EXPERT REVIEWS

Diffusion of medical technology: medical devices in India

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This review examines the diffusion of modern medical devices in India by analyzing trends in India's cross-border trade in medical devices, its domestic medical device production and utilization by households. We explore the implications of this process of diffusion for the efficacy, cost–effectiveness and equitable use of new medical devices in India, and review recent efforts to regulate the Indian medical device sector.

KEYWORDS: diffusion • domestic production • efficiency • India • inequity • medical device • regulation • technology transfer • trade

Medical device imports to India increased by 1300% between 1988 and 2008, to approximately Rupees (Rs) 51 billion (~US$1.13 billion by 2008. Exports of medical devices also increased sharply, and their total value amounted to approximately 35% of all medical device imports ($380 million) in 2008. As a share of total national output (gross domestic product [GDP]), shares of imports and exports of medical devices increased several-fold over this period, albeit amounting to no more than 0.16% of GDP in 2008. Data on the domestic production of medical devices are limited in India. However, available evidence suggests that domestic production of medical device rose sharply in recent years, from essentially negligible levels during the early 1990s to more than $700 million in 2005. Taken together, rising trade and domestic production provide strong evidence of a health sector increasingly relying on medical devices. This is further corroborated by household surveys, highlighting increased utilization of medical devices by Indians.

This rapid diffusion of modern medical devices has not been accompanied by systematic efforts for assessing newer technologies, or to harnessing them for effectively meeting national health policy goals in India. Despite some notable exceptions, the limited evidence available points to the inefficient, inequitable and inappropriate use of medical devices in India; and the potential for medical expenditure inflation. Regulations on medical device introduction and use in India are limited and implementation of regulations is poor. Health system drivers of medical device use need to be harnessed.

Diffusion of medical technology: medical devices in India

Developing countries, such as India, have much to gain from an efficacious application of medical technology, given their high disease burden [1]. Interpreted as the collectivity of drugs, methods of diagnosis, collection of health-relevant information, treatment procedures, medical devices and the organization of health services, medical technology has been associated with significant improvements in population health and healthcare use [2–5,101]. The scale, composition and speed at which medical technology reaches and then permeates through a target population, namely, 'technology diffusion', and the factors that influence its efficacy are therefore of obvious policy interest.

This review focuses firstly on the diffusion of medical devices, a key element of medical technology, in India. The focus on medical devices is motivated largely by a need to fill a gap in policy discussion and research on health and medical technology in India. Much existing debate has focused on the production of and movements in medical personnel in the form of international migration [6,7] or on pharmaceutical drugs, particularly in the context of intellectual property rights [8]. Discussions on cross-border and within-country movements of medical devices

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and their utilization in policy and research literature have been limited in India and usually confined to the use of the tools of information technology for diagnostic purposes, and sometimes to issues of maintenance [9].

India, like many developing countries, is limited in its capacity to produce and/or conduct research and development on high-end medical devices. We examine India's international trade in medical devices as cross-border movements in medical devices can potentially yield insights regarding [10]:

- The significance of international technological transfers
- The pace at which technological innovations generated abroad flow into India
- The appropriateness of the technology transferred

India does have some domestic production of medical devices and solely focusing on cross-border trade would not adequately capture the supply side of the medical device market [11,102]. Thus, available data on domestic production of medical devices in India are reviewed in this paper. We supplemented this information with household survey data, which offer an alternative, demand-side perspective on medical device use in India.

The review also discusses the implications of technology embedded in medical devices for health policy goals, such as equity, efficiency and cost containment; and assesses the system of regulatory oversight on medical devices that currently exists in India. We conclude by drawing attention to key policy implications.

Trade & domestic production of medical devices in India

Magnitude

India's total trade (imports plus exports) in medical devices stood at Rs 69.3 billion (or US$1.51 billion) constituting approximately 0.5% of the total trade volume of the country in the years 2007–2008. Figure 1 presents trends in India's foreign trade in medical devices, in constant 1999–2000 Rupees, over a 20-year period from 1988 to 2008. Immediately evident is the remarkable increase in both imports of medical devices to India, as well as exports of medical devices to other countries. In 2008, the final year for which we have data, imports were in region of Rs 51 billion (~US$1.13 billion). Between 1988 and 2008, imports increased by 1300% at constant 1999–2000 prices. Exports of medical devices increased at an even faster rate, and their total value currently amounts to approximately 35% of all medical device imports (~US$380 million).

As a share of total national output (GDP), shares of imports and exports increased several-fold over this period; although trade in medical devices (exports plus imports) remains relatively small as a share of GDP, amounting to no more than 0.16% in 2007.

Figure 1 also reveals that imports and exports both started rising significantly during the 1990s, a time of economic (including trade) liberalization and rapid economic growth in India. The growth in imports of medical devices has been much higher (typically 10% annually) than the growth in GDP (5–6% annually) (Table 1). Thus, income growth is probably not the sole explanation for the growth

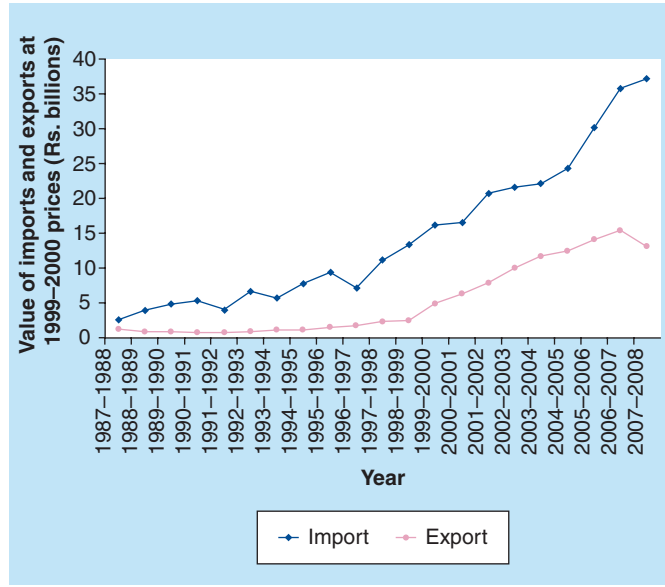

Figure 1. India's international trade in medical devices 1988–2008.
Data from [114,115].

in medical device imports. In particular, India's trade in medical devices increased sharply after 1996–1997 as it began reduce import tariffs as a follow-up to international trade negotiations. While 'life-saving' medical devices have usually been imported duty-free to India, other devices faced tariffs ranging from 40 to 60% in the mid-1980s. These tariffs were reduced to no more than 25% during the late 1990s and further to 12.5% since 2003–2004.

Prima facie, the rapid increase in imports of medical devices in the period since the mid-1990s indicates an increase in the scale at which internationally developed technology embedded in medical devices is making its way to Indian patients. Information concerning the spread of modern medical technology could potentially also be gleaned from data on foreign direct investment related to the production of medical devices or trends (and composition) in domestic production, presumably under license. Unfortunately, information on foreign direct investment related to medical devices is rather limited in India. However, additional information on production levels and trends in the domestic medical device industry can help us to draw more robust conclusions: for instance, if domestic production were observed to have grown rapidly, even as net imports were stabilizing, the domestic stock of medical devices would continue to increase rapidly. Also unclear, from trade data alone, was whether it was relatively newer technology that was being used or mainly older medical devices that were being adopted. Any conclusions to that end require an analysis of the composition of medical device imports and of domestic medical device production.

Domestic production of medical devices

At the beginning of the 1990s, the domestic industry for the production of medical devices was rather small. Baru provides an estimate of Rs 0.76 billion (at 1999–2000 prices), approximately 15% of all medical device imports during that time [11]. In Figure 2, we present estimates for 8 years, from 1998 to 2005

Table 1. India's gross domestic product and trade in medical devices, 1988–2008.

Years	Gross domestic product	Imports of medical devices	Exports of medical devices
1987–1988	9737* (Rs billions)	2.6* (Rs billions)	1.3* (Rs billions)
1991–1992	12,063* (Rs billions)	4.1* (Rs billions)	0.8* (Rs billions)
1996–1997	16,450* (Rs billions)	7.2* (Rs billions)	1.8* (Rs billions)
2007–2008	33,399* (Rs billions)	37.1* (Rs billions)	13.0* (Rs billions)
Average annual rate of growth			
1987–1991	5.5%	12.1%	(-)11.7%
1991–1996	6.4%	11.8%	17.6%
1996–2007	6.6%	16.1%	19.9%
1987–2007	6.0%	13.5%	11.6%

*Constant 1999–2000 prices; gross domestic product implicit deflator has been used.
Data from Reserve Bank of India for GDP statistics [114] and Government of India, for trade in medical devices [115].

(the most recent years for which such data are available), based on data from the Annual Survey of Industries (ASI), a series of annual surveys undertaken by the government of India [103].

As Figure 2 indicates, compared with the early 1990s, domestic production was significantly higher by 1997–1998 and continued to grow rapidly. By the year 2004–2005, domestic production had increased to Rs 35 billion at 1999–2000 prices (>US$700 million), well in excess of total imports for that year. This is likely to be a lower bound since production in the unorganized sector is not covered by the annual survey of industries. Unfortunately, no time series data are available for medical device production in the unorganized sector.

Of course, care should be exercised while adding domestic production estimates to imports to estimate the supply of medical devices available domestically. Specifically, many multinational firms involved in the production of medical devices have set up subsidiaries in India [11,104–106], so that what passes for domestic production may simply be a reassembly operation of imported parts, with little local value added. Thus, it may be useful to re-estimate domestic production as the 'net' value added after the deduction of imported parts/materials. Data from the ASI are not detailed enough to allow us to distinguish between domestic and imported materials. If we assume that all parts were imported, a lower bound can be obtained for domestic production of medical devices in India each year. For 2002, this lower bound was Rs 14.37 billion, nearly 70% of the imports for that year. Moreover, it trebled between 1998 and 2002, in other words, even if we assume that all parts were imported, domestic production rose significantly.

Taken together, rising net exports and domestic production of medical devices (including assembly operations), substantially in excess of an annual rate of population growth of 1.2% per year and health spending growing by approximately 8–10% annually, provide strong evidence of a health sector increasingly relying on medical devices. This still does not tell us anything regarding the nature of the technology embedded in these devices. To address this concern, we turn next to the composition of trade and domestic production in medical devices.

Composition

Since officially published information concerning imports and exports is also available at the '8-digit' level of classification, foreign trade statistics are a potentially valuable source of detailed information for several categories of equipment. According to these statistics, the share of diagnostic devices ranged from 30 to 40% of total medical device imports (the remainder being generally classified as 'therapeutic') over the period 1988–2008. The data suggest a wide range of diagnostic medical devices currently being imported into India, including high-end equipment, such as CT scanning, MRI and PET scanning devices, ultrasound, echocardiograph and endoscope machines, as well as the relatively less technical ophthalmoscopes and stethoscopes. Indeed, within the category of diagnostic imports, the share of imports of high-end equipment is increasing. For instance, the share of CT scanners, MRI devices and PET scanners in total diagnostic imports doubled, from an average of 10% in the mid-1990s (and an even lower share in earlier years) to 20% in 2008.

As in the case of diagnostic devices, the items being imported under the therapeutic category are wide ranging, from pacemakers, hearing aids, cardiac catheters and artificial joints to dental, ophthalmic, tubular needles and general surgical appliances. Some individual examples are noteworthy. Pacemakers accounted for nearly 9% of all therapeutic device imports to India in 2002, having grown from a share of 5–6% in the early 1990s. Given recent advancements in pacemaker technology outside of India, this level of growth would indicate that devices incorporating newer medical technology are being transferred to India at a fairly rapid pace [12] (more recent import data suggest a slight decline in the share of imported pacemakers, estimated at 8.5% in 2008, possibly in response to increased domestic production capabilities and local licensed production).

Conversely, the share in imports of some other devices has declined over time. Dental drills in medical device imports halved over the same period from already the low levels prevailing in the early 1990s. Again, this may well be on account of enhanced domestic production capability for dental drills in

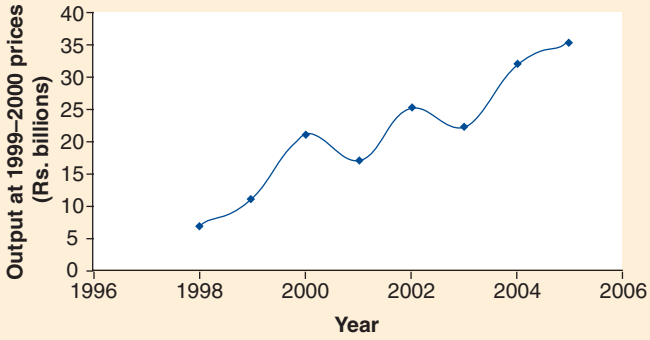

Figure 2. Domestic production of medical devices in India, 1998–2005.
Data from [102].

India, since most of the advances in rotations per minute, a key technological characteristic of dental drills, were achieved some time ago, potentially allowing for any relevant intellectual property protection to expire.

The transfer of medical technology may occur not only by means of increased imports but also by way of joint ventures and/or subsidiaries set up in the host country (foreign direct investment); and, as suggested previously, it may take the form of local manufacturers taking advantage of expiry of international patents. According to the most recent data from the ASI, there are more than 300 producers of medical devices in India [103]. However, data from the ASI are not disaggregated enough to enable us to make quantitative inferences regarding the technological sophistication and relative scale of domestic production of different categories of medical devices.

In the absence of detailed quantitative information on the composition of domestic production, we relied on data on the composition of exports of medical devices from India as an indicator of technological sophistication in the domestic medical device industry. Specifically, we assessed the ratio of exports to imports – the idea being that high export volumes (relative to imports) are indicative of competitiveness in the international market and, consequently, of the scale and sophistication of domestic production capacity. With this interpretation, the data show clearly the increasing technological sophistication of India-based producers of medical devices. For instance, the value of ECG exports amounted to approximately 40% of ECG imports at the beginning of this decade compared with 1–2% in the early 1990s. More recent data suggest a ratio of exports–imports of ECG in excess of 130% in India. India's domestic production capacity also appears to have advanced for equipment such as endoscopes, amounting to 21% of imports in 2008, compared with negligible levels just a few years earlier. Substantial domestic production capacity for export (>40% of imports) is also apparent in production for parts for x-ray equipment, pacemakers, hearing aids, surgical instruments, tubular needles and artificial joints. Even allowing for the fact that some of these may be inferior (or second-hand) products being exported to other poor countries, their substantial magnitude and sustained growth (relative to imports) does suggest technological upgrading and international competitiveness. Domestic firms also produce a range of instruments and appliances, such as needles and syringes, stethoscopes, ophthalmoscopes, x-ray machines and orthopedic components.

For some other types of high-end medical devices, exports (and presumably domestic production capability) have progressed more slowly. These include MRI and CT-scanning systems, apparatus used in PET scanning, baby incubators, angiographs, echocardiographs and heart–lung machines. Individual small-scale studies and anecdotal evidence are used to shed further light on this point. A study of the private health sector in India noted that Siemens and other large multinational manufacturers of high-end medical devices had begun to set up manufacturing and assembly units in India [11], and the pace appears to have picked up over the years [105,106]. In his study, Gross notes the recent example of the joint venture set up between Wipro India and UK-based General Electric Healthcare, for the production of diagnostic devices, such as ultrasound and CT scanners, in India [107]. Purely local producers and importers coexist, as in the pacemaker market, with Shree Pacetronix being the sole local producer (with some international collaboration) and Medtronic being one of several foreign establishments, mainly importing devices from abroad for local use [108].

Utilization of medical devices

The increased availability of high-end medical devices, whether in the form of domestic production or rising net exports in India, is reflected in utilization statistics that are available on the subject from existing household surveys. Survey data can also help to shed light on the rising penetration of medical devices into rural areas and the role of private and public sectors in the spread of technology.

A previous study demonstrated that the proportion of hospitalized patients who underwent an x-ray, ECG or ultrasound examination increased from 36.8% in 1986–1987 to 46.4% in 1995–1996 [13]; and from 3.6 to 4.4% for outpatient visitors over the same period. More recent household survey information on the use of these devices is presented in Table 2. Data show that the utilization of x-ray, ECG or ultrasound has continued to increase in the years since 1995–1996. Survey data from 2004, using identical questions to those in 1995–1996, on diagnostic device use show that 57.3% of hospitalized patients in India were assessed with x-ray, ECG or other scanning devices; with the figure being 8.9% for outpatients. Note that these are substantially higher shares compared with those in 1995–1996, pointing to a rapid growth in the use of such devices in India.

As noted earlier, household survey data are also useful in other respects: they help to better identify the regional pattern of medical diffusion and the factors that drive it. The data in Table 2 show that rural in-patients utilized x-ray, ECG and

Table 2. Utilization of x-ray/ECG/ultrasound by patients in India, 1995–96 and 2004.

Utilization	1995–1996			2004		
	Rural	*Urban*	*Combined*	*Rural*	*Urban*	*Combined*
Proportion of in-patients not reporting use (%)	56.0	46.8	53.6	44.8	38.0	42.7
Proportion of in-patients reporting free use (%)	8.9	11.7	9.8	6.2	9.5	7.2
Proportion of in-patients reporting paid use (%)	35.1	41.5	36.6	49.0	52.5	50.1
Proportion of outpatients not reporting use (%)	96.4	93.6	95.7	91.0	91.4	91.1
Proportion of outpatients reporting free use (%)	0.3	1.1	0.5	0.6	0.7	0.6
Proportion of outpatients reporting paid use (%)	3.3	5.3	3.8	8.4	7.9	8.3

Authors' estimates, sourced from National Sample Survey Organization data for 1995–96 and 2004 [23,24].
Data from [103].

ultrasound devices to a lower extent than urban in-patients For instance, in 2004, 62.0% of urban hospitalized patients used these devices in India, compared with 55.2% for rural patients. However, it is noteworthy, from Table 2, that the proportion of patients using these diagnostic services has risen faster in the last decade for rural than for urban Indian patients. Between 1995–1996 and 2004, the proportion of urban hospitalized patients using x-rays, ECG or ultrasound devices increased from 53.2 to 62.0%, whereas among rural in-patients, the proportion increased from 44.0 to 55.2%; and among outpatients, the proportion of rural residents using these services in 2004 (9%) actually exceeded that of urban residents (8.6%), reversing the situation in 1995–1996.

The data shown in Table 2 also suggest that the Indian private sector was an important driver of the observed increase in medical device use. Between 1986–1987 and 1995–1996, the proportion of patients who paid for their x-ray, ECG or ultrasound examinations increased by nearly 5% for in-patients and nearly 15% for outpatients [13]. This pattern continued over the period from 1995–1996 to 2004. Among in-patients, the proportion paying for their diagnostic services increased from 78.8 to 87.4%; and from 88 to 93.2% for outpatients. Given that during this period medical device use in the public sector was subsidized, the observed trends probably resulted from greater activity of the private sector. Evidence reported by Varshney, who found that equipment utilization rates in private ultrasound, CT-scan and MRI facilities exceed by substantial margins the utilization rates in public facilities [14], suggests a similar conclusion.

A number of factors are likely to have influenced public and private sector differentials in the utilization of medical devices, although systematic research on this subject is limited thus far. The increased purchasing power owing to rising per capita incomes, in combination with budget squeezes in the public health sector, is likely to have led to a rising demand for medical devices being directed towards the private sector [14]. Quality problems in the public sector, including a general lack of processes to ensure that the equipment in the public sector is well maintained, that adequate spare parts are available and that personnel operating the equipment are well trained may also be a factor [14]. There are also incentives on the supply side, such as referral practices, that lead patients to be directed to private sector diagnostic providers in return for commissions. In the diagnostic service sector, these commissions can range from 10 to 30% of the cost of the service [11,14]. At least some of the demand for private sector ultrasound services seems to have resulted from the popular demand for technology to determine the sex of a child [106]. The rising numbers of medical graduates practicing privately in India, many educated at expensive private medical colleges with a heavy focus on high-end care, is potentially another factor influencing the demand for new medical device technology [6,16].

Discussion & policy implications

The previous sections show that substantial changes have been taking place in the Indian medical device sector. The available evidence supports the view of a fairly rapid catch-up in medical technology in India, in the form of increased imports of modern medical devices and, lately, also by way of domestic production, whether by home-grown firms, collaborations between local and international enterprises, or by the establishment of subsidiaries of foreign firms. There is also some evidence of more intensive use of medical devices among patients in both rural and urban areas. This process is likely to have been assisted by the rapid growth in income *per capita* that has occurred in India during the last 10–15 years, of approximately 4% per year, trade liberalization in the form of substantially lowered tariff rates and reductions in other forms of trade barriers [17,109]. India's tariff commitments under the World Trade Organization negotiations have resulted in sharp cuts in the tariff rates on medical equipments and are probably an important factor in its growing trade in medical devices. The private healthcare sector has also grown, reflecting both the purchasing power of patients, perceived quality differentials between the public and private sectors, and the growing body of medical graduates in India, many of whom are educated at expensive private medical colleges.

The speed (and scale) at which medical devices have been introduced into India has no doubt helped to increase the access of at least some Indian consumers of health services to newer

medical technology. For instance, the rapid growth in the numbers of imported and domestically produced pacemakers, the increased supply of cardiac catheters and diagnostic equipment, such as angiographs, ECG and echocardiographs, all indicate an increased health-sector response to the medical care needs of an Indian population that is both aging and thought to be at high risk from heart disease [18]. As another example, the rapid increase in imports of hearing aids and artificial joints probably reflects demand resulting from long-neglected needs of the disabled in India [19]. Increased stocks of high-end diagnostic equipment, such as MRI and CT scanners, while still considerably less (in per capita terms) than Canada and Western European countries, suggest not so much an excess of services as better meeting of service delivery gaps [13]. In conjunction with a ready presence of large numbers of practitioners of allopathic medicine, the increased volume of modern medical devices has probably also resulted in what researchers in international trade would refer to as India's comparative advantage in the production of high-end medical services/procedures, relative to developed countries. The consequences are increased opportunities for 'medical tourism', and an economic incentive for doctors not to migrate abroad. These gains are likely to spread further as India begins to use its expertise in information technology to promote healthcare use among long-neglected populations, through ambulance services, expanded insurance and health information services [5,110].

These gains notwithstanding, there are ways in which the use of medical devices in India can be made more effective in addressing key health-policy goals, such as efficiency and equity in resource use. These concerns are particularly noteworthy as India faces growing challenges in the current adverse global economic climate. In the Indian public sector, for instance, inefficiency in medical device use often takes the form of underutilization relative to capacity, whether due to shortage of spare parts and poor maintenance of equipment, absence of trained personnel for operation, lack of performance incentives or simply corruption that leads to the purchase of inappropriate devices [13,14]. In the private sector, there is a risk of overutilization relative to need, whether through commission-based referrals to diagnostic services or provider-induced efforts driving patients to use more health services; conversely, there is downright misuse, demonstrated by cases in which ultrasound technology is used for identifying the sex of the fetus and subsequent, sex-selective abortions [20,106]. Both public and private providers also face an extremely chaotic market for the supply of medical devices, with shortages of maintenance engineers, particularly outside of major cities, and purchasers are often less than adequately informed concerning the efficacy of these devices [14]. The net consequence is likely to be inefficient use of medical devices.

There are concerns regarding equity as well, although the evidence on this score is rather limited. The distribution of MRI systems appears to be lopsided in India, mostly concentrated in a few urban areas, primarily large cities such as Mumbai, Chennai, Bangalore, New Delhi, Kolkata and Hyderabad [13]. This is even true for diagnostic equipment that is not as high-tech, reflected in the higher x-ray/ECG/ultrasound utilizations of urban patients compared with rural in-patients (Table 2); and in the poor maintenance and low operational rates of equipment in public sector health facilities in smaller towns [13]. As trained doctors and other medical personnel prefer to practice in urban areas, medical devices and equipment are also likely to be concentrated there. With limited insurance cover in the Indian population and constrained public sector budgets, particularly in the 1990s, differences in purchasing power are also likely to have influenced access to medical services, including medical device use [15].

Healthcare costs incurred out of pocket for in-patient stays and outpatient visits have risen rapidly in recent years, with poor individuals bearing a disproportionately greater burden of spending relative to income [15]. The rapid increase in medical device use, particularly diagnostic devices, is likely to have contributed to this medical care expenditure inflation in India. Private sector health services are the main channel for healthcare cost increases, given public sector budget constraints. These developments raise obvious equity concerns relating to the diffusion of medical technology in India.

Regulation of medical device production, import & use

Until recently, medical devices in India were poorly regulated. Importers of medical equipment could import both used and new devices with very little restriction on the type of product or its efficacy. Certainly, there was no formal technology assessment process for approving medical devices from a clinical or economic point of view. The only controls that existed to ensure that the type of equipment imported was 'useful' were differential imports tariffs and purchase practices of public sector units. Life-saving equipment could be imported duty-free, whereas other equipment faced duties ranging from 20 to 40% or even higher. With the decline in import duties beginning in the mid-1990s, even these restrictions weakened. Another mechanism that existed was purchase practices of government hospitals/institutions that issued global tenders and tended to favor equipment pre-approved for use by the US FDA or regulatory authorities in Europe [109]. Importers were also required to hold licenses for a variety of purposes, although few of these were related with ensuring the clinical efficacy of the equipment imported. Domestic producers had to satisfy standard requirements for obtaining manufacturing licenses in India [102] and providers of x-ray and related diagnostic services had to meet environmental regulations [21]. Laws against the misuse of ultrasound technology to identify the sex of the fetus also exist [22].

There have been recent efforts to more closely regulate a few medical devices in India, including efforts towards the setting up of a medical device regulatory authority. Currently, a limited number of medical devices, such as cardiac stents, catheters and heart valves, are under the regulatory ambit of the Central Drug Standards Control Organization [102,109,111]. Since the main tool by which this organization operates is the

Drug and Cosmetics Act of 1940, used to regulate pharmaceuticals, its application to medical devices has been achieved by classifying the latter as drugs. Moreover, in line with best practice, a number of requirements, such as proof of regulatory approval abroad, evidence of clinical efficacy, postmarket surveillance and so forth, have been imposed on importers and sellers of this limited set of medical devices [111]. There are also licensing requirements for domestic manufacturers of medical equipment, including specifics relating to their clinical efficacy and manufacturing practices.

India has a long history of poor implementation of regulations, which leads us to be cautious regarding any potential benefits from an expanding regulatory regime. This aside, attention to clinical efficacy, the direction in which the evolving regulatory regime seems to be heading, is unlikely to be sufficient in a resource-constrained country such as India. Certainly, regulations ensuring that devices perform as claimed by their manufacturers, especially with less than perfectly informed purchasers of devices and patients, could be useful. However, to promote more efficient and equitable use of medical devices and health cost containment requires additional steps, including 'health system' adjustments. In this light, market-centered mechanisms, such as insurance companies (or large healthcare purchasers such as the ArogyaSri scheme in the Indian state of Andhra Pradesh, or insurance being promoted under the National Rural Health Mission) or tax breaks, may be more useful in terms of promoting the spread of cost-effective medical devices and also their greater use by poorer and remotely located populations [111,112]. Oversight of public hospitals by decentralized authorities accountable to local populations may also help, such as Rogi Kalyan Samitis in the Indian state of Madhya Pradesh [113]. In smaller towns in India, training locally based individuals to operate and repair equipment, who could serve as franchisees to the supplier, could address the low rates of utilization of medical devices. The public sector could also transfer some responsibilities, such as the operation of certain types of medical devices, to private providers. Finally, extending the medical code of ethics to establishments that employ doctors (even if not owned by doctors) may curb unethical referral practices and misuse of ultrasound devices for sex-selective abortions as an alternative to, or in conjunction with, any laws to that end.

Five-year view

The domestic medical device market can be expected to continue to grow in the near future. While the ongoing global recession may result in a slow-down, growing incomes (India will remain among the fastest growing economies) and increased insurance coverage will lead to increased demand for health services and medical devices. Recent efforts by the Government of India to enhance financial allocations to health under its National Rural Health Mission will contribute to this increased demand [112]. Demand-side factors will also include the continued rapid growth of medical professionals owing to the addition of large numbers of medical graduates (>25,000 per year). On the supply side, recent trends suggest a rapidly growing domestic production capacity (and collaborations) for both local and export markets.

Ensuring that the growth in medical device import, production and use occurs in a manner that supports health-policy goals of efficiency in resource use, equity of access and cost containment will demand policy attention. The medical device industry in India is likely to see continued developments in regulatory arrangements, including coverage to a broader range of devices. A regulatory authority for medical devices in India will probably emerge over the next few years. However, such an agency would need to acquire the technical capacity of undertaking its regulatory responsibilities and, given the serious problems with the Indian legal system, implementation of any new regulatory controls will continue to be tardy.

Regulation will only be part of the story. As health insurance coverage picks up in India, insurance companies or large government-run insurance funds may well impose their own constraints on the safety and cost aspects of medical device use, possibly informed by the work of regulatory authorities in the USA and the EU. Greater attention to health system drivers of the efficiency and equity of health resource use is also likely to occur as increased resources are directed to the Indian health sector.

More generally, and not necessarily limited to India, we expect there to be greater attention to policy research related to health devices in developing-country contexts. Compared with research on pharmaceuticals and medical personnel migration, this subject has been neglected. It may also be relatively easy to track the production and trade of at least broad categories of medical devices, given the existence of a large UN commodity-level database on international trade. Crucially, perhaps, with increased interest in the spread of medical technology across borders, a number of interesting questions are worth investigating. For instance, how do medical personnel and drugs, and other elements of medical technology, influence medical device development? What is the relationship between cross-border movement of medical personnel and cross-border movement of medical devices? How might medical technology be more effectively used to benefit populations in remote and rural areas with a shortage of medical personnel?

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Key issues

- Understanding the spread (and use) of medical devices in developing countries such as India offers useful insights into the way medical technology benefits poorer populations.
- Data on trade in medical devices are a useful way to understand the magnitude and composition of medical technology flows to developing countries that lack domestic medical device production.
- Producers/importers of medical devices and healthcare providers are a key mediating mechanism in movements of medical technology across and within borders and influence whether the technology is applied in an equitable and efficient manner.
- Developing countries lack regulatory and market-directed controls on the use of medical devices and this may yield outcomes that are financially inefficient, inequitable and do not promote cost containment. Ensuring adequate oversight of medical device use poses a major policy challenge for these countries.

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Papers of special note have been highlighted as:
• of interest
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