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Editorial

Evidence-based medicine in China

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Evidence-based medicine (EBM) has been promoted in China for the past 2 decades and has had a great influence on the field of medicine. Medical students, practitioners, and policy makers have employed evidence from well-designed and well-conducted studies to optimize decision-making. This article summarizes the recent progress in EBM in China.

Development of EBM in remote areas of China

Ten years ago, many remote areas, such as Tibet, Xinjiang, the western edge of Yunnan Province, the northeast edge of Guizhou Province, and Western Sichuan Plateau, suffered from deep medical and social problems. There was a wide disparity in access to physicians practicing EBM between rural areas and big cities at that time. Physicians in rural areas have difficulty accessing the best information resources.[1] These problems have been solved with the active support by the government in ensuring the availability and feasibility of web-based[2,3] and regional medical collaboration networks. For example, the medical collaboration between Shanghai and Yunnan is one of the programs of targeted poverty alleviation in China. Furthermore, physicians in remote areas usually have difficulty reading English. Even though they can get the clinical guidelines in foreign language, they can not understand. Timely release of EBM guidelines in Chinese has partially overcome this limitation. Chinese guidelines offer the opportunity to greatly narrow the information gap between developed and remote areas.

Improvement of ethics in clinical research

Chinese researchers are now increasingly required to adhere to standard ethical practices when it comes to ethical review and approval of study protocols. At present, most universities and municipal governments in China have established an independent ethics review board. Currently, all clinical trials must be reported to the ethics committee for approval and registered in the *Chinese Clinical Trial Registry* (http://www.chictr.org.cn) or in *ClinicalTrials.gov* before they begin. The principal investigator updates the information on the website throughout the study.

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Rapid growth and government funding of clinical research

In China, deficiencies in EBM methodology training and national academic funding sources have led to little progress in the development of global evidence-based practice guidelines.[1] China recently broadened its national development agenda and included health as its major priority.[4] In 2009−2017, there was a rapid increase in the number of clinical studies sponsored by government or academic institutions, whereas industry-sponsored researches were relatively stable. Moreover, the increase in the number of clinical trials is faster than the increase in observational studies (Fig. 1).

The growth in clinical studies was mainly due to the rapid growth of government clinical research funding. During the China Five-Year Plans of 2006−2010 and 2011−2015, the Ministry of Science and Technology of China implemented priority research programs that focused on high-quality clinical research instead of the basic research that had been the previous focus. The annual science and technology funds of most universities in China increased in 2016. The number of universities with annual funds exceeding 100 million yuan increased from 234 to 256 during 2015−2016.[5]

Along with these changes, the number of published peer-reviewed articles was rapidly growing. From 1999 to 2008, 1880 clinical research articles were published in the *New England Journal of Medicine*, *The Lancet*, the *British Medical Journal*, and the *Journal of the American Medical Association*; only 0.21% of these were from the mainland of China.[1] However, during 2009−2017, the percentage increased rapidly (Fig. 2).

Improvement of EBM capacity building

Many universities have EBM teaching platforms for medical students, practitioners, policy makers, and medical journal editors. For example, with its integrated multidisciplinary platforms for EBM education, the Evidence-Based Medicine Center of Fudan University (EBMC-Fudan) has taken a leadership role in EBM education.[6] The platforms offer physicians, scientists, students, and healthcare staff the opportunity to participate in several educational projects (e.g., The Principles of Evidence-Based Medicine: Literature Searching, Critical Appraisal and Evidence-Based Clinical Decision-Making), comprehensive curriculum and programs leading to a master's degree in EBM, and national EBM workshops, seminars, and lectures. Moreover, in response to low-quality reporting of medical research in Chinese medical journals, EBMC-Fudan has been working on translation, training, and promotion of the seven most widely accepted and used guidelines: Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), Consolidated Standards of Reporting Trials (CONSORT), Strengthening the Reporting of Observational studies in Epidemiology (STROBE), Meta-analysis of Observational Studies in Epidemiology (MOOSE), Standards for Reporting of Diagnostic Accuracy (STARD), Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2), and Transparent Reporting of Evaluations with Nonrandomized Designs (TREND). Editors understand how these standards have led to improvements in the quality of the reporting of medical research.

Constructing and optimizing national and regional clinical research platforms

There have been several national comprehensive EBM platforms that have emerged as leaders in the area of EBM in China. For example, the Comprehensive EBM Platform at EBMC-Fudan was supported by China's “Project 985”. The platform is currently being adopted by various institutions in China for research design, process management, and guideline assessment.[7]

The Key Lab of Health Technology Assessment at Fudan University is one of the core members of Health Technology Assessment International and is conducting a series of studies related to leadership and development in health technology assessment, knowledge translation, health policy, health economics, and hospital management.[8]

It is worth mentioning that the EBM in traditional Chinese medicine (TCM) research platform has been established for data collection and management in TCM. Several EBM in TCM projects have been successfully completed and have been evaluated objectively. The clinical study results were published in major international journals, such as the *Journal of the American College of Cardiology*, *Journal of the American Medical Association*, *and Journal of Internal Medicine*.[9,10] The CONSORT extension for reporting acupuncture interventions (Standards for Reporting Interventions in Clinical Trials of Acupuncture [STRICTA])[11] has been launched. Some other projects related to the TCM study process have also been launched for ethics, safety monitoring, etc. The Clinical International Committee for the Design and Evaluation of Clinical Trials of Traditional Chinese Medicine was established in 2017 to promote TCM protocol review

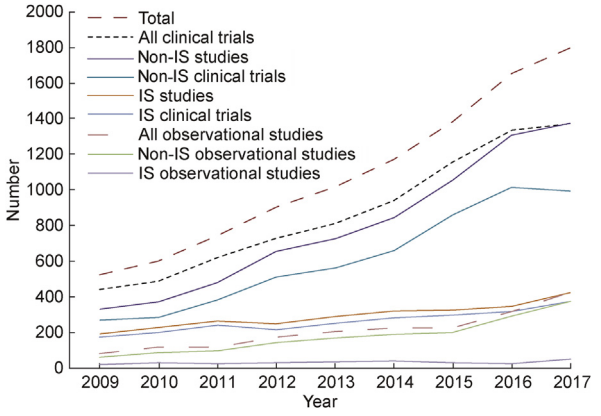

Fig. 1. Growth of clinical research in China. Number in this figure refers to the number of studies/trials in ClinicalTrials.gov with "Country = China" in the search query. IS: industry-sponsored.

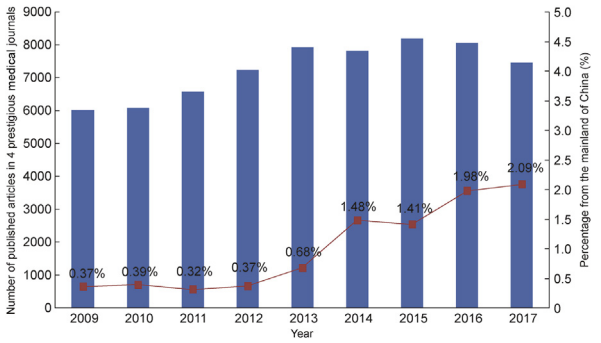

Fig. 2. Number of published articles and the percentage from the mainland of China in the *New England Journal of Medicine*, *The Lancet*, the *British Medical Journal,* and the *Journal of the American Medical Association* from 2009 to 2017. Number refers to the number of articles in the *New England Journal of Medicine*, *The Lancet*, the *British Medical Journal,* and the *Journal of the American Medical Association*, with "China" in the "author's institute" field in PubMed database.

and process management. In March 2018, the first trial registry center for acupuncture-moxibustion was approved by the World Health Organization (WHO) to promote the transparency of trials.[12]

Strengthening international collaborations

In the last decade, EBM pioneers in China have strengthened international collaborations. The Chinese Evidence-Based Medicine Center, located in West China Hospital of Sichuan University, has worked closely with internationally prestigious institutions, including McMaster University, Oxford University, and Harvard University, and has also developed the West China Chapter of the International Society for Pharmacoeconomics and Outcomes Research, and the China Center of the IDEAL (Idea, Development, Exploration, Assessment, Long-term Follow-up) Collaboration.[13] The Evidence-Based Medicine Center of Lanzhou University hosts two international platforms: the WHO Collaborating Centre for Guideline Implementation and Knowledge Translation and the Chinese Grading of Recommendations Assessment, Development and Evaluation (GRADE) Centre.[14] Every year since 2015, EBMC-Fudan has held the EBM Forum, having invited international experts from the United States, Australia, Canada, France, Switzerland, India, Egypt, and Colombia as well as experts from Hong Kong special administrative regions (SAR) and Taiwan of China to exchange their experiences with Chinese experts from all over the country about the methodologies, challenges, and opportunities of medical research, diagnosis and treatment, shared decision-making, and more.

Development and preliminary validation of Appraisal of Guidelines for REsearch and Evaluation (AGREE)-China

In recent years, EBM has been strongly recommended by professional organizations in China, and as a result, the number of guidelines has increased year by year. Nonetheless, guidelines produced by professional and government organizations in China were generally of lower quality than those from Western countries, as assessed with the AGREE II instrument.[12] Moreover, it has been difficult to employ the AGREE II instrument in China due to large inter-rater disagreement issues in the Chinese socio-cultural environment.[7] Recognizing the need for increasing the reliability of the instrument, the AGREE-China score system, based on the AGREE II, was established and validated in 2018. The aim of the instrument's developers was to generate inclusion criteria for the China National Medical Guidelines Database.[7] It is expected that the database will provide guidelines resources online during 2018−2019.

Developing the Reporting Items for practice Guidelines in HealThcare (RIGHT) statement

Medical practice guidelines aid medical staff in making clinical decisions. In 2013, researchers at Lanzhou University initiated a workshop, which was joined by 11 countries (including China, the United States, Canada, the United Kingdom, and Germany) and 8 international organizations (including the WHO, Enhancing the QUAlity and Transparency Of

health Research [EQUATOR] Network, Guidelines International Network [G-I-N], Cochrane Collaboration, GRADE working group, International Society for Evidence-Based Health Care, National Guideline Clearinghouse, and AGREE Collaboration). More than 20 experts jointly established the RIGHT working group.

The working group, which lasted 3 years, completed the RIGHT Statement, including a checklist and an explanation and elaboration statement. The 22-item checklist covered basic information, background, evidence, recommendations, review and quality assurance, funding and declaration and management of interests, and other information. It is the only reporting quality in terms of domains and items in the world that is suitable for guiding health policy and systems, public health, and clinical medicine guidelines.[15]

The future of China's EBM

The core of EBM includes three elements: best research evidence, clinical expertise, and the patients' concerns. The combination of them would provide the most favorable clinical decision-making for patients. Practice of EBM is important for implementation of *Health China 2030*.[16]

At present, there is still a lack of high-quality research evidence from China. China's vast geography and population create complexities for researchers but also offer unprecedented opportunities to study disease management and health system design.[4] Real-world data and real-world evidence play an increasingly important role in health care decisions. However, several challenges remain in the production of real-world evidence in China, particularly with regard to policies on data access, consent, and lack of privacy.[17] In addition, registry studies serve as a big-data source for real-world studies. Over 90% of Chinese hospitals use electronic medical records; however, hospital-based systems make data sharing difficult because they were developed by over 300 vendors using different data standards.[18] Medical big data analysis in hospital information systems has yet to be addressed. This requires that government and researchers work collaboratively to promote clinical data exchange standards. At the policy level, decisions are usually focused on medical insurance and may include considerations about costs and the availability of resources. China has begun to develop health policies that are informed by evidence; however, the amount of research evidence is still limited, and higher quality research is needed.[19]

When physicians make clinical decisions, in addition to the evidence mentioned above, many other factors should also be considered, including benefit and harm trade-off, resource use, feasibility, acceptability and equality, and values and preferences of patients. With regard to patients' concerns, shared decision-making is one of the most important issues in the practice of EBM and should be given more attention. Decision aids that communicate harms, benefits, and alternatives in an easily understood manner represent a possible solution to the challenges of shared decision-making.[20] We have a long way to go before attaining our goal.

Conflicts of interest

We declare that we have no financial and personal relationships with any product, service and/or company that can inappropriately influence our work.

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