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The Chinese health care system: An analysis of the current and emerging health care needs

Karen K Giuliano and Courtney M Droms

Abstract

This paper presents an overview of the health care system, current and anticipated health care challenges, and the potential for medical technology to address the health care needs of the People's Republic of China. The implications of these topics for the modification of current strategies or development of new technologies to address the current and emerging health care needs in China will be reviewed in order to assess the industry's current plans for expansion of their operations to the health care market in the People's Republic of China.

China has reformed and opened its economy since 1978 and this has had a profound impact on China as well as the entire world. The market-oriented reforms implemented in the past three decades have resulted in the largest reduction of poverty and one of the fastest increases in income levels ever seen. In 2009, China had the fourth largest economy in the world and had enjoyed sustained average economic growth of over 9.5% since 1982.¹ In the 1980s, China implemented a combination strategy of central planning combined with market-oriented reforms to increase productivity, living standards, and technological quality while not causing inflation, unemployment, and budget deficits. The government also encouraged non-agricultural activities in rural areas and promoted more self-management for state-owned enterprises, increased market competition, and promoted direct contacts between Chinese and foreign trading enterprises. China also began to increasingly rely more upon foreign financing and imports.¹ These changes to the regulatory and economic structure in China have opened up the market to foreign companies. Specifically in the health care industry, there are a variety of opportunities for international companies to enter the China market with health care products and services. This paper will provide an overview of the Chinese health care system and the recent changes in the economic, regulatory, and legal environment surrounding the provision of health care products and services. In addition, we will discuss the implications of these changes for health care marketers.

The Chinese health care system

Prior to China's conversion to a more market-oriented economic system in 1978, the central government was solely responsible for financial support and administration of the health care system.² The primary sources of payment for health care services included the Government Employee Health Insurance System, Labor Health Insurance System, and Cooperative Medical Insurance System with the majority of the population covered by one of these three plans until the early 1980s.^{2,3} Centralized funding and coordination of health care services prior to the 1980s resulted in significant increases in life expectancy, reduced infant mortality rates, and eliminated or controlled many infectious diseases.^{3,4} These accomplishments were largely attributed to efforts that emphasized preventive health care, improved access to innovative, low-cost, locally controlled health services, and increased delivery of primary health care to rural populations.⁴ During Mao's Cultural Revolution, a stronger commitment was made to establish and improve health care in rural areas of China, which resulted in transfer of medical personnel from urban to rural regions.^{3,4} A key component of efforts to improve rural health care was

training “barefoot doctors” who were hired by the government to provide health care services in private clinics in rural regions of China.^{3–5} However, these “doctors” were generally poorly trained and lacked the equipment and resources to provide care but their services were virtually free to the public.

The expansion of health care in rural areas focused on simple public health interventions such as sanitation improvements and administration of immunizations and is credited with some impressive improvements in the health of Chinese citizens. For example, infant mortality rates declined from 250 per 1000 in 1952 to 40 per 1000 in 1982, life expectancy doubled during this same time period, and there were dramatic decreases in transmission of infectious diseases.^{4–6} Notably, immunization rates of 1-year-old children exceeded 90% for both tuberculosis and measles and the rate of malnutrition among children younger than 5 years was less than 10%.⁶

As China experienced tremendous economic growth beginning in 1978, the nation’s health care delivery system also underwent radical changes. These were primarily due to re-structuring of the health care system and the reductions in financial support from the central government to pay for health care services.^{3,4} The health care system assumed a multiple tier structure headed by the Ministry of Public Health (MOH), which reported to the State Council. Each tier of the system had a Department of Public Health. The MOH managed a central budget that supported control and financing of medical schools, some hospitals, and specialized research institutions.⁴ The Bureau of Public Health (BPH) fell directly under the MOH and was responsible for management of large hospitals (500–700 beds), anti-epidemic stations, sanatoriums, and drug control institutions. The BPH was also involved with maternal and child health and monitored adherence to standards for pharmaceutical products.⁴ Wealthier provinces and municipalities in China were likely to have several large hospitals as well as access to university or “middle-rank” medical schools and other institutions involved with training and education of health care professionals. This ensured access to better care for populations residing in wealthier areas of China.⁴

The county level relied on County Departments of Public Health to manage one or more county hospitals and traditional Chinese medicine (TCM) hospitals as well as services for control of epidemics and delivery of maternal and child health care.⁴ The fourth level of the tier consisted of Township Health Centers, which may have had a small hospital (approximately 30 beds) staffed by physicians who had been trained at “middle-rank” medical schools. The primary responsibility of these Township Health Centers was control of contagious illnesses. Village Clinics comprised the fifth and lowest tier of the Chinese health care system and these clinics relied solely on services delivered by one or two “barefoot doctors” who provided care on a fee-for-service basis.⁴ Health institutions at or below the county level were considered rural and in 1990, a total of 2256 hospitals operated in rural areas along with 47,000 township health centers and 638,580 village clinics.

In addition to the government health structure, health care delivery was offered by institutions such as the People’s Liberation Army and some state owned large industries, such as the rail system. These privately funded health services supported hospitals and, in some cases, medical schools and were controlled by their respective ministries rather than the central Ministry of Health.⁴ Notably, about one third of hospitals were funded by private institutions with many

businesses in large urban areas of China having their own hospitals that were dedicated to the care of their employees.⁴

As China's economic policies radically changed in the early 1980s, so did the centralized approach to health care including financial decentralization of budgets from the central to provincial governments and reform of strategies for management and control of hospitals. These changes were intended to improve control of services by introducing more realistic pricing structures, reducing administrative staff, eliminating benefits to hospital staff (such as free or low-cost housing), and imposing limits on hospital budgets.^{3,4,7} In addition, facilities were allowed to charge the citizens for services under a fee-for-service structure established by the Price Commission.^{3,5,7,8} The impact of these changes on health care in rural areas of China was immediately evident and negative including a reduction in coverage by the Cooperative Medical Insurance System. For example, in 1975, the Cooperative Medical Insurance System covered health care services for 75% of the population residing in 90% of villages. This decreased to only 6% of villages by the mid-1980s.^{4,7} The loss of funding by the Cooperative Medical Insurance System resulted in closure of village health stations, loss of village health workers to provide services since they were not assured of payment, and an increased emphasis on provision of fee-for-service care.^{3,4} There was also a significant reduction in primary preventive care, which previously had been provided at no cost by the "barefoot doctors." Consequently, childhood immunization rates declined as did other preventive health care services and there was an increased emphasis on provision of services such as administration of new drugs, diagnostic tests, and medical technology, which were more likely to generate revenue.^{3,4} Furthermore, the government modified the salary-based system of compensation for hospital physicians to include bonuses based on the amount of revenue generated by individual physicians. Such bonuses resulted in an "explosion" of sales of expensive pharmaceutical products and use of high technology services and interventions.³

The declines in quality and type of health care services were particularly evident for rural areas of China while access to quality tertiary health care actually improved in urban areas where the population had greater financial resources pay for such services.^{3,4} One study reported that about 800 million individuals lived in rural regions of China while 80% of medical institutions were located in urban centers.⁹ While some of the more wealthy areas of China, particularly urban areas, were able to respond to decreased funding by the central government, the majority of local governments did not have the financial resources to pay for health care. One study reported that in 2003 only 55% of urban and 21% of rural populations had access to some form of health insurance, 13.8% and 15.8% of urban and rural households, respectively, incurred catastrophic medical costs, and 15.1% of urban residents and 21.6% of rural residents did not seek medical care when necessary because they could not afford the cost.^{5,9,10} Data from the National Health Accounts revealed that total health expenditures increased 40-fold from 1985 to 2005 and were estimated at US\$91.8 billion in 2005, equivalent to 5.5% of China's gross domestic product (GDP).⁹ Strikingly, investment by the central government in health care declined from 36% in 1980 to 17% in 2004.⁹ Notably, patient out-of-pocket costs for health care were estimated to increase from approximately 20% in 1978 to 60% by 2001.⁵ Research indicated that as many as 40% of ill individuals who did not receive medical care due to economic barriers; this increased to 70% of individuals who were recommended for hospitalization by a physician.⁵

In addition to the loss of financial support for health care by the central government, there was a significant reduction in the government's supervision and administration of health care delivery and quality of services. The absence of centralized legislative or official administrative rules or regulations to monitor physician performance, use of modern technologies, and introduction of new drugs from developed countries resulted in increased rates of unnecessary diagnostic tests and prescriptions for unneeded and costly medications. 9 Of particular concern was the adoption of new medications from other countries. For example, the Food and Drug Administration in the United States approved 148 new drugs in 2004; approximately 10,000 new drugs were registered in China during that same period. During this time, efforts to control the costs of medications were minimal and most prescription drug prices were quite high and frequently required out-of-pocket payment.9 Studies demonstrated patterns of over-prescribing of pharmaceutical products as well as over-utilization of tests such as computed tomography scans for patients who could afford to pay. However, patients without resources often received no care since they could not afford to pay for these medications or tests.9

There were dramatic geographic disparities in health care outcomes that were particularly evident for western provinces of China as compared to the eastern, more developed coastal regions. For example, infant and child mortality rates in many western provinces were three to five times greater compared with children residing in coastal areas. Similarly, the China National Maternal and Child Surveillance reported that maternal, infant, and under-five mortality rates for 2004 in rural areas were two to three times higher compared with those in urban areas. Furthermore, life expectancy was generally lower in rural provinces and areas with higher poverty rates.6 A key factor contributing to these disparities in health outcomes was lack of resources. While two-thirds of China's population resided in rural areas of the country in 2000, only 22.5% of the national total of health expenditures was allocated to support rural health care services.5 Hu and colleagues also reported significant disparities between and within regions and provinces of China, noting that "provisions for cost-matching do not sufficiently take account of the constrained fiscal status of many local governments in central and western China. Lower rates for cost-matching in poorer provinces would help reduce disparities and improve health equity".11

A 2008 survey of the 101,000 households in China revealed that health care was the primary concern of the population with access to care and the high cost of services cited as the leading factors that contributed to the public's dissatisfaction with health care.11 Additional barriers to care included widespread inefficiencies in provision of health care services, low productivity, inadequate resources, and over-spending on unnecessary medications and prolonged inpatient stays.11

Recent changes in government health care policies

The identification of the widespread and serious problems that confront the health care system and compromise the health of the Chinese population prompted the government to take action in 2006 to reform the health care system, outlined in the 11th Five Year Plan. The proposed plan seeks to provide access for all Chinese citizens to affordable essential health care and includes the following efforts to be accomplished from 2006 to 2010.12

- Increased investment by the government in health and improvements to the public health and clinical service delivery system.
- Enhanced emphasis on disease prevention and control and establishment of a medical safety net for the poor with a focus on leading causes of mortality in China including human immunodeficiency virus (HIV)/AIDS, schistosomiasis, and hepatitis B and effort to prevent occupational and endemic diseases.
- Strengthened maternal and child health care and promotion of the development of community health services.
- Extensive reform of the health care system reform and allocation of health resources rationally including better regulation of pharmaceutical production and products.
- Support for the development of TCM and fostering a modern TCM industry.

Since 2006, the Government has also made a commitment to more clearly define its role in health.¹² A 14-ministry working group was established to define future health care reforms and this working group is led by the National Development Reform Commission and the MOH. This working group has recently finalized plans for health reforms, which began pilot implementation in 2008.

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China has made significant progress toward achieving most of the MDGs, benefiting from the positive effects of both rapid economic growth and targeted government programs. However, these improvements have not equally benefited all of China's citizens with socioeconomically disadvantaged and rural localities least likely to benefit.¹² China also made an important commitment to the health of the nation when it signed the Framework Convention on Tobacco Control in November 2003. Ratified by China's National People's Congress in August 2005, the convention became effective in January 2006. Subsequently, China's Ministry of Health has taken steps to improve public awareness of the health risks related to smoking and inhaling second-hand smoke and to reduce smoking in public areas.¹²

Current and emerging health care needs

Overall, people in China are living longer and healthier lives with a health profile that is comparable to many Western nations. From 1980 to 2003, life expectancy increased from 67 to 71 years, immunization rates for tuberculosis and measles for children under 12 months reached 89%, and the malnutrition rate for children younger than 5 years fell below 10%.¹³ Overall infant mortality rates declined from 90 per 1000 births in 1950 to 24.1 per 1000 births in 2005

although this trend was not evenly represented throughout all regions of China. Specifically, infant mortality rates are 3- to 5-fold greater in the western provinces of China compared with the urban coastal areas.¹³ Notable statistics that characterize the impact of infectious and chronic disease on the Chinese population are presented in Figures 1 to 8. Emerging infectious diseases, such as severe acute respiratory disease syndrome (SARS) or avian influenza (H5N1), are also of great concern, particularly for their potential to quickly develop into epidemics in a highly populous country.⁶

The WHO estimates that approximately 85%–90% of deaths are attributable to chronic diseases and injuries. Chronic diseases of concern include cancer, cerebrovascular disease, chronic obstructive pulmonary disease (COPD), and cardiovascular disease (CVD).¹³ Together, these conditions are estimated to contribute to 40% of the annual death rate in China with this rate expected to increase as the population continues to age. An 18-year longitudinal study of male veterans in China revealed that the three leading causes of death were cancer, CVD and stroke, and COPD.¹⁴ The total person-years of follow-up was 18,766.28. Of the initial cohort of 1268 men, 491 had died, 748 were alive, and 29 were lost to follow up. Mortality adjusted for age, blood pressure, body mass index, cholesterol, triglycerides, alcohol, exercise, and existing disease was 2616 per 100,000 person years. The proportional mortality attributed to cancer, vascular disease, and COPD were 39.71%, 28.10%, and 16.90%, respectively. Multivariate analyses indicated that age, number of cigarettes smoked per day, systolic blood pressure, triglyceride level, family history of hypertension, stroke and cancer, existing diseases such as stroke, diabetes, and cancer, body mass index, and age at initiation of smoking were associated with all-cause mortality in these men.¹⁴

However, the burden of disease varies considerably by age group with infants and young children at highest risk of infectious diseases while older Chinese populations are significantly more likely to be affected by disability and chronic diseases. It is estimated that 70% of deaths among children under 5 are attributable to maternal, perinatal, or nutritional conditions as well as infections and communicable diseases such as sepsis, pneumonia, diarrhea, measles, and tetanus. Children aged 5–14 years are especially vulnerable to deaths attributable to injuries and accidents. In addition, mental health problems and suicide are important causes of disability and death, particularly among 15- to 34-year-olds and women residing in rural areas.⁶

Tuberculosis

China has a particularly high rate of tuberculosis with the prevalence for all forms of tuberculosis estimated at 208 per 100,000 population in 2000. The WHO estimates that there were 1.3 million new active tuberculosis cases in China in 2006, of which 600,000 were considered highly infectious. An estimated 200,000 people die from tuberculosis annually.⁶

Malaria

A massive initiative to control malaria was launched in 1955 and significantly reduced the annual number of cases from 30 million. However, malaria remains a particularly difficult issue for populations residing in border areas of the country's tropical south and in the central area of the country. There has been a resurgence of malaria in these geographic areas since 2001 with a reported malaria incidence rate of more than one case per 1000 people in 2006.⁶

HIV

China is considered to be a low HIV-prevalence country with an estimated prevalence of about 0.5%.^{15,16} Official estimates suggest that 650,000 people were living with HIV in 2007 with a range of 540,000–760,000.^{15,17} A total of 50,000 new cases and 20,000 HIV-related deaths were estimated to occur in 2007.^{18,19} Current efforts to monitor the HIV epidemic in China include surveillance by 393 national and 370 provincial sites that report to the National Center for AID/Sexually Transmitted Disease Control and Prevention.¹⁶ These surveillance efforts suggest that the first case was identified in 1985 and the epidemic was sporadic in nature from 1985 to 1988. Local transmission of HIV/AIDS occurred from 1989 to 1994 and the epidemic is now considered to have generalized to affect all 31 provinces of China.^{16,20–22} However, there are notable geographic variations in HIV prevalence rates with the highest rates evident for several provinces in central, southern and western areas of the country.^{6,15,16,19,23–25} The primary modes of transmission include sexual transmission between men having sex with men, high-risk heterosexual contact, and injection drug use.^{6,18,19,26}

CVD

Among Beijing residents, CVD mortality rates increased 50% for men and 27% for females aged 35–74 years from 1984 to 1999.²⁷ These increases were attributed to significant rises in levels of total cholesterol as well as the increased incidence of diabetes and obesity and continued high rates of smoking among men.²⁷ CVDs are expected to become a leading cause of morbidity and mortality throughout all of China in the next two decades due, in part, to the aging population as well as modifiable and non-modifiable risk factors.^{27–30}

The CHD Policy model was used to estimate anticipated increases in CVD events and deaths in China between 2000 and 2029.³⁰ Results suggested that there would be a 69% overall increase in CVD events and a 64% increase in CVD deaths during this time period.³⁰ These increases translate to 7.8 million excess CVD events and 3.4 million excess CVD deaths. The highest prevalence of CVD is predicted for adults 65 years and older with 71% of almost 1 million deaths attributable to CVD in 2030 occurring among individuals in this age cohort. The researchers further conclude that these projections may underestimate the extent of the impact of CVD on the Chinese population because they were solely based on the growing numbers of older population alone and did not consider increased rates of risk factors for CVD.³⁰

Cheng and colleagues considered the impact of risk factors for CVD such as dyslipidemia, smoking, hypertension, and obesity on the projected burden of CVD in China. They conclude that in Beijing alone, the combined effect of an aging population and exacerbation of these four risk factors will result in a 67% rise in mortality attributable to CVD between 1999 and 2010.²⁹ The prevalence rates for hypertension, hyperlipidemia, diabetes, and obesity have been estimated at 18.8%, 18.6%, 2.6%, and 29.9%, respectively, of the total adult population in China. It is estimated that two-thirds of the adult population 35 years or older in Beijing and Shanghai have hypertension.¹³ Yu and colleagues reported that 79.4%, 40%, and 11% of Chinese adults with comorbid pre-hypertension had ≥ 1 , ≥ 2 , and ≥ 3 modifiable risk factors for CVD, respectively. These risk factors included dyslipidemia, impaired fasting glucose or diabetes, current tobacco use, and overweight or obesity.³¹

Women have been recognized as an emerging high-risk population for CVD and in fact, heart disease was the most common cause of death among Chinese women in 2008 and the second leading cause of death for Chinese men in that year.²⁸ This is attributed to a high prevalence of risk factors including hypertension, dyslipidemia, diabetes, physical inactivity, and obesity. It has been estimated that 12%–35% of Chinese women aged 35–74 have one to three major risk factors for CVD.³² In 2001, the prevalence of hypertension among Chinese women was 10.7% for women aged 35–44 years, 26.8% of women aged 45–54 years, 38.9% of women aged 55–64 years, and 50.2% of women aged 65–74 years.³² Similarly, rates of dyslipidemia among Chinese women, particularly those aged 55–64 years, have risen in the past two decades. For example, total cholesterol levels in women aged 55–64 years increased from 4.7 to 5.9 mmol/L from 1984 to 1999.²⁷ Importantly, among women with total cholesterol levels \geq 200 mg/dL, only 3.4% were aware of their cholesterol level, 1.9% received treatment for hypercholesterolemia, and 1.5% had successfully controlled their cholesterol through medication. In contrast, among Chinese men with total cholesterol levels in excess of 200 mg/dL, 8.8% were aware of their condition, 7.5% had been administered treatment, and 3.5% were controlled.³³ While only a small number of women in China are smokers themselves, it is estimated that 60% of them are exposed to secondhand tobacco smoke in their homes, the workplace, and public venues and this is considered to be a major factor contributing to the rising burden of CVD on Chinese women.^{34–36} Chinese women residing in both urban and rural areas of China are also significantly less likely to be physically active or take part in work-related or leisure-time physical activities compared with their male counterparts.³⁷

Cerebrovascular disease, particularly stroke, is closely associated with many of the risk factors for CVD and several studies document significant changes in the epidemiology of stroke in China since the mid-1980s.^{38–41} The Sino-MONICA-Beijing population includes approximately 5%–7% of the total population residing in Beijing from 1984 to 1993 and approximately 1%–3% of the total Chinese population from 1994 to 2004. The project is a longitudinal surveillance study of the incidence and mortality rates for both acute stroke and ischemic heart disease (IHD) in China, particularly, Beijing. Stroke rates are monitored for adults aged 25–74 years from 1984 to 2004. A total of 14,584 stroke events occurred during the observation period with 72.3% of these classified as non-fatal. Among non-fatal stroke events, 87% of patients were hospitalized and 13% required care at a nursing home or home health care.⁴¹ While the age-standardized incidence rate of hemorrhagic stroke declined by 1.7% annually from 1984 to 2004, the incidence of ischemic stroke increased by an annual rate of 8.7% during the same time period.

The incidence of all strokes combined increased 6.7% annually during the study interval. However, annual mortality rates attributed to stroke of any type declined for both men and women including a 1.7% decline in mortality due to hemorrhagic stroke and a 0.5% decline for ischemic stroke, with the decreased trend for death due to stroke significantly greater in the second decade of the study. In addition, mean age at occurrence of stroke increased by 2.7 years for men and by 3.6 years for women in 2004 compared with the mean age at onset of stroke in 1984.⁴¹

Obesity

When compared with other Western countries and the United States in particular, obesity rates in China are quite low. It was estimated that 14.7% of the population was overweight and 2.6% were obese in 2002. By 2006, the Chinese population accounted for 20% of the world's total overweight.¹³ However, the prevalence of obesity and overweight has dramatically increased in recent decades. Current estimates suggest that 35.2% of men and 39.5% of women are overweight.²⁸ Significantly, it is estimated that 25% of Chinese children will be obese by the year 2010, creating a major risk factor for development of serious chronic health conditions.¹³ Poor eating habits and increasingly sedentary lifestyles are the primary factors thought to contribute to the rising obesity rates in China.

Cancer

Cancer is also becoming a significant health concern for China with deaths due to cancer increasing 41.5% from 1990 to 2000. The prevalence of hepatic, gastric, and colorectal cancers is high and the rate of growth of new cases is double that observed for other developed countries.¹³ Lung cancer is the most common type of cancer and the incidence of lung cancer increased by 61.3% from 1990 to 2000, which was largely attributed to the high rates of tobacco use.¹³ Current estimates suggest that approximately 60% of all adult men smoke, placing them at increased risk for various cancers as well as COPD, cerebrovascular disease, and CVD.^{13,42} Recent analyses from a multi-stage household probability sample of 5201 adults aged 18–70 years revealed that 55.5% of men and 5.5% of women were current smokers and 67.1% and 7.1% of men and women, respectively, were ever-smokers.⁴³

Smoking as a risk factor for disease

There is also emerging evidence to suggest that the prevalence of smoking is increasing among younger men and women.^{44,45} A random sample of 4724 high school students completed a self-administered questionnaire that included items assessing their smoking behaviors. Overall, prevalence rates of ever smokers and smoking in the previous 30 days were 24.3% and 9.0% for males and females, respectively. Older students were more likely than their younger peers to have tried smoking at some time and to have smoked within the past 30 days.⁴⁵ Smoking rates among college students were significantly higher in a cross-sectional survey of 1874 students attending 19 colleges in Jiangsu province. Overall, 53% of the respondents (70% male and 31% female) reported ever having smoked in their lifetime and 29% of the sample (49% male and 5% female) reported having smoked in the past 30 days. Forty-four percent of men and 6% of women indicated that they were likely to smoke in the next 6 months. These results suggest that there is a substantial amount of smoking experimentation among adolescents and young adults in China, which presents a challenge to prevent a large proportion of experimenters from progressing to regular smokers.⁴⁶

A large, prospective cohort study of 169,871 Chinese adults 40 years or older collected data on smoking and other risk factors at a baseline examination in 1991 with follow-up evaluations completed in 1999 and 2000.⁴⁷ During an average 8.3 years of follow-up, there were 17,863 deaths with 56.8% of these occurring in males. There was a significant, dose–response association between pack-years smoked and death due to any cause for both men and women after adjustment for multiple risk factors. In addition, the number of deaths due to smoking

increased with age, regardless of gender. A total of 673,000 deaths were estimated to be attributable to smoking in China in 2005. The leading causes of smoking-related deaths included cancer with 268,200 deaths, 146,200 deaths due to CVD, and 66,800 deaths due to respiratory disease.⁴⁷ Notably, lung cancer had the highest population attributable risk due to smoking at 50.6% for men and 14.8% for women. The three leading diseases associated with death among men who smoked were lung cancer, stroke, and COPD, which accounted for approximately 45.1% of total deaths attributable to smoking for men. The three leading diseases associated with smoking among women were COPD, lung cancer, and stroke and together these accounted for 31.8% of tobacco-related deaths in Chinese women.^{47,48}

Emerging health care Issues in China

Recently, China has become increasingly receptive to outsourcing for the manufacturing of medical devices and there has been a significant increase in spending on medical technology from US \$2,257m in 2003 to US \$7,026m in 2007.⁴⁹ Specifically, improved technology and quality of manufacturing efforts in China have been helpful in attracting foreign manufacturers of medical devices to China.¹³ The changing demographic profile of the population characterized by growing numbers of older individuals at risk of chronic diseases such as CVD, cancer, COPD, and stroke will result in an increased demand for both new pharmaceutical and device interventions. It is anticipated that the people's ability to purchase health care will also increase as the country's economic growth continues and there will be a rise in per capita spending on health care services.¹³ Regulations for the monitoring and control of medical devices are relatively new to China with the first such regulations established in 2001. However, the central government has taken a number of actions since that time to develop new regulations to support the medical devices market in China. These include the following efforts, which should continue to become increasingly more favorable for the medical device industry:^{13,50}

- New regulations for inserting, labeling, and packing of medical devices and equipment that are written in the Chinese language (effective July 2004).
- New device registration procedure requiring devices to undergo three batch tests (effective July 2004).
- Implementation of new registration requirements to simplify the application and review process for medical devices and equipment, which is intended to make it easier for foreign countries to export medical devices and equipment to China (effective August 2004).
- Reductions in tariffs on medical devices and equipment from 11% in 2002 to 6% in 2003 and less than 4% since January 2005.
- Implementation of a cap on the prices of medical devices and equipment to control rapid price increases (2006).
- Implementation of a cap on the price of disposable medical devices when moved from the manufacturers' location to the patient not to exceed 40%.

- A cap of 25% on price increases for implantable medical devices with a manufacturing price less than US \$617 and a cap of 20% price increase for devices with a manufacturing price greater than US \$617.

Regulatory oversight for class I low-risk and class II modest-risk devices is assigned to provincial governments while the State Food and Drug Administration (SFDA) in China regulates class III high-risk devices. These include implantable or life support devices and manufacturers of such devices are required to submit clinical trial reports, on-site inspection results, and standard documentation.¹³ Medical imaging devices are usually classified as either class II or III and the SFDA office will assist manufacturers to determine the appropriate classification for their device.¹³

The registration process for medical devices of all classes is usually about 90 days for a fee of US \$500 with approved registrations valid for 4 years. Re-registration after 4 years is required and should be initiated at least 60 days prior to expiration of registration. In addition, a written request for renewal of a registered device must be submitted 6 months before the initial registration expires. Changes or additions of manufacturing locations for specific devices require a new product registration process.¹³

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The SFDA has attempted to simplify the application and dossier process for registration of medical devices and equipment by establishing a single-step process for both actions. The SFDA regulations require submission of 12 documents in both Chinese and English. There is no need to authenticate the documentation by Chinese Embassy, which was required prior to March 2005. Currently, there are two types of registration including trial production registration and manufacturing permit registration.¹³

Direct application by the manufacturer for permission to manufacture class I domestically manufactured devices is permitted. However, domestically manufactured class II and III devices must adhere to a two-step process for registration. Initially, the registration is for the trials valid for a period of 2 years. After 7 months of completion of the trial registration, a company may apply for a manufacturing permit, which is valid for 4 years. Re-registration can occur 6 months prior to expiration of the manufacturing permit.¹³

In order to ensure safety of certain devices and equipment, including x-ray equipment, hemodialysis equipment, hollow-fiber equipment, and implantable cardiac pacemakers, the China Quality Certification Center requires a CCC. All licenses and certificates identify the name of the manufacturer in China rather than the agent or distributor. It is acceptable for

manufacturers to request certification in the name of the distributor. Foreign firms often partner with local legal counselors to ensure that their rights are protected in China.¹³

There is a government quota imposed on the purchase of medical devices and equipment as well as budget restrictions and price limits based on the size of the hospital and population likely to be served by the equipment and facility. These restrictions and price limits apply to both state- and privately-owned hospitals. However, private health care facilities have greater flexibility with their funds to purchase medical devices and equipment, whereas government-owned hospitals have little power to make decisions about the purchase of devices or equipment. Financial assistance to purchase medical devices is usually required by state-owned facilities as commercially loans are rarely awarded to these types of facilities.¹³ The sale of medical devices and equipment to a state-owned hospital requires companies to participate in the bidding and tendering process, which is regulated by the MOH. There has been a trend for manufacturers to bid prices 15% below the market price, which reduces profit margins.¹³

Implications and conclusions

Given the current set of circumstances in the Chinese health care market, the following are some of the most significant opportunities and restrictions facing health care marketers looking to expand their products or services into China.

Opportunities for health care marketers

The current health care system in China is incredibly structured. However, there are opportunities at every level of the system for foreign companies to expand into the China market. At the top of the structure is the MOH, which controls financing of specialized research institutions and the manufacturing and production of medical devices and technology. At this level there are opportunities for strategic partnerships between specialized medical research institutions in the United States, such as the Mayo Clinic or the most well-respected medical schools, to partner with similar institutions in Beijing or other large cities in China. These partnerships could provide the opportunity for knowledge and technology transfers between the two institutions. In addition, the MOH has been increasingly receptive to partnering with providers of medical devices and services, especially for companies looking to outsource the production of medical technology. As a result, companies looking for new avenues of distribution and new venues for production of medical equipment could benefit from investigating strategic partnerships with Chinese companies or the MOH.

The next level of the health care system is controlled by the BPH that specializes in maternal and child health and controls the provision of pharmaceutical products. This Bureau has received an influx of funding in the past few years as it was included in the government's MDGs. As a result, there are a number of opportunities for companies that provide labor and delivery equipment, pre-natal and neo-natal products and services, and other medical equipment providers to work with the BPH to expand their products and services into China. In addition, the BPH is responsible for the regulation and provision of pharmaceutical products around the country. One goal of these MDGs has also been to control and treat infection diseases. For pharmaceutical companies that provide products or treatments for diseases such as HIV/AIDS, malaria, or TB, there are a significant number of opportunities to provide these medications into new Chinese

market segments. In addition, given that the WHO estimates that chronic diseases, such as cancer, COPD, and CVD, affect a majority of the Chinese population, there are large markets for products offered by foreign companies that either diagnose or treat these conditions. Opportunities exist as well for non-profit organizations to partner with local organizations to provide health interventions that may prevent some of these conditions and promote healthier behavioral choices.

At the county level in China, the distribution of medical services is controlled by the County Department of Public Health and tends to be dominated by TCM practices. As a result, companies that provide products and services that are alternatives to the typical medical interventions for these chronic diseases have many opportunities to expand their distribution and collaborate with TCM and alternative medicine providers in China. At this level, the government has become acutely concerned with the disparities in medical care provided to citizens living in these more rural areas. As a result, there are a number of opportunities for the provision of lower cost products and services that could be targeted to these population groups. One of the biggest health concerns in the past has been immunization of children and adults against many infectious diseases. This provides a very significant opportunity for pharmaceutical companies that offer these types of medications for expanding the distribution of their medication and extending the product life cycle for some products that might be going off of patent or heading toward the end of the product life cycle in more developed markets.

These opportunities for pharmaceutical companies that offer products that can prevent or control the spread of infectious diseases also have an opportunity for expansion into the final level of the health care system in China, at the township level through Township Health Centers. The primary concern at this level of the health care system is contagious illness. As a result, medical safety products and pharmaceuticals that can control or prevent the spread of these diseases are of primary concern and expansion into these markets is supported and encouraged by the Chinese government and also represents a significant market opportunity for companies that provide these products or services.

Limitations on health care marketers

While many opportunities are present for expansion of products and services into the Chinese health care market, the fact that the government still imposes restrictions on the provision and distribution of health care services limits the extent to which this expansion can realistically occur. Specifically, this happens through governmental imposition of quotas, controls, and restrictions on the provision of products and services, the promotion and distribution of these products or services, and the pricing of these products and services to both institutions and consumers. For example, marketers of medical devices need to be aware of and adapt to the quota that the government has placed on the number of medical devices that can be sold to a certain institution. In addition, the government has imposed a price limit on these medical devices and in many cases requires a medical device manufacturer to participate in a bidding war, which may result in a discount of approximately 15% off of the manufacturer's normal price. Since the BPH controls the provision and promotion of pharmaceutical products, the restrictions on how pharmaceutical products can be promoted both to the general public as well as to physicians are much more strict in China than in the United States. Lastly, at the very top level of the health care system, the MOH controls the financing of specialized research

institutions and the manufacturing of medical devices. While there is evidence that they have been supportive of partnerships between Chinese and Western companies, these partnerships are also usually subject to restrictions on the amount of intellectual property or knowledge transfer that must occur from one organization to the other in order to approve a partnership agreement. The type of partnership agreement (e.g., a licensing, joint venture, or strategic alliance) might need to be adjusted based on the guidance of the Chinese government.

Clearly, the next 5–10 years are likely to witness dramatic changes in the health care sector in China as the government continues to restructure its policies and fund major improvements in order to meet their ambitious goal of providing universal healthcare coverage to all Chinese citizens by 2020. As discussed, it is the goal of the government to improve healthcare overall and to provide equal care to citizens, regardless of whether they live in urban or rural areas. As a result of these overall initiatives and the specific opportunities that we reviewed, the increased governmental investment in the health care sector will likely create substantial opportunities for health care companies that can assist the Chinese government in addressing China's most salient healthcare issues.

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Figures

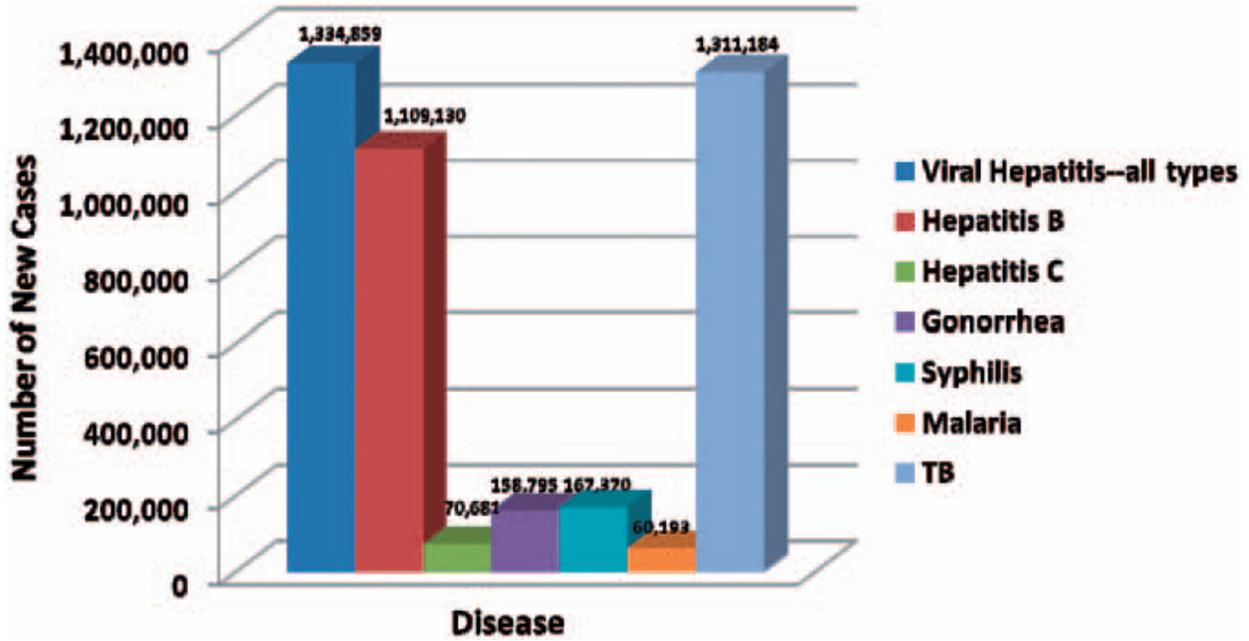


Figure 1 Number of new cases for selected communicable diseases: China, 2006.

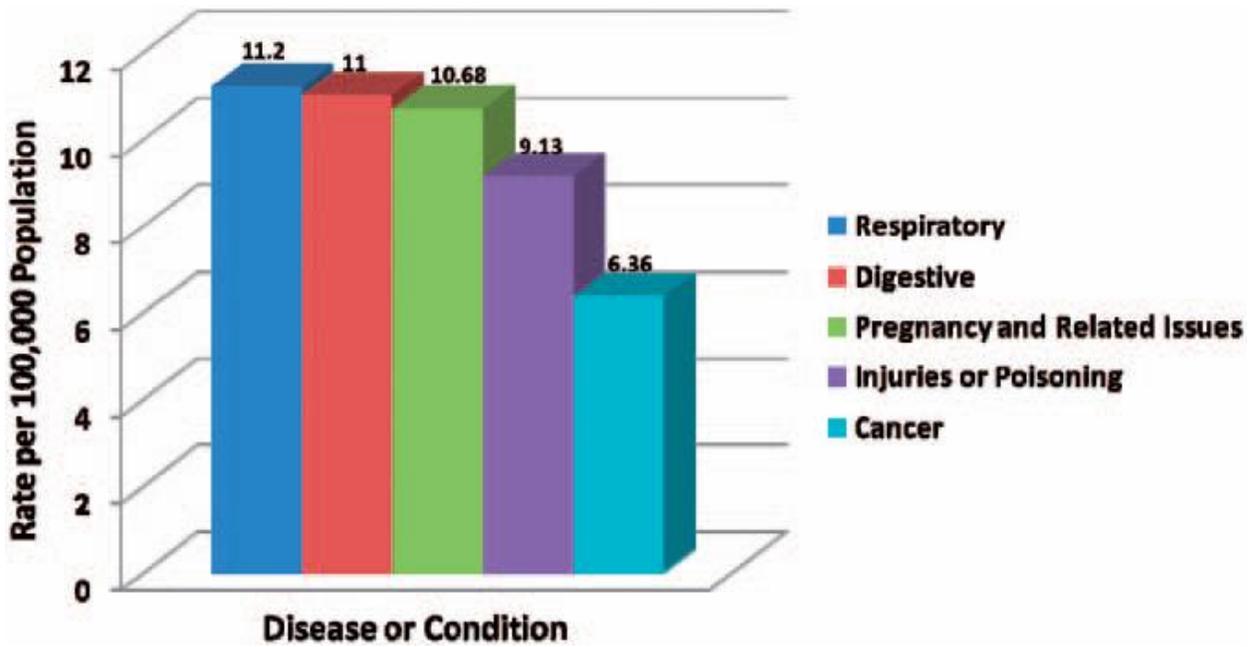


Figure 2 Leading causes of morbidity (inpatient care): China, 2002.

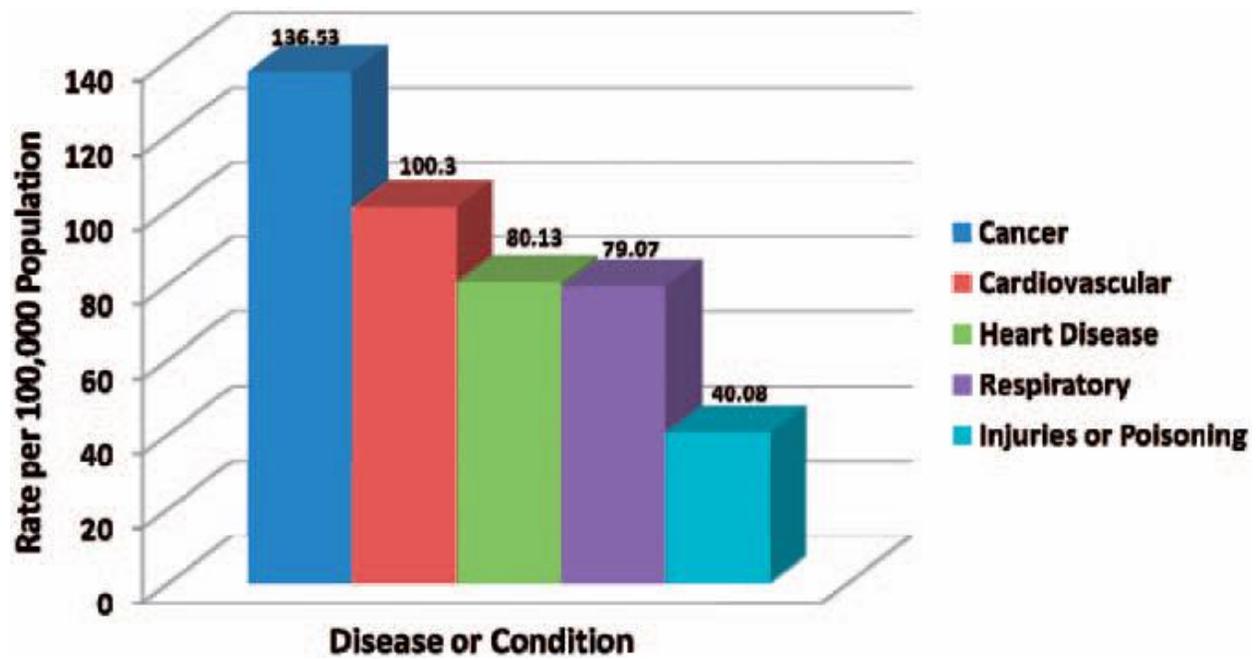


Figure 3 Leading causes of mortality: China, 2006.

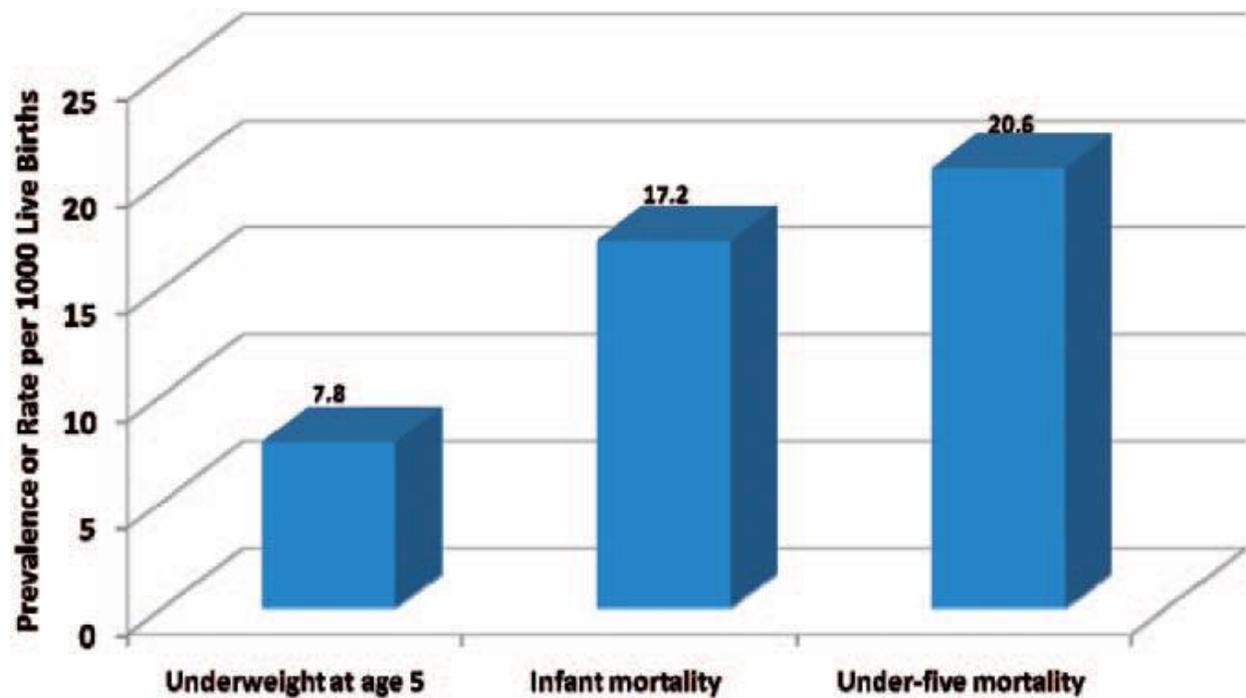


Figure 4 Child health indicators: China, 2006.

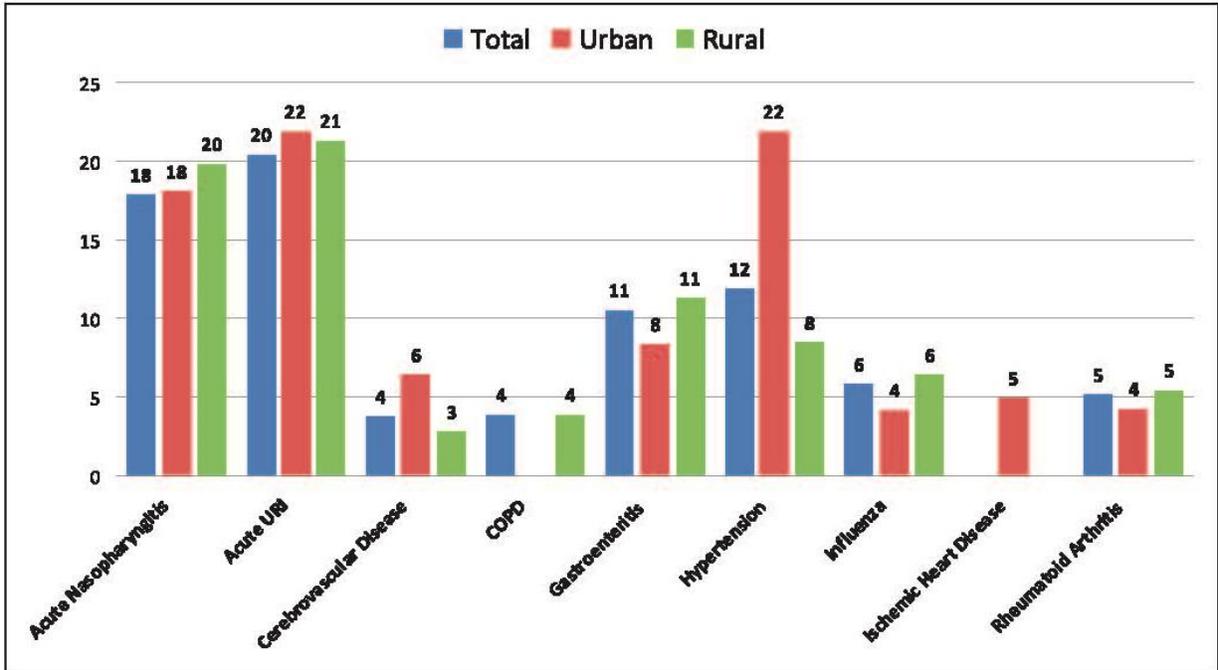


Figure 5 Two-week morbidity rate per 1000 population by major disease: China, 2003.

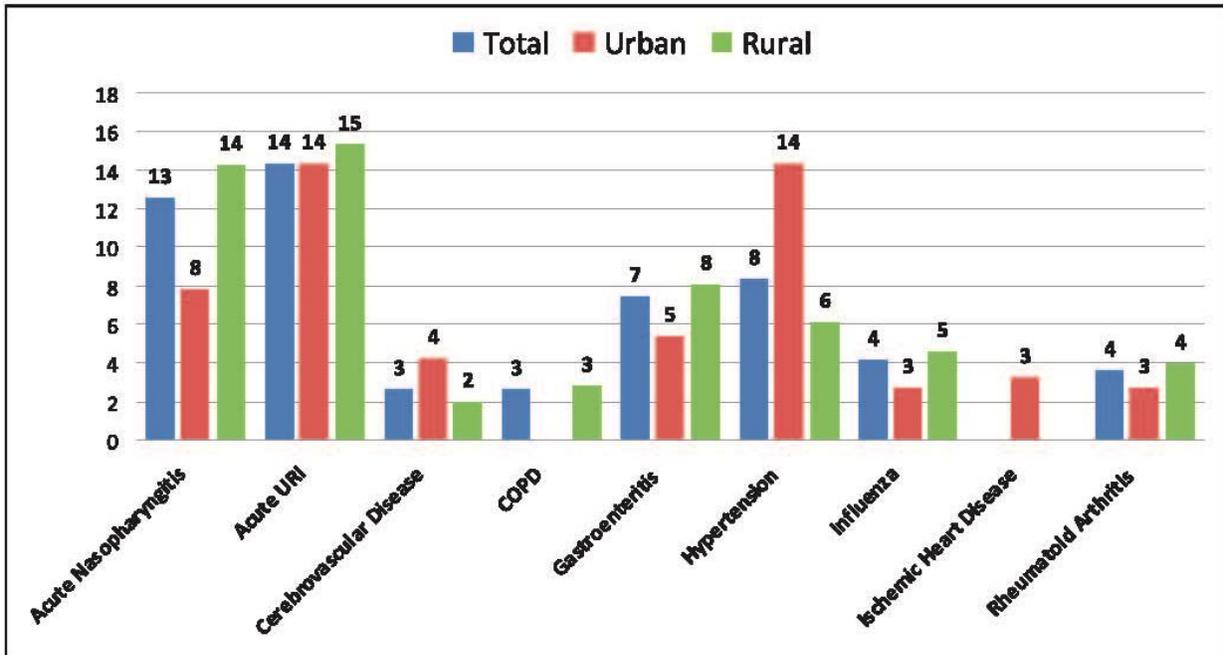


Figure 6 Two-week morbidity percent per 1000 population by major disease: China, 2003 (%).

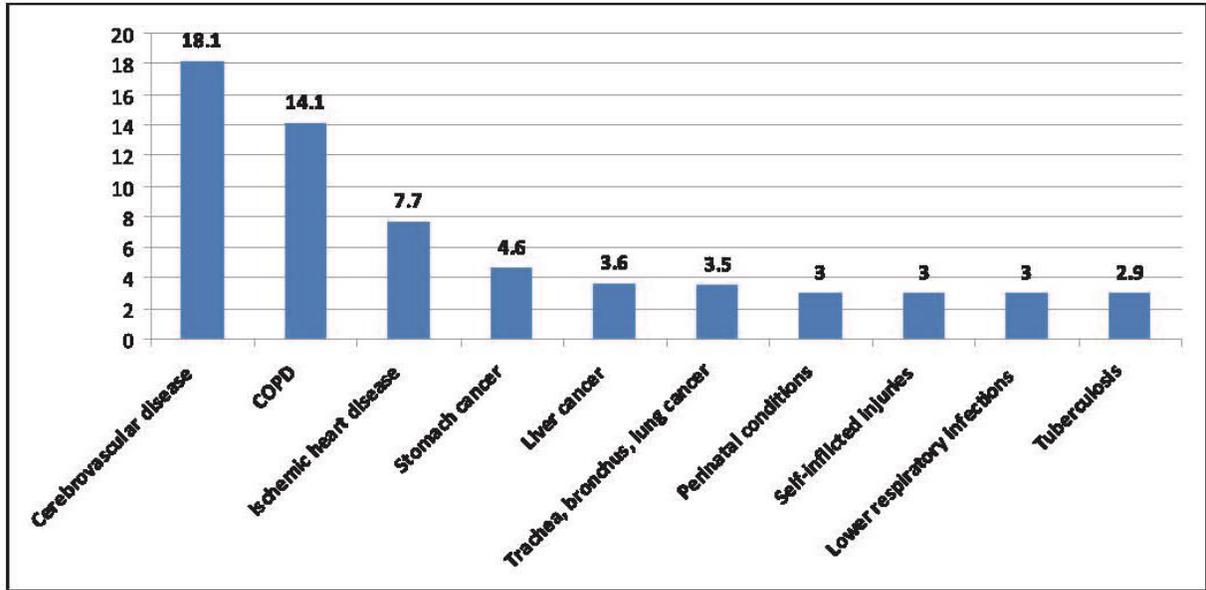


Figure 7 Leading causes of mortality by percent of total deaths: China, 2002.

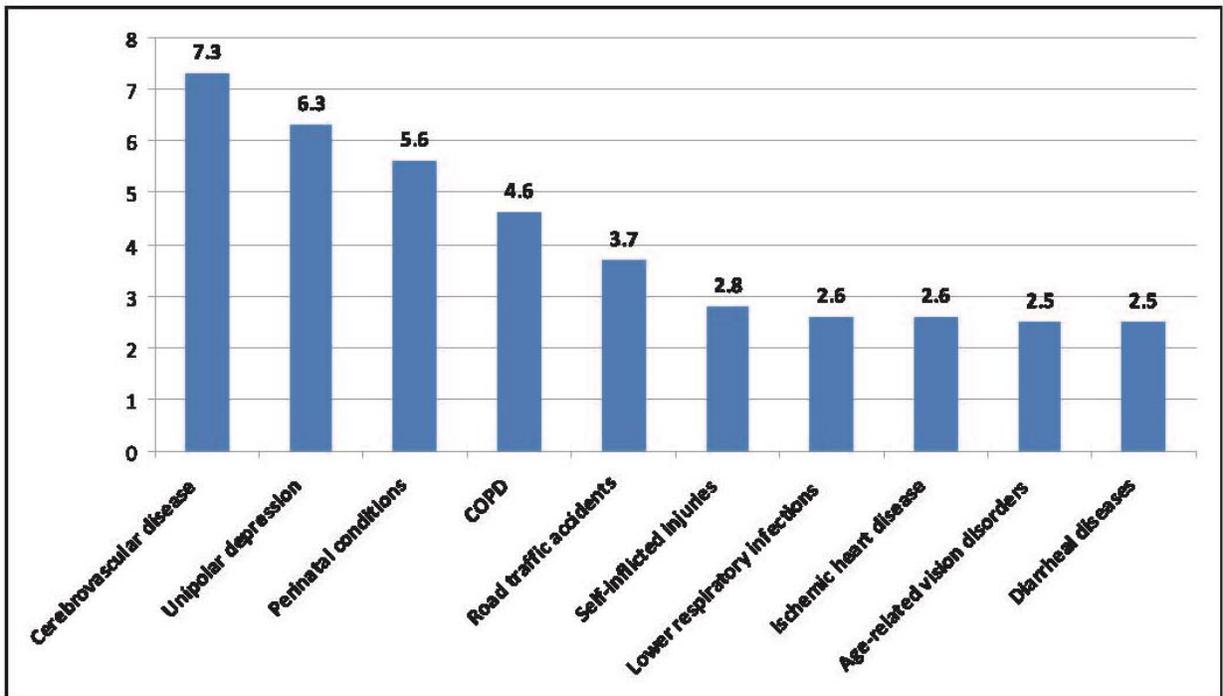


Figure 8 Leading causes of Disability-Adjusted Life years by percent of total deaths: China, 2002.