation and clinical record keeping

- Recording of the primary complaints, health history, physical examination findings, assessment, diagnosis and treatment plan;
- Accurate documentation of patient histories;
- Re-evaluation of findings and documentation of any modifications to care plans;
- Appreciation of confidentiality and privacy issues;
- Consent obligations;
- Insurance and legal reporting.

2.3.4 Adaptation of the curriculum to trainees with prior health training: Type II programmes

Type II training programmes are designed to enable those with prior health-care training, typically as a medical or other health-care professional, to add TCM to their skills. Type II training programmes have to be tailored to previous education and experience. The community of TCM practitioners and experts considers that no less than 800 hours of student/teacher contact on TCM subjects are necessary (typically 675 contact hours on theory, 185 on practical), plus not less than 500 hours of supervised clinical practicum.

The curriculum of a Type II programme is identical to that of the Type I programme, excluding those areas which have been acceptably covered through the applicant's prior training as a medical or other health-care professional. This would include specific TCM subjects as well as those Chinese and western medical subjects necessary for TCM clinical practice, to result in the same learning outcomes as Type I programmes.

Table 1 - Indicative programme structure and teaching schedule

| Subject Name | Theory | Practical | Total |
|---|--------|-------------------|-------|
| Principles of TCM | 140 | 20 | 160 |
| Chinese Materia Medica | 90 | 20 | 110 |
| TCM Formulae | 90 | 20 | 110 |
| Internal Medicine of TCM | 140 | 60 | 200 |
| Gynaecology of TCM | 70 | 30 | 100 |
| Introduction to Acupuncture | 20 | 10 | 30 |
| Dietary Therapy of TCM | 30 | 30 | 60 |
| Anatomy | 80 | 30 | 110 |
| Biochemistry and Physiology | 70 | 20 | 90 |
| Pharmacology and Toxicology | 70 | 20 | 90 |
| Pathology and Diagnosis | 60 | 30 | 90 |
| Clinical Medicine | 240 | 50 | 290 |
| Medical Ethics and Introduction to Research | 50 | 10 | 60 |
| Health Regulations | 25 | 5 | 30 |
| Medical Psychology | 25 | 5 | 30 |
| | | | |
| Supervised clinical training | | 900 hours | |
| Total | | 2460 hours | |

2.3.5 Adaptation of the curriculum to trainees with prior health training: Type III programmes

Type III training programmes are designed to upgrade the knowledge and skills of TCM practitioners without sufficient prior training. Applicants for Type III programmes may be offered credits or be considered in light of their previous training, qualifications and experience and the curriculum has to be tailored to specific needs. The syllabus of the Type III programme will include all areas addressed in the Type I programme, excluding those areas which have been learned through the applicant's prior training and experience. The community of TCM practitioners and experts considers that no less than 800 hours of student/teacher contact hours on TCM subjects are necessary (typically 675 contact hours on theory, 185 on practical), plus 520 hours of theory and 150 hours of practical on western medicine. Type III training programmes aim for the same learning outcomes as Type I programmes.

3. Training traditional Chinese medicine dispensers and distributors

Distributors and dispensers of TCM play a key role in the delivery of TCM services. TCM distributors supply Chinese Materia Medica and TCM formulae to the dispensers. TCM dispensers provide Chinese Materia Medica or TCM formulae to patients. Their work requires knowledge and skills related to regulations, procedures and techniques. Quality control is therefore a key aspect and benchmarks for training have to take into consideration the following:

- content of the training;
- method of the training;
- to whom the training is to be provided and by whom;
- the roles and responsibilities of the future distributors and dispensers;
- the level of education required in order to undertake training.

3.1 A benchmark training curriculum for TCM dispensers

TCM practitioners and experts consider that TCM dispensers require a full curriculum including basic theories and skills of TCM. A total of 1,000 hours is suggested, consisting of 800 hours of theory and practical learning and 200 hours of clinical training in an appropriate dispensary or pharmacy under the supervision of a qualified dispenser or pharmacist. This programme is for those who have completed high school education or equivalent but have no prior medical or other health-care training or experience.

In order to allow dispensers of TCM to work either independently or as members of health-care teams, at the community level or within health facilities or pharmacies, the training programme has to enable them to:

- prepare slides and identify plant species using prepared slides or pressed dried specimens in a herbarium;
- perform laboratory procedures for TCM medicinal chemistry, and the techniques of extraction, separation and identification of chemical components, such as alkaloids and volatile oils (10,11).

The programme includes elements of TCM and of Western medicine.

3.1.1 Elements of TCM

Pharmacology and pharmacognosy of TCM

- Basic concepts of medicinal plants;
- Basic methods of propagation and sustainable harvesting of medicinal plants;
- Basic methods of analysis of medicinal plants;
- Basic knowledge of pharmacology of Chinese Materia Medica;
- Properties and pharmacological actions of TCM formulae;
- Key factors affecting pharmacological actions;
- Pharmacology and toxicology of TCM formulae.

Upon successful completion of this subject, students are expected to be able to demonstrate knowledge of the characteristics of key families and species of medicinal plants, an understanding of the basic classification of medicinal plants and the skills of identifying various tissues of these plants using a microscope. Students must also be able to identify class and species of medicinal plants and herbs in powdered form, as well as proficiently prepare slides, and identify dried or pressed plant specimens for reference in a herbarium. Additionally, they must understand major pharmacological actions of the main categories of TCM formulae.

Phytochemistry

- Introduction to the development of phytochemistry and research on active chemical ingredients;
- Basic knowledge of extraction and separation of chemical ingredients of Chinese Materia Medica;
- Basic knowledge of common chemical constituents, such as alkaloids and saponins.

Upon successful completion of this subject, students are expected to be able to understand laboratory experiment procedures for phytochemistry, and to master the techniques of extraction, separation and identification of common chemical constituents.

Elements for identification, quality assurance and standardization of Chinese Materia Medica

Upon successful completion of this subject, students are expected to be able to identify and evaluate the quality of approximately 350 kinds of commonly used Chinese Materia Medica, to master the skills of stir-baking and stir-frying with adjuvants, skills in drying procedures and to be able to perform cleaning, cutting, calcining, steaming, boiling, repetition and fermentation of Chinese Materia Medica.

Distillation, evaporation, desiccation, freeze drying, extraction and separation of Chinese Materia Medica

Upon successful completion of this subject, students are expected to be able to demonstrate knowledge and skills of pharmaceutical preparation of the commonly used dosage forms, such as decoction, liquor, troche, extract, pill, tablet, powder and capsule.

Contraindications and use of TCM

Upon successful completion of this subject, students are expected to be knowledgeable of potential interactions of Chinese Materia Medica, TCM formulae and other medications.

3.1.2 Elements of western medicine

Basic theories or principles of western medicine

Upon successful completion of this subject, students are expected to be able to demonstrate knowledge of basic concepts of western medicine, and their relationship to dispensing TCM.

Introduction to research

- Basic laboratory research methodology;
- Basic critical thinking in clinical decision making;
- Ability to comprehend published papers and relevant clinical guidelines;
- Development of the necessary skills to keep abreast of the relevant research and relevant scientific literature.

3.2 A benchmark training curriculum for TCM distributors

TCM experts consider TCM distributors also require a full curriculum including basic theories and skills of TCM. It is suggested that a programme of a total of 700 hours - 500 hours of theory and laboratory/clinical practice and 200 hours of practicum in the distribution of TCM would be an adequate benchmark. This programme is for those who have completed high-school education or equivalent but have no prior medical or other health-care professional training or experience.

3.2.1 Learning outcomes of the programme

Competence in the distribution of TCM requires the acquisition of relevant technical, communication, practice, research and information management capabilities (10,11).

Technical capabilities

- Demonstrate knowledge of good manufacturing practice;
- Distribute TCM independently;
- Apply knowledge of Chinese medicine principles;
- Properly advise the application of Chinese proprietary medicine;
- Properly identify Chinese Materia Medica and TCM formulae and evaluate their quality;
- Conduct inventories and apply appropriate measures for the protection of raw or processed Chinese Materia Medica and Chinese proprietary medicines in the warehouse;
- Describe good supply practice in the context of TCM.

Communication capabilities

- Appropriately apply TCM terminology in distribution;
- Communicate effectively with practitioners and dispensers in TCM, other health professionals, regulatory bodies and, when appropriate, the general public.

Responsible and sustainable practice capabilities

- Distribute TCM within regulatory and ethical frameworks;
- Identify key business issues and draw on appropriate professional resources.

3.2.2 TCM curriculum components

Principles of TCM

Chinese Materia Medica

- History;
- Properties, channels entered, ascending, descending, floating, sinking, and toxicity of Chinese Materia Medica;
- Contraindications to and indications for usage of Chinese Materia Medica.

Upon successful completion of this subject, students are expected to be able to demonstrate knowledge of the common actions and indications of every category of Chinese Materia Medica, understand the actions, indications and classification of at least 250 commonly used Chinese Materia Medica and apply the special dosage and usage cautions of some Chinese Materia Medica.

Chinese Proprietary Medicines

- Brief history of development;
- Commonly used dosage forms;
- Labelling and packaging.

Upon successful completion of this subject, students are expected to be able to demonstrate knowledge of common features of Chinese proprietary medicines, understand the therapeutic properties and indications of 200 commonly used Chinese proprietary medicines, apply them properly and provide advice to patients.

Pharmacognosy of TCM

- Basic concepts of plant taxonomy;
- Basic methods of analysis of medicinal plants;
- Basic morphology of medicinal plants.

Upon successful completion of this subject, students are expected to be able to demonstrate knowledge of the characteristics of the key families and species of medicinal plants, understand basic classification of medicinal plants and possess the skills to identify various tissues of pharmaceutical plants using a microscope and be able to identify class and species of medicinal plants.

Elements for identification of Chinese Materia Medica

- Basic concept, purpose, evidence and methods of identification;
- Sources, collection, processing, storage of commonly used Chinese Materia Medica;
- Basic knowledge and procedures for identification of Chinese Materia Medica, possible contaminants and adulterants.

Upon successful completion of this subject, students are expected to be able to identify and evaluate the quality of approximately 250 kinds of commonly used Chinese Materia Medica.

Storage of Chinese Materia Medica

- Introduction to storage and factors that affect quality of Chinese Materia Medica;
- Routine inspection and management of stored Chinese Materia Medica, as well as methods for maintenance;
- Temperature and humidity control in a warehouse;
- Pest and moulding control;
- Measures to protect Chinese Materia Medica in storage and other factors that affect quality.

Upon successful completion of this subject, students are expected to be able to demonstrate skills pertaining to warehouse storage of commonly used and specific Chinese Materia Medica.

Marketing management of traditional Chinese medicines

- Introduction to marketing management;
- Market research and estimation;
- Product strategies;
- Pricing strategies;
- Promotion strategies;
- Retailing channel strategies;
- Global marketing strategies.

Upon successful completion of this subject, students are expected to be able to conduct market research and develop marketing strategies for supporting distribution of TCM.

Pharmaceutical administration and regulations

- Systems of pharmaceutical administration and related regulations;
- Drug administration legislation;
- Quality specifications of TCM;
- Key components of good manufacturing practice (GMP);
- Key components of good supply practice (GSP);
- Management of scheduled drugs and TCM.

4. Safety issues

The community of practitioners and experts of TCM has identified a set of incompatibilities and contraindications in TCM. These can usefully be complemented with the WHO guidelines for safety issues related to herbal medicines (12-15).

4.1 Incompatibility of Chinese Materia Medica

In classical texts, eighteen incompatible herbs (*Shi Ba Fan*) and nineteen antagonistic herbs (*Shi Jiu Wei*) are documented as being incompatible with TCM prescription. This is an important concept (16), even though current knowledge does support the use of some of the combinations. TCM practitioners and experts recommend extreme caution in the use of such combinations.

| Eighteen incompatible herbs (<i>Shi Ba Fan</i>) | | | |
|---|--------------|---|---|
| Medicine given | | Incompatible with | |
| Latin compendium Name | Chinese Name | Latin compendium name | Chinese name |
| <i>Radix Aconiti</i> | Wu Tou (乌头) | <i>Radix Ampelopsis</i> <i>Rhizoma Bletillae</i> <i>Bulbus Fritillariae</i> <i>Rhizoma Pinelliae</i> <i>Fructus Trichosanthis</i> | Bai Lian (白蔹) Bai Ji (白及) Bei Mu (贝母) Ban Xia (半夏) Gua Lou (瓜蒌) |
| <i>Radix Glycyrrhizae</i> | Gan Cao (甘草) | <i>Radix Euphorbiae Pekinensis</i> <i>Flos Genkwa</i> <i>Radix Kansui</i> <i>Sargassum</i> | Jing Da Ji (京大戟) Yuan Hua (芫花) Gan Sui (甘遂) Hai Zao (海藻) |
| <i>Rhizoma et Radix Veratri</i> | Li Lu (藜芦) | <i>Radix Adenophorae seu Glehniae</i> <i>Radix Paeoniae Alba</i> <i>Herba Asari</i> <i>Radix Ginseng</i> <i>Radix Salviae Miltiorrhizae</i> <i>Radix Scrophulariae</i> | Sha Shen (沙参) Bai Shao (白芍) Xi Xin (细辛) Ren Shen (人参) Dan Shen (丹参) Xuan Shen (玄参) |

| Nineteen antagonistic Chinese Materia Medica (<i>Shi Jiu Wei</i>) | | | |
|---|--|---|--------------------------|
| Agonist | | Antagonist | |
| Latin compendium name | Chinese name | Latin compendium name | Chinese name |
| <i>Radix Aconiti</i> <i>Radix Aconiti</i> <i>Kusnezoffii</i> | <i>Chuan Wu</i> (川乌) <i>Cao Wu</i> (草乌) | <i>Cornu Rhinoceri</i> | <i>Xi Jiao</i> (犀角) |
| <i>Flos Caryophylli</i> | <i>Ding Xiang</i> (丁香) | <i>Radix Curcumae</i> | <i>Yu Jin</i> (郁金) |
| <i>Fructus Crotonis</i> | <i>Ba Dou</i> (巴豆) | <i>Semen Pharbitidis</i> | <i>Qian Niu Zi</i> (牵牛子) |
| <i>Cortex Cinnamomi</i> | <i>Rou Gui</i> (肉桂) | <i>Halloysitum Rubrum</i> | <i>Chi Shi Zhi</i> (赤石脂) |
| <i>Nitrum Depuratum</i> | <i>Ya Xiao</i> (牙硝) | <i>Rhizoma Sparganii</i> | <i>San Leng</i> (三棱) |
| <i>Radix Euphorbiae Fischerianae</i> | <i>Lang Du</i> (狼毒) | <i>Lithargyrum</i> | <i>Mi Tuo Seng</i> (密陀僧) |
| <i>Radix Ginseng</i> | <i>Ren Shen</i> (人參) | <i>Excrementum Troglodyteri seu Pteromi</i> | <i>Wu Ling Zhi</i> (五灵脂) |
| <i>Hydrargyrum</i> | <i>Shui Yin</i> (水银) | <i>Arsenicum</i> | <i>Pi Shuang</i> (砒霜) |
| <i>Sulfur</i> | <i>Liu Huang</i> (硫黄) | <i>Natrii Sulfas</i> | <i>Mang Xiao</i> (芒硝) |

4.2 Contraindications in pregnancy

Special caution should be given to patients during pregnancy (17). TCM practitioners and experts recommend prohibition of a set of Chinese Materia Medica during pregnancy, and extreme caution in the use of another set.

| Chinese Materia Medica prohibited in pregnancy | | | |
|--|-------------------------|---------------------------------|--------------------------|
| Latin compendium name | Chinese name | Latin compendium name | Chinese name |
| <i>Radix Aconiti</i> | <i>Chuan Wu</i> (川乌) | <i>Hydrargyrum</i> | <i>Shui Yin</i> (水银) |
| <i>Radix Aconiti</i> <i>Kusnezoffii</i> | <i>Cao Wu</i> (草乌) | <i>Radix Kansui</i> | <i>Gan Sui</i> (甘遂) |
| <i>Arsenicum</i> | <i>Pi Shuang</i> (砒霜) | <i>Moschus</i> | <i>She Xiang</i> (麝香) |
| <i>Venenum Bufonis</i> | <i>Chan Su</i> (蟾酥) | <i>Mylabris</i> | <i>Ban Mao</i> (斑蝥) |
| <i>Calomelas</i> | <i>Qing Fen</i> (轻粉) | <i>Semen Pharbitidis</i> | <i>Qian Niu Zi</i> (牵牛子) |
| <i>Chalcanthitum</i> | <i>Dan Fan</i> (胆矾) | <i>Radix Phytolaccae</i> | <i>Shang Lu</i> (商陆) |
| <i>Fructus Crotonis</i> | <i>Ba Dou</i> (巴豆) | <i>Realgar</i> | <i>Xiong Huang</i> (雄黄) |
| <i>Rhizoma Curcumae</i> | <i>E Zhu</i> (莪术) | <i>Rhizoma Sparganii</i> | <i>San Leng</i> (三棱) |
| <i>Pedicellus Cucumeris</i> | <i>Gua Di</i> (瓜蒂) | <i>Semen Strychni</i> | <i>Ma Qian Zi</i> (马钱子) |
| <i>Radix Euphorbiae Pekinensis</i> | <i>Jing Da Ji</i> (京大戟) | <i>Tabanus</i> | <i>Meng Chong</i> (虻虫) |
| <i>Flos Genkwa</i> | <i>Yuan Hua</i> (芫花) | <i>Resina Toxicodendri</i> | <i>Gan Qi</i> (干漆) |
| <i>Hirudo</i> | <i>Shui Zhi</i> (水蛭) | <i>Rhizoma et Radix Veratri</i> | <i>Li Lu</i> (藜芦) |

| Chinese Materia Medica used with caution in pregnancy | | | |
|---|------------------|--------------------------------|------------------|
| Latin compendium name | Chinese name | Latin compendium name | Chinese name |
| <i>Radix Achyranthis Bidentatae</i> | Niu Xi (牛膝) | <i>Cortex Cinnamomi</i> | Rou Gui (肉桂) |
| <i>Aloe</i> | Lu Hui (芦荟) | <i>Rhizoma Curcumae Longae</i> | Jiang Huang (姜黄) |
| <i>Radix Aconiti Lateralis Preparata</i> | Fu Zi (附子) | <i>Cortex Moutan</i> | Mu Dan Pi (牡丹皮) |
| <i>Fructus Aurantii</i> | Zhi Ke (枳壳) | <i>Semen Persicae</i> | Tao Ren (桃仁) |
| <i>Fructus Aurantii Immaturus</i> | Zhi Shi (枳实) | <i>Radix et Rhizoma Rhei</i> | Da Huang (大黄) |
| <i>Flos Carthami</i> | Hong Hua (红花) | <i>Folium Sennae</i> | Fan Xie Ye (番泻叶) |
| <i>Rhizoma Chuanxiong</i> | Chuan Xiong (川芎) | <i>Natrii Sulfas</i> | Mang Xiao (芒硝) |

4.3 Dietary considerations

Food may have an impact on the outcome of TCM prescriptions. Therefore, in an attempt to maximize therapeutic effects, TCM practitioners and experts recommend restriction of uncooked, cold, spicy, hot, or greasy foods during the administration of some TCM prescriptions. However, dietary advice can be modified according to the different clinical conditions and constitutions of individuals. For example, for heat syndromes, hot, spicy, greasy and deep fried food is to be avoided; while for cold syndromes, uncooked and cold food is restricted. For patients with obstruction of *qi* in the chest, fatty meat, internal organs of animals, and wine are to be limited; while for patients with hyperactivity of liver *yang*, dizziness, and irritability, intake of pepper, chilli, garlic and alcohol are discouraged. For deficiencies of the spleen and stomach, deep fried, greasy, and raw food are discouraged.

4.4 Prevention of complications from TCM clinical practice

TCM practitioners and experts recommend careful assessment of a patient's history and the interpretation of clinical findings in order to minimize the risk of adverse drug reactions from the prescription of TCM. This includes gathering information about co-morbidities and the current use of medication, including long-term steroid use and anti-coagulant therapy.

4.5 Quality of medicines

Adverse events may be caused by contamination, adulteration, misidentification, inappropriate use of species and/or prescribing dosages. For this reason, dispensers and distributors of TCM should pay particular attention to these issues, in line with the WHO guidelines for quality control and safety of herbal medicines (18,19,20).

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Annex: WHO Consultation on Phytotherapy, Milan, Italy, 20–23 November 2006: list of participants

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