

BIODESIGN GLOBAL SOURCEBOOK: INDIA OVERVIEW

KEY INDICATORS

From independence in 1947 to 1991, India's economy was closed, socialist-leaning, and suffered anemic growth. (See Figure 1 for a map of India.) The Indian government began implementing economic reforms in 1991 as part of a bailout deal with the International Monetary Fund. Since then, India's gross domestic product (GDP), which reached US\$2 trillion in 2012,¹ has surged about six percent or more per year on average.²

As part of these economic reforms, the Indian government abolished the country's license-based import structure in favor of a restriction-free trade policy for capital goods and intermediates.³ Although tariff protection rates in India remain among the highest in the developing world, they have declined from 90 percent for certain goods in 1990 to roughly 15 percent for most items in 2010.⁴

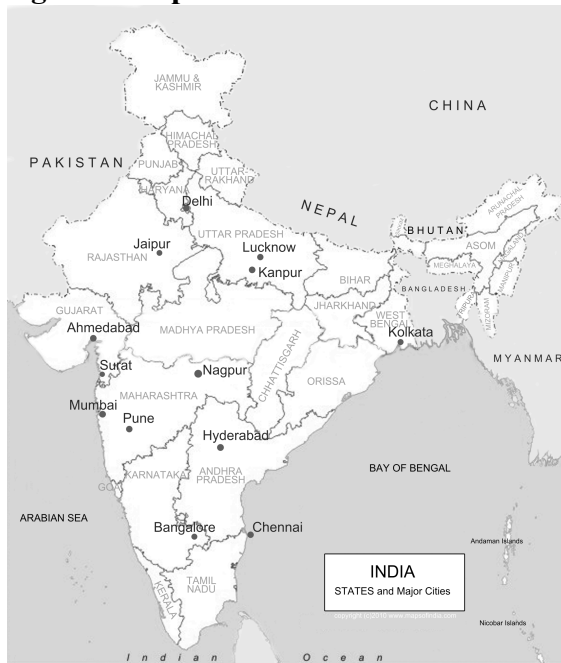
India also now allows foreign direct investment in most sectors, including foreign majority stakes of up to 100 percent in all industries except telecommunications, airlines, and banking.⁵ Healthcare has traditionally enjoyed high levels of private sector investment, with imports dominating the medical technology sector.

TOPICS

- Key Indicators
- Health System Overview
- Disease Burden
- Medical Device Industry
- Regulatory Environment
 - Healthcare Delivery
 - Healthcare Financing
- Reimbursement Issues
- Intellectual Property Practices
- Endnotes

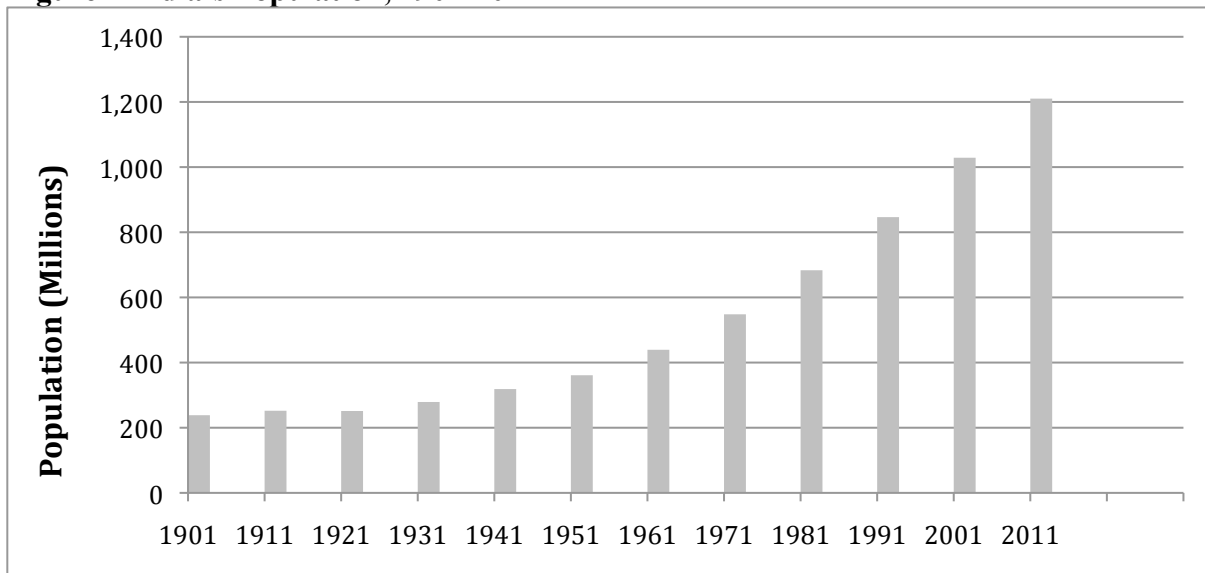
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Figure 1 Map of India

With a population of more than 1.2 billion, India is the world's second most populous nation after China. Population growth in the country has been exponential since the 1930s (see Figure 2).⁶ Projections suggest that India's population will surpass China's in 2030.⁷ The median age in India is only 26.2 years,⁸ compared to 35 years in China and almost 40 years in high-income countries.⁹ Approximately 70 percent of Indians still live in rural areas.

India's middle class is expected to grow rapidly in coming years, from roughly 50 million people to nearly 600 million between 2007 and 2025.¹⁰ This new and demanding middle class will be a strong catalyst for the development of medical devices.

Figure 2 India's Population, 1901-2011¹¹

HEALTH SYSTEM OVERVIEW

Healthcare Delivery

Over the last half century, India's public sector has steadily given up market share to the private sector in providing healthcare to Indians. Less than 10 percent of care is delivered in public facilities. As of 2001, the private sector accounted for over 90 percent of all hospitals, 85 percent of doctors, 80 percent of outpatient care, and 60 percent of inpatient care.¹² Private health systems have basic clinics, multispecialty clinics (also known as nursing homes), hospitals, and

hospital chains. Public healthcare facilities are divided into primary health centers, district-level hospitals, and tertiary hospitals.

Vast disparities in the quality and availability of care characterize India's healthcare system. State-of-the-art Indian secondary and tertiary care institutions attract both domestic patients who can afford their world-class services and roughly half a million medical tourists each year.¹³ However, healthcare facilities without adequate supplies, staff, or capacity to provide affordable care are responsible for serving a large majority of the population. A significant percentage of existing infrastructure, both public and private, is non-functioning at any given time.¹⁴ In rural settings, where the penetration of healthcare facilities has been low, patients often resort to traditional healers for healthcare.¹⁵ These circumstances have deterred the use of medical devices beyond those that are very basic and low cost.

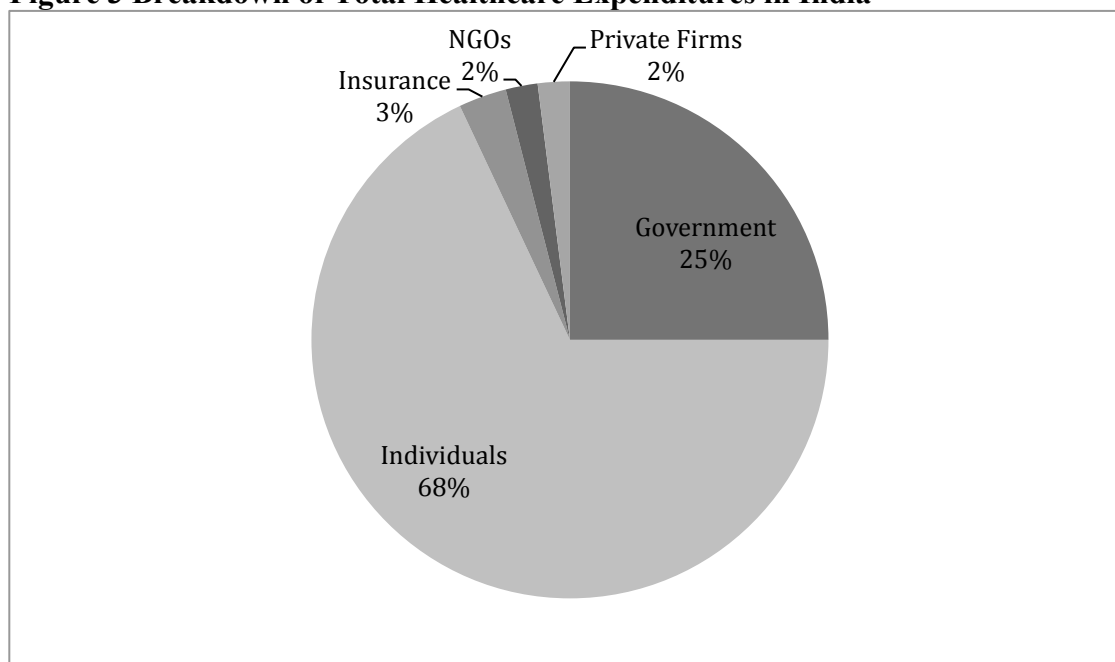
Disparities also exist between geographic regions. Southern states, such as Tamil Nadu and Karnataka, have significantly better infrastructure than Uttar Pradesh, Bihar, and other northern states.¹⁶

The good news is that India's economic growth story is propelling improvements in healthcare infrastructure. Corporate hospitals chains, such as Apollo and Fortis, are investing in cities outside major metropolitan areas and driving 15 percent annual growth in the hospital sector.¹⁷

Healthcare Financing

Low spending levels plague India's healthcare system. Healthcare expenditure per capita was only US\$56 in India in 2010 compared to US\$208 in China and US\$964 in Brazil that same year.¹⁸ India's private and public sector combined spent only about four percent of GDP on healthcare in 2010. The government is planning to increase its share from 1.4 percent to 2.5 percent of GDP over the next five years.¹⁹ Total healthcare spending is projected to increase from roughly two percent to six percent of GDP over the next decade.²⁰ This woefully inadequate level of spending is the lowest among all BRICS nations (Brazil, Russia, India, China, and South Africa).²¹ In contrast, the United States spends 17.6 percent, Germany 11.6 percent, and Mexico 6.2 percent of GDP on healthcare.²²

Although the Indian government plans to boost its healthcare outlays going forward, it only accounts for some 25 percent of total healthcare spending in India.²³ Individuals and institutions contribute the remainder, making India's healthcare system one of the world's most privatized (see Figure 3).²⁴

Figure 3 Breakdown of Total Healthcare Expenditures in India²⁵

Health insurance is rare but growing in India. Only 55 million people had health insurance in 2003. By 2010, 300 million people, mostly below the poverty line, gained access to some partial form of health insurance. Still, only three percent to five percent of patients have full or substantial coverage.²⁶

Both government and private insurers are working to increase access to insurance. Analysts estimate that about half the population will enjoy some level of health insurance coverage by 2020.²⁷ The National Rural Health Mission (NHRM), which the Indian government rolled out in 2005, will account for some of this increase. NHRM is an ambitious and wide-ranging public health program that seeks to improve healthcare delivery in rural India.²⁸ The *Rashtriya Swasthya Bima Yojna* (RBSY, translated as National Health Insurance Program) also strives to increase health insurance access for poor families that make less than US\$100 per year.²⁹

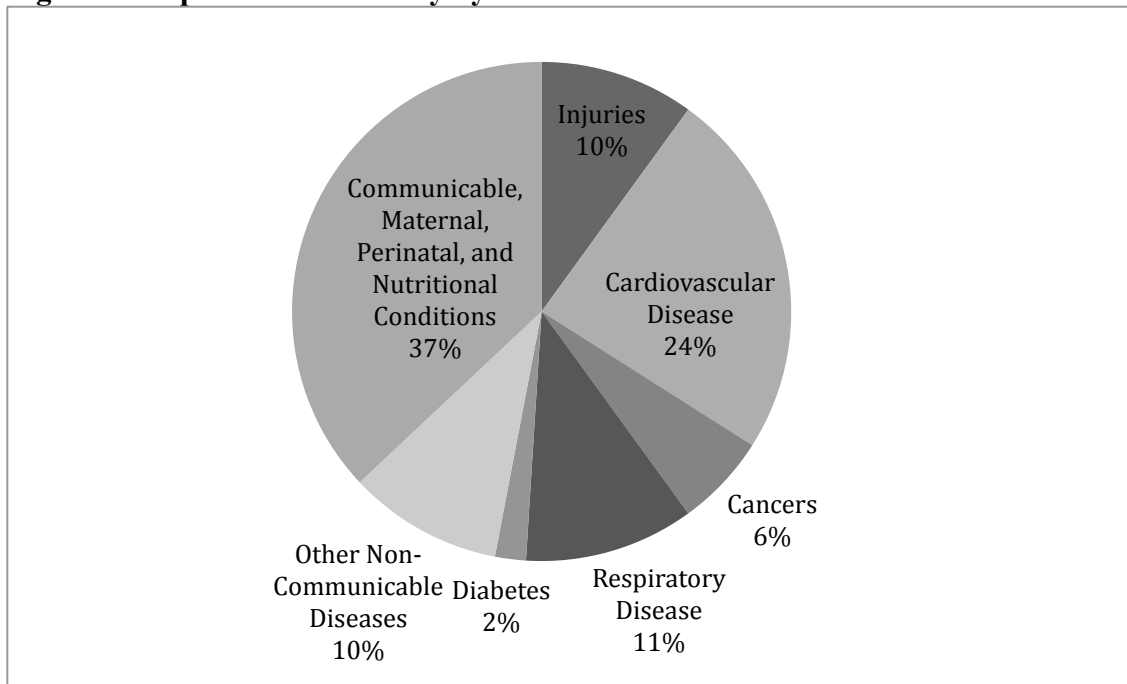
Domestic insurance providers, such as Cholamandalam, L&T General, and HDFC, as well as foreign providers in joint ventures, such as Bajaj Allianz, Tata AIG, and ICICI Lombard, are starting to become more active in the private healthcare insurance sector. Private insurance players currently serve just one percent of the Indian market, but account for more than two percent of total healthcare expenditures in the country.³⁰

DISEASE BURDEN

The average life expectancy of Indians at birth only reached 65 years in 2009, compared to the global average of 68 years. India also has some of the highest infant mortality and maternal mortality rates in the world, 44 per 1,000 births and two per 1,000 births respectively in 2012.³¹

India's disease profile is traditionally associated with communicable diseases, such as malaria and tuberculosis, or tropical diseases, such as Japanese encephalitis and dengue fever. However, coronary heart disease, diabetes, asthma, and other chronic non-communicable diseases are on the uptick (see Figure 4). Analysts predict some 60 percent of the world's heart patients will live in India by 2020.³² While these trends pose challenges for the country's healthcare system, they also present significant opportunities for medical device companies.

Figure 4 Proportional Mortality by Disease State in India³³



MEDICAL DEVICE INDUSTRY

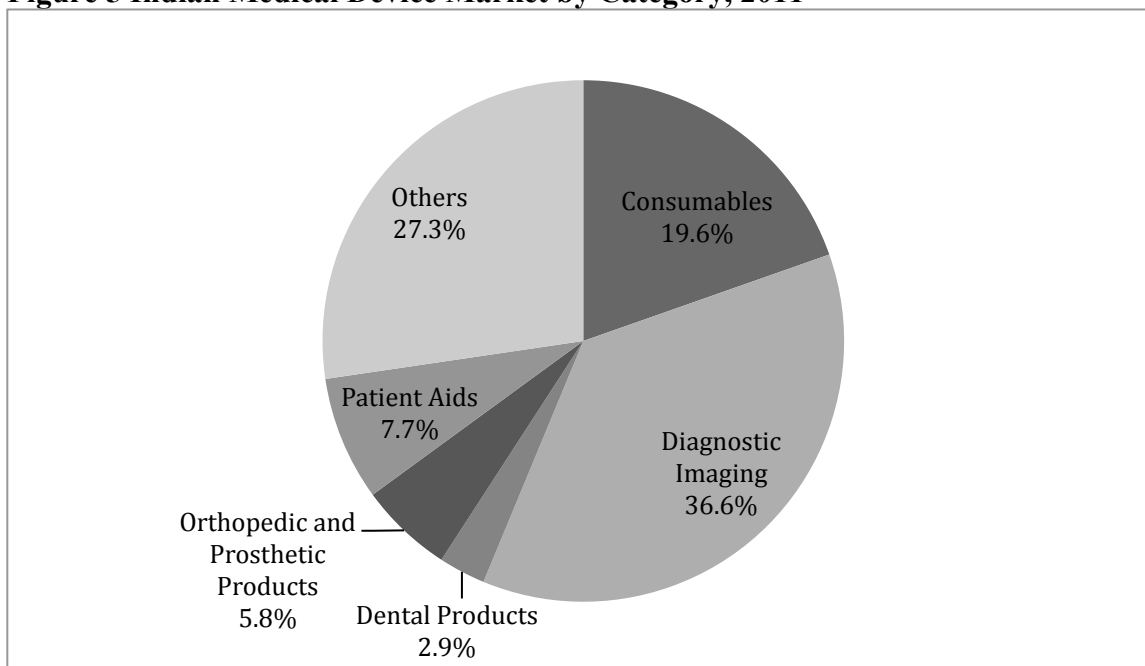
India's medical device market was worth US\$3 billion in 2010, growing roughly 15 percent over the previous year.³⁴ It is expected to expand at a 16 percent compounded annual clip during the 2010-2015 period,³⁵ far better than the two percent to three percent growth forecast for this sector in the United States and Europe. As a result, global medical technology firms view India as one of the most promising emerging markets for direct investment.³⁶

Imports currently dominate India's med-tech sector, accounting for approximately 75 percent of the devices sold in the country.³⁷ GE Healthcare, Siemens, J&J, and other multinational corporations, which normally have extensive sales and service networks, lead India's technology-intensive and high-cost device markets. Indian manufacturers suffer from a perceived lack of quality and traditionally have had trouble entering these markets. Domestic companies are highly competitive in the markets for medical supplies and consumables (sutures, catheters, etc.), which are particularly price sensitive due to low labor and manufacturing costs.³⁸ Small and medium enterprises manufacture some 60 percent of indigenous devices.³⁹

Of the medical devices sold in India, the largest category by value is diagnostic imaging equipment (see Figure 5). Suppliers sell the bulk of these high-cost items to the private healthcare sector, which is more likely to have sophisticated infrastructure capable of generating revenue to pay for the devices.

Although most high-tech products are imported, some foreign companies have set up wholly owned subsidiaries in India to develop and manufacture medical instruments. For example, GE developed a handheld ultrasound device intended for resource-constrained markets at its Bangalore campus. This device, called V-Scan, launched globally in 2010.⁴⁰ Other companies, such as Siemens, Philips, Stryker, and J&J, have also invested in large product development labs in India. These labs are often clustered around Bangalore, Delhi, Mumbai, and other major metropolitan areas, usually in government-designated high-tech parks.

Figure 5 Indian Medical Device Market by Category, 2011⁴¹



REGULATORY ENVIRONMENT

Medical device regulation is relatively new in India, although the Central Drug Standard Control Organization (CDSCO) has regulated pharmaceuticals since 1940, under the Ministry of Health and Family Welfare. The Indian government proposed regulatory guidelines for medical devices in 2008, through amendments to the 1940 Drug and Cosmetics Act (DCA). It introduced guidelines on applying drug rules to medical devices in 2012 and will present an updated bill to India's Parliament in 2013. The new bill is expected to bring all medical devices sold in India under the purview of the government agency charged with regulating medical devices, the Central Licensing Approval Authority (CLAA), which is under CDSCO.

Whereas the DCA was originally meant so primarily for drugs and pharmaceutical products, the new regulations attempt to regulate medical devices as a sector separate from drugs.⁴² Based on

advice from the World Health Organization, the U.S. Food and Drug Administration (FDA), the Global Harmonization Task Force and industry experts, India classifies medical devices into four groups according to their risk level (see Figure 6). In general, it subjects higher-risk devices to stricter regulations and a more stringent pre-market conformity assessment process.

Figure 6 Classification of Devices⁴³

Europe	U.S.	India	Device Profiles
Class I	Class I	Class A	Non sterile items or sterile items with a low potential risk: surgical instruments, urine bags, stethoscope, examination gloves
Class IIA	Class II	Class B	Sterile items, surgical gloves, urinary catheters, stomach tubes, needles, tracheal tubes, IV giving sets
Class IIB	Class II	Class C	Blood bags, condoms, non-absorbable sutures, and anesthesia machines
Class III	Class III	Class D	All active implantable devices, cardiovascular catheters, absorbable sutures, heart valves, collagen implants

For the moment, however, the CLAA only requires certain categories of devices that have been the subject of notifications in the Official Gazette of India (21 device categories in total) to register with CDSCO. These include cardiac stents, bone cements, intra-ocular lenses, orthopedic implants, and heart valves. Since CLAA currently requires pre-market reviews of only certain devices, other devices do not require registration prior to sale in India.

Under current rules, the desired result of the CDSCO CLAA pre-market review is a registration certificate for domestically produced devices and an import license for imported devices. For domestic manufacturers, the manufacturer must apply to his local state Food and Drug Administration for a manufacturing license. Import licenses are valid for 3 years, whereas domestic manufacturing licenses are valid for 5 years. Imported medical devices that have already obtained approval in the United States (by the FDA) or the European Union (by CE Marking) are allowed on the Indian market without undergoing separate conformity assessment procedures. Conformity assessments can take six months to one year to complete. The CDSCO website maintains a list of licensed indigenous medical device manufacturers of medical devices.⁴⁴

REIMBURSEMENT

As described in the Healthcare Overview section, less than a quarter of Indians have any kind of health insurance and only a sliver enjoy substantial coverage. As a result, patients usually pay out-of-pocket for healthcare purchases and are extremely cost-sensitive. Most insurance providers require patients to file claims after receiving service, causing them to bear the cost up front. Insurance normally does not cover many routine primary and secondary care visits, adding to households' out-of-pocket healthcare expenses. Health insurance providers cap the amount they reimburse insured patients for surgeries and other hospital visits. They do not reimburse

medical technology separately. Rather, the cost is covered in the reimbursement for the procedure, either to the hospital or to the patient directly.

Public healthcare facilities use central government or state level tender processes to procure medical supplies. These processes vary from state to state and can be very bureaucratic and difficult to break into for new companies. In the private healthcare sector, procurement processes for medical devices differ depending on a facility's size, location, and purchasing power.

INTELLECTUAL PROPERTY

IP enforcement traditionally has been weak in India. Before the Indian Parliament passed the Indian Patents Act of 2005 (after ratifying the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights agreement, TRIPS),⁴⁵ India enforced product patents but not process patents. As a result, companies could legally sell reverse engineered products in the Indian market. Although this phenomenon helped fuel the growth of a strong pharmaceutical industry in India, it also contributed to lax IP protection, a problem that persists to this day. Technology companies subsequently have had a hard time protecting their IP in the Indian market.

Nevertheless, the post-TRIPS scenario for technology patents in India is encouraging. Similar to other World Trade Organization member countries, Indian law now recognizes utility patents, copyrights, and trademarks as protected intellectual property.⁴⁶ India follows a "first to file" rule. If two or more applicants apply for a patent for the same invention separately, India's patent office will grant the first applicant the patent right. The patent application process takes between three and five years. Patent protection lasts 20 years. India is a contracting state to the Patent Cooperation Treaty (PCT) and Indian patent holders can file a PCT application. This allows the "priority date" or date of patent application to be recognized in other countries where the inventor may also wish to file a patent.⁴⁷

The number of patents filed each year in India has grown steadily, with the telecommunications and pharmaceuticals industries dominating Indian Patent Office (IPO) filings. Indian courts have tried several high-profile IP infringement cases. In particular, indigenous pharmaceutical companies have been aggressive in both their patent filing and defense strategies,⁴⁸ setting a crucial precedent for other high-tech industries in India. The pharmaceutical industry example also underscores IP creation and acquisition as legitimate sources of revenue in the Indian market and could be a viable business model for other companies in the healthcare sector.

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