Medical devices in India - an agenda to effective healthcare delivery

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Table of Contents

1. Foreword **04**

2. Introduction **06**

3. Challenges to access to advanced medical devices **10**

- Low awareness of disease **12**
- Shortage of infrastructure and trained manpower **14**
- Inadequate health insurance coverage coupled with poor reimbursement limits are impacting access to affordable care **17**
- Significant other costs drive affordability of procedures involving medical devices **19**

4. Case Study - Impact of Stent Price Control **20**

5. Recommendations **24**

- Build medical infrastructure closer to the patient base **25**
- Procure medical devices under public health schemes to increase accessibility and improve affordability **26**
- Increase availability of trained talent to better diagnose disease and provide necessary treatment **27**
- Culture of preventive healthcare through greater spending on healthcare, especially primary care **28**
- Usher reforms in insurance sector for better health insurance coverage & establish systems to rationally decide reimbursement price **29**
- Adopt alternate models to increase affordability of medical devices **32**
- Establish a holistic ecosystem for medical device industry **33**

6. Conclusion **34**

7. Industry views **35**

Glossary

AF	Atrial fibrillation
APHRS	Asia Pacific Heart Rhythm society
AV	Atrioventricular
AYUSH	Deptt. Of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy
BMS	Bare Metal Stent
CHC	Community Health Care
CRT	Cardiac Resynchronization Therapy
DES	Drug Eluting Stent
ECG	Electrocardiograph
ELR	External Loop Recorder
EP	Electrophysiologist
GAS	Group A Streptococcal
GDP	Gross Domestic Product
ICD	Implantable Cardioverter Defibrillator
ICTPH	IKP Center for Technologies in Public Health
HTA	Health Technology Assessment
OA	Osteoarthritis
PT	Prothrombin Time
RA	Rheumatoid Arthritis
RHD	Rheumatic Heart Disease
SSS	Sick Sinus Syndrome
URTI	Upper Respiratory Tract Infection

Foreword by AdvaMed

The fundamental purpose of the life sciences industry is allow people to live longer, healthier, more productive and independent lives. These efforts include developing and ensuring access to quality medical devices and diagnostics, to help provide the best possible care for patients. With the ever-increasing disease burden in India, and non-communicable diseases (NCDs) on the rise, it's clear that an important part of the solution to these health care challenges will be adoption of innovative medical technologies.

The global medical technology industry provides safe and effective products that save and improve lives, while also yielding savings across the health care system by replacing more invasive procedures, reducing hospital stays and allowing people to return to work more quickly. At the same time, MedTech companies in India – and multinationals that have established a significant presence in the country – provide high quality jobs in communities both large and small, and help support training of health care professionals on use of life-changing innovations. To advance these benefits of medical technology, it's essential to have the right public policies in place, including a predictable regulatory environment, to support continued investment, innovation and patient access.

The Government of India has put health care front and center with a bold set of policy and regulatory activities that have made great strides for the benefit of patients. Measures to expand access to safe and effective medical products include the recent introduction of globally harmonized rules and classification for medical devices, and establishing a Medical Technical Advisory Board. Meanwhile, some measures like price controls have not translated into improved access and affordability for patients.

It is clear that effective policy solutions to health care challenges in India and elsewhere must take a holistic approach, including a focus on the value of care, to help achieve cost optimization at various levels. The Advanced Medical Technology Association (AdvaMed), the world's largest medical technology trade association, recently commissioned a study which was conducted by health care data science firm, IQVIA, on behalf of AdvaMed, to understand the key challenges impacting access to medical technology in the country. Besides other broader areas the study focuses on, findings from the study hint that capping MRPs on medical devices has not resulted in significantly lower overall cost of procedure to patients. This, and other insights on factors limiting access to procedures, are elucidated in this paper.

Alternatives to mechanisms such as price control should be explored, that facilitate differential pricing for innovative medical technologies. This will pave way for improved healthcare access in the country, making the healthcare ecosystem stronger. What India needs at this juncture is to see the larger picture of improved healthcare access to patients, rather than just focusing on controlling the prices of devices. Therefore, concentrated efforts are required across the value chain to ensure that government policies ultimately benefit patients. This will also help in achieving the government's long-term goal of universal health coverage.

The medical technology industry – led by AdvaMed – is eager to continue discussions with India's government toward effective solutions, to help the government achieve its stated health care goals and revolutionize health care in India.

Foreword by IQVIA

With changing lifestyle and increased life expectancy, prevalence of chronic and non-communicable diseases has increased. This has led to increased demand for medical devices, which plays an important role throughout the healthcare ecosystem and enable people to live healthier and productive lives.

Realizing the importance of the medical device industry, the Government of India has taken some measures in last few years for the betterment of the sector. Initiatives include, introduction of new Medical Device Rule, classification system for medical devices, and setting up of Medical Technical Advisory Board to regularize the sector. Investment in med tech parks to provide impetus to local manufacturing of medical devices which in turn may lead to decrease in cost of medical devices and increase accessibility.

However, despite these initiatives, medical device market in India is still underpenetrated and access to quality and affordable medical service remains a challenge.

Different stakeholders have different views on addressing issues around access and affordability e.g. Government agencies have focused on reducing the price of devices, while other stakeholders holders believe insufficient funding and inadequate infrastructure are the main barriers to access.

To understand the key challenges impacting access to medical technology in the country, AdvaMed has conducted a study on the same, with the assistance of IQVIA. The study suggests that constrained infrastructure very often plays a greater role in limiting access to procedures, than affordability. For example, when the government brought stents under price control, the objective was to improve affordability and accessibility to angioplasty procedures. However, initial findings on a sample base indicate that (1) benefits to patients (2) growth in procedure volumes; and (3) average stent consumption, per patient have not indicated significant change in the short term, while the long term impact remains to be seen.

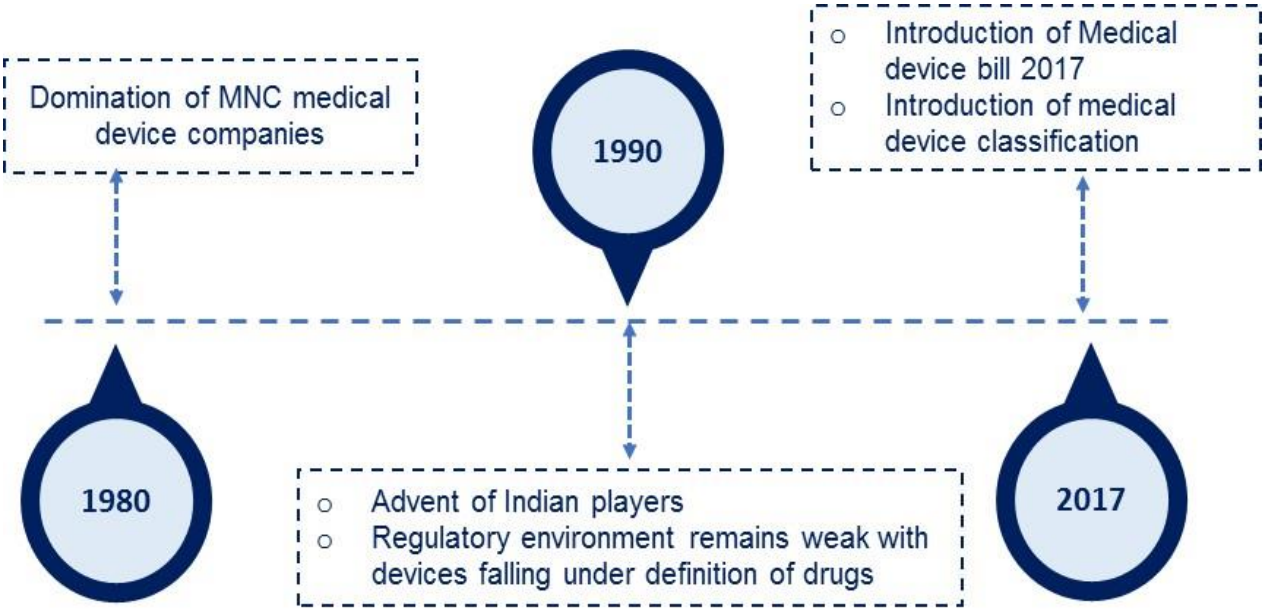
The study also provides recommendations on interventions on the part of policy makers to overcome key challenges in bringing quality healthcare, and sophisticated medical devices, to a significantly wider patient base.

Introduction

Indian medical device industry is bringing benefits of advanced medical technology to patients

The medical device industry in India is estimated to be valued at USD 4.9 bn[1] and is growing at ~17% over last few years.

Indian medical device industry is evolving towards a well established and regulated sector from being a primarily MNC dominated unregulated sector in 1980s.



Industry plays an important role in providing access to advanced medical technologies. Innovation in medical technology is enabling people to live healthier and productive lives, thus improving the overall efficiency of healthcare system.

Factors like changing demographics, rising life expectancy, increase in healthcare facilities and rising prevalence of lifestyle diseases have contributed to the growth of medical device industry in India.

While the medical device industry is growing fast, it is still at a very nascent stage, especially in comparison to similar economies such as China, Brazil, Russia or USA. Per capita spend on medical devices in India is the lowest at USD 3 as compared to USD 28 in Brazil, USD 43 in Russia and USD 304 in the USA. India's medical device industry is underpenetrated and access to quality, affordable healthcare still remains a constraint.

[1] Industry reports

Government of India has taken key initiatives in recent years to create a conducive environment for growth of medical device industry

Government of India has taken number of measures to strengthen the medical device sector ecosystem in India and ensure increased access to medical devices. Some of the prominent measures taken by the Government are highlighted next.

National Health Policy (NHP) 2017

National Health Policy 2017 aims to strengthen the Healthcare ecosystem of India by addressing the challenges of accessibility, affordability and availability of infrastructure and skilled manpower in India.

Key highlights:

- Government plans to increase healthcare spend from 1.4% to 2.5% of GDP
- The Policy puts more emphasis on preventive healthcare
- In line with the "Make in India" theme, the Policy aims to make the environment conducive for the manufacturing of drugs and devices in India
- The Policy has enlisted quantitative targets for reducing infant mortality, under-five mortality and neo-natal mortality rate, and aims to increase life expectancy to 70 years.
- The Policy proposes to address the infrastructure constraints of healthcare by improving the ratio, number of beds per 1000 in population, from current 0.9 to 2. The Policy also puts emphasis on establishing Public Private Partnership (PPP) model to address the infrastructure and human resources constraints
- To address the challenge of affordability to the underprivileged mass segment, the Policy seeks to provide free drugs and diagnostic services in the public hospitals
- With strong emphasis on primary healthcare, the Government plans to introduce health cards for easy access to primary care facilities
- In line with the "Digital India" theme, the Policy proposes to establish the National Digital Health Authority (NDHA) to deploy digital sources for measuring and improving the efficiency and outcomes of healthcare system.

Medical Devices Rule, 2017[2]

In order to separate medical device industry from pharmaceutical industry, the Ministry of Health and Family Welfare of India has introduced the Medical Devices Rule, 2017. The new rule aims to change the way medical devices are currently regulated in India. Under the new rule, medical devices will be classified, based on risk associated with them, into four classes:

[2] http://pib.nic.in/newsite/PrintRelease.aspx?relid=157955

Severity of Risk	Classification
Low risk	Class A
Low moderate risk	Class B
Moderate risk	Class C
High risk	Class D

Until now, there was no medical device specific clinical trial guidelines or framework in India. Under the new rules, the Government has made separate provisions to bring in more transparency and regulation in clinical trials of medical devices.

Currently, registration of a foreign manufacturer requires an import license as well as registration certificate for the foreign manufacturer, its site and products. Under the new rule, registration is no longer required; however, foreign manufacturers still need to apply for the import license. Further, Government has also put an end to the periodic renewal of licenses. To expedite approval, the entire process has been made online.

National Medical Device Policy- 2015[3]

To strengthen the medical device sector in India, reduce import dependence and set up a strong base of medical devices, the Government of India has drafted the National Medical Device Policy, 2015. Salient features of the Policy are described below:

- Setting up an autonomous body "National Medical Device Authority (NMDA)" to serve as the central agency for the medical device industry
- Policy outlines several financial and taxation benefits such as weighted tax deductions on R&D expenditure, low cost funding like interest subsidy to small-medium-enterprises (MSME), providing seed capital to med-tech start-ups etc.
- Minimum or zero import duty on the import of raw materials and manufacturing equipment for production of medical devices
- Setting up skill development committee under NMDA to identify skill gap and addressing this

Medical Technical Advisory Board (MTAB)[4]

The Government of India is in the process of setting up a Medical Technology Assessment Board (MTAB) under the Department of Health Research (DHR) in the Ministry of Health & Family Welfare. Key objectives of the Board are:

- Encourage and standardize cost effective health interventions to reduce cost
- Reduce overall out of pocket expenditure in medical treatment.
- Streamline the medical reimbursement procedures

In support of this effort, International Decision Support Initiative (iDSI) has received a supplementary grant from the Bill and Melinda Gates Foundation (BMGF) to support the institutionalization of HTA in India.

[3]http://pharmaceuticals.gov.in/sites/default/files/Draft%20National%20Medical%20Device%20Policy%20-%202015.pdf
[4]http://www.globalhitap.net/newsandevents/establishment-of-the-medical-technology-assessment-board-mtab-initiating-health-technology-assessment-hta-in-india/

Local manufacturing & encouraging innovation

To give a boost to “Make in India” campaign, and to encourage local manufacturing, Government announced setting up three medical tech parks[3] in Andhra Pradesh, Maharashtra and Gujarat. These parks will have in-house specialised testing facilities, and manufacturing units.

Further Government plans to setup/ promote incubation centres through appropriate incentive structure/ cost sharing to address capabilities gap in R&D infrastructure, testing quality or calibration etc. For example, Biotechnology industry Research Assistance Council (BIRAC), through its flagship schemes, has supported 100+ entrepreneurial ventures in medical technologies.

These parks and incubators are expected to provide impetus to local manufacturing of medical devices, which in turn may lead to decrease in cost of medical devices and increase accessibility.

Price control

The medical device industry has been under the scanner of various Government agencies, focusing on reducing the price of devices with an aim to make healthcare more affordable and accessible. In a move to meet this objective, National Pharmaceutical Pricing Authority (NPPA) slashed the prices of coronary stents and knee implants as much as 85% and 69%, respectively[5].

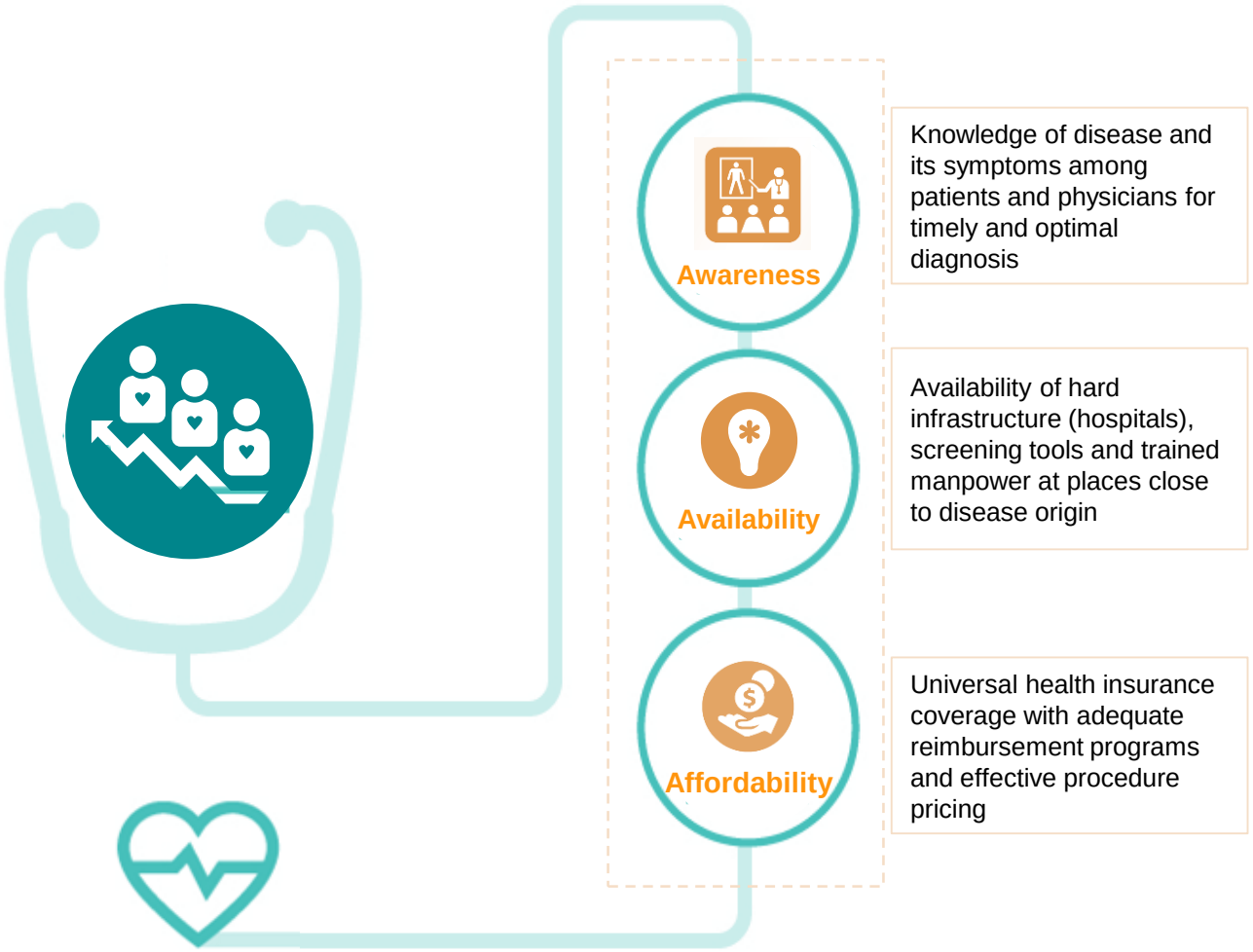
This move has led to several concerns for the medical device industry, highlighting the need for establishing right framework to identify key parameters impacting access to devices in India.

Impact of stent price control is highlighted on Pg. 20-23 of the report

[5]https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/fearing-more-price-control-medical-cos-propose-govt-to-voluntarily-cut-prices/articleshow/60330951.cms

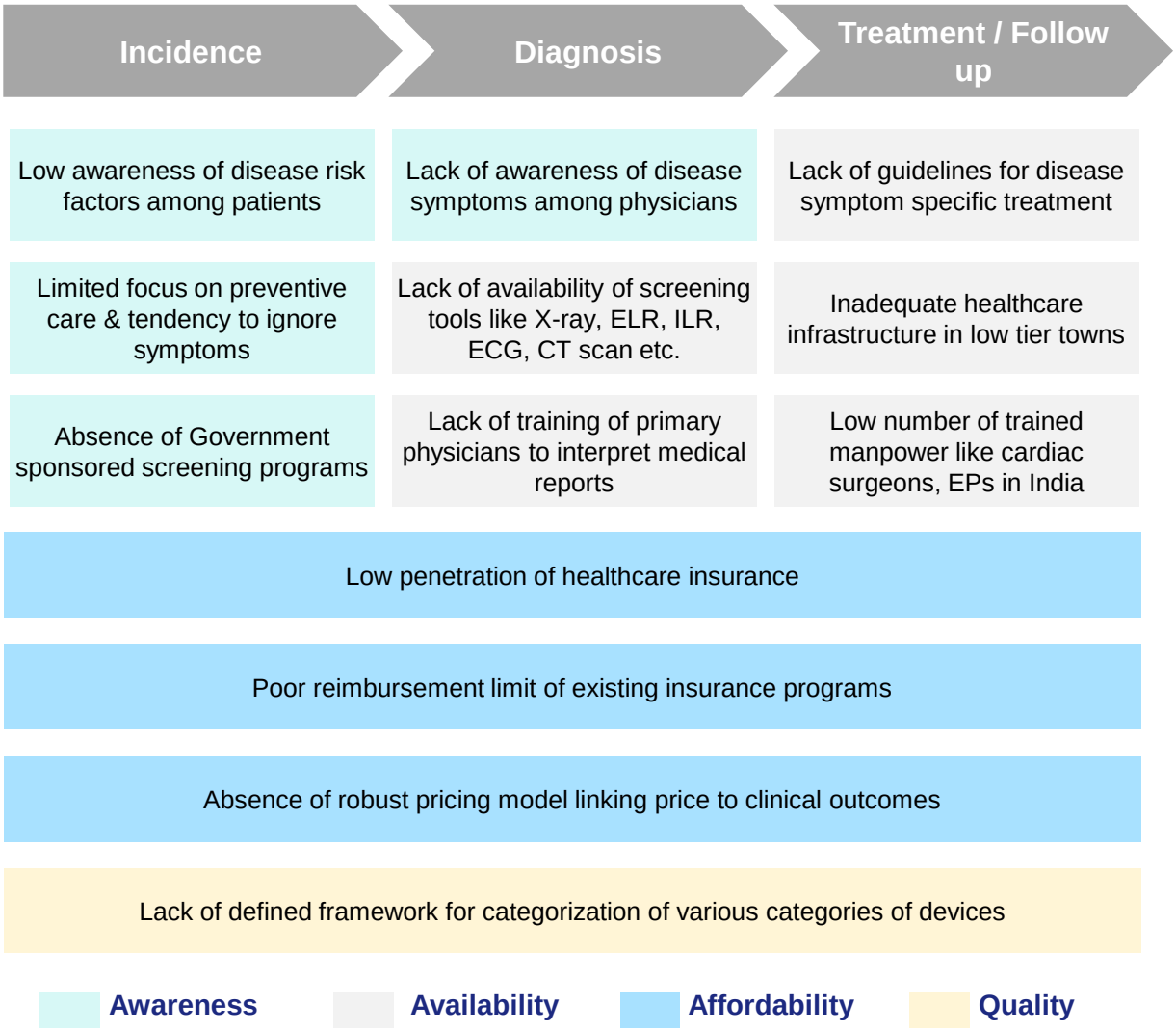
Challenges to access to advanced medical devices

Effective, appropriate and sustainable delivery of quality healthcare with advanced medical devices depend on the 3As of awareness, availability and affordability



For a large number of Indians today, health systems' goal of accessible, affordable and quality healthcare remain inadequate due to multiple challenges across the above parameters.

Challenges exist across the care pathway impacting effective healthcare delivery in India



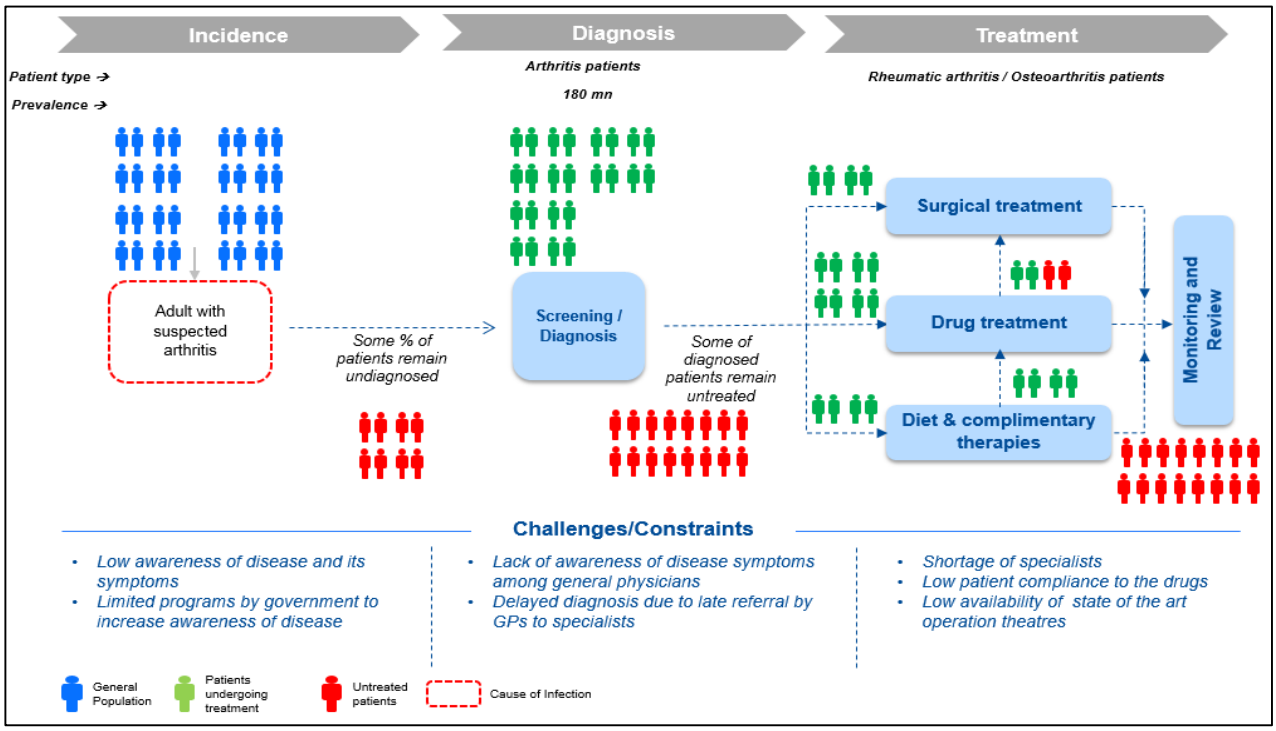
3.1 Low awareness of disease and its symptoms is leading to significant attrition of patients across the care pathway

Awareness amongst the Indian public on disease symptoms and its management has never been stellar. Multiple studies have highlighted the low awareness of disease symptoms related to cardiovascular disease, diabetes etc. among the Indian population. As per these studies, ~40-50% of the Indian population is unaware of the risk factors related to cardiovascular diseases and hypertension[6].

Low awareness of cardiovascular disease symptoms in India leading to significant attrition of patients across the care pathway is evident in case of rheumatic heart disease (RHD), where ~3-3.5 mn[7] patients suffer from the disease, however, only ~42,000 patients get the required valve surgery treatment

Likewise there are ~180 mn[8] arthritis patients in India, but low awareness and delayed diagnosis, due to late referral by general physician to specialist, is leading to significant attrition of patients across care pathway

Attrition of patients across care pathway for Arthritis[8]



Note- Infographics are for the purpose of illustration. Exact incidence of Arthritis patients not available

> In our country, patients usually lack awareness of disease and its symptoms, which leads to delay in diagnosis and treatment… contributing to significant joint deformities
>
> **Senior Orthopedician, New Delhi**

[6] http://www.ijopp.org/sites/default/files/IJOPP_7_2_2014_5.pdf, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3342579/
[7] pib.nic.in/newsite/PrintRelease.aspx?relid=128227
[8] http://www.arthritis-india.com/

Challenges at both the patient and physician level are leading to low no. of patients opting for treatment and sub-optimal diagnosis

Patient

Challenges

- Low awareness of disease symptoms among the population
- Tendency to ignore symptoms due to lack of knowledge
- Lack of Government sponsored screening programs
- Patients opting for alternative systems of medicine to avoid surgery, usually seen in case of arthritis patients

Physician

Challenges

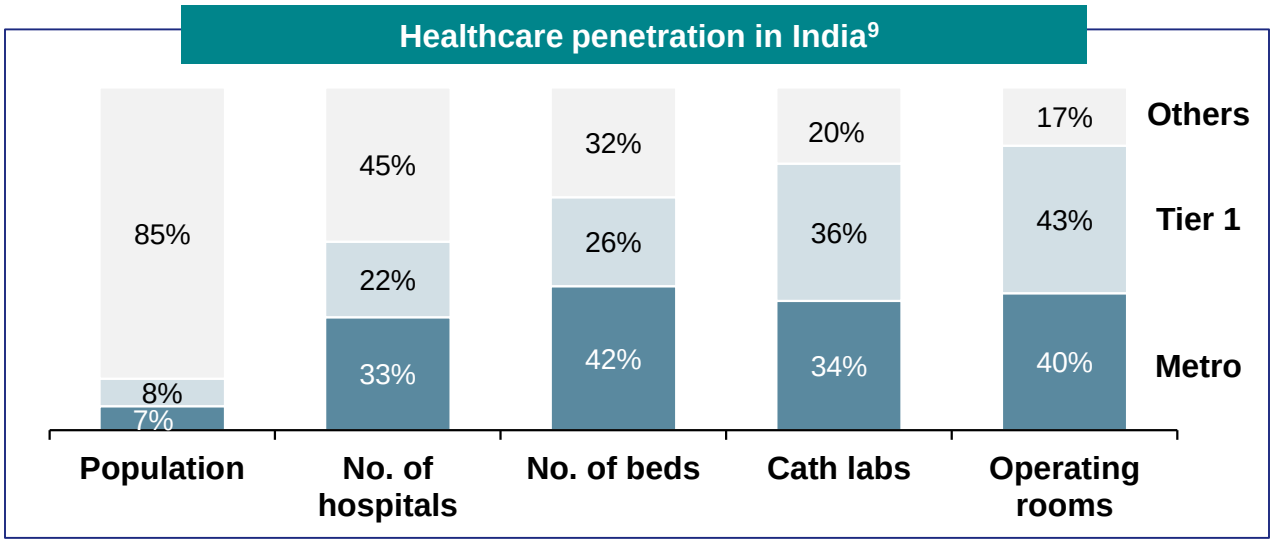
- Low awareness of disease symptoms among general physicians
- Lack of India specific protocols highlighting treatment pathway based on disease symptoms
- Delayed diagnosis due to late referral by general physicians to specialists like Cardiologist and Orthopedician
- Lack of trained physicians who could interpret medical reports like ECG, X-ray, MRI, CT scan reports, etc.
- Poor availability of long term monitoring devices like external loop recorders, Holter and internal loop recorder

Initiatives vis-à-vis affordability and accessibility will not bear fruit till awareness problem is solved

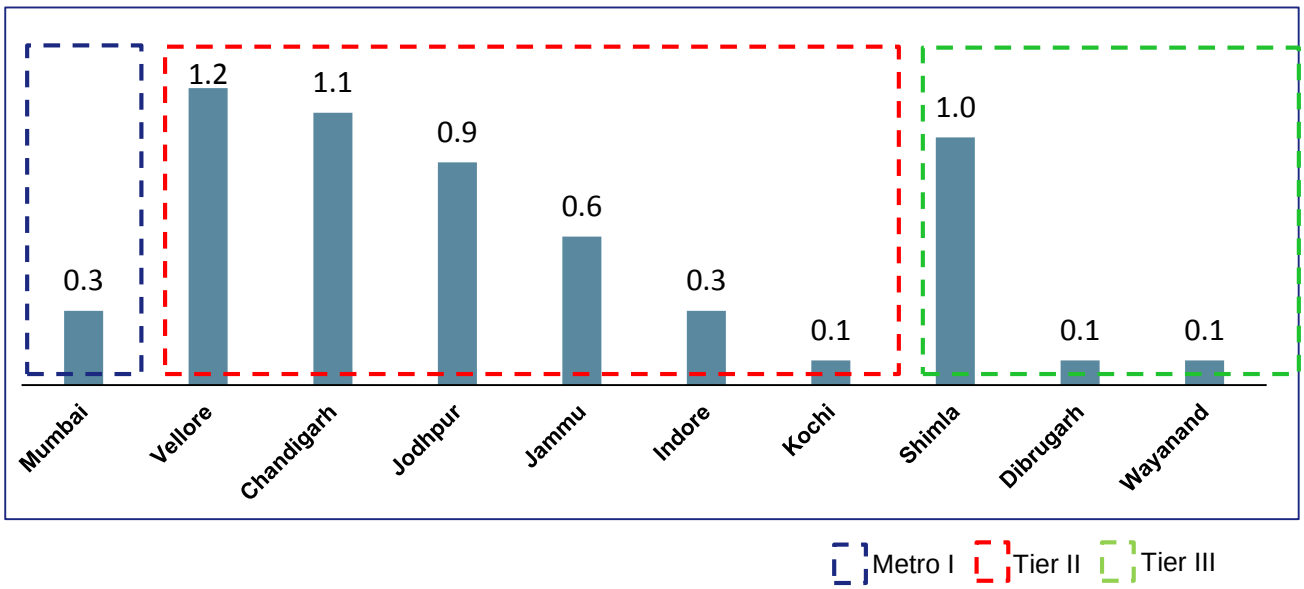
> Patients opt for lifestyle changes or dietary modifications to hold the disease condition at abeyance rather than prescribing to drug or device treatment leading to worsening of disease over time
>
> **Consulting physician, Haridwar**

3.2 India faces a severe shortage of both hard infrastructure and trained manpower closer to disease origin

More than 80% of the Indian population resides in low tier towns however, the infrastructure to provide healthcare services is skewed towards Metro cities.



Further, prevalence of disease is higher in low tier cities[10] as compared to metro cities as seen in the case of rheumatic heart disease (RHD) while key infrastructure for RHD treatment, i.e. operating rooms are skewed towards metro cities



Majority of patients needing treatment are from places other than where the treatment center is located, thus limiting access

[9] Population census, data shared by steering committee members
[10] Jai Vigyan Mission mode project, ICMR report

Even in case of cardiac stents where Government slashed prices to increase access, the primary objective was not achieved due to absence of required infrastructure.

(Details on the Impact of Stent Price Control on Pg. 20-23 of the report)

> **Our hospital has thousands of patients from within and outside the city. Our Cath lab is overbooked and there is a waiting period of 2-3 weeks for elective procedures…**
>
> **Hospital Administrator, Tertiary Hospital**

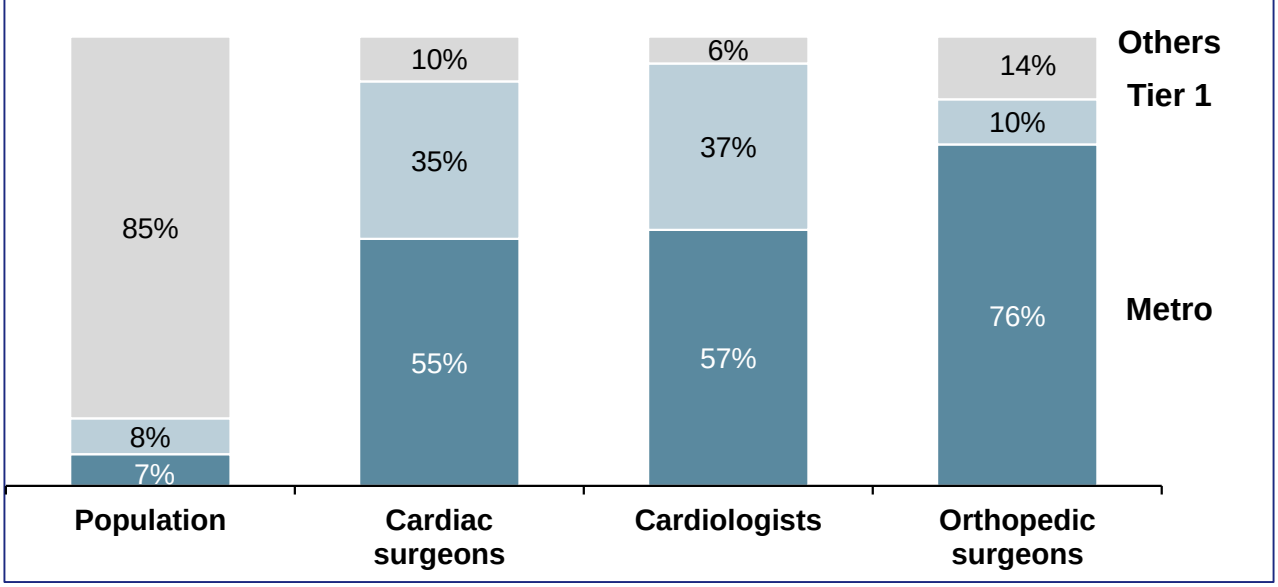
Low availability of trained manpower further restricts the access to medical devices in India

There is a dearth of trained physicians vis-à-vis the high patient population in India. The current number of qualified Cardiothoracic surgeons (900-1100[11]) and cardiologists are not sufficient to meet the rising demand for treatment. The key reasons for low number could be attributed to:

- Low number of medical seats for these specialties e.g. only ~100 seats for Cardiothoracic surgeons[14] and many of these seats remain vacant
- Lack of structured course for electrophysiology/pacing therapy in the DM/DNB curriculum
- Absence of Government sponsored training programs for doctors

Further, specialist doctors are mostly located in metro cities while majority of population requiring treatment are located in low tier towns.

Spread of surgeons in India[12]



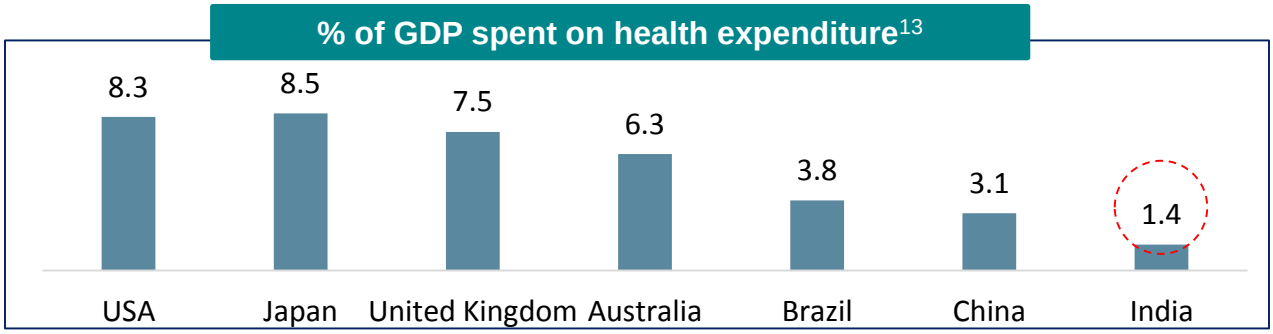
In the case of drugs, ensuring availability through efficient supply chain could increase access. However, for medical devices, presence of required infrastructure is critical to ensure access.

"Poor accessibility severely curtails the ability of medical devices to percolate in low tier cities"

[11] Vaithianathan R, Panneerselvam S. Emerging alternative model for cardiothoracic surgery training in India.
[12] Data shared by steering committee members

3.3 Inadequate health insurance coverage coupled with poor reimbursement limits are impacting access to affordable care

As per the Economic Survey 2015-2016, Government (Central and state governments combined) expenditure on health as percentage of GDP was only ~1.3 per cent. This is much lower than other developing and developed nations.



Low GDP spend on healthcare is evident in low penetration of health insurance in India, with only ~37% of population covered by some form of insurance. Further, the reimbursement limits and coverage by these Government sponsored insurance programs are not sufficient to meet the entire therapy cost.

Key challenges with the Government sponsored programs when compared with private programs are:

1. Low reimbursement limit

Reimbursement limits in pacemaker schemes varies from INR 75000-1,50,000, while a typical pacemaker surgery costs greater than INR 2,00,000[18]. Similarly, reimbursement limits in valve surgery varies from ~1,20,000 – 2,00,000 while typical valve surgery cost varies from 2,50,000 to 5,00,000[15]. Low reimbursement limit is leading to mismatch between therapy required and therapy used

2. Non coverage of all device variants

Government sponsored schemes do not cover different types of devices. In case of cardiac stents, state government schemes like Bhamashah Yojana (Rajasthan) and Mukhyamantri Amrutum Yojana (Gujarat) covered only Bare Metal Stent till earlier. Only recently, coverage is extended towards Drug-Eluting Stents (DES) as well.

Due to non coverage of DES earlier in Government schemes, patients could not receive newer generation stents which are proven to be more effective in long run.

[13] World Health Organization Global Health Expenditure database
[14] https://www.jeevandayee.gov.in/
http://www.aarogyasri.telangana.gov.in/web/guest
http://www.cmchistn.com/

3. Low post surgery coverage

There is minimal post treatment coverage in these reimbursement schemes, whereas most of these procedures involve post treatment cost, e.g. in case of Angioplasty, patients require regular monitoring with ECG, tests like Blood sugar, Lipid Profile, Renal function test and annually Echo cardiogram which is an added cost to the patient. Similarly, in the case of knee implants, physiotherapy treatment is required in no. of patients post surgery.

In the absence of post surgery coverage, patient tend to avoid these costs leading to increased mortality and morbidity in case of valves, while impacting patients quality of life in case of knee implants.

4. Lack of coverage of key surgical procedures

Some of the Government sponsored schemes do not cover key surgical procedures such as joint replacement procedures. E.g. Aarogyasri and Dr. N.T.R Seva Schemes do not reimburse patients for knee and hip replacement surgery. Due to non coverage of these procedures, patients who are in need of these surgeries either remain undertreated or usually opt for alternate forms of treatment. This leads to worsening of patients disease state.

Further low reimbursement limit restricts the ability of hospitals to select premium quality knee or hip implants, with significant evidence and international approvals, as per patient etiology.

> **Since joint replacement surgeries are not covered in schemes, patients who need these surgeries returns back untreated**
>
> **Orthopedician, Andhra Pradesh**

[15] Primary interactions with cardiologists and hospital administrators

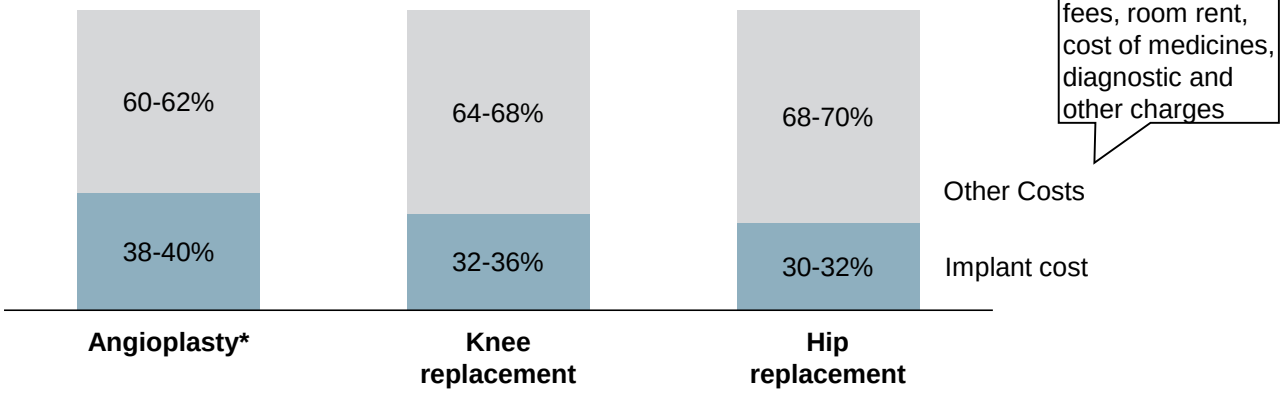
3.4 Significant other costs drive affordability of procedures involving medical devices

There are 5 key components contributing to the overall procedure cost at a hospital:

1. Device/ Implant cost
2. Doctor fees
3. Room rent
4. Drugs & Consumables
5. Diagnostic charges, hospital charges etc.

There has been an increased focus of Government to reduce the price of devices to increase accessibility to procedure, however, it has been observed that device cost is only 30-40% of the overall procedure cost, while other components of the procedure are contributing to the remaining 60-70% cost. Other costs of the procedure are mainly driven by doctor fees which is decided by the hospitals based on complexity of the procedure performed by the doctor and doctor's experience. Costs also vary with the location of the hospital (urban/ rural), hospital infrastructure and complexity of the procedure conducted.

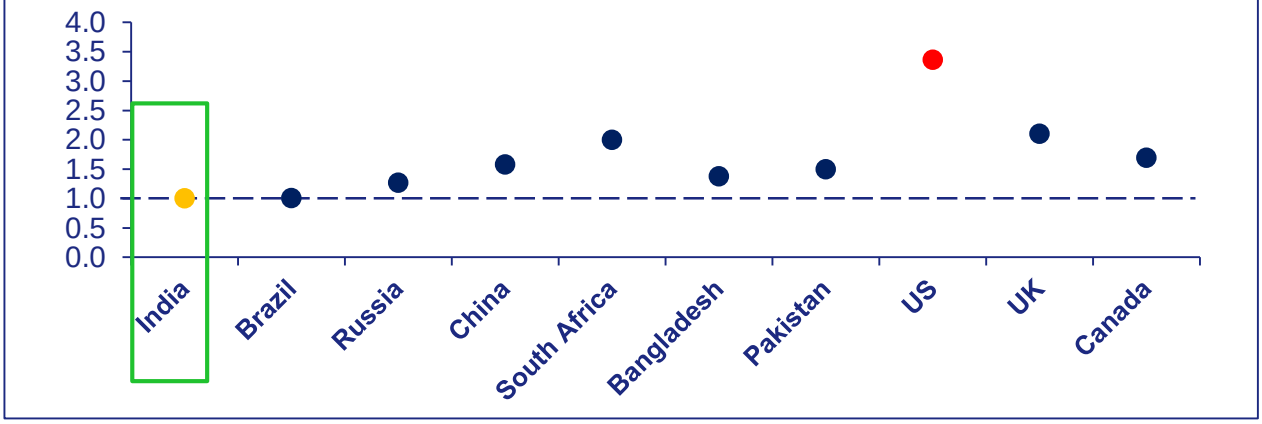
Breakup of procedure cost across components[16]



*Cost prior to stent price control

Further, cost of implants in India is already lower compared to other geographies. For e.g. In case of knee implants, cost of implant in India is three to four times lower than that of other countries such as UK, USA and Canada etc.

Orthopedic implants prices in India vis-à-vis other geographies[17]



[16] Primary interactions with Cardiologists, Orthopedicians, Cardiothoracic surgeons, Hospital administrators and patients

[17] Data from AdvaMed steering committee members

In Summary:

- Low awareness of disease & its symptoms amongst patients and primary physicians is leading to significant attrition of patients across care pathway

- Initiatives to improve affordability and accessibility are contingent on progress in first improving awareness

- There is inequitable distribution of healthcare infrastructure between large cities, where healthcare facilities are located, and smaller towns and rural, where the bulk of patients reside

- Unlike pharmaceuticals, healthcare infrastructure is critical for medical devices; poor accessibility severely curtails penetration of medical devices to low tier cities

- Lack of insurance coverage and low reimbursement limits are impacting access to affordable quality healthcare

- Devices are a small component of the procedure cost and focusing on cost of device alone will not result in affordable care

- Constraining categorization and treating different types of devices under similar category will dis-incentivize introduction of advanced technology in India

Case Study - Impact of Stent Price Control

Background

In February, 2017, National pharmaceutical pricing authority (NPPA) slashed prices of coronary stents by up to 80 percent. NPPA's decision followed the Health Ministry's 2016 notification to cover coronary stents in the National list of essential medicines (NLEM).

The move was aimed at increasing affordability to angioplasty procedure, with expected increase in the number of angioplasties performed.

AdvaMed Study

Objective

AdvaMed commissioned a study, which was conducted by IQVIA on behalf of AdvaMed, to understand the impact of stent price control on the overall angioplasty procedure cost and the total number of angioplasties performed across hospital segments.

Methodology

Study findings are based on survey and feedback of interventional cardiologists, hospital administrators and angioplasty patients (pre and post stent price control) across hospital segments (corporate chains, large private hospitals, mid-sized private hospitals and government hospitals) in metro and tier 1 towns.

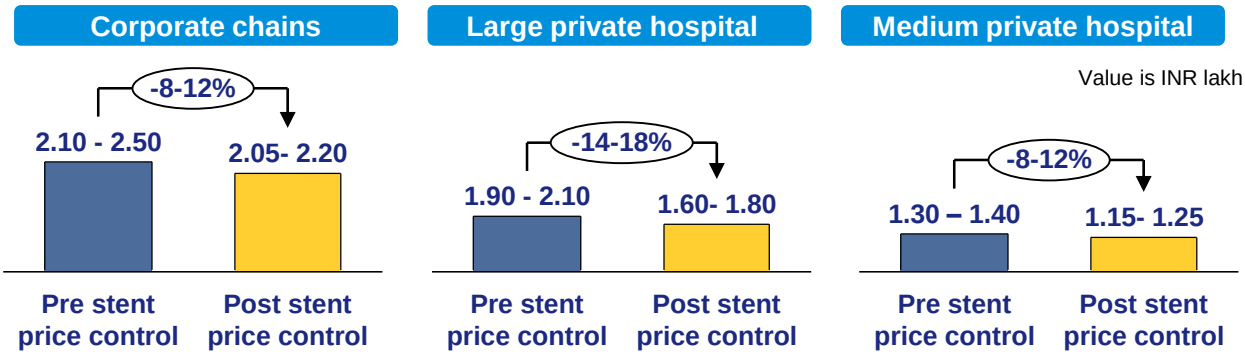
Stakeholder \ Hospital Segment	Corporate chains N=10	Large Private hospitals N=14	Medium Private hospital N=11	Government Hospitals N=10	Total
Interventional Cardiologists	10	14	10	10	44
Hospital administrators	7	9	8	4	28
Angioplasty patients	62	76	49	17	204
Total	**79**	**99**	**67**	**31**	276

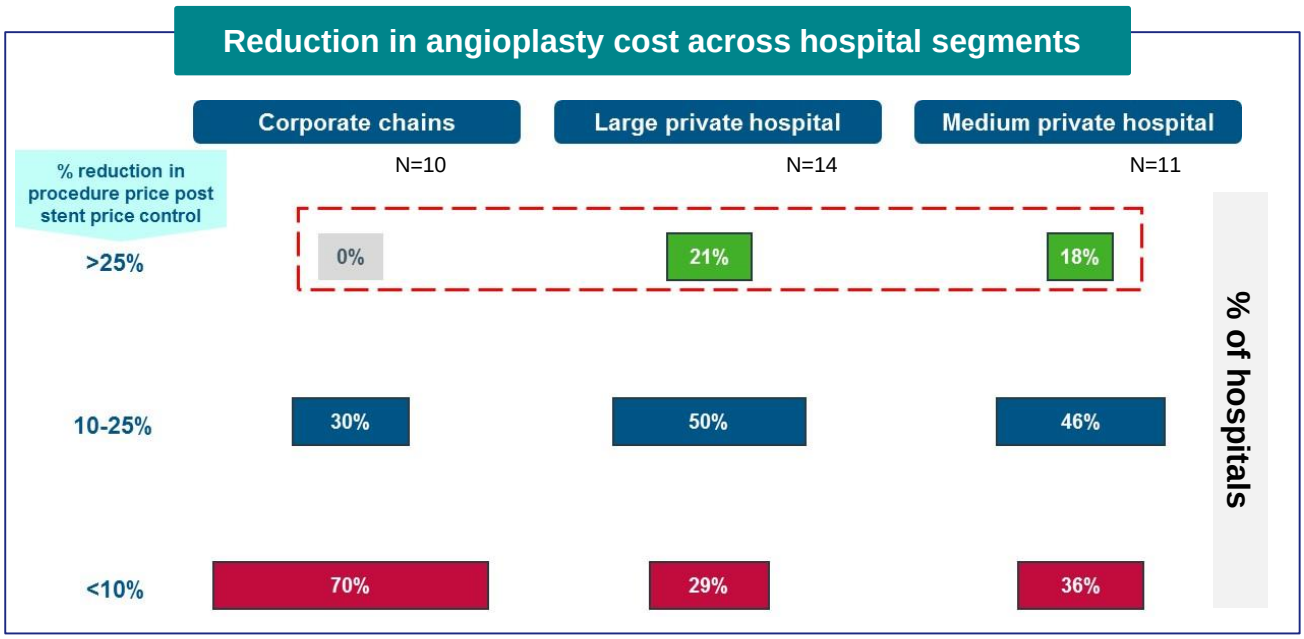
Further, interactions were conducted with sales / marketing personnel of stent manufacturers and private payers to validate the findings of the study.

Outcome

The initial findings from the study indicate that benefits to patients and growth in procedure volumes have not indicated significant change in the short term, while the long term impact remains to be seen.

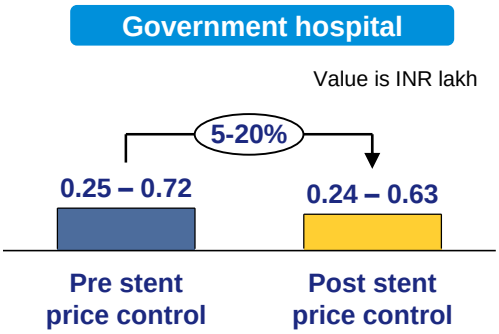
It is observed that reduction in stent price resulted in ~8-18% reduction in overall angioplasty procedure cost for patients undergoing single vessel procedure (~70% of the total angioplasty patients).



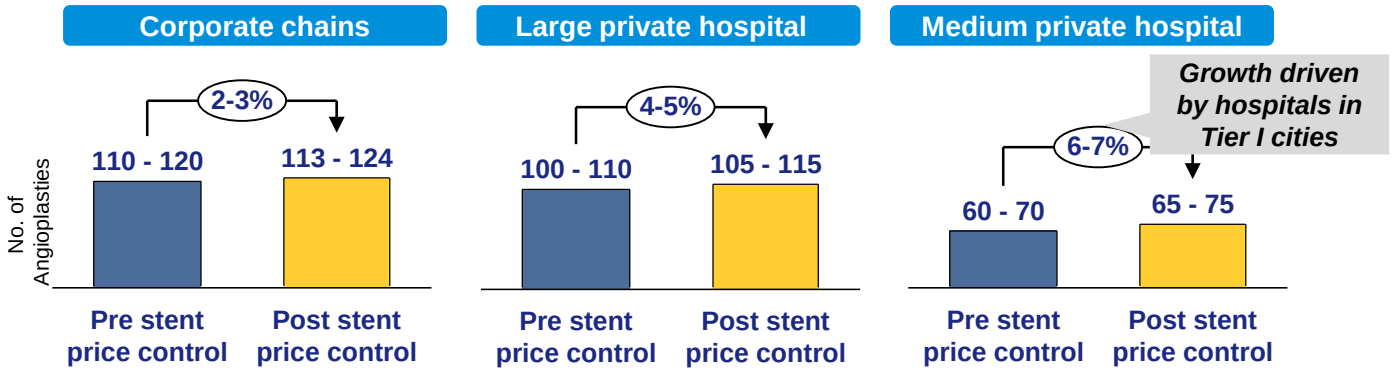


Patients at government funded hospitals have also not benefited significantly from stent price control as, stents were available at less than INR 30,000, even before price capping at majority of these hospitals.

(*In some govt. hospitals/ schemes like Delhi state govt. hospitals, Chief Minister/s comprehensive health insurance scheme, Tamil Nadu etc. price of stent was low at ~25,000 even before price control)*



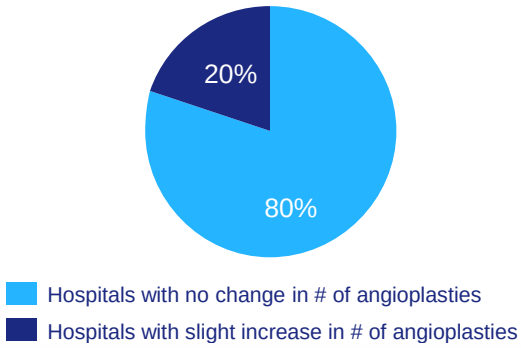
Further, there is no significant change in the growth trend of angioplasties across hospitals segments post stent price control and angioplasties continue to grow at historical rate.



> Pricing is not a constraint for patients undergoing angioplasty at our facility… patients in need of this procedure were getting treated earlier and the same is true at present
>
> **Interventional Cardiologist, Delhi**

Amongst Government hospitals surveyed, ~80% hospitals cited no significant increase in the number of angioplasty procedures performed, and even in the remaining 20%, the increase was marginal (2-5% only). Lack of adequate infrastructure was cited as the key concern impacting access to cardiac related procedures:

- Inadequate number of cath labs across Government hospitals to meet the demand
- Low availability of skilled interventional cardiologists to perform the procedure

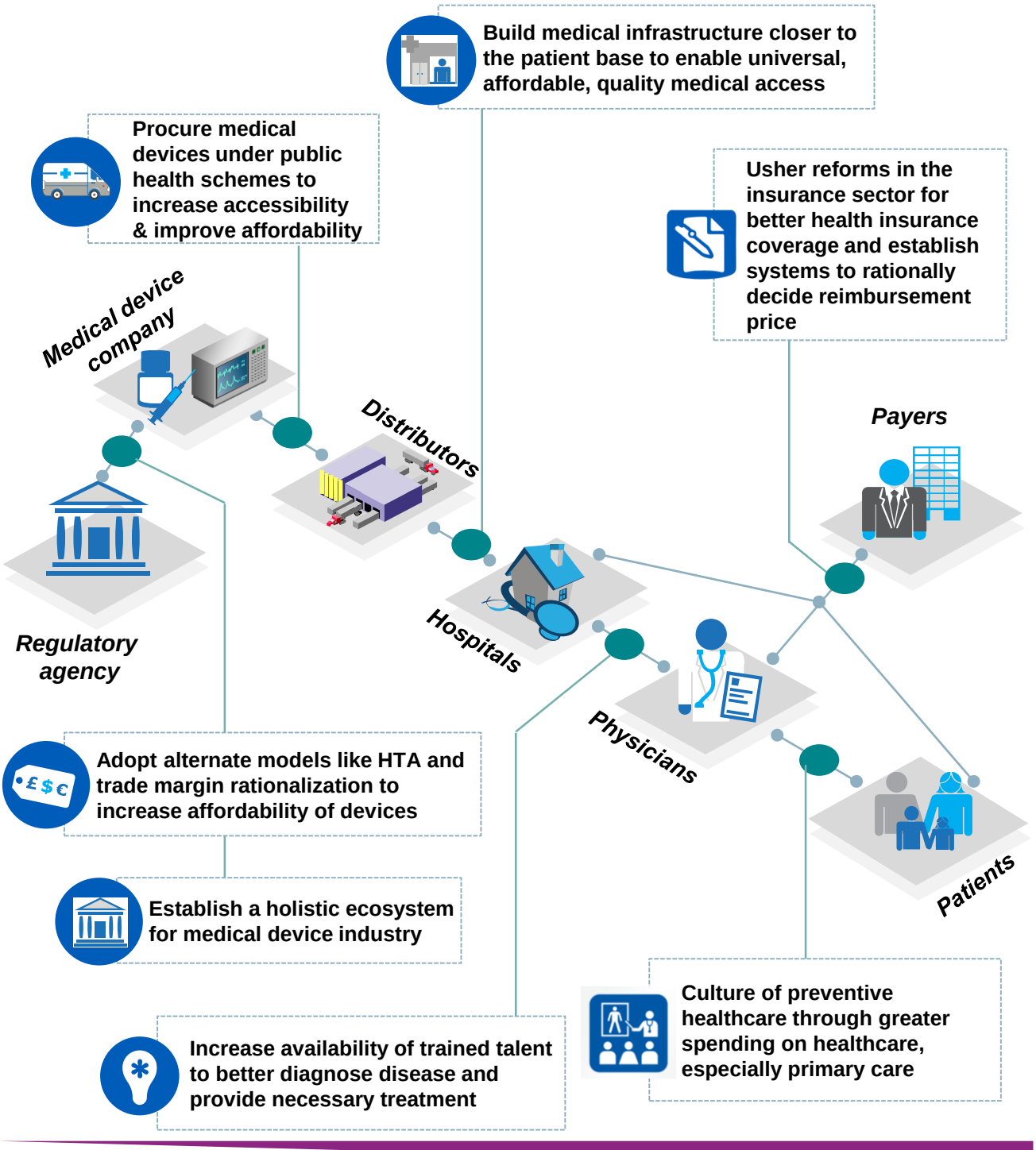


> "..Cardiac specialty has limited number of post-graduate seats, and of these only handful of Cardiologist will perform intervention….we are always overworked and patients have to wait for weeks for getting cardiac procedures performed at our facility.."
>
> **Interventional Cardiologist**

Findings from the study highlights that singular focus on controlling prices of devices without attempting to address the large picture will not improve patient access. An enhanced access to quality care requires a holistic approach encompassing cost optimization at various levels in healthcare delivery and investments to strengthen healthcare infrastructure.

Recommendations

Based on overall analysis and discussions, following key areas have been identified for ensuring effective access to medical devices



1 Build medical infrastructure closer to the patient base to enable universal, affordable, quality medical access

The following initiatives could be focused for developing infrastructure beyond metros and tier-1 cities to radically improve accessibility to medical devices across India

a) Promote public-private partnership (PPP) in the healthcare sector to address infrastructure concerns through combined efforts of public, private and development organizations. Few examples of such PPP's in India:

State	PPP example	Benefit
West Bengal[18]	Installation of diagnostic equipment's like CT scan, MRI, X-ray etc. by private providers in public hospital premises on contract basis	• Increased access to such services • Reduced cost for these services
Maharashtra[19]	GE healthcare entered into partnership with Maharashtra Government to open advanced diagnostic facilities at 22 Government district hospitals	• 24/7 in-house diagnostic facilities at Government fixed rates • Free diagnostic services to BPL patients
Karnataka[20]	The Rajiv Gandhi Super-specialty Hospital in Raichur, Karnataka is a joint venture of the Government of Karnataka and the Apollo hospitals Group	• Super-specialty health care at low cost to BPL people (infrastructure support by Govt. and operational support by Apollo)

Government is already taking steps in this direction. NITI Aayog has constituted a committee to discuss options for PPP for services (prevention, diagnosis and treatment) related to select Non-Communicable Diseases (namely Oncology, Cardiology and Pulmonology) in district hospitals

b) Harness technology to increase reach of existing infrastructure in low tier towns through telemedicine and telehealth

Organization	Details
Narayana Hrudayalaya (NH)	NH along with ISRO and Govt. of Karnataka initiated an experimental tele-medicine project called 'Karnataka Integrated Tele-medicine and Tele-health Project' (KITTH), which is an on-line health-care initiatives in Karnataka. With connections by satellite, this project functions in the Coronary Care Units of selected district hospitals that are linked with NH. Each CCU is connected to the main hospital to facilitate investigation by specialists after ordinary doctors have examined patients. This improves access to specialty care and reduces both time and cost for rural and semi-urban patients
Celes Care- Healthcare for women by women	Celes Care aims to provide women of all ages with state of the art, tech-enabled telehealth services delivered 24/7 through medical professionals, who are trained on international best practices. Women can use their mobile phones to connect with trained female physician in less than a minute. Celes' empowering, patient-centric approach has already helped over 6000 women during the company's pilot phase.

[18] http://www.wbhealth.gov.in/notice/eoi_gm1.pdf
[19] http://ehealth.eletsonline.com/2013/06/ensocare-and-wipro-ge-healthcare-enter-into-a-public-private-partnership-with-government-of-maharashtra-to-upgrade-district-hospitals/
[20] http://www.ibef.org/download/PublicPrivatePartnership.pdf

2 Procure medical devices under public health schemes to increase accessibility and improve affordability

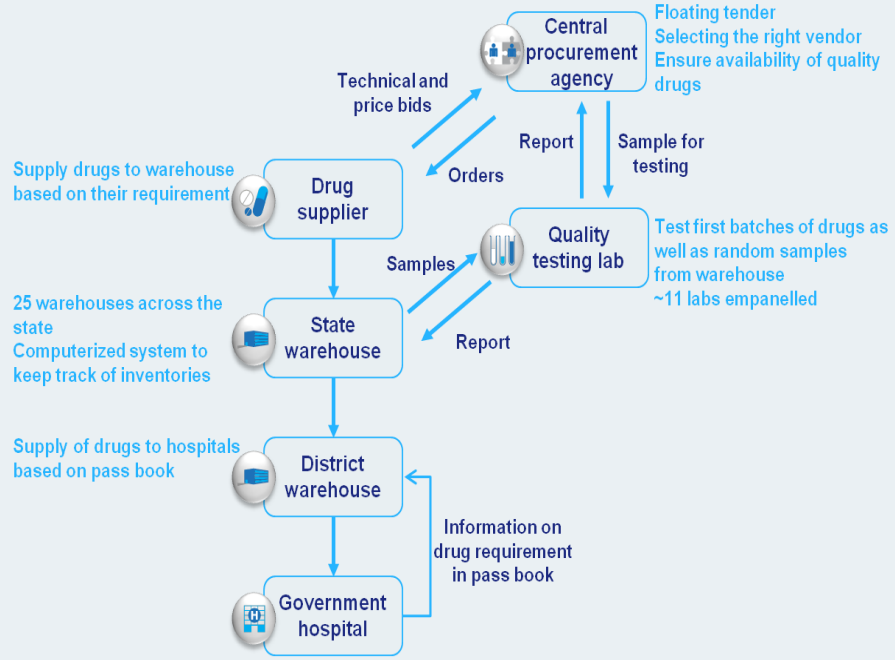
Government should focus on procuring medical devices through a centralized procedure/ mechanism in various public health schemes. This will offer the following advantages:

- ✓ Help Government meet the increasing demand for medical devices
- ✓ Enables faster public access to advanced medical devices in relatively short period of time at affordable prices
- ✓ Provides incentives to manufacturers, as this guarantees certain volumes to manufacturer

Case study[21]

Effective and efficient centralized drug procurement system followed by the Tamil Nadu government

Drug procurement in the state was scattered with every hospital sourcing drugs on its own with no standard process leading to :
- High cost of procurement
- Low visibility on inventory
- Wastage
- Low availability



- ***Improved availability***
- ***Improvised distribution of medicines across dispensaries***
  - *A study shows average availability of drugs in TN was 88% compared to 43% in Bihar*
  - *Proportion of stock-outs in TN was around 17%, with average duration of 105 days, compared to 42% stock-outs with mean duration of 105 days in Bihar*
- ***Low cost of procurement****- This system has helped Government save the cost of drugs by about 30%*
- ***Reduced stocking needs****- Procures only 240 key drugs, as against 960 done earlier*

[21] http://uhc-india.org/reports/hleg_report_chapter_3.pdf
http://www.searo.who.int/publications/journals/seajph/issues/acrossectionalsurveyofthemodelinbiharandtamilnaduindiaforpooledprocurementofmediciness.pdf

3 Increase availability of trained talent to better diagnose disease and provide necessary treatment

Supply of healthcare professionals could be increased by the following:

a) Identify areas/ regions with critical shortage of medical professionals and expand supply in medical education seats accordingly

b) Explore public private partnerships for rapid increase in medical education seats

Case study- Maharashtra medical education department planning to choose PPP based model for new medical colleges in the state

- Convert **district hospitals into medical colleges** through PPP with parties like trusts, not-for-profit companies etc.
- Government to get a **quota of 25%** seats in these medical colleges
- Admission to remaining seats can take place **through NEET** (national eligibility cum entrance test)

c) Integration of AYUSH doctors into the fold of modern medicine for primary healthcare delivery in rural areas through bridge training (80% of the training given to AYUSH doctors is identical to the one given to MBBS doctors)

Case study- ICTPH bridge training program for integration of AYUSH into rural healthcare delivery

Details	Partnerships
• **Evidence based clinical protocols** and guidelines for primary care delivery in community setting form the core of this training program • **81 major and minor ailments** included like fever, URTI, diabetes, hypertension etc.	• **Knowledge partner-** University of Pennsylvania School of Nursing & JIPMER • **Implementation partner-** SughaVazhvu Healthcare

d) Invest in technology to accelerate skill development in rural areas at minimal cost

Type	Possible benefits	Examples
Virtual training and learning	Reduces the need for additional medical infrastructure	Medvarsity
Simulated labs *creation of an artificial environment for education, assessment, and research*	Low cost training, higher learning opportunities as training done in absence of patients, no risk as patients not involved, better learning compared to standard training	MSRALC M S Ramaiah Advanced Learning Center
Online CMEs	Knowledge upgradation of doctors for better patient care	Delhi Medical Council

4 Culture of preventive healthcare through greater spending on healthcare, especially primary care

The Indian healthcare system showcases a strong bias towards curative rather than preventive care. This reliance on a treatment model is evident from the insufficient number of screening and surveillance programs marking the undertone of the healthcare delivery model. There is a strong need to change the focus diametrically and move from treatment model to preventive model.

Initiatives are required across the following:

Prevention	Timely diagnosis	Prompt treatment & follow-up
• Increase public spend on healthcare with a focus on the following: ▪ Increasing knowledge of preventable risk factors ▪ Promoting benefits of healthy living and early treatment ▪ Exposing dangers associated with late diagnosis • Education on risks associated with poor personal hygiene and sanitation • Health education on diets and benefits of physical activity	• Expand availability of trained talent through training of primary health physicians • Increase the availability of screening tools like echo, external loop recorders (ELRs), holters, X-ray machines etc. • Conduct Government sponsored mass screening programs	• Protocols/ Guidelines- develop guidelines clearly highlighting treatment pathway based on disease symptoms • Strong referral network- Develop referral chain with expansive and networked primary care

Focus on preventive care would not only facilitate in catching any illness young but also minimize the cost burden of these diseases along the treatment cycle, therefore strengthening the healthcare system in its totality.

5 Usher reforms in the insurance sector for better health insurance coverage and establish systems to rationally decide reimbursement price

a) India need to focus on universal health insurance coverage to drive access to medical devices. Multiple models could exist for universal health coverage depending on the following:

Parameter	Options	Considerations for India[22]
What services are covered?	• Basic care • Comprehensive care	• Basic care including services with maximum population impact • (Universal coverage for comprehensive care is difficult in large population countries like India)
How are services financed?	• Payroll contribution • Annual premiums • Tax payments • Contribution by government	India need to follow a mixed approach with the following: • Payroll deductions for employed • Periodic contribution to dedicated health savings accounts for rest of the population • Public contribution for disadvantaged/ BPL people
Who provides care?	• Primarily public • Primarily private • Mix of public and private	• Private sector to lead in care provision while Government to focus on primary care and under-served segments

Different approaches used by health systems in emerging markets for universal health coverage:

Parameter	Ghana	Indonesia	South Korea
What services are covered?	Comprehensive coverage- preventive, primary, hospital, and (in some cases) drug benefits to entire population	Comprehensive coverage- preventive, primary, hospital, and (in some cases) drug benefits to entire population	Comprehensive care including health check-ups, tests and diagnosis, treatments, surgeries, preventive care, hospitalisation, nursing, rehabilitation and transportation
How are services financed?	Value-added tax, investment income, formal-sector payroll contributions, household premiums	General Government revenues, contribution by employers, individual contribution by high income groups	General taxes and earmarked amount of tobacco tax, mandatory health insurance contribution by employers and employee
Who provides care?	Mix of public and private	Mix of public and private	Primarily private providers

22 Universal health coverage 3- The Lancet, IQVIA analysis

b) Further, there is a need to rationally decide reimbursement limits for different services to ensure quality care at affordable prices.

Multiple healthcare reimbursement approaches exist:

Model	Fee for service (FFS)	Episode of care payment (EOC)	Full capacitation
Details	Services are unbundled and paid for separately. Payments are linked to specific procedures, treatments, services and care settings.	A single price for all of the services needed by a patient for an entire episode of care (e.g., all of the inpatient and outpatient care they need after having a heart attack).	Providers receive a fixed amount per patient per year and are responsible for all of that patient's medical needs.
Advantages	Greater flexibility to patients for seeking the advice and consultation of a specialist whenever needed	Reduced incentive to overuse unnecessary services within the episode	As provider revenues are independent of the specific quantity and types of treatments performed, it motivates providers to be more efficient
Challenges	Reimbursement increases with the quantity of procedures, tests, admissions and re-admissions that occur, whether or not they contribute to better patient outcomes.	Does not control the no. of episodes during the stay of patient	With a fixed overall revenue for a patient, providers (and payers) may ration or deny access to expensive procedures and services even if the services can lead to better long-run outcomes.

Considering the challenges associated with different traditional reimbursement models, there is need for India to adopt innovative models like **comprehensive care payment**

Comprehensive care payment	This is a middle ground between EOC payment and traditional capitation. Under this model, a provider would receive a single payment to cover all of the services their patients need during a specific period of time (such as a year). However, this payment would be adjusted based on the health of the patients and other characteristics that affect the level of services needed. A provider would receive a higher payment if he or she has more patients with severe rather than mild heart disease

Comparison of various payment systems:

	Fee for service	Episode of care	Comprehensive care payment	Capitation
Discourages un-necessary services in an episode?	No	Yes	Yes	Yes
Pays for all necessary services in an episode?	Yes	Yes	Yes	Yes
Encourages coordination of multiple providers?	No	Yes	Yes	No
Encourages providing high quality services?	No	Yes for services affecting outcomes that occur within the episode	Yes for services affecting outcomes that occur within the payment period	No
Avoids penalty of taking sicker patients?	Yes	Yes	Yes	No
Discourage unnecessary episodes?	No	No	Yes	No

Creating efficient comprehensive care payment would require the following:

- Defining the medical condition and the covered cycle of care
- Defining and measuring the outcomes that matter
- Risk stratification approach based on patients risk factors and co-morbidities
- Estimating provider costs over the cycle of care

6 Adopt alternate models to increase affordability of medical devices

In order to improve affordability, Government should focus on adopting alternate pricing models factoring in clinical performance/ innovation, safety and effectiveness of the device. Government should not restrict to price control as the sole 'access augmenting' mechanism, as this may hamper the growth of medical device industry and restrict the access to innovative medical devices.

To achieve the twin objectives of encouraging innovation and increasing access to medical devices, Government may resort to following two strategies:

a. **Short term-** Trade margin rationalization

b. **Long term-** Building competency in health technology assessment (HTA)

Trade margin rationalization

There is a need for the Government to focus on trade margin rationalization i.e. imposing a cap on the margins across the value chain, rather than capping ceiling price of devices. Unlike price caps which dis-incentivize innovation, fixing trade margins would restrict how much a product's price can be raised from the import or manufacturing cost, but innovation would still be rewarded.

The Report of the Committee in High Trade Margins in the sales of Drugs released in March 2016 by Department of Pharmaceuticals has identified that most of the margins are earned by trade and therefore, in order to make drugs and devices affordable, recommended to cap margins from "Price to Trade till MRP" in the range of 35-50%. The report is appreciated by Medical Devices industry as a solution to make products affordable.

Further, trade margin rationalization would be better than "un-nuanced" caps on device ceiling prices because it would prevent "unintended consequences" like distributors becoming disinterested in providing these technologies to tier-II and III towns.

The issue of rationalization of trade margins in medical device sector is already under consideration by the Department of Pharmaceuticals and they have prepared a report on the same. This could be an immediate solution for enhancing access, with industry support.

Building competency in health technology assessment (HTA)

Government should develop a robust medical technology assessment program which considers factors like evidence of safety, efficacy, patient reported outcomes, real world effectiveness, cost and cost effectiveness in evaluating a medical device to arrive at the right product at rational prices for anticipated scenarios

HTA will offer the following advantages:

- Support innovations in the medical device industry
- Support Government to facilitate decisions in technology adoption
- Improved patient access to new medical devices
- Performance/ effectiveness based pricing resulting in higher value for money

7 Establish a holistic ecosystem for medical device industry

To attract world's top medtech players to establish their research and development (R&D) operations in the country and to establish a firm footing in the global market, Government of India needs to adopt a robust policy and regulatory framework.

India can replicate some of the models being adopted by other nations that have succeeded in attracting leading medical players.

- Government of India can provide financial incentives in form of extended tax holidays or weighted tax reduction for R&D investments.
- Boost local demand for medical devices by stepping up public healthcare spending which in-turn could catalyze investments in this sector

Further, Government should focus on creating an enabling regulatory landscape by creating a separate legislation system for medical devices. While, Medical Devices Rules, 2017 is a welcome step towards regulating the medical devices sector, the setting up separate notified body and distinct legislation system for devices with a focus on the following could further boost growth of the industry.

- Grant product approvals
- Instituting quality standards
- Setting up monitoring mechanisms for devices
- Expedite patent approval process for medical devices

Conclusion

Based on the current state of healthcare delivery in India, it is understood that there is still a long way to go in terms of making advanced medical devices available to the Indian patient. Due to inadequate healthcare infrastructure and absence of trained manpower, availability becomes a major concern in increasing access to medical devices.

Huge investments will be required to upgrade the existing infrastructure, in order to improve accessibility to medical devices. This would need greater involvement of the private sector and government should seek ways to collaborate with the private sector who could provide the required expertise and support.

An integrated approach that takes into consideration the interest of all key stakeholders is imperative. It is important to seek a win-win solution rather than approaches that are heavily loaded against a particular stakeholder.

Through this paper we hope to initiate a meaningful dialogue that helps design sustainable solutions focusing on effective healthcare delivery.

Industry views

"Healthcare in India has progressed tremendously in the last few years. To continue this progress and support India's vision to be at the forefront of medical technology, the entire healthcare ecosystem, including regulators, researchers, hospitals, government bodies and industry need to work together on a framework that supports innovation as well as better access to technologies for patients. Access to healthcare innovation extends well beyond affordability and pricing, and will require many people working together toward policy changes that address the entire landscape to support physicians and their patients."

Spokesperson, Abbott

"The Medtech sector in India is fairly small compared to other leading economies of the world. Comparatively, the per capita consumption of medical devices remains low at US$ 3. With the rising incidence of CVDs, NCDs and chronic diseases, the need to develop this sector to provide innovative medical solutions to tackle the healthcare burden in the country, is greater than ever.

It is essential to drive market demand and growth by enabling investments, infrastructure development, skill building, training, and improving patient access—a pivotal role that both the Government and private sector must play.

Thoughtful healthcare policies, favorable to both patients and the industry, that systematically address reimbursement, health assurance and pricing will support this growth and help India achieve its vision of Universal Health Coverage.

Medical Devices is a technology driven sector, and continued innovation is critical to sustaining long-term solutions for unmet healthcare needs. An environment with a focus on R&D and innovation, and recognition of the diverse range of technologies will boost industry confidence and investments, ensuring continued access to newer technologies and therapies from around the globe.

India's Medtech sector requires a unique set of measures that draw on the synergies of the Government, private sector, academia and patient groups, to establish collaborative approaches in finding affordable and accessible healthcare solutions."

Spokesperson, Boston Scientific

Industry views

"We applaud the government's call for affordable healthcare to all and the industry is keen to constructively partner with them in achieving this goal. While we gradually progress towards the government's long-term goal of universal healthcare for all, it will be the key to foster a supportive regulatory environment which provide the right kind of incentives and market attractiveness for all stakeholders.

We recommend an evidence-based action plan that can be adopted to meet the immediate and long-term needs of almost 1.27 billion people in India. For this, we need to consider alternatives to price control such as trade margin rationalization and more scientific approaches that facilitate differential pricing for innovative medical technologies. Capping the trade margin to 50 %, as per the DOP report will bring in a rationalized margin to various segments of medical devices, thereby, bringing down the cost of the devices, as well as more transparency in pricing.

Such a mechanism will invalidate the need for measures such as price control as fair margins are provided to all stake holders, also enabling companies to bring in differential pricing according to newer technologies. This will be symbiotic to the healthcare ecosystem, and enable an improved access to an array of medical innovations and solutions in India."

Spokesperson, Terumo

"Medical devices industry in India is still at a nascent stage and has an opportunity to grow exponentially with the right kind of policy framework. Improvements in hospital capacity, increasing number of implanting physicians, bringing awareness on disease diagnosis and most importantly raising public awareness will give the industry, the much needed boost to harness the immense opportunities on offer.

The vitality of the medical device industry is reflected in its focus on Research and Development. Innovations in medical technology improves peoples' lives, and brings the benefits of treatment to individuals whose conditions may previously have been difficult or impossible to treat. With product lifecycles in the sector averaging only 18 months between improvements, the drive to advance and innovate within the industry is continuous.

A holistic and coordinated approach towards addressing all challenges simultaneously and putting thrust on innovations will help the medical devices industry inch closer to the goal of universal healthcare and strong patient outcomes."

Spokesperson, Medtronic

About AdvaMed

The Advanced Medical Technology Association (AdvaMed), is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. AdvaMed's membership has reached nearly 300 members and more than 80 employees with a global presence in countries including Europe, India, China, Brazil, and Japan. AdvaMed's member companies range from the largest to the smallest medical technology innovators and companies. The Association acts as the common voice for companies producing medical devices, diagnostic products and health information systems.

AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation. Additional information is available at https://www.AdvaMed.org/

About IQVIA

IQVIA is a leading global provider of information, innovative technology solutions and contract research services focused on using data and science to help healthcare clients find better solutions for their patients. Formed through the merger of IMS Health and Quintiles, IQVIA offers a broad range of solutions that harness advances in healthcare information, technology, analytics and human ingenuity to drive healthcare forward. IQVIA enables companies to rethink approaches to clinical development and commercialization, innovate with confidence as well as accelerate meaningful healthcare outcomes.

IQVIA has approximately 55,000 employees in more than 100 countries, all committed to making the potential of human data science a reality. IQVIA's approach to human data science is powered by the IQVIA CORE™, driving unique actionable insights at the intersection of big data, transformative technology and analytics with extensive domain expertise. IQVIA's insights and execution capabilities help biotech, medical device, and pharmaceutical companies, medical researchers, government agencies, payers and other healthcare stakeholders tap into a deeper understanding of diseases, human behaviors and scientific advances, in an effort to advance their path toward cures. To learn more, visit www.IQVIA.com