# Asia Health Care Journal

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## *What is* the right thing to do?

Prof. Jack Wong

## Dr. Manson Fok's Macau Medical Revolution

Christopher Cottrell

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香港醫護學會
Hong Kong Health Care Federation

ARPA
Asia Regulatory Professional Association

# Traditional Chinese Medicine (TCM) Regulatory Affairs Course


**Edward YAU**
**Trainer**
BPharm(Hons), MPS, ANZCP, RPh(HK,NZ), AMRSPH, PCCM


*A Registered Pharmacist in Hong Kong and New Zealand who has been involved with the pharmaceutical industry in both manufacturing and regulatory field.*

*Experienced in managing an aseptic facility for Baxter Healthcare in New Zealand and is currently the Authorized Person of a GMP manufacturer in Hong Kong. Involved with the registration of over 100 Proprietary Chinese Medicine (pCm) products and pharmaceutical products in Hong Kong. Worked for Wai Yuen Tong Medicine Company as the Head of Quality Assurance during the period of the government's implementation of Mandatory registration of pCm products. Actively involved with industry associations in the Chinese Medicine sector.*

Traditional Chinese Medicine industry becomes a highly regulated industry. According to the Chinese Medicine Ordinance, regulatory measures relating to Chinese medicines shall be divided into two areas, including the licensing of Chinese medicines traders and the registration of proprietary Chinese medicines. This course will mainly focus on the registration of proprietary Chinese medicines.

We would recommend commercial team and of course regulatory team to get systemic and formal training in order to understand the regulations related to Chinese medicines.

**Course Details**

- Introduction to the current regulatory framework for Chinese medicines in HK
- Definition of a proprietary Chinese medicines (pCm)
- Classification groups of pCm
- Information of product - Safety, Quality, Efficacy
- Case Study - pCm
- Classification of products containing Chinese medicine but not considered as pCm
- Case Study - Food product containing Chinese medicine

**Date** 5 Jan 2012 (9:30am – 5:30pm)
**Organizer** ARPA (Asia Regulatory Professional Association)
**Venue** 15/F, Bamboos Centre, 52 Hung To Road, Kwun Tong, Kowloon, Hong Kong
**Fee** HK$5,800 per person

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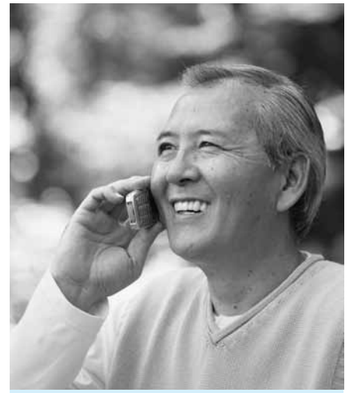
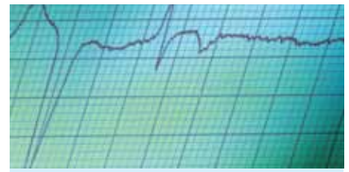
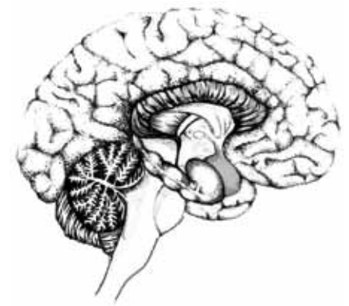


**阿尔茨海默病的治疗** 老年痴呆症危害人类的健康，其发病率逐年上升，预防和治疗老年性神经退化性疾病是现代医学面临的巨大挑战。



**Strategic areas and core functions** Seven strategic areas (QUALITY) were defined to strengthen core functions and facilitate communication in its portfolio on infection control.



**rTMS Treatment for Autism** A new personalized TMS protocol that has shown to be clinically effective in treating ASD.

# What is the right thing to do?

**Prof. Jack Wong**, Chief Editor
Director, Regulatory Affairs, Johnson & Johnson Medical
Founder, Asia Regulatory Professional Association
Email: speedxquality@yahoo.com

**Right Job**

I am a healthcare professional graduated as a Pharmacist and worked as a Regulatory Affairs director in healthcare companies. I am very proud to working in healthcare sector as my products or services have important and fatal impacts on people. My job as Regulatory Affairs director is getting the new medical products to patients by using scientific data from R&D, ensuring good quality system in manufacturers, liaising with Health Authorities and finally getting relevant certificates before supplying the products to the needed patients. The quality and speed to provide the medical products to the patients are our core jobs.

**There are 2 key challenges in our job**

**1. Quality**

To ensure good quality, many international standard bodies (e.g. ISO and BSI) and local standard bodies in US, Japan and China, etc. are actively developing better product standards for manufacturers to produce products in better specifications. After a product with good specification is developed, production of products also needs to be in good system (e.g. GMP and ISO 13485) and regularly audited by certification bodies and governments. As regulatory professionals, we need to understand the above, explain to relevant government bodies and finally get relevant certificates or approvals.

**2. Speed**

Use medical device as an example, it usually takes 90 working days to get approval in US or Europe. You may be surprised it can take up to 3 to 4 years to get approval in some Asia countries.

Regulatory Affairs job is a combination of Science, Legal affairs and Moral.

This formula that I found could also explain our job.

RA = (Science x Law) $^{\text{Moral}}$

You may understand the "Science" and "Law" part from the above formula, and now I would like to explain the moral part.

**Persons vs. Things**

To explain the moral part of RA job, I would like to start with a moral question/situation.

Suppose you are a trolley car driver driving sixty miles an hour. Ahead of you, there are five people standing in front of you. You try to stop the car but the brakes don't work. You feel bad as those five people may die.

Suddenly, you notice a side track on your right hand side but there is one person standing there. You can turn right hitting that one person but sparing the five.

What will you do? Sacrificing one life in order to save five seems to be the right thing to do.

Now consider another version of the trolley car story. You are not driver but an onlooker standing on a bridge overlooking the track and there is no side track this time. Along the track, there are five people, the car cannot stop as the brakes don't work and it is about to crash into those five people. You feel desperate to help those people. Suddenly, you notice a heavy man standing next to you. You can push him off the bridge into the path of the oncoming trolley. He could die but those five people would be saved. (Assuming this approach will work and the option of you jump onto the track will not help as you are too small to stop the trolley.)

**Will you push the heavy man?**

I studied some human right and philosophy books to better answer this question and come up with the following statement:

It is wrong to use people for the sake of the general welfare. Pushing the heavy man onto the track to block the trolley and uses him as a means, and so fails to respect him and his dignity.

We value things not just "more" or "less", but in qualitatively higher and lower ways.

Human is not a thing but a person with dignity. In healthcare sector, we are healthcare professional to help people to get good medical services/products in good speed. By respecting human dignity, we should put human dignity first and minimize all administrative, bureaucratic and political issues. ■

The Asia Regulatory Professional Association (ARPA) is an organization of Healthcare Regulatory Affairs professionals in Asia.
ARPA aims to raise the standard and social recognition of Regulatory Professionals as part of Healthcare team.
Detail of ARPA can be found in
http://www.healthcare.org.hk/Health2.aspx?id=1&Cid=0

ARPA
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# Dr. Manson Fok's Macau Medical Revolution

*By Christopher Cottrell*

"We could develop a very strong medical tourism industry here," says Dr. Manson Fok.
Coming from Dr. Fok these words are indeed strong.

After all, Dr. Fok is leading Macau's modern medical revolution. And not just for medical tourism.

As the Dean of the Faculty of Health Sciences at the University of Macau (MUST) and President of the Macau Healthcare Management and Promotion Association (MHMPA), he is bringing world class robotics technology to the city to enhance medical training and services.

Moreover, for the past year, he has organized a highly respectable series of international medical conferences: the Sino-Luso International Medical Forums.

"We're hoping to build a robust medical center here that is state-of-the art," Dr. Fok said while pointing to world class Simbionix Computer Assisted Training Simulator at his MUST facilities. The machine has simulated forceps and scissors as if it were a video game glove. On the screen, a purple organ, the liver, appears with layers of tissue for students to practice virtual surgery.

Pointing at the surgery simulator, Dr. Fok explained to a group of doctors from Italy and Hong Kong that, "This is how we train our students for real world situations." The comment impresses Italy's Dr. Enrico Storti, the chair of the board of WINFOCUS, a cutting edge sonogram firm based in Milan.

Dr. Storti said, "MUST is impressive… I've traveled to over 56 countries in the past four years, and it seems to me that this is an excellent place for growth in medical technology."




Down the hall from the Simbionix machines is a simulated ambulance. Dr. Fok said, "We train them in close quarters for spacial awareness so they know how to react in the field. We simulate stress for them with real world situations. We teach them stress management. A little stress is a good thing."

That's interesting given the types of synergy Dr. Fok is striking: real world training in Macau, international forums, and the latest technology. Case in point: the first Sino-Luso conference brought Professor Wun Jun, a Colonel with the 3rd Military Medical University, to discuss field service during the May 12, 2008 Sichuan earthquake.

Another example: The second forum had the President of the Portuguese Surgical Society, Professor Henrique Castelo, who delivered a stirring keynote speech about teaching surgery in the 21st century.

Both are germane for MUST and Dr. Storti. Dr. Storti said, "Our sonogram machines are ideal for today's first response, such as earthquake rescue. During the first hour when a patient is down, we call this the 'golden hour.' With the new portability of sonograms, we can scan wounded patients in the field without cutting them open. Sonograms are not merely about maternity. The ctice medicine in the next ten to fifteen years."

Dr. Lee, a resident specialist in accidents and emergency at the Hospital Authority's Queen Mary Hospital, further explained, "I spend a lot of time in the emergency room and this technology (for sonograms) reduces the amount of time we spend sending them to get an MRI or EKG, or from radiologists, who traditionally ran the sonograms. We're developing curriculum and training standards with Dr. Storti and WINFOCUS."

For those watching Macau's new face of economic diversification, this is an interesting development as it combines high education and real world healthcare services. In fact, MUST's surgery ward is where the Malo clinic at the Venetian goes with emergency patiences.

Added Dr. Lee, "The old image of the doctor was with a stethoscope. Now, its going to be with sonogram technology in the future."

And that future is being made now, driven by Dr. Manson Fok in Macau. ■

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# *Sino-Luso Nurses Association celebrates 20 years*

**These ladies are truly nursing Macau and Portuguese speaking countries to new levels of health.**

Meet the little known but highly influential circle of the Sino-Luso Nurses Association (SLNA), a group who celebrated two decades of healthcare and culture Saturday night at Macau Tower.

In function, they are a group of Chinese and nurses from Lusophone countries who conduct cultural exchanges and meetings to enhance care for people of all ages, bridging cultures for a creative dialogue. Linda Tran, president of the SLNA, said, "We are still like a teenager. We have grown but we still have a long way to go. We are hoping to continue our tradition of bringing ideas of medicine and performance to new levels.

"Indeed, the gathering was the first time in several years that the SLNA rekindled relationships. Tran continued, "We first started with 14 members in 1991 with a few Portuguese and Chinese nurses. Now we have over 500 members."

Filomena Gaspar President of the Portugal Nurses Association in Lisbon gave further elaboration by saying, "After the handover our ties were limited. We are now hoping to bridge the doors between Lisbon and Macau, with one being the door for Portugal to the east, and the other being the door to Macau and China in the west." Ms. Gaspar also said, "We will send two students next year to Macau to study local medicine and culture and to hopefully learn some Mandarin and Cantonese as well. We are also inviting students from Macau who speak English, and who also will hopefully want to learn some Portuguese, to come to Lisbon to learn our culture and nursing techniques."

New techniques for sure

The evening's keynote speaker, Billy Chan, speaking on behalf of Dr. Manson Fok (Dean of Health Sciences at the Macau University of Science and Technology, MUST), said, "Nurses are now working under a different healthcare environment in the public and private sectors. Nurses are needed to update their knowledge and strengthen their skills constantly in response to changing demands in Macau. And to be able to do so, we need to have good continuing nursing education (CNE) in place to meet with the needs of our nurses today." For this, MUST has already hosted three high-level Sino-Luso medical forums over the past six months, drawing doctors from all over the world at the invitation of Dr. Manson Fok. Today, they will hold a special seminar for hands on training at their state-of-the-art medical training facilities at MUST for 50 nurses from the 500 strong SLNA. They have huge popular support for this.

David Chow, Chairman and CEO of Legend Development and Honorary Consul of Macau for Cape Verde said, "My sister is a nurse and we as a society must support them." Mr. Chow's wife, lawmaker Melinda Mei Yi Chan was also on hand and said, "Nurses save so many people. We must stand up for what they are doing. Nurses are ambassadors across all ages, from birth to living to death. They give us life." ■

(L-R) Filomena Gaspar, President Nursing College of Lisbon, Billy Chan, Executive Assistant to Dean, Faculty of Health Sciences (MUST) and Teresa de Oliveira Marcel, Vice President Nursing Counsel of Portugal

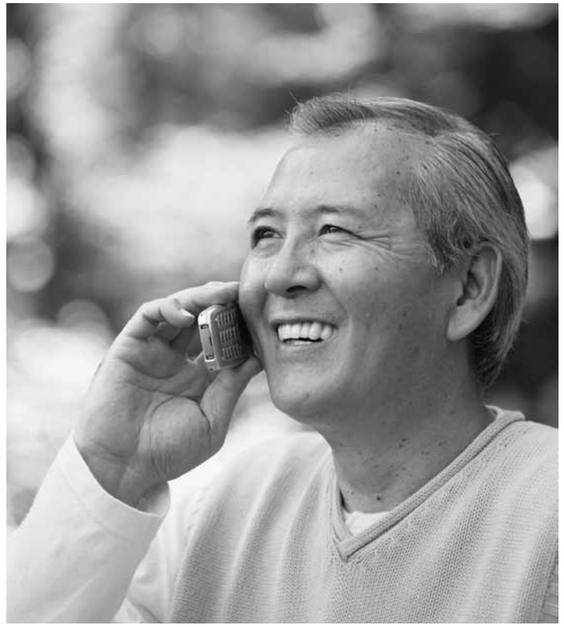
**顾怀宇教授**

*中山大学医学院解剖学教授、博士导师，专长为神经系统的抗衰老研究。*

顾怀宇教授留学美国期间，被国际著名科普杂志《SCIENTIST》以“PROBING THE MIND IN DROSOPHILA”为专题作报道。其研究内容相继发表在《神经科学杂志》(Journal of Neuroscience)、《细胞》《CELL》等国际顶尖生物医学杂志。

2009年，顾教授作为中山大学“百人计划”引进人才，回国后负责并完成国内一流的神经生物学实验室。目前主持863计划项目1项、国家自然科学基金1项、美国NIH基金资助项目2项，其主要研究方向是神经毒理、嗅信号分析、分子神经生物学等。

# 阿尔茨海默病的治疗



阿尔茨海默病俗称老年痴呆，是一种由多种病因引起的、随着年龄增长而呈现进行性发展的神经退行性疾病，临床主要表现为短时程记忆功能障碍，随后为持续性学习记忆能力减退，判断推理能力丧失、失语、运动障碍等，严重影响老年人的生活质量。

预防和治疗老年性神经退化性疾病是现代医学面临的巨大挑战，现在全世界有许多研究小组在研究阿尔茨海默病，虽然这种病的分子机制在过去20年中有较大进展，但老年痴呆确切的治疗方法依旧是医学难题之一。目前老年痴呆常用的治疗方法有药物治疗，包括中药治疗和西药治疗；非药物治疗，包括针灸治疗、行为学治疗、食疗、情志治疗、精神调养、智力训练和适当的体育锻炼等。下面我们就针对这些治疗方法一一阐述。

药物治疗包括中药治疗和西药治疗，是目前应对阿尔茨海默病的主要手段，不同的药物能在阿尔茨海默病的治疗、预防中发挥不同的作用。

在中药治疗中，人参、刺五加、银杏、石杉等均具有一定的益智和提高记忆效果，另外，一些中成药在抗痴呆方面的作用引起专家关注，如对补中益气汤、归脾汤、天王补心丹、复方丹参益智胶囊、当归芍药散六种传统补肾中药研究后证实，它们都具有抗衰老及抗氧化作用，对于老年性痴呆、神经衰弱及健忘均有一定疗效。

而老年性痴呆的西药治疗方法较多，具体分可以为以下几种：

胆碱能系统改善药物：老年痴呆的一个主要原因是胆碱含量不足。因此，具有增强胆碱能作用的药物在老年痴呆症的治疗方面发挥了重要作用，目前补充胆碱前体的药物主要为卵磷脂和磷脂酰胆碱。常用的是乙酰胆碱酯酶抑制剂，包括他克林，安理申，艾斯能，加兰他敏。

作用于非胆碱递质和受体的药物：此类药物通过改善脑内其他神经递质异常，达到改善老年痴呆症状。目前主要有：单胺氧化酶抑制剂、腺苷受体拮抗剂、NMDA受体拮抗剂。

用Aβ肽进行免疫治疗：免疫干预治疗是今后治疗老年痴呆的一个重要方向，它通过应用Aβ多肽疫苗，刺激机体产生抗体，启动吞噬细胞来清除抗原抗体复合物，从而达到清除斑块的目的。并且，直接给老年痴呆患者注射疫苗可避免老年人因免疫力降低影响治疗效果，同时不引起T细胞介导的免疫反应，可控性好。

抑制Tau蛋白异常磷酸化的药物：老年痴呆患者脑中存在大量异常Tau蛋白。Tau蛋白异常修饰、含量变化对临床阿尔茨海默病病理发生有重要作用。由于Tau蛋白的异常修饰涉及多种酶，可在此基础上发展新的治疗阿尔茨海默病药物。例如可以应用磷酸酯酶及该酶激活剂类药物，降低Tau蛋白磷酸化过程，可能对阿尔茨海默病患者的神经元纤维退化有抑制甚至逆转的作用。也可考虑用分解糖基的特异糖苷酶，抑制Tau蛋白的异常糖基化。

抗氧化药物：抗氧化药物通过消除活性氧或阻止其形成来阻止神经细胞退化，如含具有清除自由基作用的维生素E，维生素E是重要的抗氧化剂，具有自由基代谢的神经保护作用，还可能通过抑制和清除脑内β-淀粉样蛋白沉积，产生延缓衰老的作用。其它自由基清除剂还有褪黑素、姜黄素、去铁敏、艾地苯醌、甲磺酸替拉扎特等。

非甾体抗炎药物：根据流行病学的研究结果显示，经常服用阿司匹林或消炎镇痛药的老人患老年痴呆和认知障碍的可能性明显降低，这一现象提示抗炎药物具有治疗老年痴呆的潜在应用价值。

雌激素替代疗法：虽然从基础的生物资料提示雌激素可以有保护神经和增强神经的功能，但雌激素对老年人的认知功能的研究结果仍存在有争议；神经细胞营养药物。研究表明，神经生长因子(NGF)对中枢胆碱能神经元有营养作用，对改善认知功能障碍有一定的作用。

钙离子拮抗剂：细胞内钙离子超载，可造成神经细胞的损伤或凋亡。而钙离子拮抗剂可抑制钙离子通道活性，因此可以保护神经元细胞；代谢增强药物。老年痴呆患者都不同程度的存在糖、蛋白、核酸、脂质等代谢障碍，同时其脑血液流量及耗氧量明显低于同龄正常人。因此，脑代谢激活剂和脑循环改善剂，尤其是具有脑血管扩张作用的脑代谢激活剂成为老年痴呆治疗的一大类可供选用的药物，如脑复康、都可喜、喜得镇等。





阿尔茨海默病的非药物治疗在提高病患的智力水平，改善认真障碍方面亦有举足轻重的作用。

非药物治疗中，效果比较好的有针灸疗法，主要包括：体针，有报道多针透刺（如百会透四神聪；神庭透当阳，再透上星；首面透鼻交；定神透水沟；足三里透丰隆；风府透哑门；大椎透身柱；命门透肾俞；内关透神门；复溜透太溪等）治疗阿尔茨海默病效果显著。另有临床研究取中脘、丰隆、内关及涌泉、人迎、风池2组穴位，以益智化浊针法治疗取得满意效果；穴位注射，临床观察用人参注射液和复方丹参注射液于双侧肾俞、足三里、三阴交行穴位注射，效果显著；针药并用，交替针刺人中、四神聪、本神、足三里、太溪、悬钟及百会、大椎、命门、肝俞、肾俞2组穴位，配合口服中药复元汤，结果针药并用组疗效明显优于单纯针刺组。

其次，可通过行为学方法治疗阿尔茨海默病。虽然引起阿尔茨海默病行为异常的主要原因是大脑皮层神经细胞的死亡，但是药物的治疗，环境的影响，还有个人身体情况等都会影响各种症状甚至加重病情。通过行为学的治疗对改善病情有一定的效果，主要方法有以下两种：避免或消除不利的环境影响。消极的环境影响有：转换新的住所或者生活环境，药物治疗的不良反应，由于阿尔茨海默病病情加重引起的症状导致的心理影响。随着病情的加重，患者会越来越难以与他人沟通，导致患者很难说出自己的症状，我们可以通过找出其消极影响因子而消除其影响；营造积极的环境与活动。我们可以多与患者聊天沟通、安抚，还有满足他们的需要，承认他们的要求，给予充足的休息等等。并安排好患者未来的生活，使患者多参与各种活动，有益于身心愉悦。

与此同时，食疗也在阿尔茨海默病的治疗中发挥着重要的作用。现在医学表明，老年痴呆患者日常饮食宜多样化，不宜过饱。要多吃富含纤维素的食物如谷类、麦类，有益于大脑的健康保护的芹菜、黄花菜等蔬菜，富有维生素的水果如苹果等以及富含卵磷脂的食物如大豆类制品、磨菇和含有丰富亚油酸的各类坚果如花生、核桃、松子、榛子、葵花籽等。做到高蛋白，高维生素，高纤维，低胆固醇，低脂肪，低糖，低盐饮食。

最后，必要的情志治疗、精神调养、智力训练和适当的体育锻炼对患者的病情也是很有益的。人们常说，“笑一笑，十年少”，这说明精神之调养重在调节七情之气，注意保持乐观情绪，应节思虑、去忧愁、防惊恐，要宁静无惧，恬淡虚无，与世不争，知足常乐，清心寡欲。做到外不受物欲的诱惑，内不存情感的激扰。这样气血调和，健康不衰。注意维持人际关系，避免长期陷入忧郁的情绪及患上忧郁症，避免精神刺激，以防止大脑组织功能的损害。

另外，家庭和睦可以保持心情愉快，能增强抗病能力。鼓励老年人多参加社会活动，有轻度症状的患者应进行力所能及的体力活动运动，多动手动脑，稳定情绪，减少不良刺激。听音乐，读书看报，或在护理人员的指导下进行适当的益智活动如打麻将、下棋等，都可激发脑力，刺激神经细胞活力。有研究显示，常用脑，常做有趣的事，可保持头脑灵敏，锻炼脑细胞反应敏捷度，整日无所事事的人患痴呆症的比例高。

结语：老年痴呆症危害人类的健康，其发病率逐年上升。目前，仍未找到有效的治疗方法，动物的模型研究只是在不同的侧面反映一些问题。药物的治疗只能在部分病例中起到一定效果，不能从根本上解除病因，非药物的治疗只能在一定程度上减缓病情的恶化。药学工作者和临床工作者仍需在这方面深入研究，使患者早日脱离疾病之苦。■

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Edward is a Registered Pharmacist in Hong Kong and New Zealand who has been involved with the pharmaceutical industry in both manufacturing and regulatory field. He has experience managing an aseptic facility for Baxter Healthcare in New Zealand, and he is currently the Authorized Person of a GMP manufacturer in Hong Kong. He has been involved with the registration of over a hundred Proprietray Chinese Medicine (pCm) products and pharmaceutical products in Hong Kong. Edward had worked for Wai Yuen Tong Medicine Company as the Head of Quality Assurance during the period of the government's implementation of Mandatory registration of pCm products. He is also actively involved with industry associations in the Chinese Medicine sector.

# Hong Kong Proprietary Chinese Medicines Regulatory Affairs Review: The current situation

**Introduction**

The Mandatory registration of Proprietary Chinese Medicines (pCm) in Hong Kong commenced on the 3rd of December 2010. There had been different voices of both support and criticism from the pCm industry and the public in response to the implementation of this provision. Many supports this move as a result of negative publicity of several pCm products in recent years, hoping that a more regulated environment can protect the safety of consumers and raising the professional standards of this century-old profession. On the other hand, many believe that ancient traditions that had been practices for years has a different perspective when it comes to safety, quality and efficacy, and that current western scientific principles cannot be superimposed onto a trade and profession without significant adjustments and compromise.

**Historic Background of the Chinese Medicine Ordinance**

In July of 1999, The Chinese Medicine Ordinance (Cap.540) was enacted by the Hong Kong legislative council. The enactment of this ordinance was based on a need of regulating this generations-old industry both to protect public safety and to align with regulatory environment of other Asian countries. The Chinese Medicine Ordinance provided a statutory framework for mainly two industries: namely the practice of Chinese Medicine, and also the manufacture and trade of Chinese medicines (which included pCm). In September 1999, the Chinese Medicine Council of Hong Kong (CMCHK) was established under the ordinance to implement the regulatory measures imposed by the ordinance. The CMCHK, a statutory body, is comprised of Chinese Medicine practitioners, people from the Chinese Medicines trade, academic/research institutions, public officers and also directors of the Department of Health. This balances the interest of the industry and the regulatory body, providing plenty of room for industry involvement in the regulatory framework. The whole idea of self-regulation by the Chinese Medicine industry with baseline intervention from the Department of Health was the right direction because the trade and profession are largely traditional in nature. The Chinese Medicines Board (CMB) which was established under the CMCHK is responsible for regulating Chinese Medicines traders, Chinese herbal medicines and pCm. The three committees under the CMB are namely: The Chinese medicines committee (regulating Chinese herbal medicines and the registration of pCm); The Chinese medicines traders committee (licensing of Chinese medicines traders); and The regulatory committee of Chinese medicines traders (supervising and regulating the professional practice and conduct of the traders). [1]

The application period for transitional registration of proprietary Chinese medicines is from 19 Dec 2003 to 30 June 2004. In section 128 of the Chinese Medicine Ordinance it allows any proprietary Chinese medicine that are manufactured, sold or supplied for sale in Hong Kong on 1 Mar 1999, to apply within the above-mentioned application period to the Chinese Medicines Board for registration under the transitional arrangements. The Board will then issue a transitional registration certificate and a transitional registration number (HKP-xxxxx) to the applicant if the Board accepts the application. This transitional arrangement was made to minimize the disruption to the Chinese medicine trade and to allow traditional knowledge held by small businesses or Chinese medicine practitioners to continue selling their products. The allowance for these pCm products to be transitioned is based on them satisfying safety tests. For other registration requirements such as defining of quality specification and performance of stability testing were also required but a longer timeframe was allowed for the industry to perform these items. [1, 2]

Any proprietary Chinese medicines that are sold or manufactured in Hong Kong after 1 March 1999 will not be eligible to apply for the transitional registration and under its arrangements. These pCms will be processed as a non-transitional registration which means it will be subjected to all the requirements listed in the application handbook on Safety, Quality and Efficacy, depending on its registration group. Due to the large number of applications of both transitional and non-transitional registrations, the Department of Health has issued HKNT-xxxxx numbers to all non-transitional applications, providing basic safety tests reports are submitted. This arrangement gave the Department of Health time to process these enormous numbers of applications, and at the same time allow the applicant to sell these pCm products on the market lawfully even upon the implementation of the mandatory registration of pCm.

**Section 119 of the Chinese Medicines Ordinance**

Section 119 of the Chinese medicines ordinance (CMO) stipulates that pCm must first be registered by the CMB before they can be imported, manufactured or sold in Hong Kong. The CMB has outlined the requirements for the registration of pCm and any persons or organizations seeking pCm registration must fulfill requirements on the safety, quality and efficacy of the product. [3, 4]

This section was not implemented by the government due to various reasons. Mainly due to the fact that the industry needed time to complete the transitional registration of pCm by June 2004; also for the industry to apply for the non-transitional registration for the products that were not eligible for the transitional registration.

**Some of the reasons for the call for mandatory registration of pCm:**

i. Safety recall of some pCm in recent times. [5]
ii. Implementation of UMA(A)O Schedule 4 requires s119 to be implemented first. [6]
iii. The Audit Commission's comment on the Department of Health's slow progress on processing pCm transitional and non-transitional registration applications. [7]

**The current proprietary Chinese medicines registration system**

Below is a brief overview of the basics of the current pCm registration system. Most of the information can be found in the Chinese Medicine Council of Hong Kong website.





**The definition of pCm**

A proprietary Chinese medicine means any proprietary product that is composed solely of the following as active ingredients:

(i) any Chinese herbal medicines,
(ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or
(iii) any medicines and materials referred to in subparagraphs (i) and (ii) respec-tively; formulated in a finished dose form; and known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body. [3]

**Classification category of pCms**

Proprietary Chinese medicines are classified based on the composition, usage and sales history.

There are three categories that pCms can be classified into (fig.1). Namely:

1. Established medicines category
2. Non-established medicines category
3. New medicines category

Under the non-established medicines category there are two sub-categories, "Health-preserving medicines" and "Other medicines". In the "Other medicines" category currently there are only one type of pCm that fall into this category and they are single Chinese medicine granules.

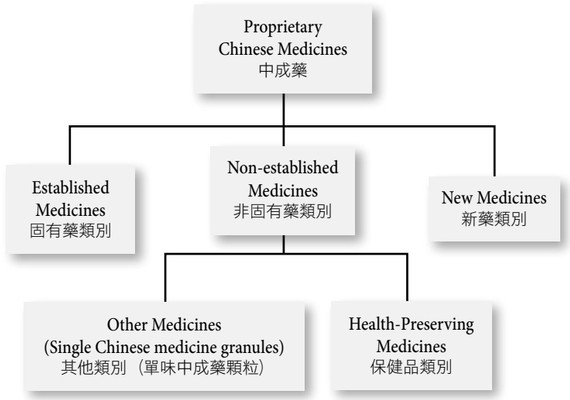


Figure 1. Classification categories of proprietary Chinese medicines

**Registration group of pCms**

There are three registration groups of pCm, Group I, Group II and Group III. These are not to be confused with the classification category mentioned above. Registration groups indicate the types of documentation that are required to be submitted upon application. Different registration groups have different registration requirements and testing that are required, such as chronic toxicity tests, teratogenic tests are not required for all pCm applications.

For pCms under the "Established medicines category" and "Non-established medicines category", applicants may choose to apply for registration in any of the three groups. However, for pCms in the "New medicines category", as their compositions, routes of administration, indications or dose forms are different from traditional use, hence scientific evidence is essential to ensure their safety and efficacy and they must be registered according to Group III registration requirements.

**The difficulties that the industry face in the current system**

The definition of proprietary Chinese medicines is a rather controversial definition. Part of the statement defines pCm as a proprietary product solely containing "any materials of herbal, animal or mineral origin customarily used by the Chinese". [3] This vague definition is a potential for confusion as it is critical for companies to know exactly when a product containing Chinese medicines falls into the pCm category due to legal reasons. The Chinese medicines division of the Department of Health provided a free service for the Chinese medicine industry to submit product information that is intended to be marketed to be classified as either a pCm or a non-pCm. This was a great initiative by the government to avoid the confusion caused by this pCm definition. However, this service was terminated at the end of June 2011, possibly due to the immense workload it caused especially after the implementation of section 119 of the CMO. It is presumed that the Department of Health would issue detailed guidelines and briefing seminars for the industry regarding how to define a pCm in the foreseeable future. Special attention shall be given to part of the industry that is less actively involved with the regulatory environment, for instance a Chinese medicine practitioner being the holder of pCm registration certificates but are only involved with clinical duties day-to-day. Without the classification service from the Department of Health, it is possible for the industry to unknowingly tread on dangerous grounds and face legal prosecution.

As section 119 of the CMO stipulates that all pCm products must be registered before anyone can sell, import or possess such items, the CMB's decision on the products issued a HKP or HKNT number now becomes crucial. [3] Before the implementation of section 119, if the CMB decides that for whatever reason the product registration does not meet their requirement they may reject the application. In this case the owner of the product may take further action to appeal the CMB's decision either through communication with the CMB or take legal action. During the entire appeal procedure the product itself, due to the fact that section 119 was not yet implemented, was allowed to be sold on the market. However if this scenario is to happen today, the owner of the pCm product must activate recall procedures as soon as a notification from the CMB regarding the rejection of their registration is received. It may sound perfectly normal in the sense that any medicinal products rejected by the regulatory agency should be recalled. But in the case of pCm registration in Hong Kong it is entirely different because most of the pCm products on the market at the moment are in the process of registration where information exchange is still taking place.

This is the health conscious era and the baby boomers and even the younger generations have increasing awareness in the importance of a healthy lifestyle. Complementary and alternative medicines and herbal supplementation have become one of the ways to maintain good health. The Chinese medicine industry is a multi-million dollar business and growing. In recent times, different types of new pCm products have emerged. Ganoderma lucidum spores products for instance is one of the more popular pCm products that are available in recent years. Ganoderma lucidum has been used in Chinese medicine for centuries and is recorded in the Pharmacopoeia of the People's Republic of China and many other Chinese medicine texts. The spores of Ganoderma lucidum however has not been recorded in the pharmacopoeia and other texts as a separate entity. Therefore many issues arises when Ganoderma lucidum spores is registered as a pCm. The quality specification of a pCm should be based on some references and in this case this is not available. Using the testing methods of Ganoderma lucidum in the pharmacopoeia is the simplest way, but this has not been proven to be transferable. Different companies may take a different approach when defining their product specification and testing methods. This may result in marked variations in product quality in the same pCm product made by different companies.

**Future developments of the system**

All eyes are on the fate of the Traditional Medicine sector, as tightening of the law increases the amount that the industry is needed to invest into their current and developing products. Companies will be calculating their return on investment and decide whether or not it is worth while registering a pCm product in Hong Kong. On top of that, there has been some noise from the government to make GMP mandatory for pCm manufacturers. This further increases the financial burden of the industry which most of them are small and medium enterprises. Although GMP is the basic requirement for the manufacture of medicines in the world, does this need to be directly applied to pCm products which all of them are over-the-counter products in Hong Kong? There seems to be very little action taken by the industry compared to the enormity of the consequences of this issue.

Another interesting area of the pCm registration is the Department of Health's acceptance of the self-developed identity and assay markers of quality specifications and testing methods of pCm. Those markers and testing methods that are not identical to the Pharmacopaeia are required to submit method validation reports. Although the Department of Health recently issued a letter to the industry, allowing more time until July of 2014 to submit completed method validation reports, the rational behind the choice of the markers itself remains an arguable issue on its own.

As said before, developing pCm in Hong Kong requires significant investment in terms of money, time and knowledgeable personnel. Some firms will very likely decide to avoid their Chinese medicine products to be registered as pCm. Whether these so-called "food" products containing Chinese medicines will cause any health issues to the consumers remains an uncertainty. But one thing is for certain, both the regulators and the regulated are in for a rough ride over the coming years. ■

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**Dr. Frank Kousaie**

*Graduated from Miami University in 1979 then attended graduate school at both Ohio State and Kent State, and then attended Creighton University, Omaha, Nebraska for Medical School.*

After graduation, Internal Medicine internship and Anesthesia residency were completed at the Cleveland Clinic and University Hospital/ Metro General. Following residency, an opening at Robinson Memorial Hospital anesthesia department was taken, and after a few years attained the Chairman of the Department position fulfilling duties of an anesthesiologist and pain management physician. An opportunity at a multi-specialty group practice for anesthesia and pain management opened up and together a freestanding surgery center was built. In 2004, a position at the Crystal Clinic opened for anesthesia and pain management. Currently residing in the Akron area and working at the Crystal Clinic, married, with four children, enjoys golf, woodworking, swimming, and outdoor activities.


# Electroanalgesia in Pain Medicine


**Abstract**

The aim of this article is to provide a brief overview of the history and current applications of electromedicine. It introduces the concepts of electroanalgesia and provides case studies using the NeuroMed Electroanalgesic Delivery System in the treatment of chronic pain.


**History**

To many the whole area of electromedicine may seem like a new development, whereas it is one of the oldest and most documented medical sciences known. Ancient records dating back to 2750 BC depict the possible treatment potential of the Nile catfish - an animal capable of producing a substantial electric current. Doctors in ancient Greece learned that the impulses emitted from electric eels placed in foot baths relieved pain and produced a favorable influence on blood circulation. Scribonus Largus a Roman physician (circa 46 AD) also documented substantial therapeutic results using electrical fish in circulatory disorders and in the management of pain from neuralgia, headaches, and arthritis.

In the 1700's, European physicians took advantage of the new devices being developed at the time. They used the science of static and stored electricity to produce controlled electrical currents and used them exclusively to treat numerous medical problems involving pain and circulatory dysfunction. During that same period Benjamin Franklin was also a proponent of the technology advocating it for many ailments including its use for "frozen shoulder."

By the late 1800's, more than half of all American physicians used some form of electromedicine in their daily practices treating many medical problems, including the management of pain and wound healing. This continued up to the early 1900's when the growing pharmaceutical industry began to push aside the use of electromedicine and discredit its role in 'modern' medicine. So its use in the US declined rapidly and made way for the panacea of pharmacological treatments.

However electromedicine continued to be used Europe and so did its development. In the 1950's, electrical signals were generated that could mimic the electrical impulses which naturally occur in all of our bodies. Using this specific type of electrical current (known as Interferential), medical electrical treatments could be applied directly to the skin comfortably, and the therapeutic effect delivered deep into the tissue.

Electromedical treatment gained wider acceptance in the 1960's when medical researchers Melzak and Wall published the "Gate Control Theory of Pain." [1] These researchers found that certain cells in the spinal cord act as a gate through which pain signals travel to the brain. If you could "overload" these neural transmitter cells with an electrical impulse then you could block the naturally occurring electro chemical pain impulses, thus relieving pain.

The Gate Control Theory provided the scientific background needed to legitimize electromedical treatment and once again repopularize its use particularly in the US. This also laid the foundation for the development of transcutaneous electrical nerve stimulation (T.E.N.S.) in the 1970's. For further reading on this topic the reader is directed to the excellent review by Dr Gordon Gadsby on the Electroanalgesia History and Contemporary Developments. [2]

**Technology Overview**

**TENS Therapy (Transcutaneous Electrical Nerve Stimulation)**

Application for topical stimulation is via two electrodes. The standard unit uses an amplitude modulated electric current which depending on its frequency either/or produces a counter-irritation signal or stimulates the production of endorphins the bodies naturally occurring pain reliever. The frequency range is typically in the 1- 250 Hz (or pps) and most units are the small battery powered type that are prescribed by a variety of medical professionals or now a days more commonly purchased directly by the patient. They are used for many applications in the management of acute pain conditions.

**Interferential Therapy (If)**

Four electrodes are used for deep tissue stimulation and are placed on the skin in such a way that the two currents produced cross directly over the affected area. Where the two currents meet, they actually 'interfere' with each other; hence the name "interferential". It works on the principle that two overlapping medium frequencies produce a lower frequency current which can penetrate more comfortably deep into the tissue. Typically the frequency ranges is 1-250 Hz but it can vary from manufacturer to manufacturer, but the basic therapy ranges are fairly consistent i.e. 80Hz to 120Hz.

This mode of therapy is routinely used by Physical Therapists (Physiotherapists) for pain relief associated with muscle strains and spasm, helping to reduce muscle weakness and increase blood circulation.

**Electroanalgesia**

In the last twenty years the field of electromedicine as expanded to include a technique called Electroanalgesia. For analgesia to be produced by electrical means a high frequency digital signal is needed with a speed so high that a complete depolarization of the nerve membrane occurs.

(See Fig 1) The Matrix Electroanalgesia device from NeuroMed incorporates a High Definition frequency generator (HDfg) capable of producing a signal of 8,000-10,000 pps. The computer assisted programs within the device continually varies the carrier frequency, and the physician is also able to change the intensity (dosage) of the current. The theory is that this complex digital electrical system is changing so often that the nervous system cannot "learn" or accommodate to the administered signal.

The clinical effectiveness of Electroanalgesia is well documented in the paper by Richard Schwartz MD [3] on Electric sympathetic block he states that "Individual and multi-center studies have both shown at least a 75% relief in pain in three quarters of the patients treated. This compares favorably to studies assessing the effectiveness of chemical block where 60% of those treated reported pain relief ". He goes on to state that, "while there are no long-term studies on the effectiveness of chemical block - at least one study of electrically induced block reported 68% having retained some relief at one year follow up". For a more in depth look at the theory of Electroanal-

gesia the reader is directed to the paper by Dr Michael Gramazio PhD titled Electro-analgesia Medicine Background/Theory available in a Clinical Summarization Report from NeuroMed Inc.

The frequency range of the NeuroMed device is 1-10,000 pps and is applied to the skin with two or four pads depending on the condition to be treated. It is used by physicians in the US for the treatment of many of the most common acute and chronic pain conditions seen in daily practice.

**Conclusion**

A Cost of Pain Fact Sheet from the American Chronic Pain Association[4] makes stark reading. It states that the World Health Organization estimates that 20% of the world's population has some form of chronic pain. It further states that the annual total ( US ) of both direct and indirect costs for chronic pain are estimated to be as high as $294.5 billion per year, with back pain alone estimated to cost in excess of $100 billion per year. And according to the pharmaceutical industry own data, pain is a $13.2 billion market.

This suggests that the costs of health care for patients with chronic pain might well exceed the combined costs of treating patients with coronary artery disease, cancer, and AIDS. [5]

Not only is there a high incidence of chronic pain and its associated costs, there is also the risk to patients involved with the over use of OTC and prescription pain killers. In the 2006 the US Department. of Health and Human Services reported that 5.2 Million American where addicted to pain killers.

The use of Electroanalgesia in the US as grown rapidly over the last ten years. It is now seen as a routine treatment option in many leading clinics and teaching hospitals. It can provide a safe, effective treatment option for patients with long term intractable pain.

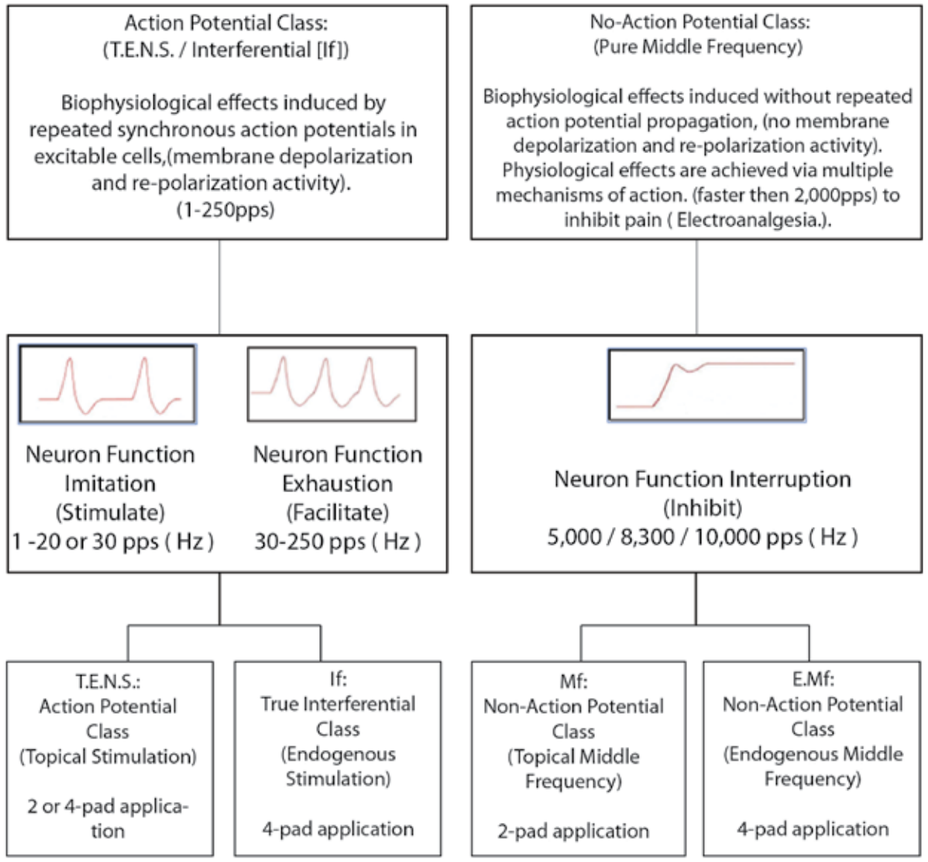


**Figure 2. pps - pulses per sec. (or Hz )**

## Degenerative Disc Disease, Degenerative Bulging Discs, Severe Spinal Stenosis, Spondylolisthesis, Back Pain and Radicular Leg Pain

A 73-year-old man first presented to the pain clinic in July of 2008. His initial complaint began with a muscle cramp in his left calf. After several months this pain slowly progressed up the back of his leg and into his left lower back. Before this episode of left calf pain, he had had no back pain and no radicular pain. Several physicians saw him; he was initially given NSAIDS, steroids, and the admonishment to "take it easy". Before his coming to the clinic, his pain began to increase to the point that he had numbness in his left foot. He described his pain as constant, with a dull ache in the middle of his back, radiating pain with both a burning sensation and the numbness. Standing or walking aggravated his pain. Resting made his pain slightly better. Additionally, he noticed that when walking in a grocery store he was leaning on a grocery cart "like an old man". Pain scale on initial visit ranged between 5/10 and 8/10.

Physical examination on initial visitation showed that he was able to come to a standing position unassisted, but walked bent forward, and favoring the left leg. He had difficulty standing on both his toes and his heels. Lumbar range of motion was decreased with forward flexion causing slight relief of his pain and extension making his pain worse. Deep tendon reflexes were bilaterally equal. There were no signs of abnormal reflexes. His sensation was decreased but not in a dermatome pattern. Motor strength was bilaterally equal except some breakaway weakness noted on the foot flexors of the left side. Seated straight leg raise was positive on the left side. His heart was regular, his lungs were clear. His back showed no signs of swelling, no redness, and no infection. He had a well-healed scar from an old pilonidal cyst.

Risks and benefits of multiple therapeutic interventions were fully discussed. He was intrigued by the non-invasive nature of electro-analgesic treatments. Because of concomitant medical diseases including hypertension, hypercholesterolemia, non-insulin-dependent diabetes mellitus and hypothyroidism he decided to go with the non-invasive electro-analgesic epidurals.

Initial treatment with electro-analgesic epidurals began and he quickly had pain relief. After the final treatment, he noticed a decrease in his left leg pain from the original pain scale of over 5/10 to a constant 2/10. Unfortunately, his back pain and muscle spasm pain was not relieved dramatically. Following these treatments, a series of electro-analgesic physical medicine treatments was completed and at that point he had almost no leg pain and his back pain was a 1/10.

He has returned to this clinic only sporadically over the last two years for occasional treatments including trigger points, acupuncture, and bringing his wife in for a complete series of electro-analgesic epidurals. ■

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**Tammy So**
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Previously she worked as the Nursing Head of Infection Control Branch in Centre for Health Protection during its early set up post SARS.

# Capacity and Culture Building in the area of Infection Control

Infection control in health care settings was given much attention after the SARS outbreak in 2003, plans were developed to tackle communicable diseases and environmental health hazards in a more strategic way.

Strategies were developed to strengthen Hospital and Community together with organization's capacity and enhance the culture building in the area of infection control so as to improve the health of the community and staff of healthcare settings by promoting excellence in the practice of infection control.

**Introduction**

In recent years, the emergence of new communicable disease such as Severe Acute Respiratory Syndrome (SARS) and swine flu as well as the global resurgence of the highly pathogenic avian influenza H5N1 posed unprecedented challenges to the entire health care system in Hong Kong. The setting up of a new focal point as the Centre for Health Protection (CHP) in Hong Kong so as to strengthen its capacity to prevent and control communicable diseases with arrangements for surveillance, the development of effective infection control as well as having a pivotal role in promoting training and research (SARS Expert Committee, 2003, Hospital Authority, 2004).

Strategies were developed to strengthen the community together with the organization's capacity and enhance the culture building in the area of infection control so that everybody, especially those working in healthcare settings, are knowledgeable about the risk aspects of their work and the appropriate protective measures necessary to maintain their own, their colleagues and their patients' safety.

**Capacity building**

It refers to activities that improve an organization's ability to achieve its mission or a person's ability to define and realize his/her goals or to do his/her job more effectively. For organizations, capacity building may relate to almost any aspect of its work: improved governance, leadership, mission and strategy, administration (including human resources, financial management, and legal matters), program development and implementation, fundraising and income generation, diversity, partnerships and collaboration, evaluation, advocacy and policy change, marketing, positioning, planning, etc. For individuals, capacity building may relate to leadership development, advocacy skills, training/speaking abilities, technical skills, organizing skills, and other areas of personal and professional development (Paul, 2000).

There is a large range of capacity building approaches --a continuum-- that includes peer-to-peer learning, facilitated organizational development, training and academic study, research and publishing.

Among the dimensions of capacity building (Paul, 2000), focus will be drawn towards human and institutional capabilities of which training and skill development are at the core while cognitive and practice dimensions related to transfer of knowledge and development of analytical skills in education and training, applying and adapting knowledge will also be looked after.

Capacity building also defined as an approach to 'the development of sustainable skills, structure, resources and commitment to health improvement in health and other sectors to prolong and multiply health gains many times over'. Capacity building activity may be developed with individuals, groups, teams, organizations, inter-organizational coalitions or communities leading to greater capacity of people, organizations and communities.

According to the framework for capacity building to improve health developed by the NSW Health Department (2001), there are key action areas to be addressed. In order to develop infrastructure, enhance program sustainability and foster problem solving capabilities, five key action areas were identified namely: organization development, workforce development, resources allocation, leadership and partnership.

Capacity building has been applied to interventions aiming to produce sustained change at levels ranging between the individual and entire nations (Sajiwandani, 1998). There are four main approaches and within each of these a range of strategies would appear to have potential for capacity building.

**Top-down organizational approach**

Building and sustaining capacity requires organizational capacity as well as the expertise of individuals (Rist, 1995). Training programs must be facilitated within organizations through decision-making processes where ensure that staff are able to participate. Organizational infrastructure also contributes to capacity development. However, co-ordination and planning are often necessary to ensure resources, e.g. personnel, equipment and facilities can be mobilized when required (Poncelot and de Ville de Goyet, 1996), and quality assurance systems may be necessary to determine whether an organization is performing optimally or to assist it to learn and improve (Muller, 1996). Restructuring which enables organizations to be more responsive to existing and emerging health issues may also result in enhanced capacity.

**Bottom-up organizational approach**

The development of technical expertise for organizations so that they can plan, implement and evaluate appropriate health programs and measures (Meissner et al., 1992; Schwartz et al., 1993). Underpinning this approach is the premise that developing a core of well-trained individuals decreases reliance on external consultants and increases local capacity to sustain efforts involve further training in a health specialization (Chalmers, 1997), broadening the skills of generalist health workers can also have strategic benefits (Poncelot and de Ville de Goyet, 1996). This approach focuses on training members of the organization and providing them with skills and knowledge which is beneficial to the individuals concerned the organization and the wider community:

**Partnerships**

The development of partnerships between organizations or groups of people who might otherwise have little or no working relationship is another approach to building capacity (Chavis, 1995). This approach is based on the assumption that providing possibilities for the two-way flow of knowledge can lead to partnerships through which the resources required to plan and implement health programs may emerge. This is especially so if prominent members of the community, including community leaders, community advocates and representatives, as well as health professionals who can facilitate health promotion efforts, are involved (Wickizer et al., 1998).

A varieties of partnership approaches to capacity building which could happen within organizations, but which could involve overcoming barriers as permeable as the boundaries of organizations would involve partnerships between different professional groups who may previously have had little interaction. Such interactions can lead to individuals gaining familiarity with new approaches and concepts and result in changed understandings, attitudes and practices (Kengeya-Kayondo, 1994; Stephenson and McCreery, 1994) as well as learning the limitations of one's own professional discipline (Kamara, 1997).

**Community organizing approach**

Perhaps the most ambitious approach that raises people's knowledge, awareness and skills to use their own capacity helps them better understand the decision making process; to communicate more effectively at different levels; and to take decisions, eventually instilling in them a sense of confidence to manage their own destinies (Schuftan, 1996). Thus, capacity building aims to transform individuals from passive recipients of services to active participants in a process of community change (Finn and Checkoway, 1998).

**Capacity & Culture Building demonstrated in the area of Infection Control**

In order to put in extra effort in building up professional expertise with a view to strengthen the Hong Kong's ability to combat any emerging and re-emerging communicable diseases, priority should be focused on capacity and culture building related to infection control. It is about the development of sustainable skills, structures, resources and commitment to health improvement to prolong health improvement leading to greater capacity of people, organization and communities to promote health as what described under capacity building (NSW Health 2001). Before relevant strategies are drawn towards such direction, a better understanding over capacity building is needed.

Capacity refers to the skills and capabilities of individuals (Philbin, 1996). Capacity also refers to an organization's ability to achieve its mission effectively and to sustain itself over the long term. Goodman et al. (1998) described capacity as the ability to carry out stated objectives while in health sectors, it played a prominent role in securing health system performance. LaFond et al. (2002) also pointed out that capacity played a critical role in the sustainability of health outcomes and in reducing reliance on assistance over the long term. Health care sector was increasingly relying on capacity building to enhance its overall performance. In order to improve health outcomes with strengthening service delivery, common strategies including expanding service provision (access), marketing services to target groups (demand creation) and raising standard of quality of care are employed.

**The Establishment of Centre for Health Protection**

The Centre for Health Protection was the newly set up organization under the Department of Health of the HKSAR which serves as a centre of excellence in disease prevention and control. Its establishment marks an important milestone of the Government's effort in enhancing its public health system to address new challenges and protect Hong Kong from communicable diseases and other public health hazards. The Mission of the CHP is to achieve prevention and control of diseases in Hong Kong in collaboration with local and international stakeholders.

The priorities are to focus its efforts on surveillance, infection control, risk communication, outbreak management, preparedness and contingency planning as well as epidemiology training and applied research.

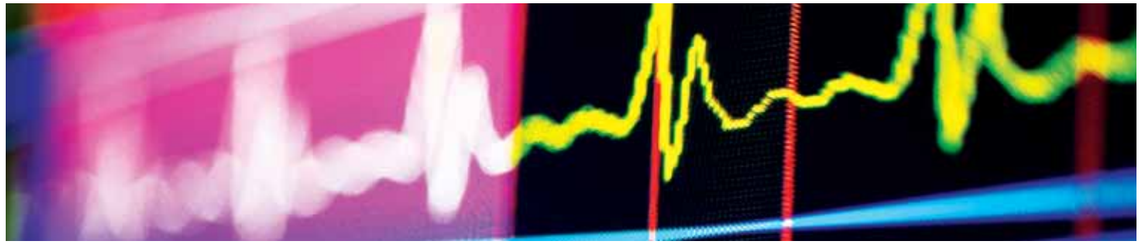
To promote the excellence in the practice of infection control in Hong Kong, an Infection Control Branch (ICB) was set up under CHP to foster an infection control culture to reduce endemic infections and minimize spread of disease outbreaks in institutions in Hong Kong by promoting excellence in the practice of infection control accomplish through five measures:

**The Establishment of Centre for Health Protection**

- Training & professional development;







- Standardization of surveillance methods on hospital outbreaks & endemic infections;
- Benchmarking & quality management in infection control practices
- Risk assessment & communication;
- Research on evidence-based infection control practice.

**Areas of work committed are:**

- Develop, promulgate and evaluate best practices in infection control at health care and non-health care settings.
- Coordinate, facilitate and support training in infection control for all levels of health care staff and personnel in health care settings.
- Support epidemiological investigation of unusual infections and nosocomial infections in hospitals.
- Conduct surveillance on infection hazards in health care and non-health care setting.
- Develop infectious disease management protocols; and
- Support quality management of infectious disease with a public health perspective.

**Through provision of infection control advice, promulgating best practices and evaluating infection control measures are:**

- Public hospitals and private hospitals of different scales including acute, extended care, convalescence and rehabilitation.
- Community institutions including long term care facilities, residential care home for elderly and mental disables.
- Government departments
- Public

As no single approach will bring about final success, strategies were employed by ICB with mixed approaches to work on the enhancement of infection control in Hong Kong. Workforce development (both internally and externally) was started with as a mean to build capacity according to the top down and bottom up organizational approach followed by the partnership with professional bodies and community. ■

## Strategic areas and core functions

**Seven strategic areas (QUALITY) were defined to strengthen core functions and facilitate communication in its portfolio on infection control:**

| Strategic areas | Core functions |
|---|---|
| **Q**uality improvement | • To support quality management in inflection control practices with a public health perspective; |
| **U**tilization review & monitoring | • To monitor standards of hospital hygiene<br>To conduct surveillance on infection hazards in health care and non-health care setting |
| **A**lignment of services | • To standardize surveillance methods and infection control measures on hospital outbreaks and endemic infections |
| **L**eaning organization | • To build a network of specialists in infection control, infectious disease management and public health and share experience |
| **I**nformation sharing & skill exchange | • To develop and promulgate infectious disease management protocols<br>• To ensure rapid risk communication on infection control topics to clients |
| **T**raining & research | • To coordinate, facilitate and support training in infection control for all levels of health care staff and personnel in health care settings<br>• To promote evidence-based research |
| advisor**Y** | • To develop, promulgate and evaluate best practices in infection control at health care and non-health care settings;<br>• To support epidemiological investigation of unusual infections and nosocomial infections in hospitals |

## Strategies on Capacity Building (Workforce Development)

Workforce development refers to a process initiated within organization and communities, in response to the identified strategic priorities of the system, to help ensuring people working within can have abilities and commitment to contribute to organizational and community goals (NSW, 2001). Related strategies represent an important component of building the capacity of an organization or community to bring about effective and sustainable changes in work practices.

**Internal Workforce Development**

In order to strengthen the internal workforce which is constituted from a group of newly recruited professional & administrative staff, several approaches were adopted:

**( I ) Organizing a team building workshop:**

With the participation of all staff to enhance mutual understanding among staff and to develop a culture of teamwork creating a climate of collaboration, it helps to enhance understanding of each other and facilitate cooperation at workplace as well as building networks.

As organization is viewed as an open system that continuously interacts with its immediate environment, examination of both internal and external factors is crucial to influence the success of an organization. Internal factors like the value and culture of the organization, standard of practices, staffs' morale and commitment all directly affect the service quality. Difference in value systems, culture and belief will create gap and tension between staff groups. Teams provide a vehicle for enabling organizations to respond to changing working environment effectively. The total quality management approach also emphasizes processes of continuous performance improvement achieved through multifunctional and multidisciplinary teams and fully participating staff (Dionne, et al., 2004). By working through team, people who possess different skills and assume different responsibilities will

then work together towards a common goal with combined effort as a team.

Multidisciplinary or interdisciplinary teams, value differences between various professional groups, can develop strong and complementary work patterns necessary to deal with complex health-related problems. Individual member outputs together with the commitment and motivation each one brings to the team contribute to the achievement of team outputs and used collectively to measure team productivity. In return, the organizational performance will heavily be enhanced by the attributes of members as well as the shared culture and value.

Team building improves coordination efforts of members result in increasing team performance with improved trust and openness. Such workshop uses high interaction group activities to increase trust and openness among team members. The activities include goal setting, development of interpersonal relations among team members, role analysis to clarify member's role and responsibilities and team process analysis (Robins, et al., 2004). Members can define the goals and priorities of the team, evaluate the team's performance and identify potential problem areas with free interchange of views. Though team building, dysfunctional conflicts between groups solved together with change in attitudes, stereotypes and perception. Instead, alternate actions will be formulated to improve relations leading to organizational success.

After the team building workshop, participants knew each other well and better working relationship would be established so that co-operation and understand among the group could be enhanced.

**( II )Organizing a strategic planning workshop:**

Senior managers participated to work out direction and strategic plans on quality improvement for the coming 3 to 5 years.

Strategic planning serves a variety of purposes in organization (McNamara, 2003) including to:

1. Clearly define the purpose of the organization and to establish realistic goals and objectives consistent with that mission in a defined time frame within the organization's capacity for implementation.
2. Communicate those goals and objectives to the organization's constituents.
3. Develop a sense of ownership of the plan.
4. Ensure the most effective use is made of the organization's resources by focusing the resources on the key priorities.
5. Provide a base from which progress can be measured and establish a mechanism for informed change when needed.
6. Bring together of everyone's best and most reasoned efforts have important value in building a consensus about where an organization is going.
7. Provides clearer focus of organization, producing more efficiency and effectiveness.

Through strategic planning, a clearer direction and strategic way of implementation can be worked out:

- The viability of program in a broader organizational and environmental context can be maintained and enhanced.
- The organization's internal growth and development in relation to external forces can be determined.
- As a proactive problem-solving behavior directed externally at conditions in the environment can be adpted.
- Organization achieve success with its mission while anticipating future changes in the environment.
- Vision of the future that may include intuition, opinions, qualitative information is developed.

**(III) Establish clear infrastructure and reporting mechanism.**

Clear role delineation and job allocation for individual member help to maximize their contribution and minimize role conflict. Staff will be grouped into various teams taking charge of different nature of jobs according to their expertise such as surveillance, training, outbreak management and clinical guideline formulation etc.

**External Workforce Development**

I. With the set up of ICB which committed to develop, promulgate and evaluate the best practices in infection control, there is still a need to understand the present position of infection control capacity in public hospitals for long term strategic planning (Zoutman, et al., 2003).

An infection control capacity review survey and need assessment in Hong Kong was organized and conducted to obtain baseline understanding over the existing workforce in the field of infection control in Hong Kong focusing on hospital services, including public and private setting before planning for measurement to strengthening of knowledge, skills or even staff requirement for infection control of healthcare facilities (O'Boyle, et. al., 2002).

A total of over fifty hospitals were involved in the survey including all private hospitals and other hospitals under Hospital Authority to assess distribution of manpower strengths, stock take the types of surveillance programme conducted and identify the training needs on infection control in these hospitals.

- Information obtained including: number of infection control nurses and infection control officers (mainly microbiologists & physicians) working in the field, their academic qualifications and training profile, further training needs and areas of focus or to be developed, etc..
- The targeted manpower ratio for infection control nurse in acute hospital setting was reviewed.
- Infection control practices activities performed by the infection control personnel and the surveillance program conducted were also reviewed.
- Results showed that all respondents held bachelor degree and had attended at least one recognized infection control training courses. Surveillance and epidemiological investigation, as well as preventing and controlling the transmission of infectious agents were the most frequently performed activities occupying more than 30% of IC practitioners' time.
- Professional training was needed to build up capacity in infection control & to empower existing staff in the field in view of the relatively young experience.
- Epidemiology and statistics were perceived as the highest priority training needs.
- Based on the training needs identified, appropriate infection control training programmes for healthcare staff will be tailor-made to strengthen the training capacity which is of paramount importance to ensure a safe infection control practice in both hospitals and community.

II. To set up and maintain a sound mechanism for pooling and sharing of professional knowledge and expertise over infection control to provide a wide range of opportunities to learn about infection control via:

- Update and promulgate guidelines over infection control to health sectors and community institutions to upkeep their awareness, knowledge and skills and facilitate the alignment of practice across healthcare settings.
- Provide easily accessible learning materials on infectious disease management and infection control via development of e-learning programmes.
- Provide regular website updates as webpage maintenance over infectious disease courses and latest information update.
- Enhance preparedness for and response to major public health emergencies by:

• Provide infection control advice input on various guidelines and contingency plans of hospitals and overnment departments.
• Liaise with HA cluster hospitals on detailed mobilization plan, surge-capacity and division of services.
• Organize or participate in hospital infectious disease drills.

- Organize regular infectious disease and infection control forum with professional groups, institutions and non-government organizations for knowledge and experience sharing as well as for communication propose. e.g. Monthly infection control forum for Infectious Disease, Clinical Microbiology and Public Health specialists from both private and public hospitals to join in. Monthly topical seminars for healthcare workers in public and private sectors.
- Maintain and extend professional competency of practitioners working in infection control, epidemiology and infectious disease specialty through overseas training or local training via seminars, workshops, commissioned programmes, etc..
- Strategic training programmes had been set up to meet specific capacity needs: Infection Control training has been provided to healthcare professionals, including infection control nurses and officers, general practitioners, officers of the Auxiliary Medical Service (AMS), healthcare related personnel eg St John Ambulance Brigade, Allied Health staff and students.
- Develop Infectious Disease and Infection Control website and e-learning programmes for professional Infection Control training to facilitate off classroom training.

III. Expand international networks by establishing collaborative arrangements with other health authorities and agencies including visit programmes and international symposiums.

IV. To improve the preparedness for health protection emergencies:

- Develop teaching aids as pamphlets, leaflets or video to promote infection control for public.
- Launch large scale public education programs or increase publicity via health promotion campaigns on important health issues related to infection control to increase awareness and facilitate infection control culture building.

V. To provide professional support and strengthen supervision system by development of cluster liaison person to build network with individual hospital cluster and provide off-site but timely support and infection control related advice upon consultation. During emergencies such as infectious disease outbreak in hospital, liaison nurse will visit corresponding hospital to provide onsite support to tide over crisis.

VI. To enhance performance management, indicators will be developed to assist performance review both over professionals and systems. Infection control related performance indicators including infection rate e.g. surgical site infection, ventilator associated pneumonia, central line sepsis, together with other data such as sharp injury rate, outbreak frequency, etc will be developed and closely monitored with the help of information technology systems for data capturing, analysis and dissemination.

**Strategies on Partnership Building**

Public awareness makes a significant difference between success and failure in health protection. Better understanding of environmental health risks will not only enable public to take care of themselves but also to co-operate with and contribute to government's preventive measures. The development of effective partnerships to address health problems is important because many of the determination of health are outside the realm of health services. Sharing planning and / or delivery of work across different organizations, involve different professional traditions and skills. Building capacity requires action from within organizations as well as between them. Hence, partnership and collaboration with other organizations help capitalize unique strengths of individual organization to work together to achieve shard or related goals to maximize the effects and benefits of the outcome. Leadership giving a clear direction and strategic vision are essential ingredients of success as is facilitating, supporting and empowering staff to develop meaningful partnership. Partnership and collaboration with local and international stakeholders are the cornerstones of the work in health protection. Locally, a close liaison with HA, healthcare professionals in the private sector, NGOs, the academia as well as community and district organizations will be maintained. On the regional front, ICB continues to foster the tie with the health authorities in the Mainland, Macao and other places. Internationally, the continual liaison with WHO and major health protection agencies and authorities to explore areas of further collaboration will be maintained.

**Related strategies targeted towards both professional bodies and public:**

• Enhance communication through better networking and liaison with public and private practitioners to have shared value over organizational objectives.
• Set up working groups, task force or committees to work with concerned departments and stakeholders to improve collaboration and enhance understanding and acceptance.
• A scientific advisory structure comprising of a Board of Scientific Advisors and Scientific Committees has been set up to advise on public health management of specified group of infectious diseases or work on specialized areas to support disease control. This collaborative arrangement has brought together knowledge and experience from across disciplines and institutes to formulate strategies and actions for communicable disease control.
• Close alliances with the Mainland, Macao and international organizations including the World Health Organization (WHO) to facilitate regular exchange of up-to-date information and strengthen communication.
• Setting up of operation panels with representatives from hospitals, universities, and central committees working on specific focus areas e.g. immunization and vaccination, vector borne / blood borne disease management, infection control and occupational safety and health, etc..
• Liaise with relevant government departments and organizations in different sectors and provide training to their staff. Staff from Hong Kong Police Force, Fire Service, Auxiliary Medical Services, Agricultural & Fishery Department, Social Welfare Department, etc..
• Establish communication channels with external professional bodies such as Hong Kong Medical Association, Doctors' Union, Infection Control Nurses' Association, universities, etc. e.g. regular annual tripartite meeting with Pearl River Delta Region including Macau, Hong Kong and Guangdong.
• Enhance risk communication network with neighboring health authorities.
• Publish health reports and disseminate useful health information continually through websites and various channels or multi-media means to increase transparency of work under ICB to gain support and cooperation.
• Strengthen regular communication with various sectors of the community including District Councils and local health care agencies by involving in health promoting exercise and public education campaigns such as the hand hygiene campaign to keep the community abreast of health risks.

As a result, specific training packages were designed for members of governmental departments, organizations, associations, groups of health care professionals and public to enrich their knowledge and skills relating to infection control with detection and management of communicable diseases. Such training package was delivered in the form of lectures, seminars, workshops, forum, practical sessions and visits.

Infection control liaisons and co-ordinators were also appointed internally for self monitoring and communication in governmental departments and auxiliary services.

**Managing Change and Organizational Culture**

After the SARS attack in 2003, the perception towards importance of infection control changed to deal with growing expectation from health care

and public has to work within the existing infrastructure in the health care arena as well as building and enhancing the culture to be set in the area of infection control.

An organization's culture is multi-layered, consisting of assumptions, values, beliefs, norms and behaviors that have developed gradually and may have become relatively unconscious. When there is a need to change the way an organization works, it may become necessary to make this implicit set of beliefs explicit as they may no longer be consistent with the actions and behaviors that are now required (Bridge, 2003). Change is critical to the survival of organizations especially with increasing competition and heightened customer expectation creating constant demands for ways to approach problems and develop solutions.

It may be relatively easy to introduce new technology, work processes and structure, however, getting people to enthusiastically support such change is a more complex and difficult task. Changes may be required to build a culture that supports the new mission, goals, strategies and practices increases the probability of success exponentially. This necessarily involves a large cross section of the organization in assessing the current system of norms and beliefs, determining what changes are needed, and designing an implementation plan.

The health care system needs a coherent set of goals and values to which all levels of the organization subscribe to create an environment which is open and participative, where ideas and good practice are shared and where education and research are valued. This requires a change in culture at all levels including: leadership commitment; consideration of the needs of patients/consumers, development of a 'quality culture' that emphasizes empowerment, flexibility and teamwork; a focus on system improvements; reliable, valid and objective information necessary for decision making is available at all levels; effective feedback processes; monitoring and evaluation of performance on a continuous basis; as well as commitment to provide training and education to all staff.

It begins with the working of multidisciplinary teams with cultural shift moving from awareness of the problems, through gaining a commitment and agreement to change, to implementation of new ways of working. To change cultural attitudes is both difficult and slow to achieve. Another important individual element in signaling the direction for an organizational culture change is strong leadership.

Leadership that is visibly supportive in everyday practice is essential to shift traditional culture in health care to such new paradigm. It is also the role of management to create desirable cultural and organizational conditions for ongoing cycles of organizational learning such as: benchmarking and quality improvement, formal professional development, mentoring and action learning, innovation and evaluation, etc. A strong infrastructure, representative and flexible enough to respond to changing needs and requirements, is required to enable fast and immediate access to those who allocate services and resources. It facilitates timely two-way communication between service users and providers.

Great efforts were input in the health care system as well as in community level to bring about changes in the area of infection control. Numerous deliverables were noted including policies and guidelines setting, communication and infrastructure building, human resources upgrading, education and training, facilities and set up, etc..

**Measuring Capacity Building**

Quantitative measures of network density or involvement (e.g. the number of people or organizations) are appropriate for evaluating partnerships and community organizing approaches to capacity building. More appropriate to evaluate whether capacity building processes have been implemented, and the impacts which have resulted from these. Firstly, the actual strategies for building capacity need to be specified and impact measures developed. The measures of capacity building were primarily those outcomes in new or changed processes (Gillies, 1998).

Secondly, measures adopted need of organizational and community processes, with the use of a qualitative case study approach for evaluation (Gillies, 1998). Thirdly, because capacity building tends to be an evolving process, different measures may be required at different stages of the intervention (Hawe et al., 1997). Fourthly, additional measures of capacity may need to be developed as the intervention evolves.

Organizational effectiveness will also serve as a long termed outcome of these capacity building strategies relating to the capacity of an organization to sustain the people, strategies, learning, infrastructure and resources it needs to continue to achieve its mission.

**Conclusion:**

Infection control in health care settings was given much attention after the SARS outbreak in 2003 with the setting up of designated organization to develop and promulgate the best practices of infection control in health care setting and in the community. Plans were developed to tackle communicable diseases and environmental health hazards in a more strategic way. To facilitate the promotion of best infection control practice and to prevent and control nosocomial infections, surveillance mechanisms, evidence based clinical guidelines, partner relationship with Hospital Authority and ongoing infection control training activities together with the conducting of applied research to fill scientific gaps and participating in public health emergency planning and drills.

As prevention & control of communicable diseases is equally important in maintaining a healthy environment and population in Hong Kong, public awareness and community support are also essential in making Hong Kong a healthier environment.. Emphasis on community liaison work, publicity as well as public educational programmes with a view to raising Hong Kong residents' hygienic standard and soliciting support of the community is crucial to enhance such culture building.

After the implementation of strategic drives in capacity building at micro- and macroscopic level in the area of infection control, a well designed maintenance programme is to be considered to uphold its sustainability as well as keeping the momentum and spirit of the personnel involved. In order to keep such momentum and enthusiasm, one has to think about the sustainability of the changed cultural attitudes especially when the impact or the painful experience / memories of SARS eventually die down or when endemics become epidemics.

The next focus will then be on something fundamental to be promulgated to general public including some basic hygiene factors such as the importance of hand washing through which infection control concept can be built on culturally.

With the great effort and strategic move towards capacity building paid by infection control, a resilient health protection system will be built and sustained by a well trained workforce, solid research expertise, an informed community, good working partnerships among agencies and sound collaboration with the regional and international communities. Such preparedness keeps Hong Kong vigilant and ready to face the threat from a wave of any emerging and re-emerging communicable disease attacks and different challenge in future.

Nowadays, the awareness on infection control has been brought up, not only among health care personnel but also fir ordinary citizens. Instead of being a health care setting or hospital issue, infection control is now a public concern and become everybody's business.

Together with the effect of culture building involving organization and community, infection control will eventually become everybody's business while keeping Hong Kong far from, if not free from, possible communicable diseases attack. ■

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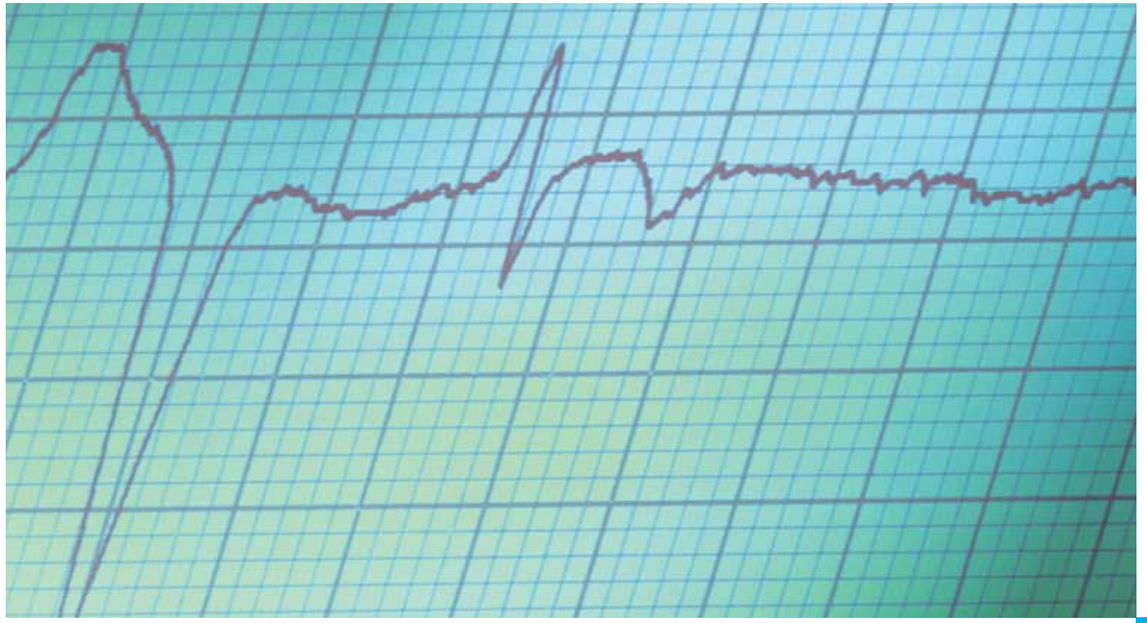


**Dr. Yi Jin**
Dr. Yi Jin received his medical degree from the Shanghai First Medical University in China in 1983 and completed his residency at the Shanghai Mental Health Institute in 1986. Following his fellowship training in consultation-liaison psychiatry at the University of California, Los Angeles, he joined the faculty of the Department of Psychiatry and Human Behavior at the University of California, Irvine (UCI), in 1987. In the past 24 years, Dr. Jin has been focused on neuroscience research in mental disorders. He currently serves as a founder of Neosync, Inc., the founder and CEO of the Brain Treatment Center, and a clinical professor in psychiatry at UCI.

# rTMS Treatment for Autism

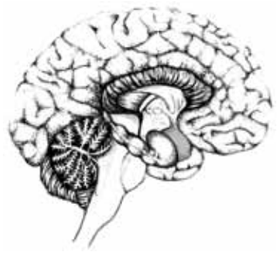
**Introduction**

Transcranial magnetic stimulation (TMS) is a novel treatment for neuropsychiatric disorders.

It operates on the physical principle of electromagnetism. Current passed through a wire coil generates a magnetic field, which is able to penetrate the scalp and skull to reach the surface of the brain. The magnetic field then induces a secondary electric current that affects local neurons (Opitz et al., 2011, Hallett, 2000). This effect also extends to distant sites through neural networks, affecting neuronal behavior accordingly (Lisanby & Belmaker, 2000).

When TMS is pulsed repetitively, the resulting electric current has the same repetition rate as the magnetic field. This pulsing stimulation, known as repetitive TMS (rTMS) can be used at different frequencies to influence and entrain brain waves (Jin et al. 2006b, 2011; Thut et al., 2011) with varying effects, depending on the frequency chosen. Investigators have described effects of rTMS on brain waves as measure by electroencephalogram (EEG; Hamidi et al., 2009) in which rTMS modulates cortical excitability and inhibition (Pascual-Leone et al., 2000) based on the chosen parameters of stimulation.

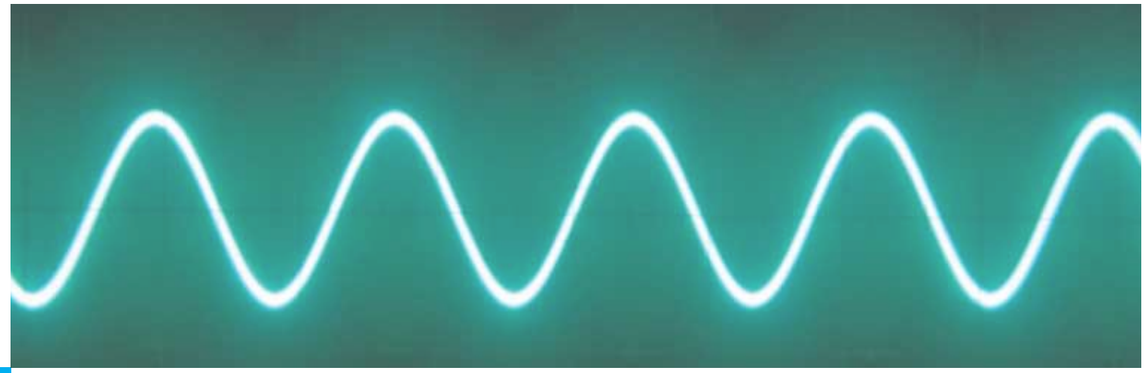
Patients with different mental disorders, including autism spectral disorder (ASD), often have disrupted neural synchronization compared to controls (Dinstein et al., 2011). The neural modulation effect of rTMS has a potential to resynchronize the brain activity and therefore may be used in treating mental disorders, including autism (Dlabac-de Lange et al., 2010; Jin et al., 2006b, 2011; Padberg & George, 2009; Zwanzger et al., 2009). In fact, stimulation at specific frequencies has been shown to not only influence brain waves (Sokhadze et al., 2010; Thut et al., 2011) but to affect ASD symptoms (Dang et al., 2009; Enticott et al., 2011). In this case report, we would like to describe a new personalized TMS protocol that has shown to be clinically effective in treating ASD.



**EEG in ASD**

EEG oscillations are representative of synchronized neuronal activity, with variation of activity reflecting different states of the brain. EEG waveforms are complex and can be decomposed into a series of consecutive frequency bands (δ: ≤4 Hz, θ: 4-8 Hz, α: 8-13 Hz, β: 13-30, and γ: ≥ 30 Hz) through quantitative analysis. The presence of activity in each of these bands can be used to further understand the current brain state.

Of specific interest in EEG is the alpha (α) wave, a cortical oscillation falling between 8 and 13 Hz that is evident while the eyes are closed. The alpha wave not only is associated with an individual's degree of relaxation but also plays a critical role in cognitive function (Hamidi et al., 2009; Jin et al., 2006a). Enhancement of alpha activity with rTMS has been linked to the reduction of positive and negative symptoms of schizophrenia (Jin et al., 2006b; Jin et al., 2011) and to improvements in spatial working memory (Hamidi et al., 2008; Preston et al., 2010). In a normal control, alpha activity is uniform across the cortex and occurs at a single frequency, with more alpha activity in the occipital cortex and a slight gradient of activity forward toward the frontal lobe (Figure 1). However, patients with ASD often show decreased alpha EEG activity as compared with normal populations, particularly in the frontal cortex of the brain (Dawson et al., 1995; Sheikhani et al., 2010). We thus hypothesize that the alpha deficit is directly associated with the neuropathology of ASD.







## Normal Releaxed in EEG

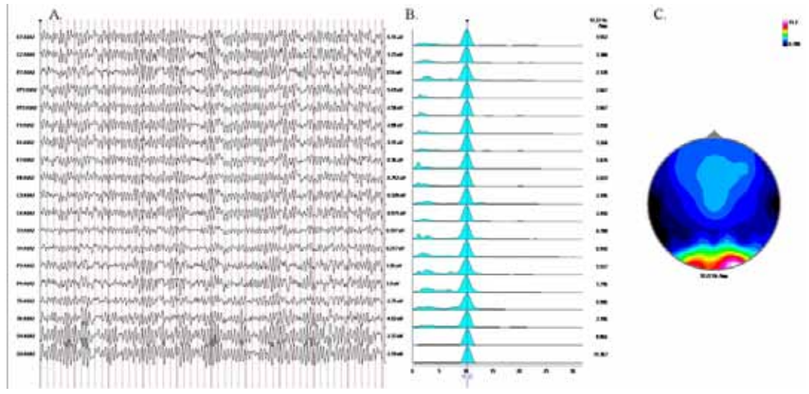



**Figure 1. Ideal eyes closed a activity and relative distribution in EEG.**
(A) 10 seconds eyes closed EEG. Montage and electrode location on the scalp is indicated on the left.
(B) Fast Fourier transform (FFT) of EEG, with peak frequency of a activity at 10-20.
(C) Top-down topographical distribution of this frequency on a simulated cortical map. The triangle on top is representative of subject's nose.

## EEG-guided rTMS Therapy

According to the physical propertt of rTMS and the resonant nature of EEG, we further hypothesize that treatment with rTMS—tailored to each patient's characteristic alpha-EEG frequency—may serve as an effective therapy for ASD by normalizing the brain wave oscillation. The treatment protocol for personalized rTMS includes a daily therapy with EEG-guided rTMS. In each treatment session, a figure-8 stimulation coil is placed above the middle of the forehead, with the edges extended to both dorsal lateral hemispheres. Stimulation is administered precisely at each subject's intrinsic alpha-EEG frequency at 80% motor threshold, 6 seconds per minute for 30 minutes. Motor threshold is defined as the minimal intensity of a magnetic pulse that consistently induces visible contralateral thumb movement. The duration of treatment varied from one month to 6 months.

rTMS therapy is generally considered safe (Hausmann et al., 2004; Moser et al., 2002; Nahas et al., 2000; Padberg et al., 1999). Immediate side effects of rTMS are generally limited to a minor headache or increased feelings of energy, with only rare cases of rTMS-associated seizures since the establishment of safety guidelines in 1998 (Wassermann, 1998).

## Case reports

**Case 1:**

JL, a 7-year-old boy, had been diagnosed with ASD for 4 years before seeking rTMS treatment at Ming Zhe Clinic. During the initial intake meeting, the boy appeared to understand commands from the clinic staff but did not have any verbal communication or direct eye contact. He moved himself by crawling and howled like an animal. His parents reported that he was incontinent, with frequent urination and bowel movements, and had extreme difficulty falling asleep at night. Following the 5-day initial trial of personalized rTMS treatment, the boy showed noticeable improvements in sleep and calmness. With continued treatment, improvement in other symptoms occurred; the boy stopped being incontinent completely after 3 weeks and started walking after 2 months. After 3 months of treatment with personalized rTMS, he started to communicate with his parents using simple sentences, and after 6 months he improved so significantly that he was enrolled into the first grade at a local elementary school.

**Case 2:**

AG was a 7-year-old girl who had lived with an ASD diagnosis for 6 years before arriving at our clinic. She suffered from hundreds of myoclonic-atonic seizures daily, which impaired her cognitive and functional abilities. Both her cognitive ability and her level of interaction were very low. After a 5-day trial of personalized rTMS treatment, the girl's seizures decreased significantly to just several per day. She also began babbling more, became more energetic, and explored her surroundings with greater interest. Following 3 months of treatment, the girl started walking on her own with minimal support and experienced no seizures for several days at a time. She became increasingly interactive and social with the individuals around her, seeking more attention. At the end of personalized rTMS treatment, she was enrolled in school and started speech and occupational therapy classes.

**Case 3:**

JC, a boy diagnosed with ASD 4 years previously, presented at the BTC at age 5. At that time, he cried and screamed throughout the day and was only content when watching a movie. He slept just 2 hours a night and exhibited constant stimming (self-stimulatory) behavior. Though verbal, the boy did not understand the words he used, exhibiting echolalia with no insight. He also ate a very restricted diet, accepting only a small number of foods when hungry. Following the initial rTMS trial, the boy started sleeping 8 hours a night and displayed a slow reduction in stimming activity that became minimal by the end of treatment. He also began showing patience and was not as quick to cry or scream when unhappy. After 1 month of personal-

ized rTMS, the boy started eating a wider variety of more nutritious foods. He began bargaining for what he wanted and was content to wait if necessary. His video interests also adjusted to those at his own age level, and he was able to start sounding out words. After 2 months of treatment, he started showing an understanding of language and began expressing his desires with words he had recently learned. He became more social with other children after 3 months of treatment, interacting and making friends. After 4 months of rTMS treatment, the boy learned to read and write words phonetically and understood personal pronouns (me, I, my). After 6 months of treatment, he could hold short conversations and had improved to the point of being only one grade level behind that of his peers.

**Discussion**

As our clinical data illustrate, rTMS shows promise for therapeutic use in ASD. Individuals who display robust changes in the frontal EEG (Fiture 2, 3) following personalized rTMS therapy often show immediate improvement in nighttime sleep, calmness, and attention. These changes may be followed by improvements in language, fine motor function, and learning capability. EEG-guided rTMS is fundamentally different from previous efforts that used rTMS to treat ASD (Sokhadze et al., 2010; Thut et al., 2011), because EEG-guided therapy is specific to each patient's EEG characteristics. Rather than treating all subjects the same, our approach targets the patient's alpha frequency, using the brain's natural resonance to entrain neurons across the cortex more globally.

## Case repo Therapeutic α-rTMS improves cortical synchrony and α power

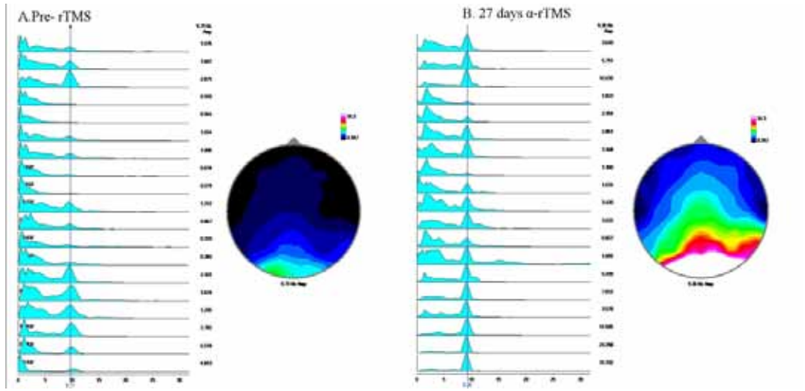



**Figure 2. Individual ASD EEG response to a stimulation. Comparison of baselinbe EEG (A) with relatively low levels of a-synchrony to EEG following 27 days of α-rTMS therapy (B). There is an increase in a wave synchrony and power compared to baseline.**

## Therapeutic α-rTMS increases and improves a activity relative to normal distribution

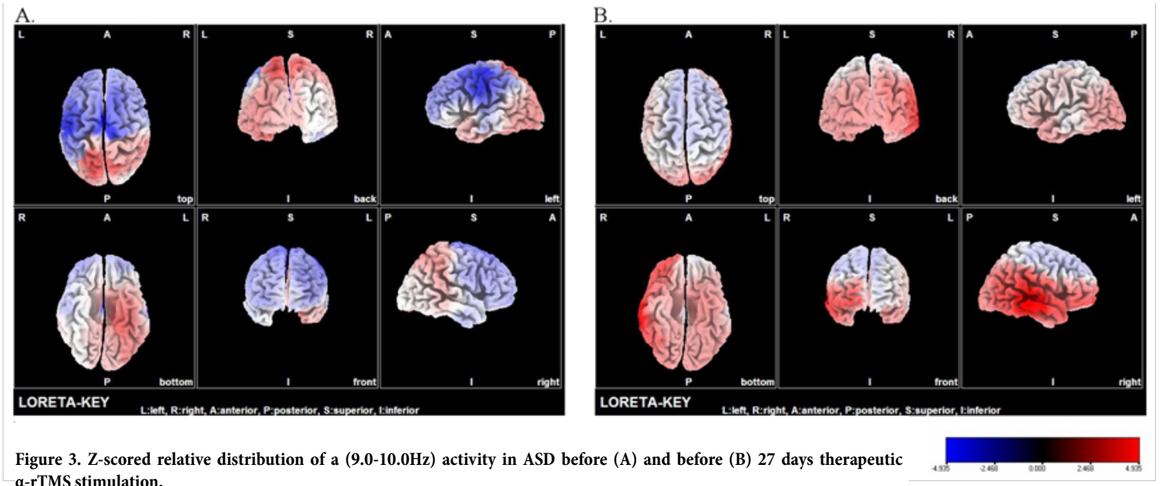



**Figure 3. Z-scored relative distribution of a (9.0-10.0Hz) activity in ASD before (A) and before (B) 27 days therapeutic α-rTMS stimulation.**





The EEG changes that we observed require further assessment to understand their implications. For example, other investigators have shown that low frequency (<1 Hz) rTMS has an effect on gamma frequency (30-80 Hz) EEG activity (Baruth et al., 2010). Further investigation is required to understand the full effects of the personalized rTMS on brain activity as well as any transient effects it may have on long-term behavior. To fully assess therapeutic rTMS, research should include double-blinded protocols, follow-up case reports, and neurocognitive assessments to gauge variability and robustness of response. In one study that assessed the long-term efficacy of rTMS therapy in depression (Janicak et al., 2010), almost three-fourths (73.2%) of the patients who initially responded to a treatment protocol similar to ours were still in remission after 6 months. This effect needs to be investigated for use in ASD.

As ASD rates have steadily increased, the possibility of a new brain-based therapy is exciting for all affected by ASD. Through regulation of neuronal communication, adjustment of electrophysiological deficits, calming of sensory overstimulation, and improvement of processing ability, we can look forward to using rTMS to help individuals with ASD achieve such benefits as an improved affect and reduced anxiety. We are hopeful that rTMS will live up to its potential as an effective therapy for ASD. ■

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**Objectives of this Course:**

- To understand about China's SFDA regulations relating to an enforcement of pharmaceutical rules, laws and legal standards in an international market.
- To learn about strategies to overcome regulatory hurdles with an aim to enhance product success in a Chinese market.

**Course Content:**

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1. Market Analysis in China
2. Global Regulatory Environment
3. Regulatory Framework in China
   a) Classification
   b) Conformity Assessment
   c) Quality System and GMP
   d) Vigilance System
4. Character and Trend of SFDA Regulation
5. Recent Updated of SFDA Regulation
6. Challenge and Hurdles of SFDA Registration
   a) Standard System and Manufacturer Standard
   b) Testing of the Standard
   c) Clinical Trial
   d) Renewal Registration
   e) GMP Requirements
7. Practice of SFDA Regulation
8. Strategy of SFDA Regulation Compliance

Part (B)

1. The structure of SFDA regulatory requirements
2. Character and trend of the SFDA regulatory
3. Challenge and some suggestion of SFDA registration.
4. Common problems in registration in China and the tackling solutions.

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*As a core team member of Merging and Acquisition of Medical Device Company in Global market and China in Mindray, he is also experienced in Merging and Acquisition of Global and Chinese Medical Industrial.*

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