

Appropriate Policies for Medical Device Technology: The Case of India

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THE TERM “MEDICAL TECHNOLOGY” IS GENERALLY TAKEN TO ENCOMPASS THE entire set of attributes associated with inputs that go into the provision of medical services. These include pharmaceuticals, medical devices, medical procedures and the organization of health services themselves (Mohr et al. 2001).¹ A change in medical technology is usually taken to imply a change in one, or more, of the above attributes. Thus, the development of new drugs to treat people with HIV, the emergence of angioplasty and coronary-stents for coronary artery disease, and the development of magnetic resonance imaging (MRI) and Positron Emission Tomography (PET) for diagnostic purposes are all examples of changes in medical technology under this definition.

In India, policy and research concern with the introduction and spread of medical technology been limited, thus far. The exceptions are pharmaceutical drugs and the regulation of diagnostics for sex determination of the fetus (Balakrishnan 1994; Govindaraj and Chellaraj 2002; Mudur 1999). Discussions on medical devices, when they have occurred, have focused on corruption and other problems in public procurement (Johnson 2003; Sudarshan 2003).

In contrast, in developed countries, the subject of medical technology has attracted research and policy attention over a considerably wider area. A particularly fruitful line of inquiry has been the impact of medical innovations on health expenditures, and the pathways through which these expenditure increases occur. An influential strand of this literature argues that technological change accounted for more than 20 percent of the multi-fold increases in health spending that occurred in the United States during the period from 1980 to 2000, mainly due to increased volume of utilization and higher prices (Mohr et al. 2001; Newhouse 1992).

Following from this, research in developed countries has tended to follow two directions: first, to analyze factors leading to the development and subsequent increased use of advances in medical technology; and second, to inquire whether the added expenditures yield gains in health that outweigh the costs. Examples of the former include examining the role of provider payment mechanisms, the system of medical education, learning processes among practicing doctors, education levels among potential consumers of care, defensive medicine in response to malpractice law and government regulations on the spread of newly developed technology; and on factors that influence the development of malarial drugs (Baker and Wheeler 1998; Bikhchandani et al. 2001; Bryce and Cline 1998; Danzon and Pauly 2001; Finkelstein 2003; Jonsson and Banta 1999; Lleras-Muney and Lichtenberg 2002; Kremer and Sachs 1999; Ramsey and Pauly 1997; Rosenthal et al. 2001, Weisbrod 1991).

As to the question of whether added expenditures on medical innovations yield sufficiently large health gains, the central conclusion of the existing literature is that increases in expenditures associated with medical technology are not a “social bad”. Thus Cutler and McClellan (2001) conclude that improved heart attack treatments (such as angioplasty with stents) and new methods for neonatal care and depression have yielded life-expectancy gains that, when valued in monetary terms, are at least six times their increased cost. Lichtenberg (2004) argues that the launch of new chemical entities (drugs) accounts for almost 40 percent of the increase in life expectancy

1. Each of these terms can, in turn, be more precisely defined. For instance, the Global Harmonization Task Force (GHTF) defines a “medical device” as “Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or other, similar ... article, intended by the manufacturer ... for human beings for ... diagnosis, ... investigation ... supporting or sustaining life...” (GHTF 2003, p.5)

in a sample of 52 countries during the period 1986 to 2000. Cutler and Meara (2001) examined the declines in mortality in the United States during the 20th century, and found that most of the declines are associated with technological advances - initially the emergence of antibiotics and later, better procedures for addressing cardiovascular disease and neonatal mortality. A recent survey of 225 U.S. primary care physicians identified magnetic resonance imaging (MRI) and computed tomography (CT), along with angioplasty as having contributed significantly to the length and quality of life of patients (Fuchs and Sox Jr., 2001); although the value of such diagnostic devices is contentious because populations of other developed countries such as Canada, continue to have excellent health systems and with much less reliance on MRI and CT-scan technology.

Presumably for the reasons above, Deaton (2004) suggests that the rapid transfer of knowledge and skills made possible by closer global links has the potential of leading to great improvements developing country populations' health and consequently, of reducing inequalities in global health status. It is also not surprising thus, that Cutler and McClellan (2001, p.12) conclude, "...medical spending as a whole is clearly worth the cost" (Italics ours).

Relevance of Medical Technology Discussions to Indian Policy Makers

The above discussion ought naturally to be of to concern Indian policymakers, and for several reasons. First, there are likely to be continued pressures on the demand side towards adoption of medical innovations. An increasingly open trade environment in India and heightened global interlinkages will likely increase the awareness of newer medical technologies in India and rising incomes, along with the spread of voluntary insurance will make such technologies more affordable to the average Indian. These tendencies towards increased demand will be accentuated by an ageing Indian population. Indeed as its population ages, many of the innovations in developed countries that have significantly greater numbers of elderly populations will become increasingly relevant to India's population. These tendencies are likely to be further exacerbated by "medical tourism" that is currently being promoted by the private sector and some government officials in India (Fernandes 2003).

Second, there will be supply side pressures, as medical institutions seek to adopt the latest innovations in a bid to attract not only customers, but also leading medical professionals who might otherwise choose to practice elsewhere, or to migrate abroad (for example, Baru 1998). This will likely have a cascading effect on the nature of training provided in medical institutions - more diagnostic intensive, with presumably less focus on clinical skills. To this one can add increased efforts of suppliers of medical devices and other products to sell their products in rapidly growing markets such as India.

It is, therefore, easy to project that with demand- and supply side- effects, the volume of new medical products in

India will expand. Prices may rise as well, as suggested by some analyses of the impact of India's drug patent regime moving from process patents to product patents. The limited public resources currently available to spend on health means that governments at the center and the state levels in India may need to set priorities regarding the use and adoption of medical innovations, and their diffusion, at the very least, in public facilities.

One might suspect that, by their very nature, public sector budgetary limits force new medical technology adoption in public facilities to progress at a slower rate than in private institutions. However, success in this endeavor is not guaranteed, if there are incentives to obtaining new equipment and adopting newer procedures, including greater prestige, and the need to prevent poaching of medical personnel by private sector institutions. The existence of corruption in procurement procedures may also positively influence technology adoption. A paradoxical situation may arise where health care costs could nonetheless be increasing at a fast rate in the public sector without any corresponding gains in health, if the public sector functions inefficiently.

Effort may be needed to shepherd developments in the private sector as well. The large amounts currently spent out of pocket by Indian households on health care do not eliminate the need for public policy on medical innovation, given a setting where doctors and suppliers of new technology are in a position to decide health services consumption patterns. Thus, public intervention may be needed, or safeguards introduced to ensure that the innovations used yield the highest health benefits relative to expenditures; and intervention may also be needed to address any inequalities in access that might result on account of differential physical and financial access to innovations.

In thinking about these issues in the Indian context, a major handicap is the lack of good information on medical technology flows and the factors driving these flows, and the resulting impact on outcomes of interest - such as the cost of care, inequality in access to care, and ultimately, health outcomes. This paper is a first step in the direction of filling this gap, by bringing together existing data and new information on the way medical technology is diffusing in India, its use patterns, and in its potential implications.

To keep the discussion manageable, we focus on technology embodied in medical devices. Four main research and policy questions are addressed:

- What do we know about the spread of new medical device technology in India and what are the main factors underlying this tendency?
- How effectively is available medical device technology in India being used in terms of its impacts on the costs of providing health care and on inequalities in access to health care?
- What is the state of regulations in India with regard to medical device technology?
- What is the appropriate strategy (including public/private partnerships) towards medical innovations and the avail-

able basket of medical technology and what can we learn from the experiences of developed countries in this regard?

In practice, addressing these questions in research has proved to be difficult even in the United States, a country with rich data sources. In India, where data are sparse it is difficult to meaningfully address these questions beyond a small-subset of issues and categories of medical innovations. Thus, in analyzing how modern medical technological innovations embedded in devices are spreading and are being used in India, we focused primarily, but not exclusively, on diagnostic equipment such as MRI and CT-scans. An absence of domestic production for such diagnostic devices means that reasonably accurate estimates of the flows of such devices in India can be constructed from foreign trade data.

Our analysis of import flows of modern diagnostic medical devices is supplemented, in the paper, with a discussion about the efficiency with which available medical devices, diagnostic and non-diagnostic, are currently being used in India. This analysis is valuable because it has the potential of highlighting the cost and effectiveness implications of the introduction of new medical devices. Inefficient use of existing medical devices has implications in that in a regime of changing technology, it may be a pointer to rising health expenditures without corresponding improvements in health outcomes of interest.

We used data from several sources for our analysis. These include import statistics (on both quantity, and unit prices) from official foreign trade data of the Ministry of Commerce, utilization and expenditure information from household consumer expenditure surveys and health care utilization and expenditure surveys of the National Sample Survey Organization (NSSO). These data were supplemented by selected case-studies of the utilization of imaging equipment in the public and private sectors, recently undertaken by one of the authors on behalf of the National Commission on Macroeconomics and Health (NCMH); and by a detailed analysis of the functional status of medical equipment in public sector hospitals operated by the Andhra Pradesh Vaidya Vidhana Parishad (APVVP).

Flows of Medical Devices into India

Tables 1 and 2 present data on the volume, and the value, of imports of a selected set of diagnostic medical devices into India, such as CT-scanners, MRI systems, the linear ultra-sound scanner; angiograph, endoscopes and electrocardiograph (ECG).² These devices all have the characteristic that they are predominantly manufactured outside India, so that import flows offer a reasonably accurate picture about their pace of diffusion into India.

The data in these tables were obtained from commodity-level foreign trade statistics compiled by the Ministry of Com-

merce, and careful readers will note a number of obvious shortcomings in the information presented. First, the categorizations used are potentially overlapping – for instance “whole body scanners” as recorded by Indian customs can be both the X-ray (CT-scans), or of the magnetic resonance imaging (MRI) variety; unfortunately, the official trade statistics do not make a clear distinction between the two. Moreover, the distinction between a “CT apparatus” and a “CT-scanner” is not obvious, since these terms are used interchangeably in the profession.³

Second, it seems that the volume units used for “MRI Apparatus” in the trade statistics data are not identical to a “full MRI system” since a quick calculation using the information the two tables reveals that doing so would lead to unrealistically low unit cost estimates for, say the most recent years 2000–3. Now some of this could be the result of imports of older MRI models and/or imports of used equipment. It is also possible that the term “MRI apparatus” refers to individual components of the MRI system, including major replacement parts, so that several such components make up a fully functional system. Thus these statistics cannot allow us to immediately infer how many completed MRI systems have been imported into India. Presumably, a similar concern holds for items under the term “CT Apparatus” as well.

Despite these obvious data issues, the information in Tables 1 and 2 is still quite illuminating. Note that with perhaps a slight blip during the period 1994–7 both the volume, however measured as well as the real value of imports of medical devices have experienced sharp increases in the 1990s. For items that serve essentially as consumables, or have well defined units, such as catheters and endoscopes, there is a clear increase in utilization. For devices such as MRI’s and CT-scans, the increase could also be due to the increased rate of imports of spare parts, as the cumulative number of devices present (installed) in the country increases over time, or new equipment. Both factors are likely to be associated with increased utilization. The data in Table 1 on trends in CT-scan imports and the extremely sharp rates of increase in CT Apparatus units is not inconsistent with this claim.

Although we do not provide the calculations here, it can also be easily checked from the numbers in tables 1 and 2 that per unit cost (value/volume) for almost all of the devices examined here has either remained stable, or declined during the period under consideration. There are three possible scenarios consistent with this: (a) lowered prices of older models and their spare parts with medical innovation in developed countries; (b) newer models becoming available at prices that are essentially similar to the past prices for what now have become “older” models; and (c) changing composition of the “Apparatus” category for MRI and CT scans. Since (c) applies only to the case of categories “CT Apparatus” and “MRI Apparatus”, we conclude that innovation in the medical device sector is accompanying price declines in medical

2. A cardiac catheter is used as a diagnostic device. But unlike other devices discussed in Tables 1 and 2, it is a consumable (thrown away after use).

3. Nor can one simply guess that a CT-scanner (non-whole body) and a whole body scanner is a subset of “CT apparatus” because it can be readily checked that in some years the sum of the value of the two types of scanners, exceeds the value of the “CT apparatus” category.

Table 1**Import of selected medical devices to India by volume, 1991-2003**

Device type	Three year totals			
	1991-94	1994-97	1997-2000	2000-03
CT apparatus	NA	>73	206	1810
CT scanner (NW)	113	167	181	176
MRI apparatus	NA	78	113	807
Scanner (whole body)	68	61	49	116
Cardiac catheters (000s)	1092.54	1000.35	1171.03	1774.93
Electrocardiogram	171	231	3713	9347
Linear ultrasound scanner	742	1135	1737	4733
Endoscopes	1862	2114	2526	9590
Fibrosopes	NA	627	1049	2691
Angiogram	NA	NA	72	176

Note: NW = CT scanner other than for the whole body; measurement units of CT and MRI apparatus are based on Indian Customs definitions. Source: Foreign Trade Statistics of India

devices, or quality improvements, or some combination of both. Notice that our results would be even stronger if the prices were expressed in US\$ terms, since the Rupee depreciated against the US\$ during this period at a rate much greater than the rate of inflation (Government of India 2004).

The Demand Side

So far we have looked at the supply-side picture and inferred trends in the spread of medical diagnostic technology in India – both in terms of units, as well as in terms of actual utilization of the equipment from import data. Corroborating evidence is available, even if not sufficiently device-specific, from household survey data on the use of diagnostic services. Tables 3 and 4 present information from household surveys on health care utilization and consumer expenditures in India. Data from two large household health care and utilization surveys suggest (in Table 3) that the likelihood of undergoing a diagnostic test, by an average inpatient, or by an average outpatient, increased during the period from 1987 to 1996, the two points in time at which the two surveys were respectively conducted. To be sure, the different categories of diagnostic tests (ECG versus ESG versus CT-scans, say) were not distinguished by the household survey questionnaire; but the thrust of the data seems clear enough.

Similarly, table 4 shows that diagnostic expenditures by households nearly doubled during the period from 1993-94 to 1999-2000, whether taken as a proportion of aggregate household spending, or as a proportion of aggregate health care spending by households. Even more remarkably, diagnostic expenditures accounted for one-fourth (25 percent) of the increase in the share of health care spending by households that occurred during this period. The evidence in table 3 on the increased per patient usage of diagnostic services suggests that at least some of the increase in expenditures would have been accounted for by increased use of diagnos-

Table 2**Import of selected medical devices to India by value, 1991-2003 (Rupees in millions)**

Device type	1991-94	1994-97	1997-2000	2000-03
CT apparatus	NA	>53.81	544.01	1647.47
CT scanner (NW)	357.08	187.41	234.58	464.46
MRI apparatus	NA	557.75	713.67	2687.96
Scanner (whole body)	422.94	213.04	312.33	436.45
Cardiac catheters (000s)	542.32	473.47	1621.18	2364.04
Electrocardiograph	102.12	109.60	289.03	226.43
Linear ultrasound scanner	388.63	689.66	816.16	2477.50
Endoscopes	97.00	125.33	108.65	399.02
Fibrosopes	NA	47.55	71.53	90.42
Angiograph	NA	NA	567.05	804.11

Note: NW = CT scanner other than for the whole body; measurement units of CT and MRI apparatus are based on Indian Customs definitions; GDP deflator used to convert Rupee prices into 1993-94 prices. Source: Foreign Trade Statistics of India

tic services.

Taken together these bits of information in tables 3 and 4 suggest that: (a) Diagnostics use is increasing over time in India; (b) that people are paying more often for diagnostic services; and the net result of these tendencies is that the overall share of diagnostic care spending (which is the result of some mix of increased use and increased payment) in total household budgets is also increasing over time.

Why did this happen? There are a number of candidate reasons. For a start, the spread of new diagnostics can be expected to be the natural outcome of scientific progress. This process would also likely have been facilitated by the liberalization in the foreign trade regime in India, a process that took root in the early 1990s. Unfortunately, it is not straightforward to test this latter hypothesis since the definitions of various commodities in foreign trade records were not spe-

Table 3**Proportion of patients getting an X-ray/ECG/ESG scan in India, 1986-87 and 1995-96**

Care type and residence	X-Ray/ECG/ESG/ scan	
	1986-87	1995-96
Inpatient		
Rural	33.63	43.06
Urban	45.16	52.07
Total	36.82	46.39
Outpatient		
Rural	2.90	3.61
Urban	5.47	6.34
Total	3.57	4.41

ECG: electrocardiograph; ESG: electrosonogram Source: 42nd and 52nd rounds of the National Survey Sample Organization's household surveys.

Table 4

Diagnostic, health and total expenditure of Indian households, 1993-94 and 1999-2000

Expenditure categories	1993-94			1999-2000		
	Rural	Urban	Rural + Urban	Rural	Urban	Rural + Urban
Inpatient						
Diagnostic Exp /Total HH Exp (%)	0.05	0.05	0.05	0.09	0.10	0.10
Diagnostic Exp /Total IP Exp (%)	5.47	3.99	4.85	6.82	7.16	6.95
Total IP Exp/Total HH Exp (%)	0.89	1.19	1.00	1.37	1.44	1.40
Outpatient						
Diagnostic Exp /Total HH Exp (%)	0.06	0.09	0.07	0.15	0.15	0.15
Diagnostic Exp /Total OP Exp (%)	1.23	2.52	1.60	3.08	4.21	3.43
Total IP Exp/Total HH Exp (%)	4.55	3.42	4.15	4.72	3.62	4.31
Inpatient + Outpatient						
Diagnostic Exp /Total HH Exp (%)	0.10	0.13	0.11	0.24	0.26	0.25
Diagnostic Exp /Total OP+ IP Exp (%)	1.92	2.90	2.23	3.92	5.05	4.29
Total IP+ OP Exp/Total HH Exp (%)	5.44	4.60	5.15	6.09	5.06	5.71

HH = Household; IP = Inpatient; OP = Outpatient Source: Consumer Expenditure Surveys of the National Survey Sample Organization, 1993-94 and 1999-2000

cific enough to identify imports of specific items such as MRI-and/or CT-scanners in the period prior to 1991.

Other factors are likely to have played a role as well. Given India's health system, where the bulk of health care spending is by households, technology innovation will also be driven by consumer demand expressed in terms of purchasing power. The period since the early 1980s has been characterized by rapid increases in incomes in India, which may very well have contributed to the rising demand for better quality care, including better diagnostic services. Since this period has also been a time of severely constrained government budgets, one might naturally expect to see any evidence of such a tendency in a growing private sector. Thus table 5 which presents survey data on whether households who obtained diagnostic services paid for them, or not, indicates that the share of "free" diagnostic services has declined over time. This is entirely consistent with the evidence in table 4 which shows increased proportions of household spending directed to diagnostics.

Into the above mix, one can add the role of medical practitioners and diagnostic service suppliers themselves in promoting the use of diagnostic services. It is well-known, for instance, that many medical practitioners in both the public and private sectors have informal contracts with private providers of diagnostic services and pharmacies that yield them a commission on each referral made to the concerned pharmacy or diagnostic service provider. Financially large investments in diagnostic equipment put extra pressure on diagnostic service providers to offer incentives to individuals (qualified and unqualified practitioners) who may be in a position to offer such referrals. Baru (1998, pp.112-4) cites evidence from Hyderabad that this commission could be as much as 10-15 percent of the cost of a diagnostic test. Varshney (2004) found that an average of 10 percent of total expenditures of diagnostic service providers consist of "business development" payments to doctors; and the share may be as high as 30 percent for high-end diagnostics such as MRI and CT scans.

Table 5

Patients getting an X-Ray/ECG/ESG, by payment mechanism, All India, 1986-87 and 1995-96

Care type and residence	1986-87 (%)			1995-96 (%)		
	Free	Part-free	Payment	Free	Part-free	Payment
Outpatient						
Rural	21.58	5.28	73.14	9.14	0.35	90.51
Urban	29.16	5.49	65.35	11.16	1.09	87.75
Total	24.63	5.37	70.01	9.69	0.55	89.76
Inpatient						
Rural	39.69	3.12	57.19	35.75	10.57	53.68
Urban	46.22	3.70	50.08	41.94	13.69	44.37
Total	41.91	3.32	54.78	38.01	11.71	50.28

ECG: electrocardiogram; ESG: electrosonogram
Source: NSSO household surveys of 1986-87 and 1995-96

Not all centers give incentives, of course, and commissions are especially common among unqualified medical practitioners. Overuse may also result on account of internal referrals in corporate/private hospitals where there may be performance targets for consultants.

Cross-country evidence

To supplement the discussion on the role of different factors in influencing the spread of medical technology, we carried out a regression of a measure of MRI imports on a set of supply- and demand-side explanatory variables, for a set of non-MRI manufacturing, primarily developing, countries. Using data from the World Bank's World Development Indicator's database and the United Nations, we inquired whether inflows of MRI equipment into countries were systematically related to countries' levels of per capita income (a proxy for effective demand), doctor-to-population ratios (a catch-all for supplier driven factors) and the role of foreign-aid (a demand side factor). We used country-reported import data on MRI equipment flows in a sample of 49 MRI equipment-importing countries (with negligible capacity to produce MRI equipment on their own). The main findings are reported in table 6. While it is difficult, at this point, to ascribe causality to the relationships for obvious econometric reasons, the fairly strong relationships (in the expected direction) between imports of MRI equipment per capita, per capita real GDP and the doctor-to-population ratios are worthy of note.

Are these flows achieving the desired objectives?

The obvious question is: Did the spread of diagnostic devices in India improve outcomes valued by policymakers, relative to the expenditures incurred? Answering this question is not

straightforward, because although one can claim on the basis of the household expenditure data that medical diagnostic devices import inflows reflect increased demand and contributed to increased diagnostic services utilization and spending in India, the impact on outcomes such as access and equity is less clear; even less so for health improvements

One rough method to check for efficiency in resource use is whether the supply of equipment such as magnetic resonance imaging systems in India was excessive, relative to some pre-agreed "norm." Alternatively, one could look to whether the equipment is underutilized, relative to some notion of full capacity. A study for the state of Pennsylvania in the United States suggests a norm that ranges between 3,000 and 3,500 scans per MRI per year, as appropriate (Bryce and Cline 1998). Alternatively, one can try examining the number of MRI sites per capita in other countries and take that as the norm. Baker and Wheeler provide an estimate of about 1.45 MRI sites per 100,000 people in the United States in the mid-1990s. The use of United States data to develop a norm is, needless to say, troublesome given that there are quite legitimate concerns about excessive medical technology and medical expenditures in that country, relative to health outcomes achieved. Thus, the situation in other countries that may have managed their health resources somewhat more efficiently ought also to be considered. Rublee (1994) provides estimates of 0.11 MRI per 100,000 people in Canada. This range of MRI per-population estimates - between Canada and the United States - can serve as a norm for our purposes.

The Radiology Association of India (RAI) website estimates that roughly 50 MRI's and 350 CT-scanning facilities currently exist in India, whereas a recent estimate based on discussions with wholesalers of diagnostic equipment assesses the number of MRI's to be of the order of 70-100, and CT scans to be about 300 (Varshney 2004). However, these appear

Table 6

Correlating MRI imports to potential explanatory variables

Explanatory variable	Dependent variable: Average MRI imports (2001-2003) per capita			
	Model I	Model II	Model III Except Africa	Model IV Except Africa
Constant	-0.395 (0.155)	-0.369 (0.154)	-0.377 (0.184)	-0.365 (0.183)
Per capita GDP (1995 US\$)	0.083** (0.016)	0.070** (0.018)	0.084* (0.045)	0.076** (0.020)
Doctors per 1000 population	0.092** (0.039)	0.084** (0.039)	0.086** (0.018)	0.080* (0.045)
Foreign aid per capita (US\$)	0.021 (0.020)	0.020 (0.020)	0.011 (0.027)	0.011 (0.027)
Average MRI imports 1998-2000 per capita		0.300 (0.202)		0.253 (0.226)
N	49	49	40	40
R2	0.508	0.531	0.488	0.506

Note: Regressions are based on data from the United Nations and World Bank. All major exporters of MRI products were excluded from the sample.** Statistically significant at the 5-percent level of significance.

to be serious underestimates of the number of CT scans, since Table 1 suggests at least 931 CT-scans in India (we have included only whole-body scanners in our list of CT-scans), even if we ignore items listed under “CT-apparatus”.⁴ That would suggest that the actual number of CT-scans exceeds RAI estimates by nearly 166 percent. If we assume similar rate of RAI underestimation for MRI’s, the estimated number for magnetic resonance imaging sites in India is 133, which translates into 0.0133 per 100,000 people. If we combine our estimates of the number of CT-scan and MRI facilities, that still comes to only about 0.11 CT/MRI units per 100,000 people. Overall, therefore, the number of CT-scan and MRI diagnostic facilities in India does not seem to be excessive, even in comparison to Canada.

There may be an issue about distribution of diagnostic equipment sites though, since high-end diagnostic facilities such as these are typically located in urban areas, particularly major metropolitan areas. Taken as a proportion of India’s total urban population only, the estimated number of MRI/CT-scans in India constitute about 0.39 per 100,000 people. Even this is substantially lower than just the number of MRI sites per capita in the United States, and is almost certainly likely to be lower than the combined MRI/CT per capita numbers for Canada.

Another way to try to infer excessive supply (or otherwise) of diagnostic equipment is to examine utilization rates in relation to some standards. For instance, if utilization rates are too low, one may judge that there are “too many” medical devices in the market.⁵ A recent study obtained information on two Delhi hospitals, one public and one private, and one stand-alone private diagnostic facility in Delhi, for this purpose (Varshney 2004). The findings of the Varshney case studies are rather stark. In the private sector, the MRI unit conducted 7,500 scans per year while being operational for a total of 360 days a year. In contrast, the public sector MRI facility was used for only 740 scans, and the facility was operational only 300 days per year. Clearly the public MRI unit appears to be seriously underutilized. Whether this indicates excess capacity, relative to need, is unclear since the poor may forgo diagnostic services altogether if there are problems of access. The functioning of this unit at below capacity, if symptomatic of a broader problem with public sector facilities, would suggest that poorer groups have unequal access to new technology, even when subsidized by the public sector.

There are good reasons to believe, however, that there is geographic inequity in the location of diagnostic sites, and that may indicate spatial inequity in access as well. Data for 70 MRI sites identified in Varshney (2004) suggest a lopsided distribution: 63 percent (44) of the sample MRIs were located in 5 major cities (Bangalore, Chennai, Delhi, Hyderabad and Mumbai) with a combined population of no more than 45 million (or 4.5 percent of India’s population), and composed of the most well off individuals in India. Thus, one adverse outcome of the introduction of state of the art diagnostic

services, at least at the present time, is inequity in access to high technology health care, whether valuable or not for health outcomes. The cross-country evidence in table 6 suggests similarly that modern diagnostic technology is likely to be directed towards richer countries/areas with high doctor-to-population ratios.

Another area of concern is misuse of technology. Policy-makers in India have been particularly concerned about the use of diagnostic services such as ultrasound for sex determination, and implications for female feticide. While the practice has been banned in India, it is commonly understood that it still continues illegally, given that both the user (demander) and the supplier of diagnostic services gain from it, and monitoring is potentially costly.

Efficacy of Medical Equipment Use in the Public and Private Sectors

The previous section focused on advanced medical diagnostics and suggests that in the aggregate there may not be an excess of diagnostic devices such as CT-scans and MRI sites in India. It presented some evidence of regional inequity in location; and it briefly pointed to a problem with an existing mechanism (public sector provision) to partially address inequities related to financial access. That is, government facilities that are often the sole affordable source of advanced technological devices to the poor do not keep their equipment functional, or are otherwise unable to preferentially provide services to the poor. How policymakers handle the entry of new technology obviously has important health policy outcomes.

The above discussion also suggests that thinking on policy approaches to address medical devices and the technology they embody needs to go beyond the effective harnessing of the new technologies. In particular, an examination of the effectiveness with which health facilities in the public and private sectors currently use their equipment is potentially very valuable. This would help focus attention on health system features that might lead to wastage of resources if left unattended at a time of technological change, and refocuses attention on the challenge of efficiently providing public sector health services to the less well off.

Equipment Use in the Public and Private Sectors

We use two sources of information on the public sector utilization of medical devices, mainly durable equipment: for the state of Andhra Pradesh from the Andhra Pradesh Vaidya Vidhana Parishad (APVVP); and from a study undertaken for the National Commission on Macroeconomics and Health by Varshney (2004). Information on the private sector is primarily from Anil Varshney (2004).

The data from APVVP covered 74 community health centers, 55 area hospitals and 21 district hospitals run in Andhra

4. We assume that all CT-scans purchased prior to 1991 are no longer in use.

5. Of course, assessing utilization rates of equipment may be tricky in assessing optimal capacities if there is supplier induced demand.

Pradesh. Unfortunately this data cannot always be separately broken down by diagnostic and non-diagnostic equipment. A priori, however, there is no reason to believe that findings for the two sets of equipment ought to be different. This data highlights several areas of concern to policymakers with respect to equipment in government health facilities. In particular, (a) government facilities face an acute shortage of basic equipment; (b) the equipment on the premises is not always functional; (c) and there are potentially serious problems with regard to time taken for installation and repairs. Similar findings for a selected set of developing countries are presented in Mavlinkar et al. (2004).

Consider availability. If even the most basic equipment is unavailable, the introduction of newer technologies, if it were to occur, would lead to inefficient use of resources, especially if cheaper investigations were substituted by more expensive ones. As of 2004 the value of medical equipment at community health centers, district and area hospitals under APVVP ranged between 70-85 percent of that required under norms focused on acquisition of basic, not the most advanced technology. Notice that this “superior” situation occurred after a long period of stewardship and World Bank support, and unlikely to be representative of other, more backward states in India. Their situation would be more akin to APVVP hospitals in 1993 - when available equipment ranged from 25 percent to 75 percent in value relative to norms set by the government.

Even when equipment was available, it was not fully functional. This possibility raises questions about whether the new technologies, if introduced, can effectively be used at all. In 2002, between 45-51 percent of “major” medical equipment at area hospitals and community health centers, was classified as either non-usable, idle, or with low utilization rates. Only at the high-level district hospitals was the situation better, with an average of 15 percent for the three categories; in 1993, the situation was, of course, much worse with 28 percent of the major equipment, even in district hospitals, being either underutilized, or not functional.

There are other kinds of wastage as well. For instance, it took an average of between 2-4 months to install X-ray and ultrasound equipment at the from the time it was received at a APVVP run district hospital during the period 2000-2, with the lag being substantially greater for lower-level area hospitals and community health centers. Even these lag times were substantial improvements over previous periods.

The findings for APVVP hospitals are reflected in the case-studies undertaken by Varshney (2004) of diagnostic devices at public hospitals in New Delhi. For instance the time from ordering to actual commissioning of MRI, CT-scan and Ultrasound equipment at the public hospital was four times that of comparable private facilities. Delays occurred at every-stage in the ordering and delivery process at the public hospital - deciding upon the type of equipment needed, clearance of payments to the supplier of the equipment, incomplete electrical and other pre-installation preparatory work at the time of receipt of the equipment. This does not include the time taken for “needs assessment” a process that could poten-

tially take years at a public hospital. In addition, utilization rates following installation were not always up to the mark, as indicated by the number of cases scanned by the MRI unit at the public hospital. The latter may reflect more than just a breakdown of equipment - as we discuss in some more detail later. Varshney (2004) also undertook an analysis of public and private diagnostic facilities in one district in Rajasthan. The findings are similar to those from Andhra Pradesh and New Delhi: that relative to private facilities, the “down-time” in public hospital equipment was greater, reflecting fewer operational hours as well as the poor functional status of equipment.

The obvious implication of the inefficiencies outlined above is that the cost of production of diagnostic services (and indeed for all other types of equipment) and the overall quality of service is likely to be different under public and private sector managements and operation. Table 7 reports unit cost findings that have been derived from data presented in Varshney (2004, Table 4.2.1). Even ignoring the costs of delays and consequence foregone benefits in improved health in the public sector, the evidence suggests that private sector investi-

Table 7

Unit cost calculations of diagnostic investigations in New Delhi

Institution	Estimated average cost of investigation			
	Ultrasound	CT Scan	MRI scan	Others
Public hospital	589	2700	50250	29
Private hospital	350	3333	NA	45
Stand alone diagnostics centre	503	1999	4285	26

All figures in INR (total cost includes fixed consumable cost)
Note: Estimates are based on calculations and numbers reported by Varshney 2004.

gation costs are somewhat lower than in public facilities, with the case of MRI being especially stark in this regard. Unit cost calculations based on data from Rajasthan are similar in spirit to the results from New Delhi, and in some ways highlight the unique problems faced by lower-level public health facilities in India. The ultrasound equipment at the facility was non-functional, so that even though technicians were being paid and space occupied, no diagnostic investigations were done.

But these unit cost estimates form only a part of the picture, since there are significant quality differentials in service provision. For instance, an outpatient visitor scheduled for an ultrasound had a typical waiting time of 2 months, and a month or more for a CT-scan in the public hospital in New Delhi. The wait list for an inpatient ranged from 3-10 days for diagnostic services in the public hospital. Moreover, following completion of an examination, the report was available typically after a delay ranging from 3 to 5 days, and hard copies of the report were not usually accessible to the patient. This is to be contrasted with private services where the services and the report were typically available on a

“same day” basis. In addition, the mode for reserving slots for undertaking the tests, making payments and completing other administrative activities appear to be considerably more complicated in public facilities (Varshney 2004).

Why are there such differences in quality and cost in the public and private sectors?

The proximate causes are obvious: non- or partly-utilized equipment, resulting in fewer investigations, with personnel and other costs either similar to, or higher than in the private sector. But what are the underlying reasons for this state of affairs?

The causes of the poor functioning of equipment in the public sector, relative to the private sector range cover a wide range - from the unavailability of personnel needed to operate it (the absence of a radiologist in the district hospital in the Varshney study explains the lack of utilization of the ultrasound machine), poor co-ordination of procurement and installation processes, poorly trained staff and a general lack of accountability. Many of these same factors, together with financial constraints explain why when equipment in public facilities runs into a shortage of spare parts or otherwise experience technical problems, it takes a long time to get running again. For instance, suppliers of medical equipment point out that, public sector facilities take a long time to pay outstanding dues and there are problems with corruption. Moreover, personnel in these facilities tend to delay the reporting of problems with equipment. Poor follow-up and/or financial shortages mean that government agencies sometimes do not insure equipment once the warranty period has expired - and that may render equipment non-functional without any financial redress as soon as it runs into a technical hitch. These problems are particularly severe in public facilities that lie outside the major metropolitan areas, since their financial and human resource constraints are even greater.

In contrast, Varshney (2004) points out the obvious advantages that arise on account of a clear line of accountability and financial risk bearing in the private sector. He compellingly argues that the direct consequence of financial accountability are that response time to potential problems is much faster, getting better trained staff and careful handling of equipment gets high priority and maintenance and insurance contracts that minimize financial risk are common, particularly for major pieces of equipment.

Problems with the medical device supply and maintenance industry in India

Of course, the private sector has its own problems, as reflected previously in the discussion on the possible overuse and misuse of diagnostics and other medical devices in India. These concerns often lie at the root of policymakers' efforts to regulate private providers.

Then there are problems further down the supply line. First, there is effectively no quality regulation on the sale of high-tech medical devices, with existing ISI (Indian Bureau

of Standards mark) standards limited to a small subset of low-cost medical equipment. This is in contrast to strict quality controls on what can be sold/imported in the countries of the European Union and the United States (see below), and even China. Imports of second-hand medical devices in some categories of up to 10 years old are also allowed into India (Harper 2003) with the consequence that a lot of substandard second-hand medical devices are currently flowing into and around the country. The only regulation that currently exists relates to protections relating to radiation. But there is little or no control on what the equipment does relative to its claimed effects, its technical specifications and the like.

In addition, however, both private and public health facilities and diagnostics providers face problems related to the continued operation of medical equipment in India, so that costs of medical device operation are higher than they would otherwise be. Availability of good quality spare parts is a serious problem faced by both the public and private health service providers in India. While especially acute for older equipment spare parts for which are no longer made by the original manufacturer, the absence of any sort of oversight in the medical device market means that there are a lot of equipment suppliers who simply do not deliver follow-up services, making it costly search exercise for purchasers to sort through alternative providers. This is an important issue, because the expenses on spare parts of diagnostic equipment typically tend to exceed by several times, the original cost of the equipment over its lifetime; and because of the rapidly changing imaging technology which makes new models obsolete almost as soon as they begin operation.

A related challenge is a severe shortage of technical experts for repair work when needed, on medical equipment. Varshney (2004) notes that companies selling the equipment have probably the best engineers, but they often engage third parties, whose personnel are not as skilled, to help with the execution of maintenance contracts. The shortage of “company” engineers means that only the very persistent clients are able to get hold of them for maintenance and repair needs. In general, and for reasons mentioned above, the private sector is able to manage this process better than the public sector. Public sector facilities located in areas outside major cities are the most severely hampered, thereby contributing to long idleness times for equipment and a resulting wastage of resources. The option of engaging company engineers is not even available to those who obtain second-hand equipment.

One might reasonably argue that the market will do the sorting, with more reliable suppliers pushing out the less-reliable ones. Over time this may well turn out to be the case. But the adjustment process may well be long and costly, as appears to be the case in India. And it is unclear how and whether a resource-constrained public sector, and its facilities in remote areas, will be able to adequately respond to these adjustments as they occur. With rapidly changing technologies, the process may be even more arduous as purchasers are asked to sort through increasingly complex technical specifications.

What needs to be done?

The set of recommendations proposed here are intended to serve only as a guide for more detailed policy responses, and mainly reflect the concerns outlined in the preceding sections.

We divide our discussion on policy recommendations relating to medical devices into two: (a) regulatory recommendations on the new and second-hand medical devices market; and (b) recommendations on health systems aspects of the medical device use, including the potential for public-private partnerships.

As noted above, in India there is essentially very little regulation of the medical device industry; even less by way of quality-, or benefit-cost assessment. In thinking about the appropriate policy steps to take, note that countries in the European Union, the United States, and Canada have, at the minimum, regulations that require devices perform as claimed by their manufacturers, or sellers, before any product can be marketed. In the United States this regulatory responsibility is executed by the Food and Drug Administration (FDA). In the European Union, this function is essentially that of an autonomous implementing agency, known by different names in various countries (e.g., Medical Device Agency in the United Kingdom). Typically the process involves suppliers being required to produce documentation on performance, and it may also involve verification, such as by independent (privately run) “notified bodies” that undertake this for the EU in consideration for a fee. The assessment also typically includes meeting the requirement that any harmful effects of the device (adverse health outcomes) are an “acceptable” risk.

Next, there are requirements that ensure that any harmful effects that come to light after approval of market entry are also covered by regulation, including possible withdrawal of the permission to enter the market. Typically, this process involves some form of record-keeping in the form of a history of adverse incidents, and associated steps and sanctions. It may also involve voluntary reporting by patients and users of the equipment, or statutory reporting by manufacturers and diagnostics service providers. The regulatory authority is also responsible for putting out safety notices for information to the general public.

These two requirements appear sensible. However, it is arguable whether an India-based regulatory authority and/or autonomous entities are capable of undertaking the quality checks required at this point in time. We understand that a committee of the Indian Council for Medical Research (ICMR) recently proposed the setting up of an Indian Medical Devices Regulatory Authority (IMDRA) along these lines. This recommendation needs to be acted upon, but as an independent authority, and NOT under the Director General of Health Services (DGHS), as proposed by the government. When formed, the IMDRA may find it worthwhile to piggyback on publicly available information on licensing status and medical device performance from either the European Union, or the FDA, or both.

There are, however, areas where the proposed Indian Medical Device Regulatory Authority can potentially be extremely

useful. This is in the area of ensuring some order in the medical device market - to distinguish fly-by-night operators from more reliable sellers of devices, to ensure that sellers of equipment provide adequate levels of spare parts and technical training, to maintaining price lists and the like. Presumably, the effectiveness of this effort may require working in collaboration with the buyers of such equipment and its sellers. In particular information on the different sellers and their terms and conditions ought to be available at this regulatory agency. This could be linked to some compulsory registration mechanism, again developed in consultation with the sellers of equipment and purchasers.

Once we are past basic quality requirements and the requirements of clinical efficacy, issues of cost-effectiveness become pertinent - that is, are the outcomes achieved by the medical device worth the cost? This raises questions about whether there need to put limits on the number of medical devices overall, across regions and the like. It also raises questions as to how to rank different medical devices by health sector priority; whether the public sector ought to purchase them; and ultimately what to do once priorities have been defined. The technical method of addressing such questions comes under the rubric of “technology assessment,” and several countries do departments undertaking medical technology assessment. To set up such offices means having personnel with a collective range of skills in bio-engineering, law, medicine and social sciences, and they are often politically extremely sensitive because of the potential impact their recommendations may have on medical device markets. For partly these reasons, the office of technology assessment in the United States was a casualty in the early 1980s, having been set up just a few years earlier. The role of technology assessment is obviously valuable, however. In a resource constrained setting such as India’s, relying solely on the market to guide the growth of medical technologies may lead to a lot of wastage. Nor is it easy to focus on the public sector alone, if doing so leads to manifest inequities in access; or, a loss of high-quality personnel to the private sector.

Several countries have experimented with (and many continue to do so even today) on various additional restrictions on the number of medical devices. These include “certificate of need” (CON) requirements, which require establishing a need for a facility in an area, prior to getting a license for it. Some provinces in the United States, such as Pennsylvania, as well as countries such as Australia, Canada and Netherlands do have CON requirements, although the effectiveness of such measures in curtailing the spread of technology has been questioned (Cline and Bryce 1998). It might also be argued that in India, it is much too early to be thinking about CON requirements given that many major diagnostic medical devices such as MRI’s and CT-scans are barely making their entry into the market. Another issue of concern is that CON requirements might restore the “license-permit” raj with its concomitant implications for corruption.

Thus attention has been directed to other, market-centered, mechanisms by which the objectives of cost-effectiveness can be met, fully or partially. One option is to create incentives

for the integration of the role of health care providers (including diagnostics service providers) with that of health insurers, in conjunction with a prospective payment (capitation fee) system. This combination ought to reduce incentives for over-consumption of health care generally, including diagnostic care. HMOs are an obvious example of this phenomenon, and there is some evidence that HMO concentration has curtailed the pace of MRI diffusion in the United States (Baker and Wheeler 1998).

Another method may be to educate physicians better about medical technologies, including not only their benefits also their economic and potentially harmful side-effects; similar efforts could be directed at students in medical schools in India. There is some evidence that physicians do respond to information of this type in a way as to reduce the use of harmful expensive technologies, although relying on this option is probably not the preferred option.

Recommendations on health system features

In addition to a better regulatory approach to the medical device market, there are other health policy-related activities the government could do, to address several of the inefficiencies discussed earlier in the paper. In thinking about appropriate strategies, we are guided by the consideration that excessive reliance on regulation and outright bans is, in light of the Indian experience historically, unlikely to work effectively.

As our first example, consider the challenge of the misuse of diagnostic medical devices. The use of ultrasound scanning equipment for sex determination continues till today despite a government ban in India. With both the demander (consumer) of services and supplier of services in a mutually-beneficially arrangement, the government is unlikely to be effective with purely punitive measures. Plus, overly strict regulation tends to be abused by authorities to harass service providers and doctors. Government policies may thus need to take the form of small steps that ensure that only trained radiologists operate such machines; that there are education campaigns against this practice (currently ongoing); and perhaps ensuring that better information is available on the spread of ultrasound equipment, so that policy efforts can be more effectively directed to geographic areas and communities deemed to be most at risk.

Now consider the issue of overuse. It is generally difficult to pinpoint “overuse” as defensive medicine is likely to become increasingly prevalent in the future, patients are typically in favor of more technology intensive interventions, and there are no “set norms” for optimal use. As the Indian market

increasingly opens up to insurance companies, however, it is entirely possible that instead of the expected increases, diagnostic use may be limited by insurance audits. For instance, Ramsey and Pauly (1997) found that even fee-for-service insurance plans led to curtailing of excessive diagnostic equipment use. To this one may add a policy of extending the medical code of ethics to establishments that employ doctors (even if not owned by doctors), and grievance cells that involves professional associations and the medical device regulatory authority. One may also want to think about developing model guidelines for doctors to follow in assessing patients, although this again relies on self-regulation that has not worked well in India thus far.

A final issue revolves around ensuring that resources invested in medical equipment in public hospitals are not wasted owing to non-use, particularly in smaller towns and cities. These mean first that procurement and installation processes have to improve. The example of APVVP cited above suggests that this can be done, by hiring technically proficient staff and by empowering them. Decentralized financing authority to hospital committees would also help. Finally, at least in smaller towns, the need for better trained staff to operate and repair equipment is critical. Perhaps large scale contracts with sole suppliers, in return for extensive skills training and maintenance support may be the way to go. Varshney (2004) suggests that one could explore the training of local district-level staff who could serve as franchisees to the supplier. This could help avoid the costs that result from delayed response to repair requests from the government hospitals. In connection with training, there is obviously also a great need to train clinical engineers through courses offered at, say the Indian Institutes of Technology. Such curricula are readily available at institutions in the United States and elsewhere.⁶

In the concern for more effective usage of medical devices in India, one could consider an alternative scenario whereby the public sector could hand over some of its responsibilities to private providers. Varshney (2004) gives examples of three case studies (in Delhi, Meerut and Kolkata) of private-public partnerships in the provision of diagnostic services along these lines - with the private partner operating the equipment in space made available in the premises of the public hospital. The chief gain to the private provider was in terms of a ready clientele, whereas the public sector hospital benefited in terms of proportion of patients getting free services and a functioning facility. The experience has tended to be mixed, owing mainly to a shortage of patients going to the facility - a combination of doctors referring patients to outside facilities in return for a consideration, patients seeking second opinions prior to get the diagnostic done, and the like.

6. We are grateful to Dr. Valiathan for this point.

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