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A Comprehensive Evaluation System for the Application and Promotion of Chinese Medical Devices

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ABSTRACT
Medical equipment not only plays a key role in a robust national health care system, but also forms one of the two industrial pillars in modern medicine, the other being therapeutics. In today’s world, the development of medical devices has become an important measure of national scientific/technological progress and economic modernization.

China’s medical device industry started small, but has grown rapidly. Yet neither its production capacity nor its research and development ability can match the market demand. The Chinese government believes that the development of the medical device industry has an important role to play in promoting social development. In an effort to improve the policy environment and support this industry, in 2011 the “Domestic Medical Device Product Application Demonstration and Evaluation Project” was created. Suzhou City, due to its unique geographical and industrial characteristics, was chosen as the site to launch this project.

This article focuses on the establishment of a scientific information management and evaluation system as part of the abovementioned project, which will provide a mechanism to ensure the long-term quality and stability of the medical device industry in China. A total of 180 companies have been enrolled to date, making over 1,000 different devices. Also in the system are 17 large medical institutions in Suzhou City that act as evaluation sites. Thus far, the medical products that have been through the evaluation process represent a total value of 60.6 million yuan (US$9.7 million), while the applications described herein promise to benefit over 400 million people.

INTRODUCTION
Reviewing data collected since the 1980s, developed countries show a 1:1 ratio when comparing output from the pharmaceutical industry with the medical equipment sector (1). The United States is the industry leader in medical devices, with sales accounting for over 35% of the global market, followed by Western Europe (30%) and Japan (11%) (2). The total sales from the global medical device market have risen from US$187 billion in 2001 to US$355.3 billion in 2009, representing a compound annual growth rate over this period of 8.35%. In 2013, global sales totaled US$400 billion (3). The Chinese medical device industry has developed rapidly, particularly in the last two decades, with the industrial output rising from 59.2 billion yuan (US$9.5 billion) in 2007 to 140 billion yuan (US$22.5 billion) in 2011, representing an average annual growth of 24%. Output in 2013 exceeded 200 billion yuan (US$32.1 billion). But the delayed inception of the medical device industry in China resulted in the uneven development of this sector. This has created inflated health care costs and insufficient access to state-of-the-art medical equipment and the latest treatments, especially in rural locations. According to statistics from the Chinese Medical Association, 35% of patients nationwide go directly to large hospitals, while only 7% choose urban community medical rehabilitation centers. Citizens distrust older, cheaper technologies, while new equipment resources in the few larger hospitals that can afford them are very limited. China is therefore faced with the challenge of improving the quality and availability of medical devices in underserved areas in order to create a balanced and equitable health care system. To this end, the government is improving the policy environment for the health care industry, guiding a more objective allocation of health care resources, and supporting industrial development in the medical device sector. In late 2011, through two ministries (the Ministry of Health and the Ministry of Science and Technology) a demand-oriented, innovation-driven, and collaboration-based project was initiated called the “Domestic Medical Device Product Application Demonstration and Evaluation Project.” Jiangsu province, one of the 10 evaluation sites, was first to launch this project in the city of Suzhou.

RESEARCH METHODOLOGY AND FINDINGS
Studies to test and validate medical devices require the involvement of scientific research institutes, medical institutions, government administration bureaus, and medical device companies as well as patients. The purpose of such testing is to enhance the quality of domestic medical devices and further their industrialization, to eventually improve health care overall. Below, we discuss the establishment of long-term supply and service mechanisms in parallel with the industrial development of medical devices in China as well as a scientific information management and evaluation system to support device testing.

Project Implementation
To ensure that the desired objectives are achieved, various teams have been put in place to aid the implementation of the Domestic Medical Device Product Application Demonstration and Evaluation Project. A project leadership team—composed of representatives from research institutes, local governments, and health care institutes—is responsible for the supervision, guidance, and direction of the testing as well as addressing any problems that might arise. The leadership team oversees the project execution team (composed mainly of staff from those institutions participating in the project), which is responsible for selection of medical institutions and representatives from participating companies, as well as overall organization and coordination. Finally, the expert evaluation team, also working under the leadership team, provides independent evaluation and feedback based on the information collected from the companies and medical institutions involved, from the actual testing of the devices, and also from patient feedback.

The main steps in the evaluation process are as follows (also see Fig. 1):

1. Products and institution participation. The project execution group reviews medical institutions and companies, and selects those products deemed most needed by the medical institutions; companies/institutions are then invited to join the project.

2. Evaluation process. Selected companies provide specific medical devices to corresponding hospitals for evaluation. The evaluation team collects feedback from doctors, patients, and scientific experts following the evaluation period, which is then provided to the medical device companies in order to improve and upgrade their devices. The research institutes provide scientific and technological support for the companies during the upgrade process, while the enhanced research platforms and market information generated through this process aid the research institutes in exploring new ideas and applications. Concurrently, the medical institutions provide clinical information and testing facilities for the companies and offer essential practical information to enhance the product improvement process. By making domestic medical devices available to medical institutions, particularly those lacking up-to-date facilities, health care costs can be reduced and consensus can be built regarding standards of technical support and personnel training needed for proper application of the devices. Through this process, the research and medical institutions as well as the medical device companies can generate a strong cooperative
relationship, supporting each other and generating a positive outcome for all.

3. Evaluation results: Through the process of constant evaluation and iterative improvement, it is hoped that domestically produced medical devices will reach a level of quality that is recognized and accepted by the global device market. Concomitantly, the research and development ability of research institutes as well as the overall vitality of domestic medical device industry will improve, resulting in a strengthening of the treatment programs at medical institutions and the training of larger numbers of medical personnel needed to run, support, and maintain the medical devices in use. This will create a virtuous cycle of medical device research and development, application, and promotion.

Information Management System

In order to improve efficiency and ease of management for the evaluation of medical devices in China, an information management system was established. The names and details of all companies, medical institutions, and experts have been entered into a database system for easy access and searching.

As part of the evaluation workflow, the project execution team uploads information on those medical devices selected for evaluation into the system database; medical institutions and enterprises already in the system can then be paired with device companies and a cooperative relationship established through the signing of a contract (outside of this system). Following the evaluation period, product feedback is uploaded and the final report submitted to the relevant enterprises in a secure, easy-to-use, and closed-loop management system (Fig. 2).

Presently, 52 devices have been allocated to large, national hospitals for evaluation, while 108 are being used in smaller, regional hospitals, and 91 are being tested in community health centers. Over 250 more devices are ready and waiting to enter the evaluation process. One example of a product currently under evaluation is a remote, real-time heart monitoring and health management system from the Jiangsu Yocaly Health Management Company. More than 500 heart patients are currently using this device, and to date it has been used by over 30 million people. An example of success on the institute side is the Suzhou New District People's Hospital, which has upgraded eight major pieces of equipment through evaluation projects, including an ultrasound device and digital X-ray machine from Mindray Medical and other well-known Chinese companies. A positive outcome was also achieved at the Liu Garden Community Health Center, which received a digital X-ray machine from Yuwell Medical, making it the first community center to use such a high-end device. It also established a remote diagnostics network together with larger municipal hospitals and thoroughly upgraded its medical equipment, including diagnostic systems, ultrasound equipment, and biochemical analyzer, amongst others, enabling it to provide robust primary health services to the surrounding community.

SUMMARY AND OUTLOOK

We have to date completed a preliminary assessment of the information management system and long-term supply and service process for the industrial development of medical devices in China using an evaluation system paradigm. The real advantage of this setup is that a large number of new and novel medical devices can be provided to hospitals, not only improving the level of service in Chinese medical institutions, but also providing a means to promote the improvement of medical devices and at the same time reduce health care costs. The targeted allocation of suitable products to primary health care institutions in particular has been very positively received.

With this in mind, we believe that the use and expansion of the evaluation system should be continued in order to promote innovation in the medical device space, create better products, and bring them to market more quickly. This will both benefit public health in general and accelerate development of a strategic emerging medical device industry.

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