



MedTech:
The Keystone for
AYUSHMAN BHARAT

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Current State of Public Healthcare in India

Patients in India largely depend on private setups in case of serious illness, mostly through Out of Pocket expenses while only about 27% have any kind of health insurance. This pushes as many as 55 million people into poverty each year

The Global Experience of Public Health Coverage Rollout

A number of countries with economies similar to India have successfully implemented their public healthcare schemes and India can take many lessons from their experiences

Ayushman Bharat – The Game Changer

The ambitious scheme would offer 10 crore Indian families a health insurance cover of upto ₹ 5 lakh annually for secondary and tertiary care. There would be no cap on age or family size

Ayushman Bharat – Concerns of stakeholders

In addition to the huge gap between the existing and required infrastructure, human resources, capital and funding, there are other roadblocks which need attention. Among these are diverse laws and multiple regulatory authorities that are governed by different ministries

Road map for Ayushman Bharat

The government has taken a few immediate steps to address the issues with regard to Human Resources (HR) but much more needs to be done. The Ministry of Skill Development is likely to play a crucial role here

Foreword

India's healthcare system faces substantial challenges. There is a huge gap in the public healthcare infrastructure with the shortage of skilled workforce and disparity in the urban and rural facilities. This can be attributed to inadequate expenditure by the government on healthcare. With this crunch, people in India largely depend upon private healthcare.

Successful universal health coverage has so far eluded India. The current healthcare system is biased towards curative care due to the absence of health insurance cover, under-diagnosis or no diagnosis and improper care. People have to pay out-of-pocket bills which makes healthcare unaffordable for a large group of people. To mitigate this undesirable situation, India is now heading towards achieving universal healthcare coverage through the Ayushman Bharat Program.

Though it will be no small feat to achieve the core objectives that it has set for itself, Ayushman Bharat has the potential to transform once and for all the perception of the Indian public towards government healthcare schemes. If the scheme is implemented in a methodical and systematic manner, the healthcare landscape shall truly be transformed.

There is an urgent need to bring systematic enhancement in the healthcare system. The government must identify the crucial role of various stakeholders, protect their interests and promote public-private partnership for capacity building. The present policy structure and regulatory framework still appears to be lacking in a cohesive and tangible action plan to address problems pertaining to the core of the healthcare system i.e. access, affordability and accountability.

To sustain Ayushman Bharat scheme and make further improvements, a huge investment is required at various levels not only from the government itself but also from the private sector. The government must also identify additional sources of financing for the scheme's successful operation. It should encourage investor-friendly environment to attract substantial investments from the private sector.

The role of the private healthcare sector cannot be undermined as they bring knowledge and expertise from different international markets. These players contribute to the ecosystem by providing quality care products and services, training the healthcare workers and bringing operational efficiency for which they have to make huge investments. The efforts on creating infrastructure and service delivery would fall short if the access and ability to use medical technologies is missing. The medical technology (MedTech) sector has a key role to play in enabling training and educating the healthcare workforce.

How the MedTech industry can contribute and support towards smooth implementation of Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) is a subject that requires extensive deliberation. With this goal in mind, Medical Technology Association of India (MTAI) is organizing the MTAI MedTekon 2018: MedTech-Vitalizing Ayushman Bharat. This conference is a unique platform for patients, providers, payers, healthcare industry and authors of Ayushman Bharat to come together and discuss various aspects of the program and its increasing outreach.

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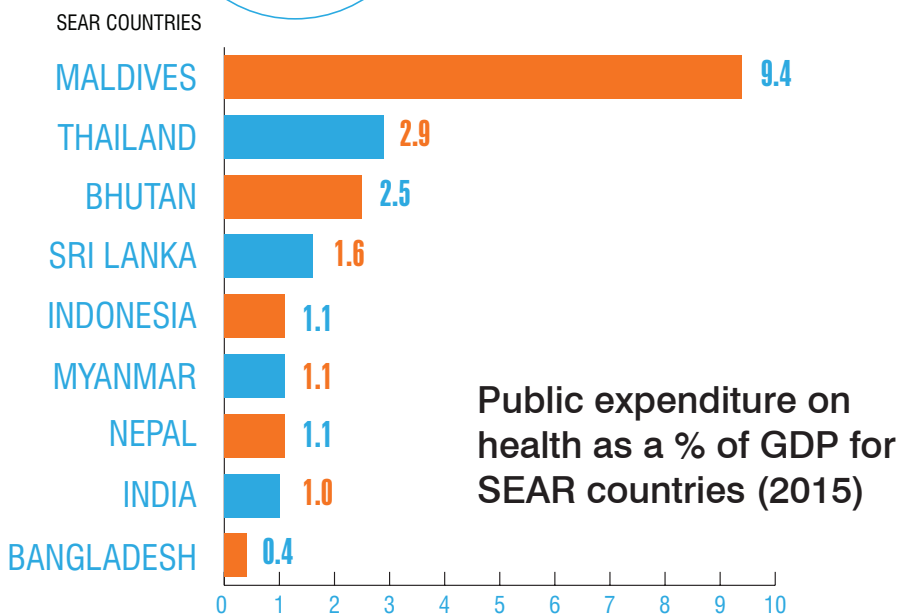
CHAPTER 1: CURRENT STATE OF PUBLIC HEALTHCARE IN INDIA



The healthcare system in India is driven by public and private institutions where both play very different roles. While the government provides healthcare at the primary, secondary and tertiary levels, there is a burgeoning number of private hospitals designed for high-quality tertiary care.

Patients in India largely rely on such private setups for a serious illness. This is often expensive and involves high Out-of-Pocket (OOP) bills. Currently, only 27% people in India have health insurance coverage, and high out-of-pocket expenses push nearly 55 million people into poverty each year.

Most of the better insurance schemes including the government-sponsored Rashtriya Swasthya Bima Yojana (RSBY) and the state-level schemes were introduced only after the turn of the century. Older schemes such as ESIS (Employees' State Insurance Corporation) have not been able to keep pace with the subsequent demands in terms of changing trends in illness and healthcare delivery.



Source: National Health Profile (NHP) 2018

Poor insurance coverage has resulted in as much as 68% of healthcare expenditure in the country being OOP. This constitutes about 4-5% of the average household budget, and around 11% of the non-food budget; also, the monthly budgets of such families have no provision for any catastrophic health events.

India needs to catch up with its neighbors

India's public spending on health is a dismal 1% of GDP, which is way less than the global average of 6%. India is only above Bangladesh (0.4%) among ten countries in the WHO's South-East Asian Region, while the public healthcare spends of other neighboring countries like Bhutan and Sri Lanka stand at 2.5% and 1.6% of GDP, respectively.



INDIAN HEALTHCARE IMPORTANT FACTS:



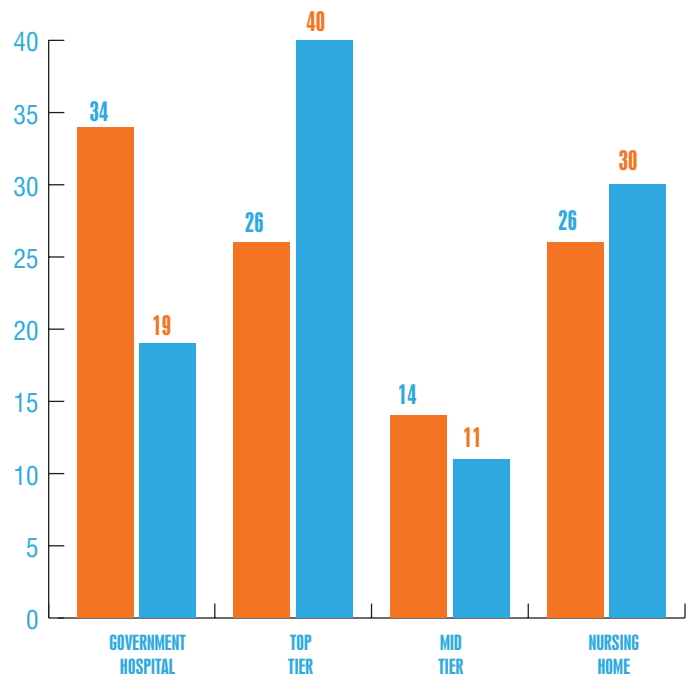
Number of beds per 1,000 population is **0.9** lowest among BRICS nations and far below the global average of **2.9**

60% of hospitals, **75%** of dispensaries and **80%** of doctors are in urban areas serving only **28%** of population



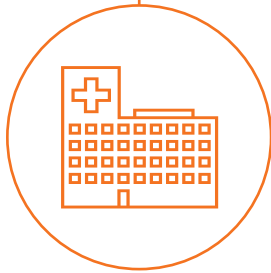
476 medical colleges in India

Shares in healthcare spending in India (in %)



2005 2015

Source: IBEF



- Lack of awareness among people
- Lack of appropriate infrastructure and equipment
- Shortage of trained medical and para-medical staff
- Lack of preventive care
- Delay in appropriate healthcare intervention
- Dual disease burden of communicable and non-communicable diseases

A huge gap between tier 1 & 2 and smaller towns

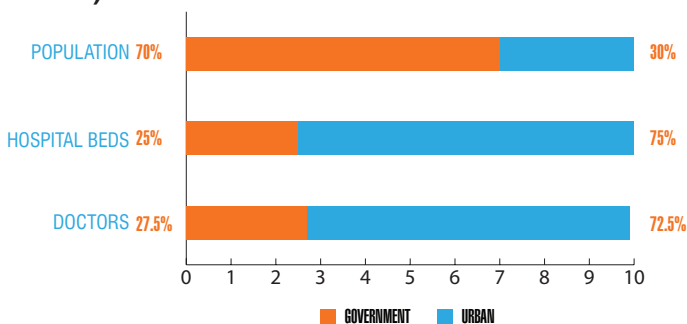
About 27% of the Indian population lives in its eight biggest cities, while the other 70% lives in the rural and semi-urban part of the country. There are 23,583 government hospitals in India having 710,761 beds, out of which 19,810 hospitals are in rural areas with just 279,588 beds and the balance 3,772 hospitals are in urban areas with disproportionately high 431,173 beds. To cater to the needs of the rural & semi-urban population there are an additional 156,231 sub-centers, 25,650 primary health centers and 5,624 community health centers. The doctor-to-patient ratio in rural India, as per the Health Ministry statistics, stands at 1:30,000 which is well below the WHO's recommended 1:1,000. With most of the country's private hospitals and the majority of specialist doctors residing and working in the big cities and availability of quality infrastructure and better connectivity in metropolitan areas, we get a picture of plentiful healthcare facilities for a small percentage of the population.

As a contrast, the Tier 3-4 cities and villages, have less than 5% of specialist physicians who cater to the rural demand which is largely dominated by doctor-owned small to mid-sized centers offering mainly primary and secondary healthcare.

Healthcare in rural India is in a dire need of upgradation and is the biggest concern for the 70 per cent of the population residing there. The hospital bed capacity in Tier 3 and 4 cities is in need of a significant improvement to ensure proper healthcare delivery. According to a study, India would need 3 million beds by 2025, 1.54 million doctors and 2.4 million nurses to achieve the recommended 1:1000 doctor-patient ratio.

Considering the competency gap in metro and Tier 3-4 cities, the healthcare distribution strategy needs to be different than that of the bigger cities. The hiring and training of the local workforce requires due attention, which can be facilitated through workshops and bridge courses. Exhaustive localized surveys to identify the needs in various cities and rural areas are necessary to determine the kind of demand for the workforce in each of the zones.

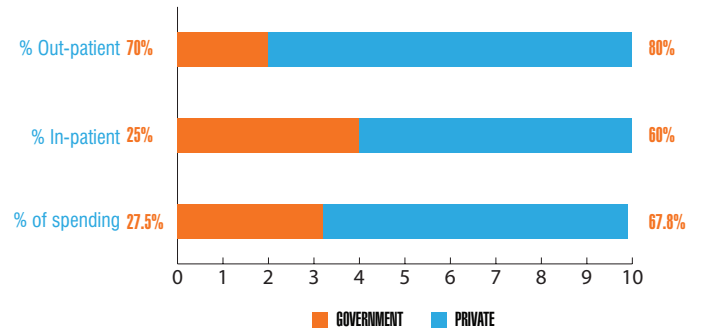
Infrastructure is skewed towards urban areas (Region/Approx. % of total in 2012)



Source: Bain-Nathealth (2015).
Aarogya Bharat India Healthcare Roadmap for 2025.

- Ensuring health facility in every district with skilled health workers
- Training of local human resources through regular courses and workshops
- Affordable medicines and technologies
- Awareness programmes on key diseases and treatment in local languages
- Building local distribution networks and storage capacities

Private sector has a dominant share in healthcare



Source: SEBI (2015). Narayana Hrudayalaya Red Herring Prospectus. Apps.who.int. (2016). Global Health Expenditure Database

Where are we heading?

To give a relief to its vast underprivileged population, the Indian Government proposed the Ayushman Bharat-National Health Protection Scheme (NHPS) during the General Budget 2018-19 as a landmark initiative towards achieving universal health coverage (UHC) target by 2030 as positioned by the Sustainable Development Goals.

This health insurance scheme aims to cover nearly 55 crore beneficiaries from over 10.74 crore “deprived” families as per socio-economic and caste census (SECC) data with an annual health cover of ₹5 lakh per family per year taking care of almost all secondary care and most tertiary care procedures.

Amidst the above backdrop, implementing AB-PMJAY, particularly in Tier 3-4 cities will be a significant challenge. Mere availability of health insurance does not guarantee efficient healthcare delivery unless the ecosystem required to make it accessible and available on time at ground zero is present.

For Ayushman Bharat programme to succeed, it will require the coordinated effort of all stakeholders in the complex healthcare industry including health insurers and TPAs, providers, the pharmaceutical industry, the medical device & diagnostic industry and, educational institutions to complement their efforts.

Though it will be no small feat to achieve the core objectives that it has set for itself, Ayushman Bharat has the potential to transform once and for all the perception of the Indian public towards government healthcare schemes. If the scheme is implemented in a methodical and systematic manner, the healthcare landscape shall be truly transformed.

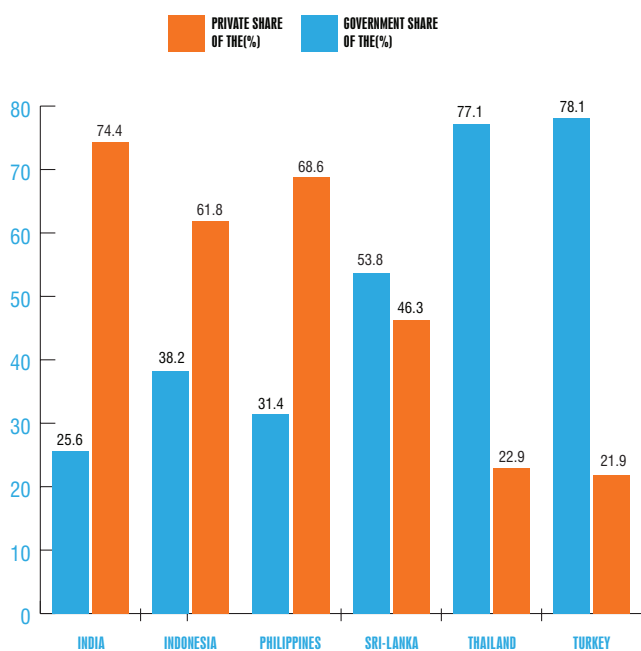


CHAPTER 2:

THE GLOBAL EXPERIENCE OF PUBLIC HEALTH COVERAGE ROLLOUT



Government share of total health expenditure (%)



Source: WHO Data (2015)

Several developing countries with economies similar to India, have implemented their Public Health care schemes successfully. If we study these public healthcare insurance schemes, we would find many pointers for India's path-breaking Ayushman Bharat Programme, which will be the largest scheme of this kind in the world. There is a learning opportunity from the experiences of countries like Indonesia, Philippines, Sri Lanka, Thailand, and Turkey. While the universal health schemes in these countries are mainly funded by their respective governments, the private sector also plays a major role in actual healthcare delivery.

COUNTRY	GOVERNMENT SHARE (%)	PRIVATE SHARE (%)
INDIA	25.6	74.4
INDONESIA	38.2	61.8
PHILIPPINES	31.4	68.6
SRI LANKA	53.7	46.3
THAILAND	77.1	22.9
TURKEY	78.1	21.9

INDONESIA

Indonesia's national health insurance scheme, Jaminan Kesehatan Nasional (JKN) is administered by the Badan Penyelenggara Jaminan Sosial (Government insurance company). Launched in 2014 and funded through general tax revenues, the scheme has already enrolled about 75% of the population and aims to provide comprehensive health care needs to Indonesia's entire population by 2019. The scheme is administered in two formats: One for the self-employed and other for the employees, and the premium paid by either category is determined separately.

In Indonesia, the introduction of an e-catalogue with an exhaustive list of medical devices is expected to increase competition within the medical device industry and help in getting a supply of quality yet cost-effective products.

PHILIPPINES

The government of the Philippines has generated substantial revenues for UHC through alcohol and tobacco tax reform. PhilHealth scheme has built reserves of funds over the years to prevent any delay in the process.

The health coverage program in the Philippines called Philippines Health Insurance Corporation (PHIC) has been in operation since 1996. Also called PhilHealth, the entire government-backed scheme has achieved a population coverage of 93% as of 2017 end. It has ensured decentralization of health services to local government units (LGUs) and rural health units (RHUs) which were given the responsibility for the financing and provisioning of health services. In 2012, the mechanism to incentivize the utilization of funds and verification was introduced which resulted in better outpatient care.



SRI LANKA

Sri Lanka's universal health scheme named National Health Services (NHS) is administered directly by the Ministry of Health (MOH), from the time of its launch in 1930. Funded by the general tax revenues of state and central governments, the national scheme offers protection to the entire population. The cornerstone of Sri Lanka's health scheme agenda has been supply-side efforts to ensure strong service delivery. The doctors in government hospitals can supplement their salaries during off-duty hours and patients willing to pay Out-Of-Pocket (OOP) can receive more personalized care from these doctors through their off duty clinics.

A clear separation between preventive and curative service provision at the local level is a unique feature of the Sri Lankan health system. The government facilities account for approximately 50% of all outpatient visits, 95% of all hospital stays, and nearly 100% of preventive health care.

In Thailand, the government has harmonized the emergency medical care financing system across the three schemes so that patients do not need to be verified before medical care is provided and equitable distribution of health outcomes is ensured. The financing systems for renal replacement therapy and for HIV/AIDS patients are also being harmonized.

Thailand has three main public schemes – the Universal Coverage Scheme (UCS), the Social Security Scheme (SSS), and the Civil Servant Medical Benefit Scheme (CSMBS). All three are spearheaded by the government through the National Health Security Office (NHSO). Launched in 2002, the scheme collectively offers protection to 98% population (76% under UCS, 7% under CSMBS and 15% covered under SSS). The payment mechanisms focused on capitation and case-based payments with an overall budget, send strong cost-containment incentives to the providers. The scheme also has a monitoring and evaluation system in place.






TURKEY

Turkey launched its Universal Health Insurance (UHI) in year 2003 with the objective of achieving efficient, productive and equitable organization of the resources in the healthcare system. Administered by the government’s Social Security Institution (SSI) the scheme covers 98 % population. It provides supplementary add-on payments for some high-cost interventions to improve utilization. The scheme is primarily financed by payroll deduction and premium (for self-employed) and non-working people are funded entirely by the government. One of the challenges faced by the scheme is around informal or illegal payments demanded by healthcare providers.

Health indicators in Turkey are monitored at the national level through a web-based integrated health information system called “SAGLIK-NET,” which is used to share electronic health records of individuals among health institutions.



A comparative account of these healthcare schemes of the above countries provides a lot of insights which reveal the benefits as well as the shortcomings of such schemes. While India is getting ready to implement the much-needed UHC, it can consider these key takeaways to build it further for a successful implementation of Ayushman Bharat (AB-NHPM).

					
	INDONESIA	PHILIPPINES	SRI LANKA	THAILAND	TURKEY
Name of the Scheme	Jaminan Kesehatan Nasional (JKN)	PhilHealth	National Health Services (NHS)	Universal Coverage Scheme (UCS)	Universal Health Insurance (UHI)
Launched in	2014	1996	1930	2002	2003
Population Covered	75%	86%	100%	98%	98 %
Administered by	Government	Government	Government	Government	Government
Special Feature	Created an e-catalogue with an exhaustive list of medical devices to get quality & cost-effective products	Generated substantial revenues for UHC through alcohol and tobacco tax reform	A clear separation between preventive and curative care provision	Harmonized emergency medical care system so that patients do not need to be verified before medical care is provided	Integrated health information system for electronic health records of individuals

KEY TAKEAWAYS FOR INDIA'S AYUSHMAN BHARAT



Need for a separate dedicated national regulator cum administrator for the implementation of the scheme.

Categorization of population based on the degree of immediate need and their susceptibility to diseases.

Monetary rewards to encourage early detection and preventive care of diseases. Need for effective supply-side management of human resources, essential drugs and facilities to ensure effective service delivery.

Targeted recruitment policy to increase intake of students from remote and rural areas into public health institutes.

Compulsory service in rural areas for three years for medical, dental, and pharmaceutical graduates from public universities.

Enhanced financial allowances to doctors but with mandatory services in the remote region – to discourage illegal or informal payments.

Central procurement system for medicines and medical devices to ensure effective utilization and proper deployment.

Accountability framework for quality monitoring.

Standardized claim review process and use of online claim process.

An evidence-based, systematic process to do reviews and take decisions.

A more inclusive approach that integrates contribution from the private sector should be encouraged instead of imposing complicated regulations.

Collective universal scheme to defragment the healthcare schemes at state levels if any.

Need for effective supply-side management of human resources, drugs, and facilities to ensure effective service delivery.

A more inclusive approach that integrates contribution from the private sector should be encouraged instead of imposing complicated regulations.

Chapter 3:

AYUSHMAN BHARAT - THE GAME CHANGER



Ayushman Bharat in a nutshell

Announced in the Budget
2018



To be launched on
September 25, 2018

50 Crore
beneficiaries
(80:20 rural-urban split)



₹5 Lakh
hospitalization cover per
family per year

No cap on family
size and **age**



Families identified
as per Socio-Economic
Caste Census
2011

While Indian population yearns for good quality and affordable healthcare, only 27% of them have the necessary insurance to avail the same. This insurance, however is only a scant cover. According to a recent study by Public Health Foundation of India (PHFI), the abnormal out-of-pocket health expenditures push around 55 million people below the poverty line annually, out of which 38 million fall into poverty due to spending on medicines alone. In the wake of the huge disease burden in India, healthcare services come to the citizens at the cost of their housing, education, food and other priorities. The implications are more severe for the weaker socio-economic segments of the populace. Health expenditure is considered catastrophic if it constitutes 10% or more of the overall consumption expenditure of a household and for an average Indian family it is around 11% of the non-food budget.

Despite multiple government-sponsored insurance schemes already available in the country, the overall penetration has remained very low. The major shortcomings of these existing schemes include inadequate insurance cover, low enrollment, delayed payments to hospitals and lack of coverage for outpatient costs, which resulted in their under-performance.

India has been in dire need of a comprehensive health scheme with far-reaching impact enabling last mile coverage. Therefore, to give a relief to its underprivileged population, the government proposed the Ayushman Bharat-National Health Protection Scheme (NHPS) during the General Budget 2018-19. The scheme aimed at making path-breaking interventions has now been officially announced by the Prime Minister, Mr Narendra Modi in his 72nd Independence Day speech. The scheme, now rebranded as 'Pradhan Mantri Jan Arogya Abhiyaan', is slated to launch on 25th September 2018 with the slogan 'Ayushman Bharat Ho, Bharat Ayushman Ho'.

To streamline the health service delivery system and to provide seamless support to the beneficiaries, the National Health Agency (NHA) will appoint an Ayushman Mitra (AMs) at each Empanelled Health Care Provider (EHCP). These AMs will be certified frontline health service professionals who shall be present at these EHCPs (hospitals) and shall serve as the first point of contact for beneficiaries. The AMs shall primarily work on operating the beneficiary identification systems, undertake transaction management and guide the beneficiary about the overall benefits of AB-PMJAY.

The AB-PMJAY, however, doesn't cover diagnostics and is less focused on preventive healthcare reforms. This can have severe implications for non-communicable diseases which are the cause of major health expenditure in the current scenario. Furthermore, post-hospitalization expenditure is another neglected aspect of this scheme. As the implementation of Ayushman Bharat is in nascent phase, these aspects can be further reworked upon and included in the coverage to provide a holistic package.

As there is no cap on the funding for the implementation of the Ayushman Bharat, the current estimate is approx. ₹12,000 crore, 60% of which will come from the central government. Under the scheme, the government estimates the cost of insuring each family to be about ₹1,100. Implementation will be through insurance companies or a society/trust or a mixed model.



Estimated cost of scheme -
₹12K crore, to be funded
by the Centre & States in
60:40 ratio

30
States & UTs on
Board to Date



To be
merged with existing
state schemes

Package rates for **1,354**
procedures



Cashless
and paperless process

To be implemented through
insurance company or
Trust/Hybrid model



Understanding Ayushman Bharat from key stakeholders' perspectives

The success of Ayushman Bharat largely depends on the synchronization of efforts between the main stakeholders i.e., the government, insurance companies, healthcare providers, and pharmaceutical and medical technology industry. In addition to these, information technology and human resources form an important part in ensuring the last mile healthcare delivery. In addition to strengthening the number of healthcare professionals, the government would need to focus on skilling, re-skilling and up-skilling programs for existing as well as additional workforce. In a nutshell, the Public - Private Partnership would improve equity, efficiency, accountability, quality and accessibility of the entire healthcare service.

The government must also identify additional sources of financing for the scheme's successful operation and build an automated system for monitoring. A grievance redressal forum must be created to ensure timely resolution of complaints without intervention of civil or consumer courts. Further, the government must install a competent regulator for monitoring and ensuring equity and healthy competition among various players. The onus of providing mechanism for feedback and timely redressal of complaints also lies with the government.



Role of various stakeholders

Pharmaceutical Industry

- Ensure low cost, good quality drugs
- Reduce supply-side shortage

Healthcare Providers

- Quality health services
- Focus on accreditation
- Operational improvement to reduce cost.
- Ensure availability of beds
- Work with the government for the appropriate package rates

Insurance Companies

- Negotiate with the government for package rates
- Enhance system automation
- Build capacities for effective claims management, actuarial capacities, clinical audit capacity and hospital scrutiny

MedTech Industry

- Work with Government for package rates
- Training and skilling building of the healthcare workforce.
- Ensure availability of Medical Technology

Diagnostics Industry

- Ensure availability of necessary diagnostic systems in urban as well as the rural area at the affordable cost

Information Technology

- Development of IT architecture to link patient data, hospital data and insurance companies with Socio-Economic Caste Census (SECC) and Aadhaar data
- Digitization of data and process to the reduction of costs

The Government

- Identify additional sources of financing
- Build in system automation for monitoring and grievance redressal
- Regulators to ensure fair competition



Healthcare providers - the backbone of AB-PMJAY

From ensuring quality health services to operational improvement to reducing cost, hospitals/healthcare providers will be the hotspot of Ayushman Bharat. It will be their job as a provider to ensure the availability of beds and timely care. At the same time, they must work with the government to set appropriate package rates. The government must ensure that the empanelment process of healthcare providers is conducted in a transparent, time-bound and non-partisan manner based on specific criteria, eligibility and guidelines and also mandate a feasible package rate which is sustainable for these providers. Timely delivery of better health outcomes to the patients must not be hampered due to any miscommunication between the insurer and the provider.

Insurance companies to act as enablers

Due to an underdeveloped health insurance market, the coverage has been only available for the urban middle and high-income populations. However, the health insurance landscape is expected to undergo a complete overhaul and increase its outreach to poor and lower middle class.

The major role of the insurance companies would include negotiating with the government on service package rates, administration of the insurance policies, processing of claims and timely payments to the EHCP. Among the challenges would be to ensure that claims are genuine, clinical services are audited and hospitals are scrutinized effectively.

The major challenge, however, is that the private insurance players are not too keen with government's decision to keep the private retail and group insurance companies under the GST ambit, which they say makes it less attractive.

Pharma and MedTech are the lifelines of AB-NHPS

The role of pharmaceutical and medical technology industry is vital as they would provide the medicines and latest medical devices & equipment to the healthcare providers.

The pharmaceutical industry must ensure the availability of affordable generic and bio-similar drugs while maintaining quality at all times, which will require stringent quality checks. The increase in the speed of manufacturing and distribution besides proper storage will help in reducing any shortage in the supply when the demand goes up.

The entire infrastructure and service delivery efforts would fall short if the access and ability to use medical technologies is missing. Besides ensuring the vital supply of medical devices and high-end equipment through the wide network of distribution channels, the MedTech companies have a key role to play in enabling training and educating the healthcare workforce. Since there will be a requirement of a massive skill development exercise of allied healthcare professionals, the industry can contribute through its expertise by training the doctors, nurses, and primary healthcare service providers and making them patient ready.

While it is understood that the government intends to come

up with a new pharma policy which will unify and synergize the pharma and medical devices sector, the focus on indigenous manufacturing and cheap products should not come at the expense of quality.

Altogether, execution of Ayushman Bharat will be a challenge as it would involve identifying and focusing on appropriate success factors which will involve allocating the right financial support, incentivizing all stakeholders and ensuring effective coverage for beneficiaries.

In the long run, the scheme shall focus on strengthening the primary care, inclusion of out-patient treatment and a public healthcare delivery system and achieve health coverage for entire population of India.

Chapter 4:

AYUSHMAN BHARAT – CONCERNS OF STAKEHOLDERS



The Ayushman Bharat program, as a national-level public healthcare scheme for the largest democracy in the world is not just an ambitious target but a complex task to implement within the present healthcare landscape. Before the full rollout of the implementation is undertaken, there are several challenges which require due attention by the government. To achieve the objectives of the program, a coordinated effort will be required from the various stakeholders involved in the value chain. In an ecosystem where different stakeholders play different critical roles, there is a concern that even if a single cog in the wheel is unhinged, the overall scheme can flounder.

In addition to the huge gap between the existing and required infrastructure, human resources, capital and funding, there are other roadblocks which need immediate attention of the government. There are several diverse laws, administered by several regulatory authorities and overseen by different ministries that impinge the healthcare sector. The present policy structure and regulatory framework still appears to be lacking in a cohesive and tangible action plan to address problems pertaining to the core of the healthcare system i.e. access, affordability and accountability.

One single uninformed policy decision with respect to any stakeholder, which is not in sync with the current requirement, can affect the whole ecosystem adversely. The government has to strike a balance among all the spokes of the wheel and therefore, it is necessary to move from an ad-hoc approach to a nuanced and overarching policy structure. This will end the uncertainty and trust deficit among the stakeholders and promote the ease of doing business which in turn will be beneficial for the sector and ultimately for the patients.

Concerns/Challenges from the healthcare industry

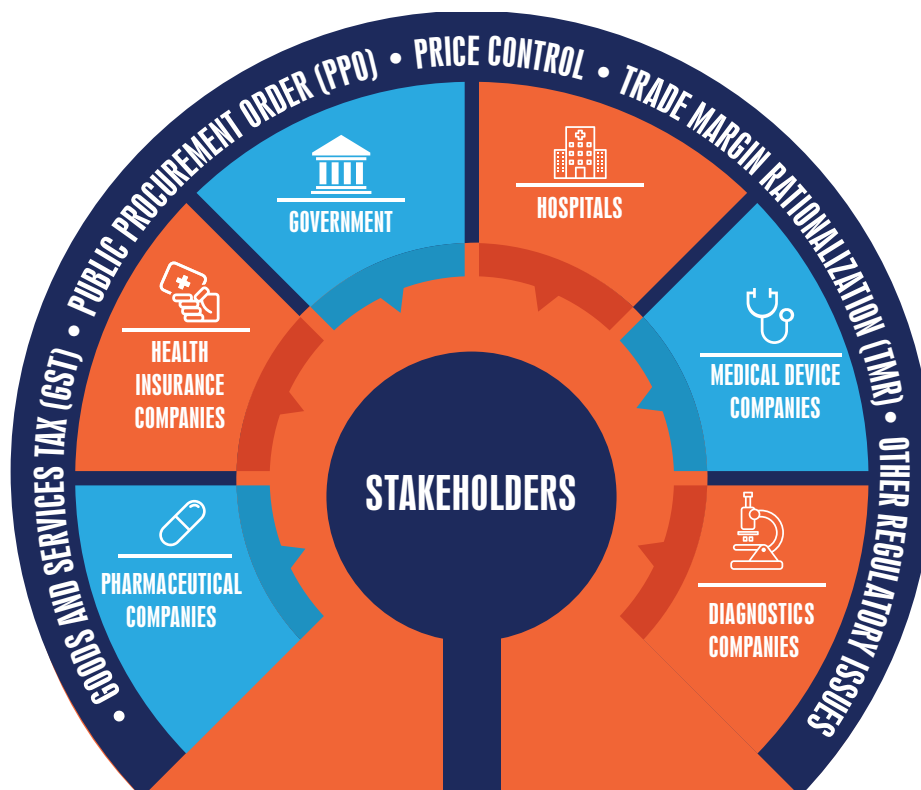
The stakeholders from the healthcare industry have a vital role to play in the implementation of AB-NHPS to achieve its objectives. However, there are several challenges that the stakeholders face which could be very critical to their ability to contribute and will directly or indirectly influence the success of the mission. The government should engage with the stakeholders, identify and address these concerns to eliminate the gaps which may come underway:

STAKEHOLDERS	CONCERNS	CHALLENGES
Hospitals	<ul style="list-style-type: none"> • Viability of package rates • Timely payments with no deduction in it 	<ul style="list-style-type: none"> • Maintain the quality • Maintain working capital • Transparency
Insurance Companies & TPAs	<ul style="list-style-type: none"> • Trust model adoption by states • Lowest bid will make premiums unviable 	<ul style="list-style-type: none"> • Medical claims management • Fraud control mechanisms • Prevent delay in reimbursement
Channel Partner	<ul style="list-style-type: none"> • Limited trade margins • Payments getting blocked due to non-payment or delayed payment by hospitals 	<ul style="list-style-type: none"> • Predict the market demand • Resources for effective supply chain • Make products available
Drugs & Devices Companies	<ul style="list-style-type: none"> • Price control & subsumed package rates • Choking of capital due to delay in payment in the value chain 	<ul style="list-style-type: none"> • Maintain quality • Being viable • Bringing new technologies

The major challenges before the government in the implementation of AB-NHPS are:

- Budget allocation and availability of funds by the center and state governments
- Mechanism and vehicle for raising the capital and resources
- Coordination between the Center and State
- Creating awareness among beneficiaries
- Availability of hospital beds in tier 2-3 cities and rural areas (nearly 2 lakh more beds needed to enable the scheme to run at full capacity)
- Price for insurance companies (unviable premiums and threat from adopting trust-based model) and private hospitals (pricing of health packages)
- Appointment and retention of experts and skilled professionals, especially in rural areas
- Viability for drugs and devices companies to support the scheme
- Emphasis on quality products and services
- Availability of quality medicines, medical devices and consumables
- Monitoring the quality of healthcare services delivered at the ground level
- Vigilance and monitoring for defaults and frauds
- IT infrastructure and internet connectivity
- Address the concerns and establish synergy among the stakeholders

Present challenges of healthcare industry



Price Control

In 1970 for the first time, the government had restricted the profitability of pharma companies through the Drug (Prices Control) Order (DPCO). Since then a number of DPCOs have been brought in to regulate the prices of drugs. In 1997, the Ministry of Chemicals and Fertilizers established an independent body of experts through a resolution, called National Pharmaceutical Pricing Authority (NPPA), with an objective to fix or revise the prices of controlled bulk drugs and formulations. Its mandate extended from the National List of Essential Medicines (NLEM) to monitoring the prices of decontrolled drugs.

The NPPA has played an active role in the price control of various drugs with an objective to provide affordable healthcare.

Since the medical devices and consumables are regulated under the Drugs and Cosmetics Act, 1940, the classification of these devices as "Drugs" brought these under the purview of the DPCO and subjected them to the same kind of price control as drugs. Medical devices for the first time were brought under the price control regime beginning with the price ceiling of coronary stents in December 2016 which was again extended to include knee implants in August 2017.

The medical device industry is hugely different from the pharmaceutical industry. Medical technology and devices evolve continuously and require high investment for research and development. The "one size fits all" approach of regulatory policy may hamper technological advancements and may force the market to stop innovating further. Such an un-nuanced attempt will not improve patient access and will most likely end up smothering this dynamic and vital industry. The industry wishes no further price control on any medical device which does not have any positive impact as intended.

Trade Margin Rationalization

NPPA's price capping move was well-intended and was aimed at bringing down the overall cost burden on patients. But the unintended consequences that manifested were not just limited to hiking up of procedure costs, industry's aversion to introducing newer technologies, and poor investor sentiments. So much so that the FDI in the MedTech sector which has started soaring thanks to the Government bringing it on the automatic route in 2015, also plummeted. It was also felt that the effect of such a move might actually restrict the patient access in the longer run. So, the industry demanded and supported Trade Margin Rationalization (TMR) as a possible solution to the problem. TMR, if implemented, can prove to be an effective tool to control the Maximum Retail Price (MRP), with a possibility to reduce it by upto 73% and hence make healthcare affordable for the patients.

A report on The Committee of High Trade Margins in the Sale of Drugs commissioned and published by the Department of Pharmaceuticals (DoP), recommends that the trade margin should be the difference between the Price to Trade (PTT) - the price at which the manufacturer or marketing company sells the drug to

the distributor or stockist (the first point of sale), and the price to patient (MRP). The report adds that "the government should consider capping the overall trade margins, thus, giving a level playing field to every trade channel. The Industry should have the flexibility to decide intra-trade channel percentage considering multiple factors of market access and supplies".

The government has had stakeholders' consultations on this subject beginning from October 2017 to ascertain their viewpoints and there after the government's think-tank NITI Aayog floated a consultation paper in June 2018 with suggestions from the stake holders. The industry expects from the government that TMR should be implemented as recommended in the DoP report based on PTT as the first point of sale which will take care of various aspects of the market, ease of doing business and quality and affordable access to medical technology in the country.

Another important emerging reality is that in the wake of the Dollar and Euro depreciating this year by up to 20%, the government needs to revise the ceiling of 10% annual increase on MRP which the DPCO mandates.

Public Procurement Order

In June 2017, the Department of Industrial Policy and Promotion (DIPP) issued the Public Procurement Order (PPO), 2017 (earlier termed as preferential market access – PMA) and identified DoP as a nodal agency to implement it for the medical device sector. Under this, public procurement for public healthcare organizations will give preference to goods manufactured in India rather than the imported items. The sole intention behind this move was to promote Make in India for the medical device industry. While this was lauded in principle by associations such as MTal who have a deep manufacturing foot print in India it could prove damaging in cases where the technology does not exist within the manufacturing ecosystem.

This fateful order on public procurement policy for enhancing local production and giving a boost to Make in India for medical devices came as another blow to the industry which was already struggling with other pressing issues. Imposing such requirements and giving preference to local suppliers to the level of 100% of the value will limit the market access and will deny a level playing field for suppliers of technologies that are currently not produced locally.

Almost 70% of the products (by value) and almost 80% of the critical care devices are currently imported. An immediate implementation of any level of local content requirements without a foundational assessment of the capacity of local production and import, may go counter to the true objective of Make in India. This kind of policy may also give rise to mushrooming of substandard and low-cost device providers which could be catastrophic to the health of the nation. A vigorous step wise plan for Make in India looks the sustainable way forward. Andhra Pradesh Medical Technology Zone (AMTZ) seems a good step in such a direction.



Goods and Services Tax

The Goods and Services Tax (GST) is hailed as the biggest tax reform since independence. There were many types of prevailing tax systems in the past and to make the tax system more uniform, GST was introduced in July 2017.

GST rates were supposed to be tax neutral, meaning; the overall tax incidence post-GST should have been equal to the embedded tax rate under the pre-GST regime. But in reality, the medical devices have suffered from higher GST rates. Under the GST regime, tax slab for the medical device sector is pegged at 12% and for some devices the rates are even as high as 18% and 28%. This has affected the overall cost structure of the healthcare sector coupled with further increases in customs duty to the tune of almost 50%. Earlier, most of the medical devices attracted CVD rate of 0-12.5% and the VAT rate for almost all products were in the range of 5% but now the overall combined incidence of subsumed taxes on most of the devices comes to about 6-8%. This has resulted in most of the medical device effectively being charged 6-10% higher tax.

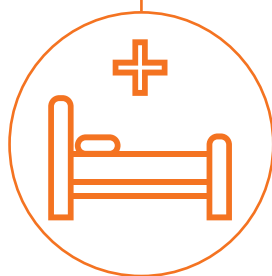
On the other hand, the healthcare services have been exempted under GST instead of being zero-rated, leading to cascading effect of the high GST on hospital cost, as the hospitals can no more take input GST credit. The government should, besides reducing the GST rate on medical devices to 5%, make healthcare services zero-rated. This would effectively reduce tax incidence on hospital input costs leading to lower healthcare service charges for the patients.

The role of medical technology is vital, how can healthcare delivery be achieved without medical devices? Can it be imagined that a healthcare system be set up without the support of these devices and technologies? As stated time and again, the case of medical devices requires, and deserves, its own focused and exclusive agenda. There is an urgent need to set that agenda together with governments, healthcare experts and providers, practitioners, the private sector, academia and most importantly, the patient representatives. The overarching umbrella of Ayushman Bharat provides an opportunity to do so.



Chapter 5:

ROADMAP FOR AYUSHMAN BHARAT

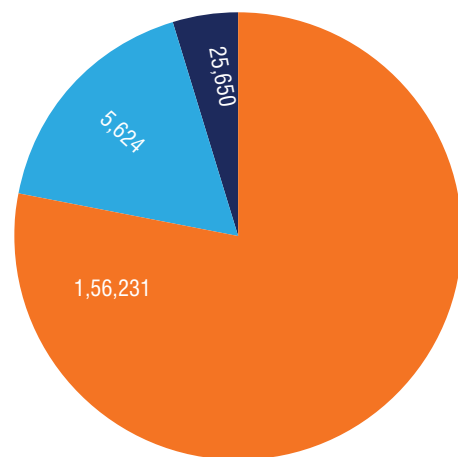


Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) has already been dubbed as a game changer for the Indian healthcare system. It has the potential to become the most far-reaching social program initiated by the government. But for the scheme to fulfil the aspirations of the vast Indian populace, a lot of effort needs to be put in towards consolidating current resources and making way for new ones.

India has just a couple of health economists, biostatisticians, epidemiologists or public health managers and there is an acute shortage of human resources at all levels of the system. By the time AB-PMJAY becomes fully operational in 2022, it will require almost 2.2 million people at every level, from the highly qualified clinical specialists and super specialists to nurses and technicians, allied health professionals to hospital administrators, IT experts to insurance executives and healthcare planners to community health workers to support the system.

As on 31st March 2017, there were 156,231 Sub Health Centers (SHCs), 25,650 Primary Health Centers (PHCs) and 5,624 Community Health Centers (CHCs) in India. However, most of these facilities suffer severely from poor infrastructure, under-staffing and lack of equipment and medicines. Only 11 % of SHCs, 16 % of PHCs and 16 % CHCs meet the Indian Public Health Standards (IPHS). According to Rural Health Statistics 2017, there is an 82% shortfall in total surgeons, obstetricians and gynaecologists, physicians, and paediatricians across CHCs in India. Furthermore, over 6000 SHCs did not have even an auxiliary nurse midwife/health worker. Under the AB-PMJAY initiatives, the

Current state of public healthcare system (as on 31st March, 2017)



PRIMARY HEALTH CENTER

COMMUNITY HEALTH CENTER

SUB HEALTH CENTER

Source: Annual Report of Department of Health & Family Welfare for the year of 2015-16



government aims to upgrade 150,000 (of the existing 180,000) SHCs and PHCs to Health & Wellness Centers (HWCs) by 2022.

The government has taken a few immediate steps to address the issues related to human resources (HR). It has planned a rapid expansion of medical education as it forms the apex of the healthcare pyramid. The government recognizes that it is the quality of graduating doctors and specialists that determines the quality of services in the healthcare and hence has undertaken suitable amendments in the Graduate and Post Graduate Medical Education Regulations for making common counselling for admission in medical colleges mandatory. The post-graduate seats have also been increased by over 8,500 and under-graduate seats by over 16,000.

The network of medical colleges is getting expanded in a big way by upgrading 58 district hospitals to medical colleges and introducing super specialty blocks to 70 existing medical colleges. 24 new medical colleges have also been planned in this year's budget only. 20 state cancer institutes and 50 tertiary cancer care centers are also being set up. There are 22 new All India Institute of Medical Sciences (AIIMS) planned across the country to reduce

the regional imbalance in tertiary care. There are many other initiatives such as increasing the retirement age of doctors to 65 years, setting up more medical and nursing schools, multi-skilling of doctors which will prove to be effective in overcoming such shortage.

In addition to this, the government has taken a target to train 14 lakh candidates by 2025 under the Skill India program. The Ministry of Skill Development and Entrepreneurship (MSDE), jointly with the Ministry of Health and Family Welfare (MoHFW) and the Ministry of Human Resource Development (HRD) have partnered and signed a MoU with Indira Gandhi Open University (IGNOU) under the 'Skill for Life, Save a Life' to make youth more employable in the healthcare sector and find opportunities of employment.

The National Health Agency (NHA) has signed a MoU with National Skill Development Corporation (NSDC) for skilling one lakh Arogya Mitras (AMs), the certified frontline professionals who shall serve as the first point of contact for beneficiaries of AB-PMJAY scheme. NSDC through the Skills Development Centers under the larger National Skill Qualification Framework including



Pradhan Mantri Kaushal Kendra (PMKK) platform will train and certify Arogya Mitras who will be stationed at each hospital. NSDC through Health Sector Skill Council (HSSC) is preparing training content and will train staff at PMKKs across all the states. In future, this platform is also expected to contribute to the skill development of staff other than Arogya Mitra.

Although these initiatives look very promising and will improve the current status of manpower, there is urgent requirement of training at the clinical front. It is only the trained clinical staff which can make efficient healthcare systems, however, providing training, recruiting and sustaining them will be a huge task under AB-PMJAY program. The clinical side of human resource demand is complex where the candidates passing out of colleges have to go through various on-the-job training. They need to be trained to handle various devices and equipment to become industry and patient ready.

Furthermore, these candidates need to upgrade their skills from time to time to keep up with the new technologies and procedures through continued medical education (CME) programs. The CMEs provide them the opportunity to get education materials, guidance and training on the effective use of equipment and devices, and hands-on training for the procedure and technique associated with those devices. These programs have a very crucial role in ensuring the efficacy of various procedures and the overall patient safety.

The clinician training influences the clinical outcome directly. Until now, such education programs are being carried by the Medical Technology (MedTech) companies. This is a highly technical and focused exercise which involves lots of efforts and investment. The requirement of trained clinical staff for AB-PMJAY would be a challenge which the private sector alone would not be able to handle.

The industry bodies/associations can join hands with the government to strengthen and drive this initiative. They can conduct such trainings by establishing centers of excellence.



The Medical Technology Association of India (MTAI) member companies alone contribute significantly towards skill and capacity building and provide training to more than 2.5 lakh healthcare professionals annually across the value chain through various CMEs, workshops, centers of excellence and seminars. These professionals include vascular surgeons, interventional radiologists, nephrologists, oncologists, general surgeons, urologists, radiologists and paramedic staff.

The time has come for the government to recognize the role and contribution of the MedTech Industry. This critical part of the skill building cannot be done in isolation but in collaboration where the



MedTech Industry has a vital role to play. It is essential to facilitate public-private partnership to create a long-term eco-system for healthcare worker training through the participation of MedTech industry.

India is committed to achieve UHC as a signatory to the globally agreed Sustainable Development Goals. In order to achieve this goal through AB-PMJAY, there is a requirement to evolve innovative strategies to facilitate and create an effective management of resources. The industry participation should be encouraged and quality healthcare must be at the center of any policy decisions. There is a need to create an enabling environment for all stakeholders so that it is through a wide-ranging partnership that AB-PMJAY becomes sustainable and is able to serve the un-served and under-served people of India enduringly.



Shortage of medical personnel

FACILITY	STAFF	NUMBER OF FACILITIES AUDITED	NUMBER OF STATES COVERED	ESSENTIAL NUMBER OF STAFF AS PER IPHS NORM	SANCTIONED STRENGTH	MEN IN POSITION
District Hospital (DHs)	Doctors/ specialists	111	23	3,445	3,503	2,298
	Staff Nurse	111	23	5,878	5,379	4,405
	Paramedical Staff	111	23	3,653	2,315	1,679
Sub-District/ Sub-Divisional Hospitals (SDHs)	Doctors/ specialists	43	10	810	580	369
	Staff Nurse	43	10	734	869	587
	Paramedical Staff	43	10	1,132	716	437
Community Health Centres (PHCs)	Doctors/ specialists	238	25	1,234	817	305
	Staff Nurse	236	24	2,360	4,540	1,303
	Paramedical Staff	236	24	1,413	1,143	861
Primary Health Centres (PHCs)	Doctors/ specialists	295	15	295	369	235
	Staff Nurse	421	22	1,281	665	466
	Paramedical Staff	458	25	2,290	2,059	1,506
Sub-centres (SCs)	Auxiliary Nurse and Mid-wife (ANM)/ Health Worker (Female)	560	10	608	575	519
	Health Worker (Male)	1,376	26	1,376	1,032	453

Source: Report of the Comptroller and Auditor General of India on Performance Audit of Reproductive and Child Health under National Rural Health Mission (2016)

Chapter 6:

THE WAY FORWARD

The present Indian healthcare system confronts many roadblocks including but not limited to infrastructural gaps, underutilization of existing resources, fragmented healthcare delivery system, inadequate skilled human resources, high out-of-pocket expenses, poor health insurance coverage, inadequate government finances, unregulated market, rural-urban imbalance, and high emerging disease burden. These challenges make the system complex, inaccessible and unaffordable for the majority population.

As it sets the objective to serve the unserved and under-served, India is getting ready to implement the much-needed universal health coverage. The Ayushman Bharat program is such a gigantic scheme that it will require the perfect combination of strategies, political will and vision. The present policy structure and regulatory framework appear at some places to be lacking in addressing the real problem. The government has to strike a balance among all the spokes of the wheel and for that, it is necessary to move from an ad-hoc approach to a nuanced and overarching policy structure. This will end the uncertainty and trust deficit among the stakeholders and promote the ease of doing business which will be beneficial for the healthcare system in the longer run.

The Ayushman Bharat scheme has the potential to change the perception of the Indian healthcare landscape provided it is implemented in a methodical and systematic manner. It will require thorough planning, proper utilisation of resources, collaboration among stakeholders, synergy between the public and private players, transparency and accountability systems, etc.

For the scheme to be successful, the pre-requisites are many and thus will require huge financial resources and investments at various levels. The government should promote an investor-friendly environment and proactively

engage with the investors from the private sector. It should also engage with multiple stakeholders from the private provider space with a common agenda – making the collaborative effort to achieve the goal of Ayushman Bharat.

The success will also depend upon the quality care supported by the latest technology. The knowledge and expertise from the private sector coupled with support from the public sector will make an effective eco-system. Within the private sector, the MedTech industry has a vital role to play. An effective healthcare system cannot be imagined without quality medical devices, training and skill building.

The required transformation in the present healthcare system is only possible through working together and building synergies for creating greater gains for the healthcare as well as the people of the country. Otherwise, it could prove to be a daunting task to ensure and achieve health coverage envisaged. The industry keenly awaits the implementation framework from the government.

We at MTal, stand for greater patient access and will continue to promote the role of medical technology in delivering quality healthcare. We will continue to engage with the government at various levels to explore how the MedTech industry can effectively contribute and support it to enable last mile coverage for Ayushman Bharat.



About Medical Technology Association of India (MTal)

Medical Technology Association of India (MTal – pronounced as Em-tai) is a not-for-profit organisation duly registered under sub-section (2) of section 7 of the Companies Act, 2013 and Rule 8 of the Companies (Incorporation) Rules, 2014.

MTal is an association of research-based medical technology companies who have made remarkable investments by setting up a large number of R&D centres and manufacturing plants in India. MTal represents a wide spectrum of the medical device and equipment industry with global experience in innovation and manufacturing.

All the time stressing on the three hallmarks of healthcare – Quality, Consistency and Patient Safety, we want to be a responsible voice of the industry. We are committed to improving access to affordable and quality healthcare for patients.

MTal collaborates with the government, healthcare professionals and other stakeholders for creating innovative solutions provided by the medical technology industry. We are also committed to find a space for all the medical technology companies commensurate to their contribution to improving healthcare in India.

MTal looks to partner with the Government of India in setting a roadmap for growth of medical devices industry by bringing in even bigger investments, through technology upgradation and knowledge dissemination in the provider space, through members who can contribute towards furthering FDI and the government's 'Make In India' initiative.

MTal has been actively involved with all the key stakeholders such as Ministry of Health and Family Welfare, Department of Pharmaceuticals, Ministry of Commerce and Industry, Niti Aayog and even the Prime Minister's Office. In a short period of time of our presence, we have made some strategic and path-breaking efforts.

We believe that the medical technology sector can create new jobs, skill India's talent pool on new technologies and help expand affordable healthcare through innovative solutions.

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