

# **Solve the problem of medical and health services and promote the development of innovative medical technology**

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Since the reform and opening up, China's medical service system has undergone many reforms and has undergone earth-shaking changes. In terms of medical and health insurance, the employer-based urban medical insurance system (i.e. social welfare and labor protection insurance) and the rural cooperative medical system that had served the majority of the population have exited the stage, replaced by basic medical insurance for urban and rural residents, and basic medical insurance for employees. This new system has covers more than 95% of the population, initially established as a medical security system to adapt to the market economy system. In terms of the number of medical and health institutions, by the end of 2017, the total number of medical and health institutions nationwide reached 987,000, an increase of 12,000 compared with 2013, of which the total number of hospitals reached 31,000, an increase of about 6,000 from 2013; the national medical and health institutions hospital beds reached 7.94 million, an increase of 1.758 million compared with 2013, the number of hospital beds per 1,000 people among medical institutions increased from 4.6 in 2013 to 5.7 in 2017, and the number of licensed assistant physicians per thousand people increased from 2 in 2013 to 2.4 in 2017. The number of registered nurses per thousand people increased from 2 in 2013 to 2.7 in 2017. In terms of medical and health services,

the total number of medical treatments and services in national medical and health institutions reached 8.18 billion in 2017, an increase of 870 million compared with 2013, and the number of hospitalizations was 240 million, an increase of 50 million compared with 2013. Among public hospitals above the second tier, 81.4% carried out clinical pathway management, and 86.3% participated in the mutual recognition of peer to peer examination results. As of the end of 2017, average life expectancy in the country increased from 74.8 years in 2010 to 76.7 years in 2017, and the infant and child mortality rate and maternal mortality rate both achieved the United Nation Millennium Development Goals ahead of schedule.

At the same time, in terms of health care costs, due to changes in population migration and structure, changes in the types and structure of diseases, the introduction of new medical treatment technologies, and the improvement of living standards, medical and health costs have grown rapidly. From 3.17 trillion yuan in 2013 to 5.16 trillion yuan in 2017, the average annual growth rate is 13%, which is twice the growth rate of China's GDP during the same period. The proportion of health care costs to GDP increased from 5.5% in 2013 to 6.2% in 2017. Social health expenditures (mainly medical insurance expenditures) increased from 1.14 trillion in 2013 to 2.12 trillion in 2017, an average annual increase of 16.7%, which put heavy pressure on basic medical insurance funds, and some regions have even been unable to make ends meet.

With the aging of the population and the rapid growth in demand for better health care services, China's medical expenses will continue to grow at a high rate in the future, and pressure on medical insurance funds will continue to increase. On the

basis of keeping the personal self-pay ratio below 30%, it is obviously impossible to meet the demand of 1.3 billion people for medical and health services by simply relying on increasing government expenditure. Therefore, the way to improve the efficiency of the use of medical insurance funds, establish new operational and performance systems in public hospitals, achieve a reasonable reform of the medical service price system, and establish a high-quality and efficient medical service system is by encouraging innovation, and introducing new technologies and new products. That is the main way to solve the problem.

In order to solve these problems, the central government carried out drastic reforms and restructured relevant government departments in 2018, and established a new National Health Commission, the National Healthcare Security Bureau and the State Food and Drug Administration, in an effort to create a healthy healthcare related policy environment. The policy environment encourages and supports R&D innovation, optimizes market access, controls costs reasonably, and promotes diversified and multi-level medical and health services.

As the world's leading medical and health company, Abbott has been providing innovative technologies and products to countries around the world for many years, and has also contributed to the improvement of health care services in these countries. We are now proposing the following recommendations for building a high quality and efficient health care system and the practical application of innovative medical device products in China:

**I. First, increase government investment in medical insurance and establish a high quality and efficient medical service system.**

**i. Continue to increase investment in the medical and health fields and maintain a continuous increase in total health expenditure.**

The total cost of health expenditure is an important indicator of a country's health status. In 2017, China's total expenditure on health expenditure was 6.2%, compared with some advanced countries, such as 11.7% in France, 11.3% in Germany, and 9.3% in the UK. There is still a considerable difference from 8.3% in Japan. In 2017, total per capita health expenditure in China was about US\$560, while in America it was US\$9500. Total per capita health care expenditures in China were about 1/17 of the US. China's fiscal expenditure accounts for the proportion of total health expenditures, was only 24.6% in 2017, far below the average of 45% in OECD countries. China has become the world's second largest economy. As the people's demand for high-quality health care continues to increase, the government must continue to increase financial expenditures, narrow the gap with the government's investment in the health sector in advanced countries and gradually establish a high-quality and efficient medical care service system.

**ii. Develop a diversified supplement to medical insurance to reduce the medical burden on patients.**

The financing of China's total health expenditure is currently mainly composed of government budgetary health expenditures, social health expenditures and residents' personal health expenditures. In 2017, government budget expenditures accounted for about 30.1%, personal expenditures accounted for 28.8%, and social health expenditures reached 41.1%, a proportion which was obviously high. Social health expenditures are currently mainly borne by medical insurance funds,

and the pressure is huge. In China's health financing system, people's awareness of commercial health insurance plan) is not enough. At present, the varieties and coverage of commercial health insurance are very limited. The future role in medical insurance has great potential for development. In 2012, global commercial health insurance premiums accounted for 15.3% of total health expenditures, and as of 2016, China's commercial health insurance premiums accounted for only 2.37% of total health expenditures. As an important supplement to basic medical insurance, commercial health insurance can not only provide personalized and unique services for different groups of people, but can also relieve the pressure of medical insurance funds and reduce the medical burden of patients.

## **II. Second, promote medical technology and product innovation to create a good policy environment.**

### **i. Create an open and transparent policy environment to promote the healthy development of the health care industry.**

The medical health industry is a special field, and medical technology and products are also special commodities, which are different from other industries. First of all, the medical and health industry needs government permission to operate, its products and services are used to cure diseases and save people; secondly, the development of the industry is highly dependent on industrial policies, and medical and health policy largely determines the direction of development. In the past few years, the Chinese government has largely been public and transparent in formulating policies in the field of health care. When formulating policies for certain special medical service product areas or pilot

policies, we recommended that both the central government and local governments not only publicly listen to suggestions from all sides, but also that they open effective communication channels to prevent awkward situations that when visiting relevant departments and officials. Many hands make light work. Only by extensively listening to opinions and fully discussing and verifying can we ensure the rationality, fairness and operability of policy, and encourage the innovation, research and development and production of medical technology and products, so as to realize the healthy development of the healthcare industry.

## **ii. Provide policy protection and make innovation sustainable**

Continuous innovation is the source of the development of the medical and health industry. Innovation requires the government policy support and guidance in all aspects of product development, production, and application. Any missing link in the chain will affect the coordinated development of the entire industry. As we all know, the health care industry has a long innovation cycle and is a high-input, high-risk industry. According to a study from Stanford, an innovative medical device needs 3 to 7 years to go through pre-clinic research, clinic trial approval, clinic trials, post-market research, and re-approval. The average investment for each device is \$31 million (approximately RMB 214 million). For high-risk medical devices, the average investment per device is as high as \$90 million (approximately RMB 621 million). In order to make innovation sustainable, the government needs to provide policy guarantees for various aspects such as market access, clinical path, and medical insurance payments, so that enterprises can have adequate funds to be put back into new R&D to make innovation sustainable.

### **iii. Optimize market access policies and accelerate market access for new products.**

Due to the particularity of the medical and health industry, after an innovative technology or product is approved for the market, it must go through pricing, bidding and other processes before entering the medical institution for use by doctors and patients. Although in the past few years, the State Food and Drug Administration has introduced a number of measures for reviewing new drugs and medical devices, speeding up the review process and providing a quick review channel for innovative products, completing the review of new products is only the first step towards market access. From the development of samples for the clinical use of an innovative medical device, it usually takes 2-4 years to approve a new medical service project, and 2-3 years to go through a centralized procurement/online bidding cycle. However, National Medical Service Price Regulation has not been updated since 2012. This has hindered the promotion and use of new products. Therefore, the government should speed up the process of review and approval, establishment of new service projects, bidding procurement and updating of the medical insurance catalogue, so that truly valuable new technologies and new products can be put into clinical use as soon as possible so that Chinese patients can use them as soon as possible and live a healthy life brought by new technologies and products.

## **III. Third, promote the review and approval of the international standards, and accelerate the market entry of products.**

### **i. Adjust the classification of medical devices to be in line with international advanced practices.**

China's classification of medical device is not yet in line with international standards, and the definition of three types of devices is rather broad. In the European Union and the United States, only 10% of medical devices are included in the third category of the highest risk, but in China, the proportion of medical devices classified as Category III high-risk is as high as 33%. For example, in the United States, Japan, Canada, and Australia, medical imaging products and radiotherapy products belong to Category II devices, while in China they belong to Category III devices. Therefore, manufacturers often need to submit more complex materials and conduct clinical trials. This not only increases the time and cost of registering products in China, but also increases the workload of reviewers and disperses limited review resources.

**ii. Standards and clinical trial requirements should match product risk level.**

The application materials requirements and local Chinese clinical trials should be based on the safety and effectiveness of the product, and based on the risk of submitting materials that are of substantial help to patient safety and treatment. The average innovation cycle for products in the medical device industry is 18 months, and most clinical trials last at least 2-3 years. Implementing unnecessary clinical trials will result in the Chinese market at least falling behind the international two generations of technology. We recommend that China's relevant regulatory agencies and technical agencies adopt a risk-based testing model that requires clinical trials only if the product safety and clinical effectiveness have not been proven, or if the product has specific and provable benefits to the patient's health. This approach can balance the best interests of regulators, industry and patients.



#### **IV. Fourth, encourage the diversification of medical services to meet the multi-level medical needs of patients.**

##### **i. Encourage innovation to meet the diverse needs of people with different abilities to pay.**

The needs of clinical patients are the driving force behind the innovation of medical service technology. Innovation can provide doctors and patients with more convenient and efficient diagnosis and treatment, as well as a better quality of life, even saving lives that could not be saved. For example, patients suffering cardiac arrest have a high risk of death. An implantable cardioverter defibrillator (ICD), a high-end cardiac pacing product, is a small medical device that can be implanted in the chest or abdominal cavity of a patient. After a high-risk patient is implanted with a defibrillator, when a rapid ventricular arrhythmia occurs, it can be converted to a normal heart rhythm within a few seconds, reducing the incidence of sudden death. With more than 500,000 patients in China who died from heart attacks every year, ICD is the best innovative medical device to save their lives.

##### **ii. Medical insurance support to encourage patients to have the right to choose clinical treatments.**

Ability to pay has also increased, but basic medical and health services have been unable to meet their needs--especially for elderly patients. The high-paying community is steadily and rapidly growing in demand for efficient testing, safe treatment, and quality care. China is currently experimenting with payment

method reforms, and it is recommended not to limit patient's right to choose clinical treatments. The clinical application of multiple treatment options and pathways can be used to compare and evaluate long-term medical quality and efficacy of different medical technologies and products, and to calculate total costs, providing evidence and data support for the development of reasonable and incentives for innovative reimbursement policies.

**iii. Medical insurance (social welfare) and commercial insurance coexist to meet the multi-level medical needs of patients.**

As the full coverage of basic medical insurance increases and medical needs rise, due to pressure on the medical insurance fund, it is recommended to encourage commercial insurance companies to participate more in social medical insurance services to improve the health financing mechanism and management efficiency. Through the establishment of a multi-channel medical insurance system, taking into account the medical needs of people at different levels and in different regions, the patients' disease burden will be rationalized and the accessibility of health services will be improved.

**V. Fifth, establish a big data driven medical technology and product science evaluation system**

**i. Improve the efficiency of the use of medical insurance funds and establish an evaluation system for medical technology and products.**

Although China's basic social insurance has provided basic coverage for its people, it is still a developing country. In order to maximize the usage of limited resources,

to treat and save more lives, establishing a scientific evaluation system, and improving the efficient use of medical insurance funds is a very important part of the medical service system. Good quality products and the single use price of technology will be higher on average than products with unproven medical results, but these good quality products can often determine the best treatment by improving clinical efficacy, shortening hospital stay and reducing continuous medical expenses. They can also reduce the total cost expenditures, and achieve a more efficient use of the health care fund, thus reducing the economic burden of patients. Based on today's big data processing capabilities, we can use scientific models and data to find the best treatment, rather than focusing solely on "expensive" or "cheap" for a single product price. Establishing an evaluation system for such technologies and products as early as possible to improve the efficiency of the use of health insurance funds in a more comprehensive and scientific manner is the best way and direction to achieve a quality and efficient medical service system.

## **ii. Promote value-based procurement based on a quality and efficient medical service system.**

Practice is the only criterion for testing truth. This standard is the quality and clinical efficacy of medical and medical technology products. In a market economy, high-quality products must have a reasonable market price to support the competitiveness of quality products in the market and ensure the healthy development of the medical industry. Establishing an evaluation system for medical technology and products means preventing throwing bad money after good. Our procurement activities should make full use of the technical assessment

under the guidance of health economics in a high-quality and efficient medical service system, and adopt procurement activities based on value rather than price to avoid low-cost disorderly competition and quality compromise and ensure that patients are safe and effective. High quality and reasonably priced products and services should become the norm. They are also one important part of a high quality and highly efficient healthcare service system.

In summary, in order to overcome the hurdles of health care services, our government should draft and implement efficient, reasonable and sustainable policies in the areas of innovation, approval process, market entry, procurement, evaluation, administration and insurance. When we look back on the history of human society's economic development, every significant reform originated in technological innovation. Therefore, we believe that only through the establishment of a rational system, allowing innovative medical equipment and technology to enter the healthcare service system and serve doctors and patients, the difficult task of promoting the healthy growth of the healthcare service system can be achieved.