

Research Assessment Exercise 2020
Impact Case Study

University: Hong Kong Baptist University
Unit of Assessment (UoA): 6 Chinese Medicine

Title of case study: Achieving High Impact on Health Policy, Professionals Behavior Change and Wellbeing of Chinese Medicine Clinical Practice

(1) Summary of the impact

Our school has 17 clinical centres in Chinese Medicine (CM) and these centres attracted more than 1,500,000 patients totally. Through more than 20 clinical studies in the last six years, we have provided evidence-based Chinese Medicine clinical practice guidelines (CMCPGs) to build Hong Kong's first CM hospital. This case study describes the impact pathway involving:

- a) Conducting evidence-based Chinese Medicine clinical trials and implementing CMCPGs to standardize professional practice thus providing strong support to the Hospital
- b) High impact on the community healthcare strategy of Government by building up the HKBU-Jockey Club CM Disease Prevention and Health Management Centre.

(2) Underpinning research

Achieving High Impact of Chinese Medicine Clinical Research and Service

During the last six years, we have conducted more than 20 high-quality CM clinical trials. Furthermore, our School also facilitated the integration of our clinical trials in CM with pharmacological, biological researches, and offer education and services in clinical trial design, oversight and analyses of clinical trial results. With total funds of over HK\$10 million from the Government and we have invested enormous efforts into methodology development in clinical trials with Chinese medicine clinical use. Prof. Bian Zhaoxiang and his research team established a collaboration with the Faculty of Medicine at The Chinese University of Hong Kong (CUHK) to develop a Chinese herbal medicine formula for the treatment of Irritable Bowel Syndrome (IBS). Prof. Lyu Aiping's and Prof. Zhang Ge's team collaborated with the Beijing Tide Pharmaceutical Company Limited and signed two cooperation framework agreements for collaborations in drug discovery to treat chronic inflammatory diseases, autoimmune diseases and joint diseases. Prof. Li Min's team has been searching for active compounds in TCM which can specifically remove the toxic protein aggregates from brain.

Conducting evidence-based Chinese Medicine clinical trials and establishing Chinese Medicine clinical practice and reporting guidelines to provide strong support to Chinese Medicine Teaching Hospital

Based on 17 clinical centres in our School, the new drug development in common chronic diseases, such as functional digestive diseases [3.1, 3.2], rheumatoid diseases [3.3], and neurodegenerative diseases [3.4] have achieved great success. In addition to the clinical trials' findings, Prof. Lyu established the pathways to build up the CM clinical practice guidelines, and Prof. Bian explored the standardization of CM clinical trial reporting guidelines.

Our School implemented the first CM evidence-based clinical practice guidelines (CPGs) in Hong Kong and involved in development of guidelines in CM. A national survey of 4503 CM doctors in 28 provinces of China showed that most doctors regarded CPGs-recommended therapies as safe (92%), economic (84%), and effective (76%). Approximately four-fifths of the CM doctors selected 'acceptable' (60.84%) and 'acceptable after revision' (19.23%) regarding their understanding and application of the CPGs [3.5]. Led by Prof. Bian, an international group of experts has recently published a recommendation for reporting clinical trials with Chinese medical formulas (CONSORT-CHM Formulas 2017) in *Ann Intern Med.* [3.6].

High impact on the community healthcare strategy of Hong Kong Government by building up the HKBU-Jockey Club Chinese Medicine Disease Prevention and Health Management Centre

In view of an ageing population affected by chronic diseases, our School has received a fund of HK\$95.18 million from The Hong Kong Jockey Club Charities Trust to launch the “Jockey Club ‘Embrace Health’ Chinese Medicine Programme”. The Centre is the first health service organization in Hong Kong with the core concept of “prevention before disease onset” with four health management platforms. It also meets the need of the government to promote the development of primary care. Our project has recruited 5,300 Hong Kong Chinese elderly population, and will conduct preventive care with CM approaches and follow up for five years.

(3) References to the research

Peer-reviewed journal articles:

1. Cheng CW, Bian ZX, Zhu LX, Wu JC, Sung JJ. Efficacy of a Chinese herbal proprietary medicine (Hemp Seed Pill) for functional constipation. *Am J Gastroenterol* 2011; 106: 120-129.
2. Zhong LLD, Cheng CW, Kun W, Dai L, Hu DD, Ning ZW, Xiao HT, Lin CY, Zhao L, Huang T, Tian K, Chan KH, Lam TY, Chen XR, Wong CT, Li M, Lu AP, Wu JC, Bian ZX*. Efficacy of MaZiRenWan, a Chinese Herbal Medicine, in Patients With Functional Constipation in a Randomized Controlled Trial. *Clin Gastroenterol Hepatol*. 2018 Apr 12. pii: S1542-3565(18)30341-0. doi: 10.1016/j.cgh.2018.04.005.
3. Liang C, Guo B, Wu H, Shao N, Li D, Liu J, Dang L, Wang C, Li H, Li S, Lau WK, Cao Y, Yang Z, Lu C, He X, Au DW, Pan X, Zhang BT, Lu C, Zhang H, Yue K, Qian A, Shang P, Xu J, Xiao L, Bian Z, Tan W, Liang Z, He F, Zhang L, Lu A, Zhang G. Aptamer-functionalized lipid nanoparticles targeting osteoblasts as a novel RNA interference-based bone anabolic strategy. *Nat Med*. 2015 Mar; 21(3):288-94.
4. Song JX, Sun YR, Peluso I, Zeng Y, Yu X, Lu JH, Xu Z, Wang MZ, Liu LF, Huang YY, Chen LL, Durairajan SS, Zhang HJ, Zhou B, Zhang HQ, Lu A, Ballabio A, Medina DL*, Guo Z*, Li M*. A novel curcumin analog binds to and activates TFEB in vitro and in vivo independent of MTOR inhibition. *Autophagy*. 2016;12(8):1372-89. doi: 10.1080/15548627.2016.1179404.
5. Liu MY, Zhang C, Zha QL, Yang W, Yuwen Y, Zhong LL, Bian ZX, Han XJ, Lu AP. A national survey of Chinese medicine doctors and clinical practice guidelines in China. *BMC Complementary and Alternative Medicine*, 2017;17:451.
6. Cheng CW, Wu TX, Shang HC, Li YP, Altman DG, Moher D, Bian ZX*, CONSORT-CHM Formulas 2017 Group. CONSORT Extension for Chinese Herbal Medicine Formulas 2017: Recommendations, Explanation and Elaboration. *Ann Intern Med*. 2017 Jul 18;167(2):W7-W20. doi: 10.7326/M16-2977

Key Funding:

1. “Health Hong Kong” Hong Kong Baptist University and Jockey Club Chinese Medicine Disease Prevention and Health Management Centre. The Hong Kong Jockey Club Charities Trust. HK\$95,180,000 (2017-2022)
2. The Development of Chinese Medicine Clinical Practice Guideline in Hong Kong. Hospital Authority. HK\$500,000 (2014-2015)
3. The Development of Chinese Medicine Clinical Practice Guidelines (CPG) in Cancer Palliative Care in 2014/2015. Hospital Authority. HK\$500,000 (2015-2016)
4. The Development of Evidence-based Integrative Medicine Clinical Practice Guidelines in Hong Kong. Fong Yun-Wah Research Fund. HK\$1,200,000 (2015-2017)
5. Efficacy and safety of Chinese Medicine JCM-16021 on IBS patients: A randomized placebo controlled trial. ITS/14/148FP. HK\$4,997, 712 (2018-2020)

Key Patents:

1. Bian ZX., Sung JJ, Leung WK, Liu L, Wu JY. “Prevention and treatment of IBS with Chinese herbal compounds, extraction and its application”. CN Patent No. CN 101176777B & HK Patent No. HK 1118014, filed on 9 November 2006.

2. Lu AP. "Randomized Controlled Study to Evaluate the Clinical Outcomes of Rheumatoid Arthritis Treated with Method of Activating Blood Circulation by Removing Blood Stasis". Chinese Clinical Trial Registry. Registration number: ChiCTR-TRC-10001014. Registration Date: 30 August .CN Patent No.: CN102716129B. Filed on 29 March 2011.
3. Min LI, Juxian SONG, Chuanbin YANG, Yu ZENG, Sandeep MALAMPATI, Hongjie ZHANG. MTOR-independent activator of TFEB for autophagy enhancement and uses thereof. Patent No.: US9540299 B2; 2017-01-10.

(4) Details of the impact

Impacts include: health policy, public education and services, commercial benefits on industry.

Our School has 17 clinical education, research and service centres, attracting more than 1,500,000 patients over the last 15 years and has delivered commercial benefits for the university to support more research. We have conducted more than 20 evidence-based clinical trials on CM and published more than 100 SCI papers to impact on the clinical practice behaviors of CM Practitioners. Besides, through various public lectures, talks and seminars, periodic publications in newspapers, magazines and internet platforms, various community activities and outreach events, we have contributed to citizens' awareness and understanding of CM treatment has been enhanced. In the past five years alone, the Division has delivered, through newspapers, radio, television, and the internet, over 1,000 articles and public lectures, thereby building a sound foundation for citizens' understanding and reception to CM health knowledge.

Our School's research also impact on the government's healthy policy. We have always been dedicating to the establishment of the first Chinese Medicine Hospital in Hong Kong and our research has provided great support for its implementation. Through continuous efforts, the government has announced in the Chief Executive's 2017 Policy Address a "plan for a Chinese medicine hospital at Tseung Kwan O" [5.1]. In item 246, it was stated that "the current-term has been actively promoting the development of Chinese medical professionals and Chinese medicines with a multi-pronged approach, which includes establishing a regulatory regime, encouraging local tertiary institutions to promote Chinese medicine professionals, supporting scientific research and innovation for Chinese medicines.". In the 2018 Policy Address, the government further emphasized its plan to establish the Chinese Medicine Hospital Project Office and the Chinese Medicine Unit to push the Chinese Medicine Hospital start-up.

To meet the challenge of an ageing population and the public's rising expectations, the government is planning and implementing initiatives to promote the development of primary care, and formulating reference frameworks for specific population groups and chronic diseases [5.2]. Prevention of diseases and management of one's health have a long history in traditional CM, and over the years have proven to be effective. Prof. Bian, Prof. Lyu and their team have secured the Jockey Club to provide HK\$95.18 million to establish the "HKBU-Jockey Club Chinese Medicine Disease Prevention and Health Management Centre". This centre aims to prevent diseases following the CM way by providing "pre-sick" and "post-sick" patients with preventive, life-nourishing and health-preserving services [5.3]. This is the first and largest-scaled preventive Chinese Medicine Centre in Hong Kong.

The new CM for IBS is also the first Hong Kong-developed compound mixture to be granted a clinical trial certificate by the China Food and Drug Administration (CFDA). At present, only single compounds can be registered under the Chinese Medicine Division of the Department of Health, Hong Kong. However, Prof. Bian made a breakthrough by convincing the Hong Kong SAR Government to conduct clinical trials in Hong Kong [5.4]. HKBU, CUHK and PuraPharm have agreed to complete the clinical trials and register the herbal composition as a new medicine in Hong Kong and China [5.5, 5.6]. This case is unprecedented that it will change the public's perception of CM. In addition, it will encourage future government policies on the registration of new CM.

(5) Sources to corroborate the impact

1. The Chief Executive's 2017 Policy Address, item 245.
<https://www.policyaddress.gov.hk/jan2017/eng/p245.html>
2. The Chief Executive's 2018 Policy Address, items 176, 177, 178.
https://www.policyaddress.gov.hk/2018/eng/policy_ch06.html
3. Letter from the Jockey Club Charities Trust to inform the approval of Chinese Medicine Disease Prevention and Health Management Centre
4. Letter from the Division of Chinese Medicine, Department of Health, Hong Kong. The letter informed the approval of clinical trial and drug testing for the new Chinese medicine
5. “港首個中西醫成果 腸胃病新藥將應市”. 星島日報. November 11, 2016.
<http://std.stheadline.com/daily/article/detail/1503792/日報-港聞-港首個中西醫成果-腸胃病新藥將應市>. Accessed July 31, 2019.
6. “培力中醫藥科研產業見成果”. 成報. November 15, 2016.
<http://www.singpao.com.hk/index.php?fi=new&id=10167>. Accessed July 31, 2019.