Evidence-Based Medicine in China

Youping Li, PhD,1 Xin Sun, PhD,2 Li Wang, PhD2
1Chinese Cochrane Center, West China Hospital, Sichuan University, Guo Xue Xiang, Chengdu, China; 2Chinese Evidence-Based Medicine Center, West China Hospital, Sichuan University, Guo Xue Xiang, Chengdu, China

China Needs Evidence-Based Medicine (EBM)

China is the biggest country in the world that has 1.3 billion population. The health of the population has been one of the issues most relevant to sustainable development of the economy and society. However, limited availability of health services is unable to meet the enormous health needs. The estimated annual incidence of cancers 1.3%, cardiovascular diseases 50%, infection diseases 2.7% in 2003, whereas only 1.50 clinicians, 1.03 nurses and 2.40 ward beds per thousand are available to provide services in 2004 [1]. With the rapid shift of infectious diseases to chronic diseases in the Chinese population, the health spending is increased dramatically. The national health expenditure in 2003 has been tripled to 658.41 billion Renminbi (RMB) compared to that in 1995 [1], whereas an increase of national health budget from 38.734 billion in 1995 to 111.694 billion in 2003 [2] cannot cope with the steep climbing of health expenditure. It is a big challenge to utilize the limited health-care capacity to keep all the population healthy.

On the other hand, the health resource use is highly imbalanced across China. In the economically developed regions, the health-care services are improperly and excessively utilized, whereas health professionals and technologies are less available in regions with less developed economy. This situation has been further complicated by the low efficiency of utilizations of health services, on which a large number of avoidable adverse events of medications occur each year to cause additional health resource use.

Since early 1990s, these problems have been increasingly evident in China. Although the central and local government paid great efforts to address these problems, the health-care system is yet to be improved. The World Health Organization (WHO) Report [2] ranked China 144th place out of 191 member countries for the overall health services. Both policymakers and clinicians feel the strong need to make policy and clinical decisions based on solid evidence. Coincidently occurred in the world was the burgeoning of the international organization in 1993—the Cochrane Collaboration—which aims to produce, maintain, and disseminate the best evidence to improve the effects of health care, and a new field in clinical medicine in 1992—EBM—that focuses on improving the health-care pattern. These historical events have become the incentives that promoted the introduction and development of EBM in China.

Development of Research and Practice Platforms in China

In November 1997, the Chinese Evidence-Based Medicine Center (CEBMC) was approved to be established at West China University of Medical Sciences. In 1999, the Chinese Cochrane Center, which is also based at West China University of Medical Sciences, was successfully registered with the Cochrane Collaboration. In 2002, the Chinese Cochrane Center developed its Hong Kong branch at the Chinese University of Hong Kong.

The value and potential of EBM in medical education were recognized by the Chinese Ministry of Education. In 2002, the Virtual Research Center of EBM (Ministry of Education) was approved. The following year, the discipline of EBM was approved by the Ministry of Education to train the first group of postgraduates for the future researchers and policymakers.

EBM in the Policymaking Process: The Government Efforts

Development of EBM and Use of Evidence in the Ministry of Health

The birth and development of Chinese EBM is attributable to the Chinese Ministry of Health. On the contrary, the development of EBM also benefits the Ministry for the development of varieties of policies. The Chinese Ministry of Health is the major regulation body of the medical policy in China. To improve the efficiency of decision-making, the Health Technology Admission Office was established, which applied the best available evidence in major policymaking. Since the establishment of the Office, varieties of health technology programs were assessed, including aided reproductive technology, legislation of brain death, medical
risk management, development specialist training systems, and development of evidence-based clinical practice guidelines.

National Science Foundation of China
The value of EBM for policymaking was first recognized by the National Science Foundation of China in 1996. Early in the new millennium, the foundation reported to the State Council that EBM was one of the few science subjects in China that could be in line with the research cutting edge in the world. In 2005, the foundation established the first fund for EBM.

Application of Evidence in Reproductive Health Policymaking
At the request of the WHO, China started the program of evidence-based evaluation of reproductive technologies in 2001. In 2003, the WHO took efforts to evaluate these technologies for inclusion of WHO Model List of Essential Medicines. Two years after the WHO initiative, China attempted to develop a system to monitor, assess, and manage the risk of the contraception devices. The evidence prepared will be used for the system, and the concept of EBM will also be incorporated into the decision process that monitors and selects the devices efficiently.

EBM for Medicines Evaluation in the State Food and Drug Administration
At the request of WHO, China started its program on evidence-based evaluation and selection of essential medicines 2001. In 2002, a program on evidence-based evaluation of three categories of pharmaceuticals and traditional Chinese medicines (TCM) for inclusion to the National Essential Medicines List was commissioned. The methods of health technology assessment were used by identifying clinical and economic evidence of these medicines, and critically appraising their validity and generalizability in the context of the Chinese setting. In 2004, an updated selection of essential medicines was developed, in which the prioritized medicines were assessed systematically by identifying and critically appraising the evidence. This was a significant milestone of EBM in terms of its use in the evidence-based policymaking.

In 2005, methods for pharmacoeconomic analysis of essential medicines in the Chinese setting were developed. In 2006, the draft of the guide of pharmacoeconomic analysis has been circulated and received praise for the initiative.

Bureau of TCM
From 2000, the topic of EBM has been the key method to promote the internalization and standardization of TCM and has been incorporated into the main grant application for TCM research.

Ministry of Education
The EBM has been highly emphasized in the medical education. In 2003, the first textbook of EBM for the undergraduate medical students was published. With the further development and dissemination in the Chinese universities, an edition of the national textbook of EBM for medical undergraduate students was proposed in 2006. In the same year, the 4th Asian-Pacific Conference on EBM was held with the joint efforts of the Ministry of Health and Ministry of Education.

Military Department of Health
The Military Department of Health started its EBM practice in 2002. In 2003, the severe acute respiratory syndrome broke out, of which China was the most attacked country. In the following year, the experiences of managing the emergent disease were proposed to summarize. The methods of EBM were used in the evidence preparation and policymaking processes. In 2006, the 11th National Five-Year Development program was initiated. A proposal of developing a system of evidence-based rational use of medicines was made and successfully approved.

EBM Practice and Exploration: Nongovernmental Organizations
Chinese Cochrane Center, CEBMC, and Ministry of Education Virtual Research Center of EBM
Since 1998, the Chinese Cochrane Center and CEBMC opened courses on EBM for 3000 undergraduates, 2500 graduates, and 217 residents. More than 200 lectures and workshops involving 40,000 participants have taken place since 1998. The Ministry of Education EBM Training Programme that started in 2004 appointed the centers to train university teachers who teach EBM and a total of 265 lecturers have been trained through the course.

Educational efforts include the development of Chinese Clinical Trial Database that hand searched 109 Chinese journals and identified more than 10,000 trials, of which 1500-2000 trials were submitted to the Cochrane CENTRAL register per year. The production of Cochrane systematic reviews has rapidly increased. By the end of 2005, 108 titles, 75 protocols and 28 reviews were produced from the Chinese reviewers. The rate of increase of contributors and authors in China is more than 10 times of the Cochrane Collaboration. China has been in the list of the 10 countries with the most contributors to the work of the Cochrane Review Groups since 2004, and the only country in this short list categorized as low or middle income by The World Bank.

Chinese Medical Doctor Association (CMDA). The CMDA was established in 2001. Just upon its estab-
lishment, the EBM was highlighted. In 2004, the EBM subcommittee was established under the CMDA.

Chinese Medical Association. Since 2002, the Chinese Medical Association recognized the value of EBM.

EBM in universities. Many other Chinese universities have developed their university-based center for EBM, including Beijing University, Fudan University, Lan Zhou University, Guang Xi University of Medical Sciences, and Zhe Jiang University. Several universities have developed courses for EBM postgraduate and undergraduate courses.

Conclusions
The birth and development of EBM in China was a result of practical needs, governmental support, and international efforts. The further development of EBM will be full of challenge and opportunity. But we are confident to promote further the development in China. The EBM in China is part of the world efforts, and the world involvement in EBM cannot be without the Chinese role.

References

Drug Control and Formulary Management in Malaysia

Samsinah H. Hussain, RPh, PhD
Department of Pharmacy, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia

Introduction
From the year 2000, the national drug expenditure has seen an increase from RM346 million ($91 million) to RM915 million ($241 million) in 2005. From the year 2004 to 2005, an increase of 13.3% was recorded [1]. Factors that may contribute to this increase include increase in drug prices, a growing and aging population, higher expectation of the public regarding equality in assessing therapy, long-term drug treatment and polypharmacy, improvements in diagnosis and treatment of diseases, and technological advancement that produces newer expensive drugs [2,3].

Drug Registration and Regulation in Malaysia
A statutory body known as the Drug Control Authority (DCA) is responsible to ensure that medicines marketed in Malaysia are safe, efficacious, and of quality. This is done through a systematic registration, licensing, and surveillance scheme which is part of a man-

datory product registration process. The National Pharmaceutical Control Bureau is an organization under the Pharmacy Division. It is responsible for the Quality Assurance program and performs the operational function of the DCA. This include activities such as product evaluation, product assessment (laboratory testing), Good Manufacturing Practice inspections, processing of product certificate and licences, postmarketing surveillance, and monitoring of Adverse Drug Reaction.

Malaysian Ministry of Health (MOH) Drug Formulary
In Malaysia, drugs that are made available for use in the public health-care system are controlled through the MOH Drug Formulary. The MOH Drug List was first introduced in 1983 and contains a list of drugs that have been approved for use in the MOH hospitals and institutions. The use of nonformulary drugs requires prior authorization and approval by the Director-General of Health. The use of this formulary does not include the private hospitals and teaching hospitals. By the end of 2005, there were 1322 preparations listed in the formulary. Drugs in the formulary are classified