

Realizing the full potential of MedTech Industry in India

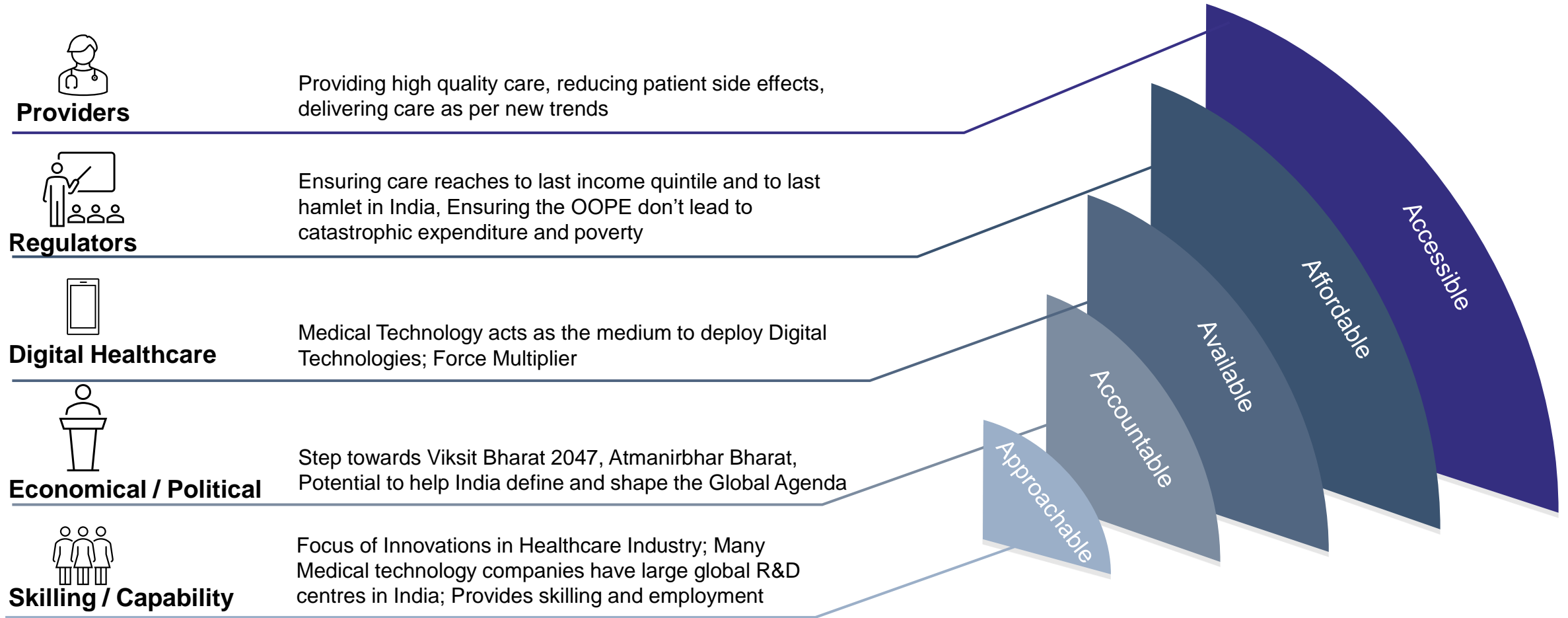
March 2025



EXECUTIVE SUMMARY



MediTech Industry lies at the fulcrum of Indian Healthcare ecosystem and is the MAJOR “connecting link” between payors, providers, regulators and all other stakeholders



The sector has the potential to become a **30 Billion USD Industry by 2030**, and help attain the vision of a Viksit Bharat

Key areas for MedTech sector
(5-year plan to achieve Viksit Bharat by 2047)



Strategic Priorities

- Ayushman Bharat – Universal healthcare
- Atmanirbhar Bharat
- Make in India to increase Self Reliance - reducing import dependency; increasing Affordability
- Increasing Treatment Affordability

Strategic Enablers

- Research and Development
- Ease of Doing Business
- Digital Technology led growth strategy
- Increasing Market Access- Assured Demand Generation via Ayushman Bharat; ABHIM
- Innovation & R&D
- Supply Chain Resilience
- Meditech Export Promotion Council/policy

Policy Nudges

- MedTech Mitra/Single Registration
- PRIP Scheme (Moving from Volume to Value)
- PLI Scheme for devices and components
- HTA Assessments
- Accelerated Digital Health Adoption & expanded insurance coverage on health continuum

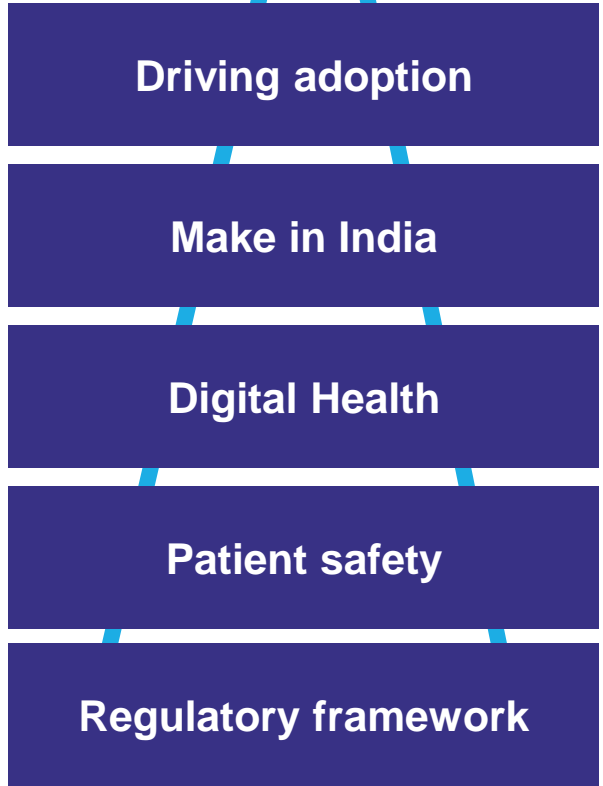
5 key moats identified to help attain this full potential of the MediTech Industry



- Secondary Data Analysis from Multitude of Sources
 - Syndicated Reports
 - Government websites and Publications
 - Other Data bases
- Industry stakeholders (C-Suites, Government and Market Access and Policy Affairs)
- Government Stakeholders (Niti Aayog, DOP)
- International Experts



5 moats



Implementation focused ideas for accelerating reforms with targeted actions taken today that will help reform the existing Indian MedTech ecosystem

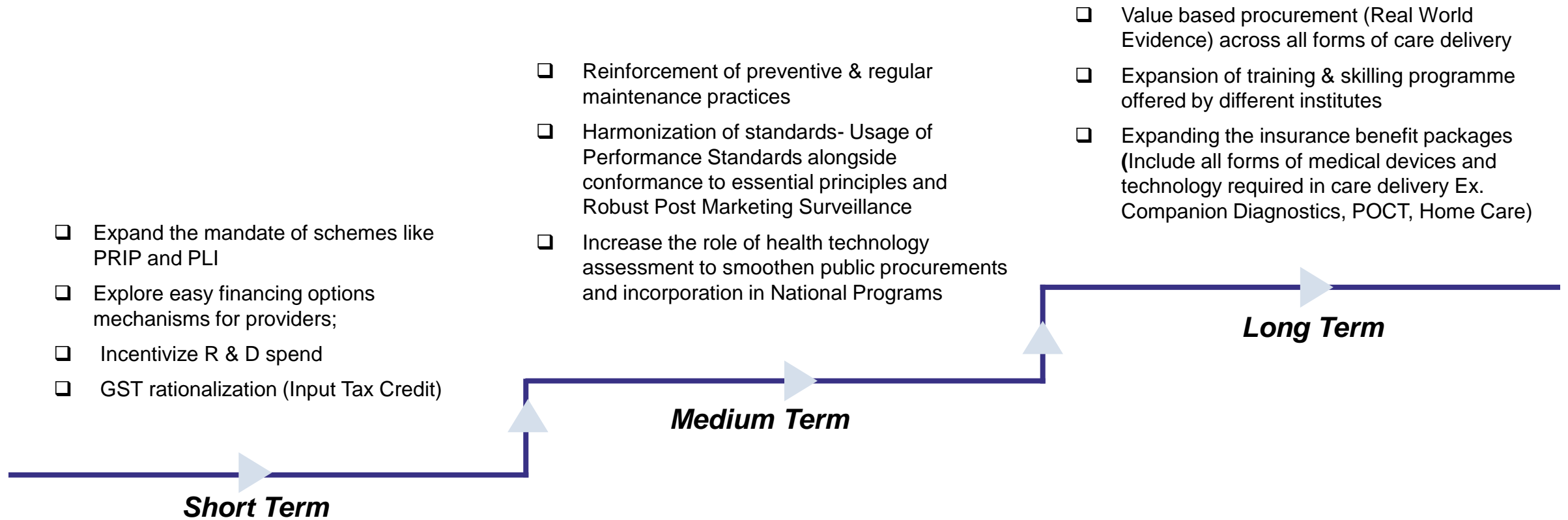


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Stimulating the “Make in India” ecosystem



Promoting Device Led Digital health adoption



Promoting Safe usage of Medical Devices



Regulatory framework for fostering industry best practices



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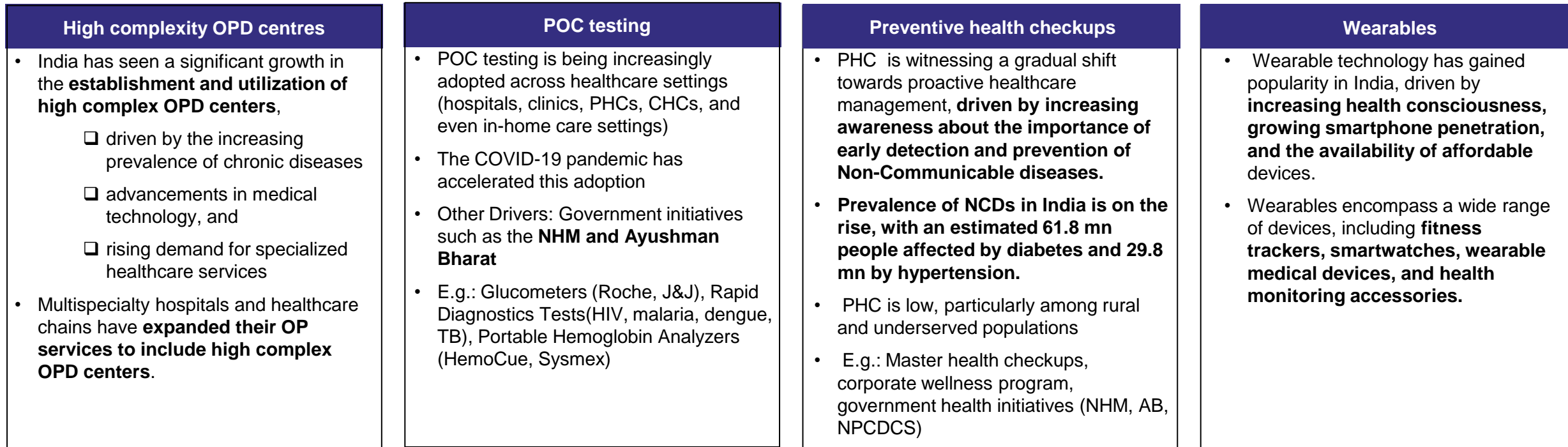
Driving Last Mile Penetration of MedTech Industry in India











Medical devices are indispensable in the modern healthcare ecosystem, supporting the transition towards more patient-centered and proactive care models



The landscape of healthcare is evolving towards more decentralized models with a focus on **outpatient care, preventive measures, and remote monitoring**. This shift necessitates the increased usage of **medical devices across various settings outside traditional hospital beds**


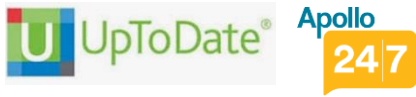





MedTech is connecting the healthcare ecosystem by making it efficient & improving the quality of care through real-time data & accurate results (1/4)

	Patient	Hospital	Public Healthcare	Country's initiatives	
Problem	Long distance between healthcare facility & patient with high-cost of travel ¹	Missed treatment and screening for health conditions ²	Lack of availability of resources like diagnostic centres ³	Long waiting hours ⁴	Lack of knowledge related to disease ⁵
MedTech Solution	 <p>Teleconsultation: E- Sanjeevani has accounted for over 1.60 Cr consultation. 53% consultation have been taken by women.</p>	 <p>TB medication adherence: IoT based device to monitor the TB treatment. The medication are filled for 15 days in the cartridge and if not taken, patient is sent alarms every 15 min also a visit by healthcare provider if still not taken. Observed 90% adherence to treatment.</p>	 <p>30+ test in single platform, independent of electricity or internet: 1Mn beneficiaries tested & 2.5Mn no. of test conducted so far.</p>  <p>Cough sound analysis (AI): 86.82% accuracy to detect pulmonary TB. Used for mass screening; Results in 10 sec</p>	 <p>Monitoring heart conditions: Application to communicate between the implant & clinic, leading to reduced hospitalization and patient confidence. Delivery of value-based care enhanced</p> <p>Online appointment: Real time tracking of patients & doctors schedules</p> 	 <p>AR & VR: Helps to educate patients about health conditions, pre- & post-operative care</p>  <p>Enables physicians to draw the explanation of disease condition on template which have option to customize according to need of patient, improving health literacy</p>

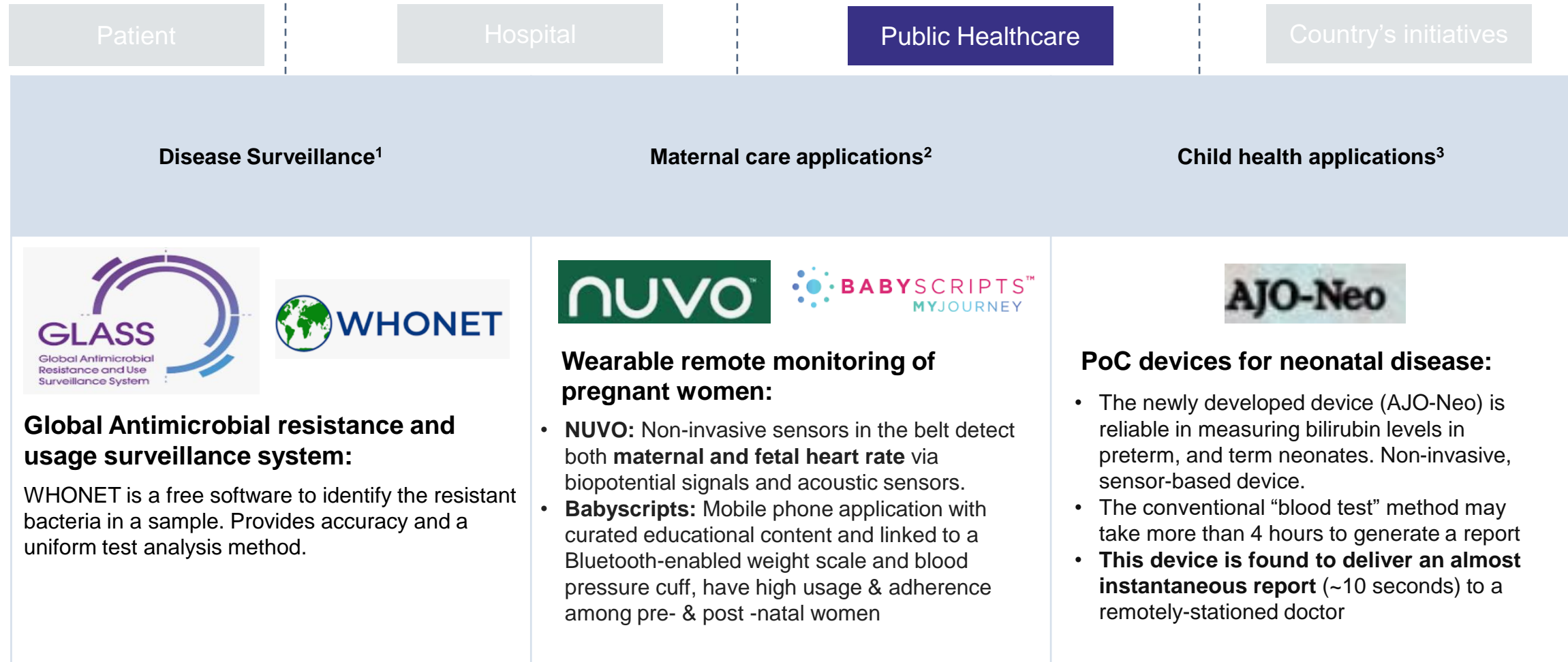
Source: (1) PIB 14th Jan 2022 on e-Sanjeevani, (2) (3) (4) (5) Websites of the organisations

MedTech is connecting the healthcare ecosystem by making it efficient & improving the quality of care through real-time data & accurate results (2/4)

	Patient	Hospital	Public Healthcare	Country's initiatives	
Problem	Past medical history of patient ¹	Medical errors ²	Workforce shortages ³	Patient injury leading to complications ⁴	Infection prevention ⁵
MedTech Solution	 <p>ABHA ID apps & 'Scan & share' service provided:</p> <p>The services aid in instant registration (OPD) via tokens. 10 lakh people have availed the service in first 6 months of launch. Patients can use smartphone with ABHA app or eka.care to scan hospital codes and create, share their personal ABHA ID electronically</p>	 <p>CDSS for effective decision:</p> <ul style="list-style-type: none"> The AI research center has developed a CDSS which consists of a suite of AI-powered tools Helps in staying updated along with notifying the physician for better treatment & in case of any contraindication <p>Prevention of medication error & surgical error</p>	 <p>Digital microscope to tackle delays in reporting due to shortage of lab technicians:</p> <p>The solution is AI-based microscope to scan slides for malaria, which could be further used for whole slide scanning for urine, sputum etc. It has TAT of 15 min for malaria & accuracy of 99%.</p>	 <p>Reducing patient risk of falls via AI-based behavioral analysis and notifying care providers:</p> <ul style="list-style-type: none"> Fall detection system comprises a computer, a camera, and a network system. The fall detection method is based on AI algorithms offered by SpeedyAI, Inc. The human detector achieves a held-out accuracy of 89% and a training accuracy of 94% 	 <ul style="list-style-type: none"> 30-40% of hospital-acquired infections are related to contamination of healthcare worker hands. The UV Robots disinfect operating theatres, pantries, and washrooms within hospitals. The touchless technology offered by STERO-360 makes for safe, effective, and rapid UV Sterilization of various facilities.





Source: (1) PIB for ABHA ID, (2) (3) Websites of various organisation, (4) A 8 camera fall detection system using human fall pattern recognition via ML by low-cost android box, and (5) International society for Infectious disease

MedTech is connecting the healthcare ecosystem by making it efficient & improving the quality of care through real-time data & accurate results (3/4)



Sources: (1) WHO website, (2) Maternal care: Walter JR, Xu S, Stringer JS, Rogers JA. The Future of Remote Monitoring for Pregnancy. Bridge (Wash D C). 2022 Spring;52(1):16-24. Epub 2022 Mar 29. PMID: 38111590; PMCID: PMC10727511., (3)AJO-Neo: PIB

MedTech is connecting the healthcare ecosystem by making it efficient & improving the quality of care through real-time data & accurate results (4/4)

	Patient	Hospital	Public Healthcare	Country's initiatives
Problem	Demand & Supply of resources ¹	Lack of clarity on Health Financing ²	Lack of digital governance ³	Patient Tracking ⁴
MedTech Solution	 <p>Make in India:</p> <ul style="list-style-type: none"> In March 2022, Wipro GE Healthcare announced a new 35,000 sq. ft. medical device manufacturing factory in Bengaluru. This facility will manufacture CT, ultrasound imaging devices, cath lab equipment, patient monitoring solutions, ECG machines and ventilators. 	 <p>Decision on health premium based on risk assessment:</p> <ul style="list-style-type: none"> Premiums planned by the organization can be customized based on the physical fitness level of person as tracked by wearable devices Up to 100% return on premiums are offered using applications like 'Activ fit' (by Aditya Birla) to track the physical activity of the person per day. 	 <p>Serves the function of registration, appointment scheduling, identity verification, vaccination and certification. Digital assets leveraged:</p> <ul style="list-style-type: none"> Electronic vaccine intelligence network - Supply chain management Digital Infrastructure- Verifiable certificates Digi-locker- Save medical documents on cloud Surveillance & action for events following vaccination - Track adverse events 	 <p>Digital platform to monitor TB cases, provide treatment, incentive, community support & knowledge on TB</p> <p>There are roughly 13.5 lakh TB patients registered in the Nikshay portal, out of which 8.9 lakh active TB patients have given their consent for adoption. The Ni-kshay digital portal will provide a platform for community support for persons with TB. (As per PIB – 2022)</p>

Source: (1) How is the 'Make in India' Med-tech transforming coming along report by Bio spectrum, (2)Aditya Birla health Insurance website, (3) Exemplars in Global Health report on COWIN, and (4) PIB & Nikshay portal

Growing public awareness and the quest for quality of care contribute to higher demand

Growing population

Currently India's population is ~1.41 Bn and is expected to reach 1.66 Bn by 2050

Ageing population

Increase in life expectancy from ~69 years in 2020, projected to increase to ~74 years by 2050 leading to increase demand for MedTech solutions like fall detection system

Affluent population

Annual average HH income has increased by 35% over the last decade doubling the proportion of affluent and elite. By 2030 it is estimated that 20% of HH will be elite / affluent

Increased affordability

Rapid expansion of Government sponsored, group and retail Insurance schemes. ~70% Indians expected to have some form of Health Insurance cover

Growing healthcare infrastructure

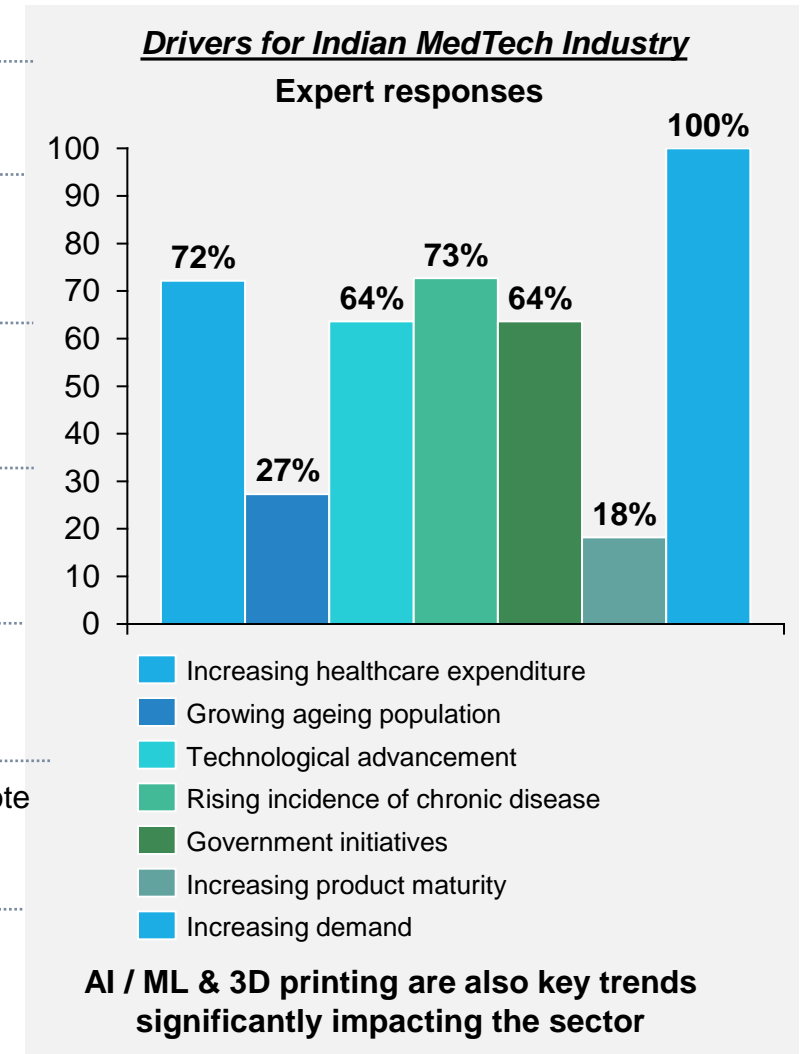
In 2023, the hospital bed market share was 834.61Mn growing at CAGR of 7.99% and the fastest growing segment is ICU bed accelerating the need for medical device as well.

Government Initiative

PLI scheme, Med Tech mitra, Make in india and HWC (Health & Wellness Centre) established in hilly & remote areas also demand medical devices to improve accessibility of healthcare services.

Increasing prevalence of Chronic disease

As of 2023, nearly two-thirds (62%) of all cardiovascular deaths in Indian populations are premature; Harvard School of Public Health in 2014 estimated India's economic losses due to CVD between 2012 and 2030 at US\$ 2.17 trillion.



However, the overall penetration / adoption of MedTech remains low in Care pathways in India (1/2)

	Diabetes	CVD	Tuberculosis	Breast Cancer	Neurology
USA	<ul style="list-style-type: none"> ~2.4 million diabetic patients use continuous glucose monitor (CGM)¹ Hyperbaric oxygen therapy, Negative pressure wound therapy, Smart mat, etc. are used for the treatment of Diabetes foot ulcers (DFU). 	<ul style="list-style-type: none"> 35.5% surgeries are performed by robots 30-40% patients use Implantable cardioverter defibrillator³ According to the Centers for Disease Control and Prevention (CDC), around 12.1 million people in the U.S. are expected to suffer from atrial fibrillation (AFib) by 2030⁷. Sales of cardiac rhythm management devices in the US are projected to reach US\$ 6.3 billion by 2025⁸. 	<ul style="list-style-type: none"> 75% patients are diagnosed with AI enabled devices for Tuberculosis⁴ 	<ul style="list-style-type: none"> AI-based technology is used for the pre-screening of Breast cancers in schools. 	<ul style="list-style-type: none"> AI/ML-enabled devices (compared to 2022- 15%) are expected to reach 30+% by 2024
India	<ul style="list-style-type: none"> 0.07 million patients uses CGM² DFU are treated using surgery, amputation and medication Lifestyle modification and self-glucose monitoring is more prevalent 	<ul style="list-style-type: none"> Less than a thousand surgeries are done by robotics Only 25 Implantable cardioverter defibrillators are used in a million population Approximately 40,000 to 50,000 Arrhythmia / Heart failure patient receive cardiac rhythm management like pacemaker, implants as per observational study in 2017⁹. 	<ul style="list-style-type: none"> 25% of the tuberculosis diagnosis is done by Medical devices or AI⁵ 	<ul style="list-style-type: none"> Very few patients are being diagnosed with the AI-based thermal detection pre-screening 	<ul style="list-style-type: none"> Neurological diseases are mostly treated using medication, lifestyle modification and surgeries

Sources: 1. American Diabetes Association and CGM white paper, 2. Technology streamlining diabetes management in India by Biospectrum, WHO Data, 3. American Heart Association, 4. Radiology Society of America, 5. Revolutionizing TB diagnosis by unleashing the power of AI by India Health Fund, 6. AI/ML Medical Devices FDA by Enerxen 7. Grand view research report on cardiac rhythm management devices 8. Future market insights 9. Profiling cardiac arrhythmia and heart failure patients in India: The Pan-arrhythmia and Heart Failure Observational Study

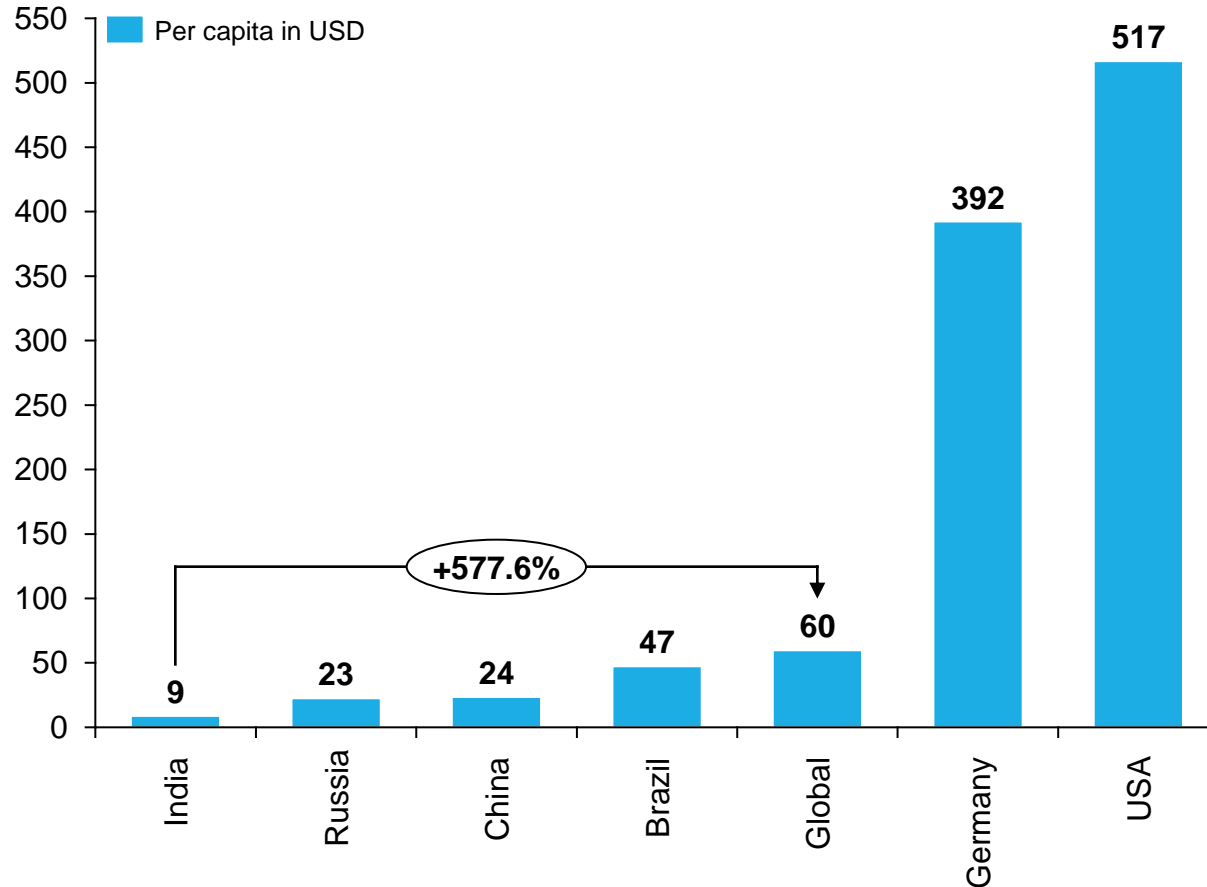
However, the overall penetration / adoption of MedTech remains low in Care pathways in India (2/2)

	General Surgery	Gynaecology	Nephrology	Orthopaedics	Auto-immune
USA	<ul style="list-style-type: none"> The percentage of general surgery procedures using robotic surgery rose from 1.8% to 17% from 2012 to 2022¹ Robotic surgeries in general surgery increased by 30% in the US in 2019 	<ul style="list-style-type: none"> Robotic procedures for gynecologic procedures increased by 6.5% in 2022² Portable Fetal monitoring devices are being used to monitor the pregnancy easily and affordable 	<ul style="list-style-type: none"> ~80,000 patients get their dialysis done by mobile devices³ 4 out of 10 surgeries are robotic 	<ul style="list-style-type: none"> 8 lakh knee transplants and over 4.5 lakh hip replacements are done in the USA every year⁴ 	<ul style="list-style-type: none"> 1 in 3 patients in USA uses wearable devices to track autoimmune disorders⁶
India	<ul style="list-style-type: none"> A few surgeries are being done using the robots; mostly done by the surgeons 	<ul style="list-style-type: none"> Robotic gynae surgeries in India are in the early development and adaptive phase 	<ul style="list-style-type: none"> Dialysis is mostly done at dialysis center or hospitals Only 3-4 cities have robotic surgery facility available 	<ul style="list-style-type: none"> 1.5 lakh knee transplants are done every year⁵ Total hip replacement surgeries done is 3646 / lakh population annually 	<ul style="list-style-type: none"> It is usually controlled by medication and life-style modification

Sources: 1,2. SM strategic market research, 3. Telemonitoring system for patients with chronic kidney disease undergoing peritoneal dialysis: Usability assessment based on a case study by PLOS, 4. Joint Replacement Surgery American College of Rheumatology, 5. PIB, 6. Monitoring Autoimmune Diseases Using the iShU App mHealth

This is reflected in the low per Capita Spending on Medical Devices in India as compared to other countries, leading to sub-optimal health outcomes

Per Capita Spend on Medical Devices (2023)



USA & Germany have the highest spend on medical devices



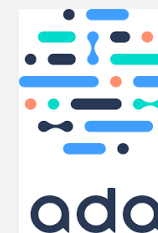
USA

- The U.S. is the largest medical device market in the world, comprising over **40% of the global MedTech market**
- From 1980-2019, **5 years were added to the U.S. life expectancy**
- **38% reduction** in no. of patient days in hospital



Germany

- Cluster programmes to collaborate & innovate between manufacturers
- **One standout Berlin-based start-up is Ada Health**



- Ada has created an **artificial intelligence (AI)** powered health platform intended to support clinical decision making
- Over **10 million assessment** are carried out (2019)
- Users can describe their symptoms to an AI powered symptom checker, which will then make a **preliminary assessment for them to take to their GP**

Source: Statista, analysis & From \$12B to \$50B: Supercharging India's Medical Device Industry Growth, Advanced medical technology association network Medical device network (Germany)

Going forward, the demand for MedTech devices is likely to be influenced by increasing healthcare infrastructure and paradigm shifts happening in care delivery

Screening & Preventive health



Remote diagnosis

Easy to operate machines can diagnose the patient sitting in a village and transmit data to be read by physician in the city

Continuous Health monitoring



M-Health

Sync data of the patient by enabling post care monitoring or early diagnosis

72.7% of the experts were extremely optimistic about reducing the long-term healthcare burden with the help of MedTech industry

- Survey Findings

Diagnosis & Consultation



Telemedicine

Patient can remotely consult a physician or specialist

Internet of Medical Things (IoMT)

Reducing the cost by maintenance remotely through central triggering mechanism

Treatment & Restoration



VR for surgery

Surgeons can perform the operations through the remote control led robots

E- ICU

Remotely monitoring vitals and trigger the patient treatment far off



Increased provider-MedTech linkage is considered critical for the growth and expansion of the industry

*""The **increased adoption of medical devices hinges on provider engagement**. Technologies like robotics offer enhanced safety and precision, benefiting both patients and healthcare professionals. However, widespread implementation faces hurdles, notably cost and reluctance from some hospitals. **To foster adoption, industry and government must collaborate on solutions that prioritize patient outcomes, creating a win-win scenario for all stakeholders.**""*

-Ravi Valia, Medtronic

*"The opportunity lies not merely in bed expansion, but in the strategic allocation of resources within hospitals. **Investing in advanced medical equipment like MRI machines or upgrading CT scanners can significantly impact Average Revenue Per Occupied Bed (ARPOB)**. However, the feasibility of high-end equipment investment, such as robotic surgery systems, hinges on ARPOB justification and the hospital's strategic focus on enhancing patient care."*

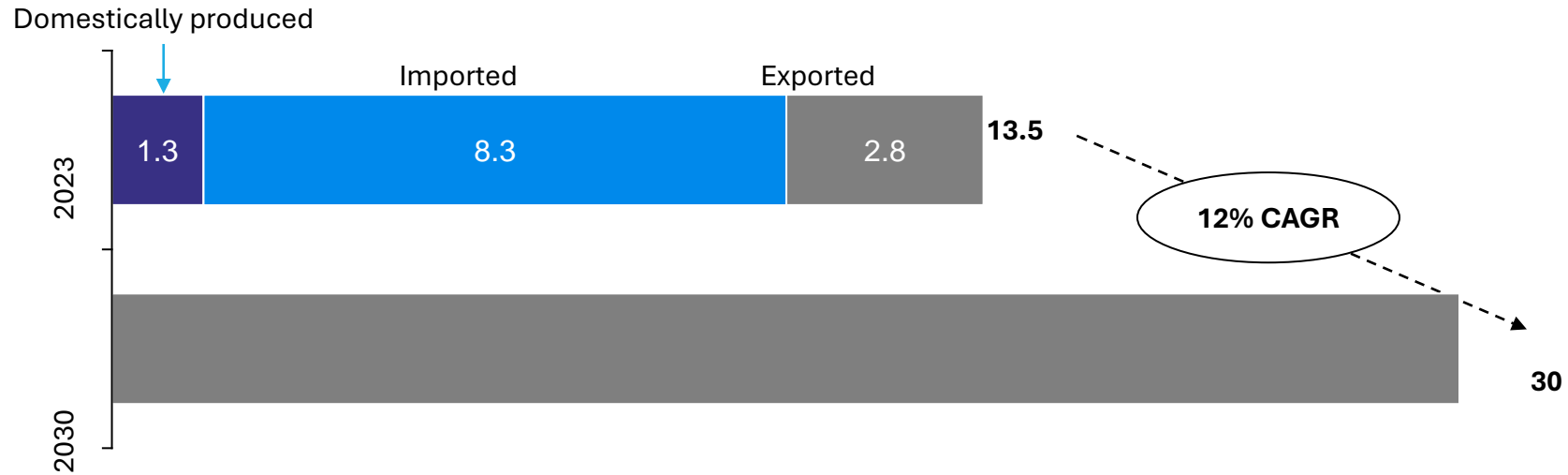
- Amit Chander, IFC

The per capita consumption of medical devices in India ranks among the lowest globally. However, this trend is expected to change as both government-sponsored health insurance/assurance programs and private health insurance penetration increases covering the bottom and top of the pyramid respectively. To enhance healthcare affordability and foster the growth of the MedTech industry, the government should assure domestic demand by expanding the scope of government health insurance schemes by including OPDs, post operative care etc. and ensuring private health insurance penetration by becoming affordable for the missing middle.

- Shobha Mishra, GE

India will have demand of \$ 30 Bn worth medical devices to meet the needs of changing healthcare and growing services

Indian MedTech Market Size US \$, Billion)



Changing Paradigm



- Chronic disease
- Population
- Elderly population
- Care delivery

Increasing demand for health infrastructure



- Hospitalization bed
- Medical devices
- Services
- Point of care solutions
- Tier 2 & 3 cities coverage

Recommendations

Increase linkage between provider and MedTech

- ❑ **A Standardized Treatment Guidelines (STGs):** Healthcare providers to create evidence-based guidelines
- ❑ Adoption of **interoperable and compatible medical technologies** and systems that facilitate seamless integration and data exchanges
- ❑ **Creation of channels** for collaboration and knowledge-sharing **between smaller and larger hospitals** to facilitate technology transfer, training, and capacity-building
- ❑ **Health Technology Assessment** that help us conduct comparative effectiveness studies, cost-benefit analyses, and user satisfaction surveys to assess the impact and value of MedTech interventions
- ❑ **Conduct training and education programs** like Workshops, seminars, and online courses that cover topics such as device operation, patient monitoring, data management, and safety protocols

Increase Insurance benefit package

- ❑ Expand packages to include **comprehensive coverage for outpatient care** (dressings, Diabetic Foot Ulcer etc.), including diagnostics, consultations, medications, and procedures
- ❑ Inclusion of wide range of **specialized diagnostic tests and procedures** specific to cancer detection, staging, monitoring, and treatment planning
- ❑ **Access to advanced diagnostics**
Technologies which includes coverage for state-of-the-art imaging techniques (e.g., MRI, PET-CT), molecular diagnostic tests and innovative biomarker assays

Easy finance options

- ❑ **Leasing and equipment rental programs** without the need for substantial upfront investment. Offer lease-to-own options, operating leases etc. for equipment upgrades or buyouts at the end of the lease term
- ❑ Develop **flexible financing solutions** tailored to the unique needs and financial constraints of providers. Offer customized financing packages with adjustable repayment terms, grace periods and interest rates
- ❑ Collaborate with equipment suppliers, manufacturers, and distributors to provide **vendor financing and supplier credit arrangements**. Negotiate favourable financing terms, extended payment terms, and deferred payment options with equipment vendors
- ❑ Advocate for **government subsidies, grants,** and financial incentives in acquiring high capex MedTech services. Lobby for funding programs, tax incentives, or low-interest loans specifically earmarked for investments in medical equipment and infrastructure upgrades in underserved or rural areas

02

Stimulating the “Make in India” ecosystem

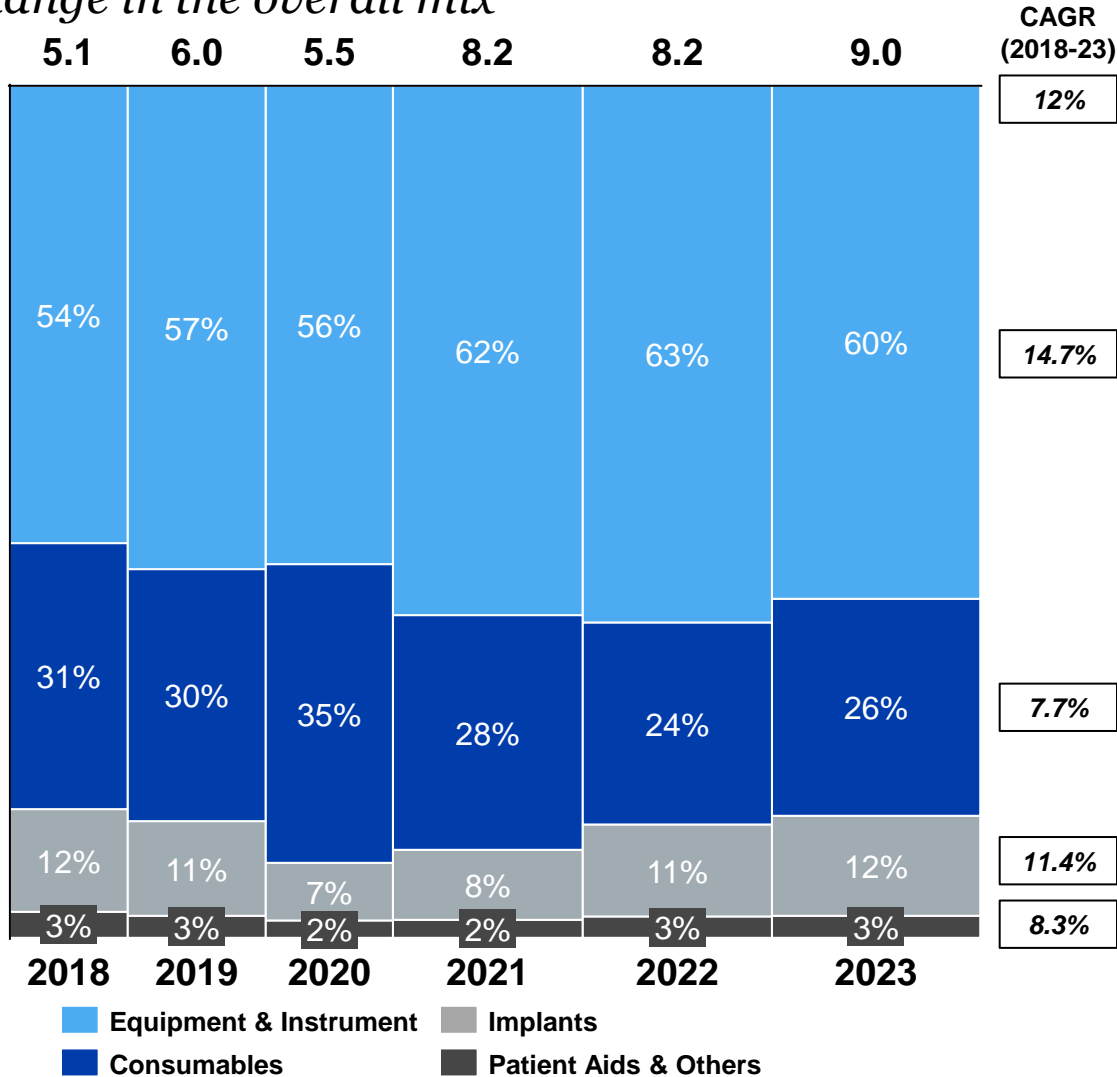
For the first time, medical device imports contracted by 4% and export grew 14% in 2023. In this trend continues, India can be import neutral by 2029

- Dr Jitendra Sharma



India MedTech industry is predominantly an import dependent Industry

Imports grew from USD 5.1 Bn to USD 9 Bn at a CAGR of ~12% between 2018-2023 with no significant change in the overall mix



Notes: Import value multiplied with 1.4 to reflect the realization achieved by manufactures
Source: PwC Analysis, Fitch report 2023, Trade map data

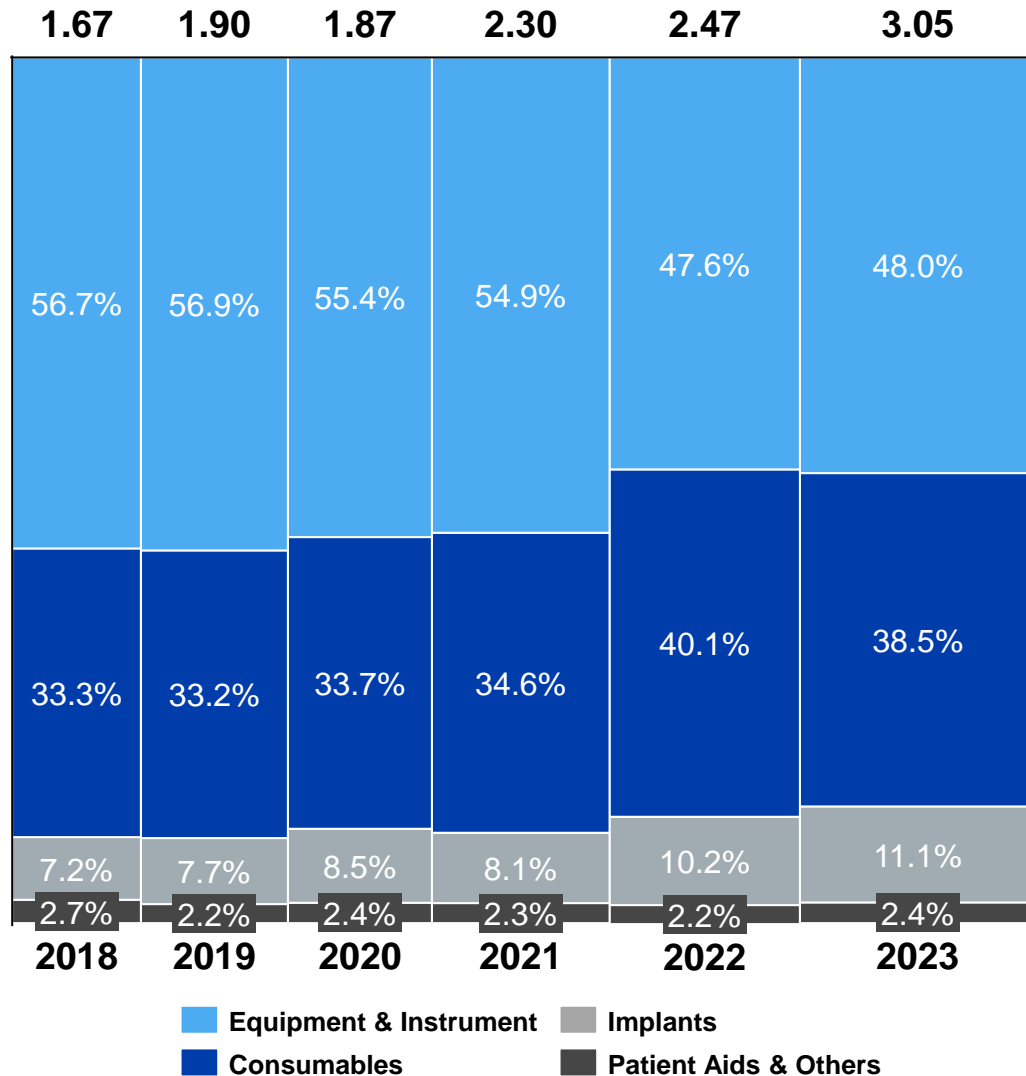


“There is no doubt over India’s intention to become a global hub for manufacturing medical devices. But for this to be a reality quickly, the ecosystem must bring together its strengths and start building its domestic market. To enhance healthcare affordability and foster the growth of the Medtech industry, the key is to **achieve economies of scale in manufacturing, increase per capita consumption of medical devices, deliver world class quality products and eventually rise up the value chain**, meeting the evolving requirements of the Indian healthcare providers, surgeons and patient community. The opportunity is ripe for India to develop as the global MedTech hub; how successfully we seize it will define the industry status. Alongside conducive industry policies, the approach towards mitigating the current challenges will help carve a niche in the global devices market and enable local manufacturers to step up for the country, powered by the ‘Make in India’ initiative.”

- Anish Bafna, CEO & MD, Healthium Medtech

Top 10 countries importing from India (USD Bn)

Exports from India has grown from USD 1.6 Bn to USD 2.23 Bn from 2018 to 2023 with a CAGR of 13%



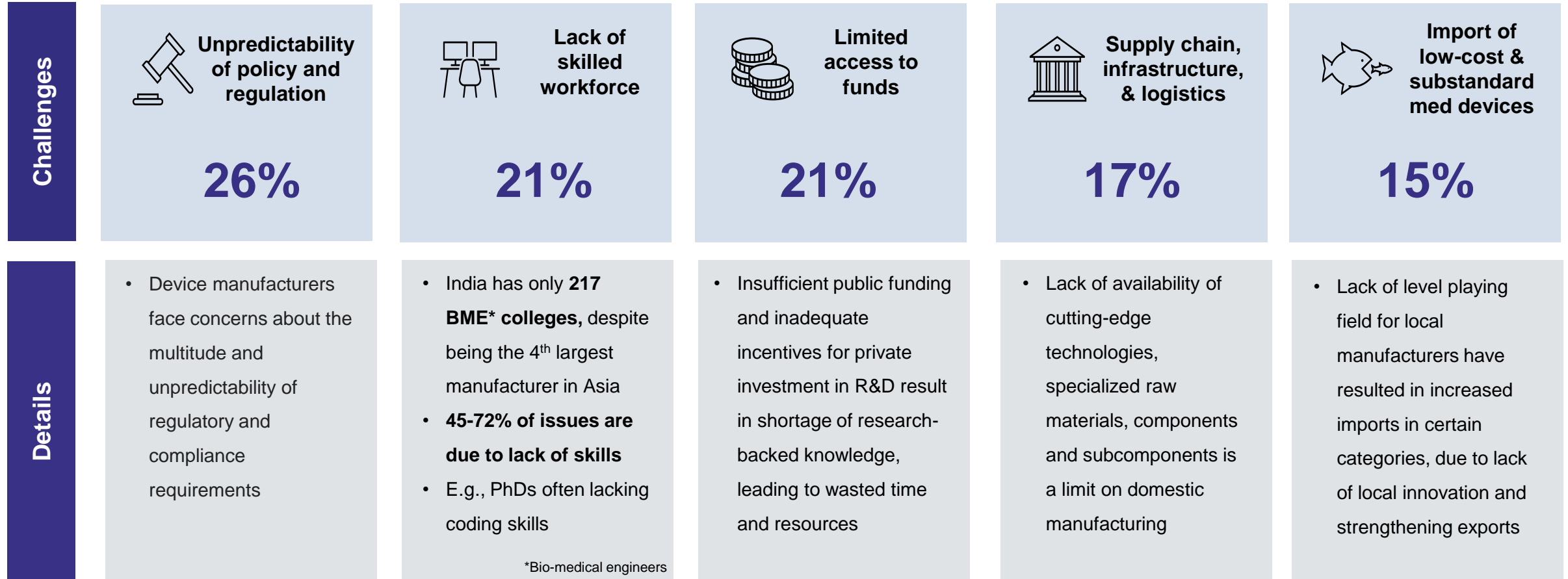
45.5% survey respondents feel a need for improvement in market access initiatives & trade agreements along with export financing & incentives (27.3%)

“The future of the Indian MedTech industry will be shaped by its ability to innovate, adapt, and collaborate effectively. **While 'Make in India' continues to be pivotal, the focus is now expanding to 'Design, Innovate & Make in India'.** Ultimately, our collective efforts are aimed at building Brand India as a synonymous with excellence, innovation, and reliability in the MedTech sector.”

- Himanshu Baid, Managing Director, Poly Medicure

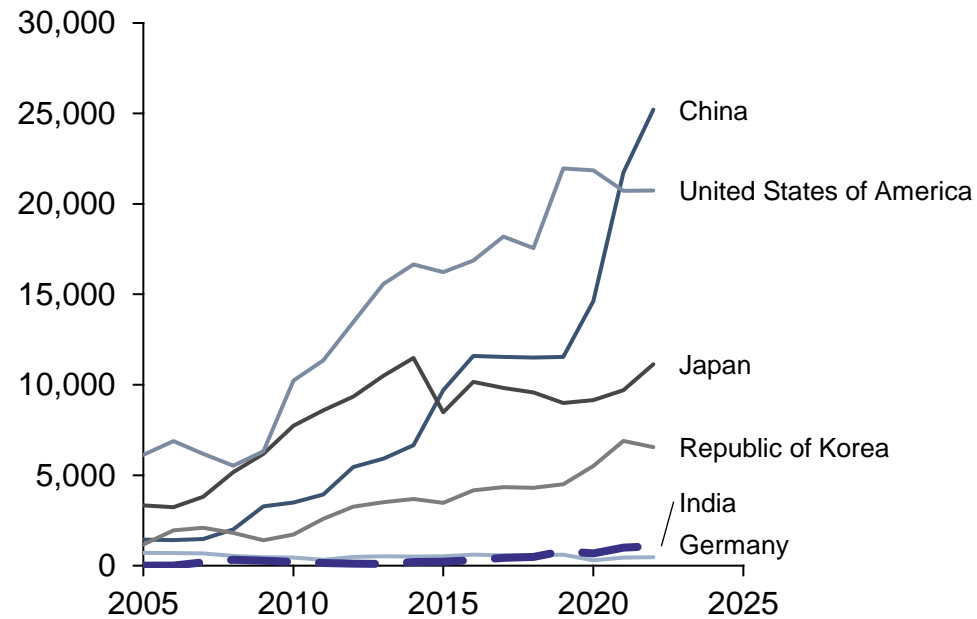
Source: PwC Analysis, Fitch report 2023, Trade map data

Low domestic manufacturing is cited as being due to a multitude of reasons like supply chain issues, domestic demand, capability, and skill-sets



The lack of local innovation is clear when comparing the number of Medical Technology patents granted to India versus to other countries

Number of Patent Grants for Medical Technology



- The annual number of patents granted to India in Medical Technology has successfully increased in the last 15 years
 - <200 in 2007 to >1000 in 2022
- They still account for <1.5% of total worldwide patents
 - >80K Patent worldwide in 2022



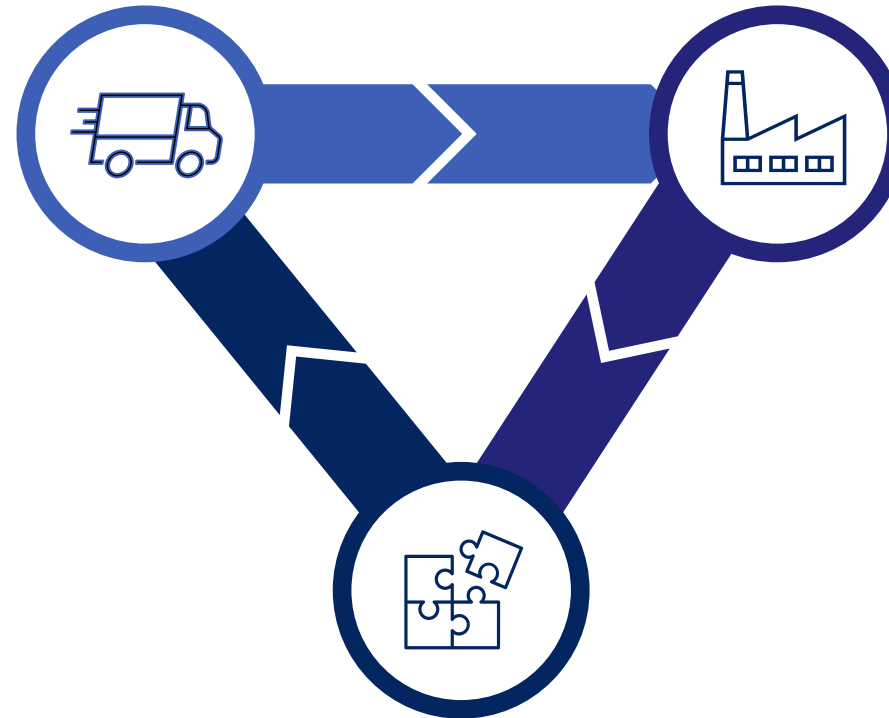
“The intersection of technology and healthcare presents immense opportunities for India's MedTech industry to drive transformative change, improve patient outcomes, and establish the country as a global healthcare hub. The MedTech industry is poised for significant growth, driven by increasing demand for quality healthcare, innovative technologies, and evolving government policies.”

- Shishir Agarwal, President and MD,
Terumo

Multiple government initiatives have already begun the process of stimulating the domestic MedTech market and unleash the industry's potential

Export Promotion and Market Access

- **Market Access Initiative (MAI) Scheme:** Acts as a catalyst for sustained export growth
- **National Medical Device Promotion Council (NMDPC):** Promotes the growth and competitiveness of India's MedTech sector
- **Free Trade Agreement (FTA) with EFTA Countries:** Developing Trade and Economic Partnership Agreement (TEPA) with Switzerland, Iceland, Norway, and Liechtenstein
- **Strategic Sector Manufacturing Initiative (SSMI):** Drives strategic manufacturing growth in key sectors, including MedTech.



Enhancing Domestic Manufacturing

- **Advancing Local Value-Add and Exports (SCALE) Committee:** Public-Private Partnership initiative focused on localization, component manufacturing, and employment growth.
- **Production Linked Incentive (PLI) Scheme:** Fosters collaboration between public research bodies and private firms for innovation and commercialization.
- **National Medical Device Policy 2023:** Aims to expand the medical devices sector for domestic and global markets

Innovation and Collaboration

- **MedTech Mitra:** Supports and mentors startups and innovators in medical technology.
- **Public-Private Research Initiative Program (PRIP):** Attracts investments and boosts domestic manufacturing for global competitiveness.

Export Promotion and Market Access

Boosting global market presence through the Market Access Initiative and National Medical Device Promotion Council

About Market Access Initiative (MAI)

Market Access Initiative (MAI) Scheme is an Export Promotion Scheme envisaged to act as a catalyst to promote India's exports on a sustained basis. The scheme is formulated on focus product-focus country approach to evolve specific market and specific product through market studies/survey. Assistance would be provided to Export Promotion Organizations/Trade Promotion Organizations/National Level Institutions/ Research Institutions/Universities/Laboratories, Exporters etc., for enhancement of exports through accessing new markets or through increasing the share in the existing markets. Under the Scheme the level of assistance for each eligible activities has been fixed.

The **National Medical Device Promotion Council (NMDPC)** was also established to **enhance competitiveness of domestic exports and brand India as a manufacturer of medical devices.**

Level of Assistance provided under MAI

- **75% of cost borne** by government for market studies
- **75%, 50% & 25% of easing and rental charges for 1st, 2nd & 3rd year** for opening showroom and warehouses
- Participation in trade fairs **will cover 2/3rd of actual expenditure under categories like venue cost, publicity cost, cost of catalogue, Interpreters charges** (ceiling of 50 lakhs) similarly for reverse visit of prominent foreign buyers
- **50% assistance for 2 years for publicity** campaign (ceiling of Rs 50 lakhs/Year/market)
- **50% of rental charges of display space in International departmental stores** will be provided as assistance
- Research & product development – selected exporters & council would assist in upgrading the product. 25% of total approved cost subjected to a **ceiling of 50 lakhs for each product** and balanced 75% would be borne by exporters

Export Promotion and Market Access

Expanding export incentives by signing FTAs with EFTA countries and through the Strategic Sector Manufacturing Initiative

India-European Free Trade Association signed Trade and Economic Partnership Agreement (TEPA), 10th March 2024

- India has been working on a Trade and Economic Partnership Agreement (TEPA) with EFTA countries comprising Switzerland, Iceland, Norway & Liechtenstein. EFTA is one important economic block out of the three (other two - EU & UK) in Europe. **Among EFTA countries, Switzerland is the largest trading partner of India followed by Norway**
- TEPA will give impetus to “Make in India” and Atmanirbhar Bharat by encouraging domestic manufacturing in different sectors including such as **Infrastructure and Connectivity, Manufacturing, Machinery, Pharmaceuticals, Transport and Logistics etc.**

Strategic Sector Manufacturing Initiative (SSMI)

- The initiative focuses on enhancing component manufacturing to **strengthen the supply chain and produce devices listed in the GTE (Global Trade Exemption) list**
- This initiative aims to **reduce India's dependency on imports by boosting domestic production capabilities.**

SWISS MEDTECH WELCOMES FREE TRADE AGREEMENT WITH INDIA

- 11 March 2024, The new FTA stipulates that India will completely abolish customs duties (currently between 11% & 13.75%) **for a substantial proportion of medtech products within a maximum of ten years – or reduce them by 50% within five years.**
- The government officials pointed out that the deal will help India diversify its pharma and chemical imports away from **China, dependence on which has been a long -standing concern for the country.**
- **Medical devices, Food Processing & Chemical sector to receive chunk of \$100 bn investment under India-EFTA FTA over 15 years**

Enhancing Domestic Manufacturing

Boosting local production and export capabilities through the Advancing Local Value-Add and Exports (SCALE) Committee

SCALE Initiative

Steering committee for Advancing Local Value – Add & Export is a PPP initiative that has been set- up to **increase localization, component manufacturing and employment in the country** and fast- tracking growth of the Indian manufacturing sector. As one of the sunrise sectors, MedTech is included in the SCALE Committee.

Sector Involved

11 sectors: auto components, automobiles (including EVs), capital goods, chemicals, drones, **medical devices**, aerospace and defense, leather and footwear, textiles, and space.

Overall Target

Increase exports in these sectors from \$160 billion to \$500 billion by 2030

Initiative for Medical Devices

Export Promotion Council* for Medical Devices under the administrative control of Department of Pharmaceuticals, Government of India, being the nodal Department for the medical devices sector.

Dr Pawan Goenka, Chairman of the Steering Committee on Advancing Local value-add & Exports (SCALE), highlighted that India is at a pivotal moment of unlocking the full potential of the manufacturing sector.

The sector currently contributes about US\$ 450 billion to India's overall Gross Value Addition (GVA), accounting for a share of about 14.6%. He mentioned that the SCALE Committee is trying to address a host of horizontal issues like demand aggregation within the manufacturing sector and across areas including, EoDB, cost-competitiveness, Brand India, etc.

- FICCI 96th meeting

Source: India-targeting-500-billion-exports-from-10-11-sectors-by-2030, Report by nbctv & FICCI – Press release & Annual report 2022-23, Ministry of Commerce & Industry

*The committee will be responsible for communication, supply, & overseas enquiry, etc.

Enhancing Domestic Manufacturing

Incentivizing domestic MedTech manufacturers through the Production-Linked Incentive (PLI) scheme

1

The success of this inaugural scheme led the government to launch the Rs. 15,000 crore PLI-II scheme, aiming to boost cost competitiveness in the global market, expand components manufacturing, and incentivize medical devices excluded from the first PLI list

2

26 Applicants for manufacturing of Medical Devices have been approved for 138 products under the PLI scheme with total financial outlay of **Rs.3,420 cr. for the period 2020-21 to 2027-28**. Investment of around **Rs. 875 crores** have already been grounded towards capacity creation under the scheme.

3

13 Greenfield plants were launched under the PLI-II towards achieving self-reliance in manufacturing of wide range of medical devices

4

Financial incentive is given to selected companies at the rate of **5% of incremental sales** of medical devices manufactured in India and covered under four Target Segments of the scheme i.e. (1) Cancer care equipment, (2) Imaging Devices, (3) Critical care devices, and (4) Body implants.

5

Penicillin G isn't produced in India since last 30 years; now it will be produced in India under the Atmanirbhar bharat

Enhancing Domestic Manufacturing

The National Medical Device Policy is shaping the future growth and regulation of the MedTech industry

National Medical Device Policy (NMDP)

Vision: The Policy envisions to place the Indian medical devices sector on an accelerated growth path with a patient-centric approach to meet the evolving healthcare needs of patients by building an innovative and globally competitive industry in India. This aim is *to emerge as the global leader in the manufacturing and innovation of medical devices by achieving 10-12% share in the expanding global market over the next 25 years.*

Mission: The Policy will facilitate the growth of the medical devices sector that not only serves the needs of the Indian market but that of global market as well.

Significance of the policy:

- The policy is expected to provide the required support and directions to strengthen the **medical devices industry into a competitive, self-reliant, resilient and innovative industry**
- It can place India's medical devices sector on an accelerated path of growth with a patient-centric approach to **meet the evolving healthcare needs of patients.**
- With the new policy in place, the Centre aims to **reduce India's import dependence to nearly 30%** in the next couple of years; **manufacturing hubs.**
- The policy **aligns with the Public Procurement Order and the Land Border Order** in letter and spirit, ensuring that growth of the sector adheres to national priorities



Survey findings:

- **81.8% of the experts feels it is important for Indian government to promote locally manufactured Med-Tech products** in private sector
- **Experts were optimistic about the recognition of 'Make in India' and 51.5% feels it is extremely important to promote locally manufactured MedTech products** in public tender

Innovation and Collaboration

Catalysing MedTech innovation and providing support mechanisms for small enterprises through MedTech Mitra

MedTech mitra | Handholding MedTech innovators for clinical evaluation, regulatory facilitation and uptake of new products
 A NITI Aayog-ICMR-CDSCO initiative

Fostering product development through Engineers- Clinicians Partnership

Handholding Support

Information cell

- Regulatory Facilitation
- Pre-clinical/clinical evaluation
- Guidelines & HTA (Health Technology Assessment)
- Uptake of new products

- Applicable standards testing and/or manufacturing facilities
- Funding Opportunities
- I.P. Advisory

Pillars of Strengths for “MedTech Mitra”	
Key facilitators	ICMR- Medical Device & Diagnostic Mission Secretariat under the guidance of NITI Aayog- Atal innovation mission
Regulatory Strategy	Partnering with the National Regulatory Authority CDSCO for regulatory strategy streamlining
Pre- compliance Gap Analysis & testing	<ul style="list-style-type: none"> • Trusted knowledge partners • Bureau of Indian Standards (BIS) • Kalam Institute of Health and Technology, Vishakapatnam (KIHT) and Andhra Pradesh MedTech Zone (AMTZ)
Pre-Clinical Evaluation	<ul style="list-style-type: none"> • State-of-art facilities with established capabilities for pre-clinical studies • ICMR- national Animal Resource Facility for Biomedical Research, Hyderabad • ICMR-DHR- large animal house facility at MATZ • ICMR Institutes
Clinical Evaluation	<ul style="list-style-type: none"> • ICMR-Intent (Indian Clinical Trial & Education Network)- Pan India network of 47 clinical centers/hospitals/medical colleges with established capacity for clinical research
Health Technology Assessment	DHR-Health Technology Assessment in India having unique capability for evaluation of appropriateness and cost effectiveness
Policies & Guidelines	DHR centers for guidelines for providing evidence-based guidelines for healthcare in India

Source: ICMR

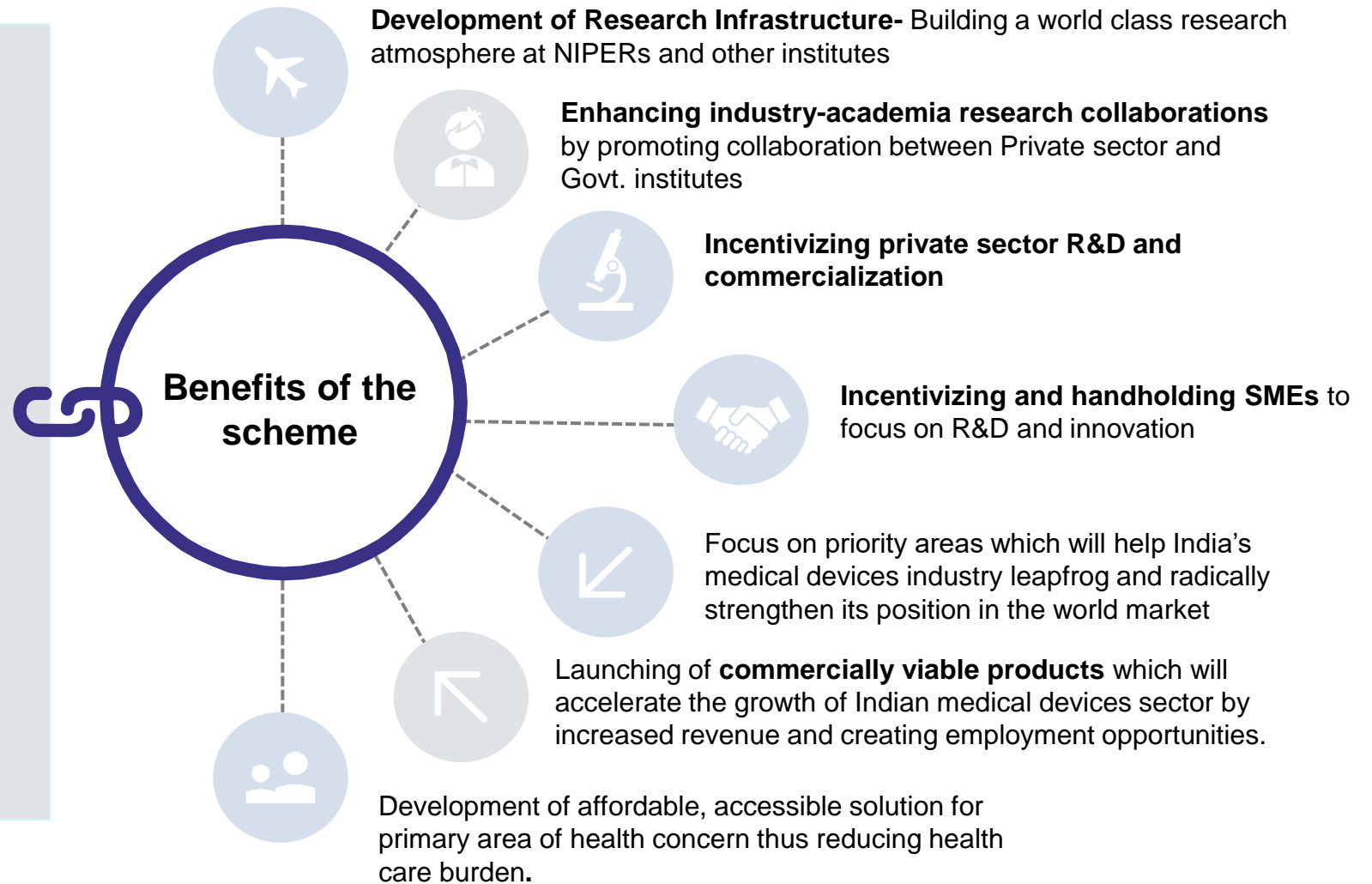
Innovation and Collaboration

Enhancing collaboration between the public and private sector through the Public-Private Initiative Program

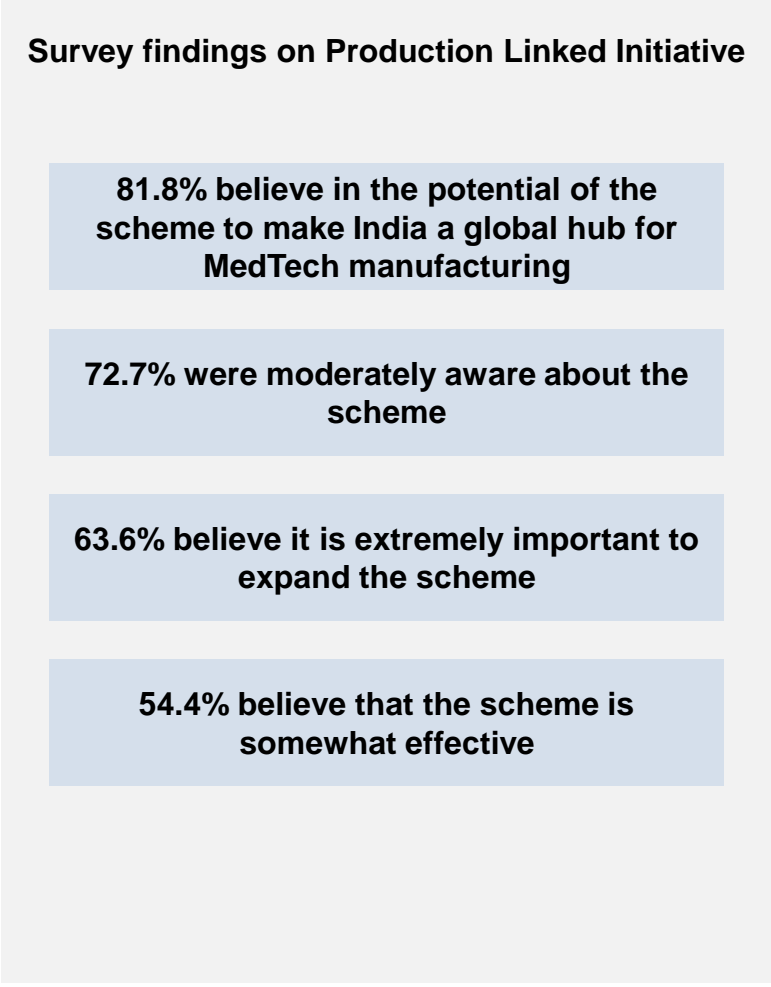
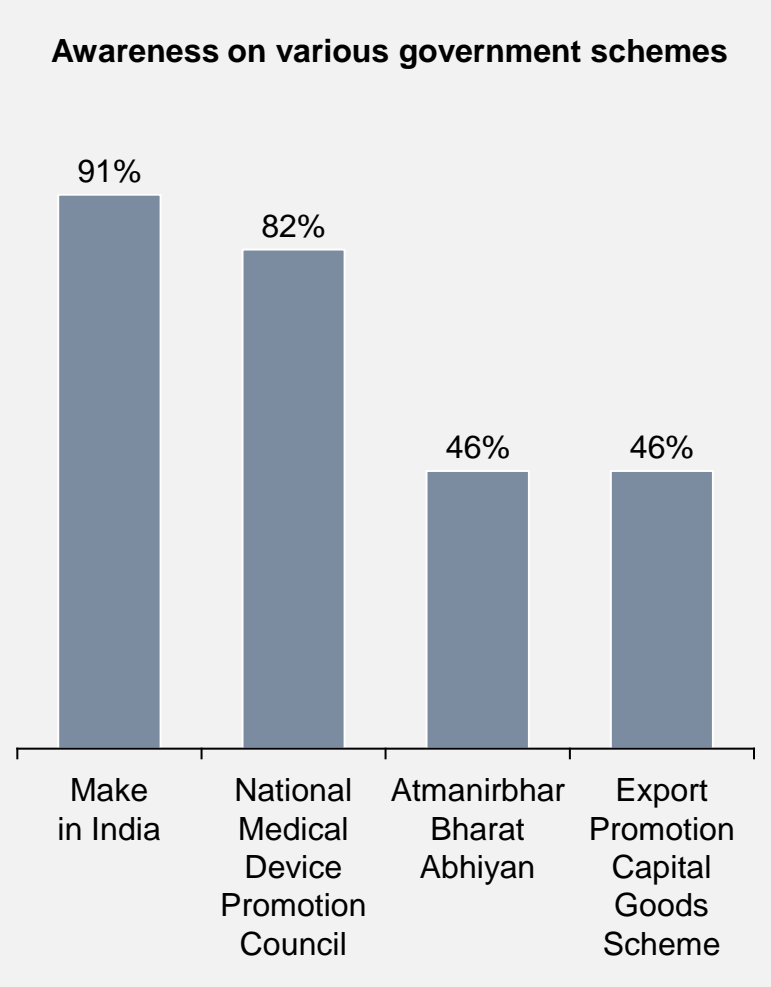
Survey findings:

81.8%

Experts believed it is extremely important for Indian government to expand & support PRIP scheme



Industry Respondents are positively aware of these multiple initiatives launched to make India a manufacturing destination for Medical Technology



- Others**
- 63.6% experts feels the main benefit of **International collaboration** in the MedTech sector is **access to advance technology**
 - 72.7% feels **academic institutes plays critical role in supporting innovation** in MedTech
 - 63.6% feels that current development in **incubator & accelerators is playing significant importance** in growth of MedTech sector

Survey revealed that 45.5% experts feels market access & trade agreement needs improvement along with export financing & incentives (27.3%)

Source: Survey findings

Atma Nirbhar MedTech Scheme for Strengthening of Medical Devices has begun to fund the strategies outlined by the National Medical Device Policy in 2023

Strategy	Regulatory streamlining	Enabling Infrastructure	Facilitating R&D and Innovation	Human resource development	Brand positioning & Awareness creation
Components	<ul style="list-style-type: none"> Streamline the "Single Window Clearance System" for licensing medical devices 	<ul style="list-style-type: none"> Establish Large medical device parks with world-class infrastructure facilities near economic zones Creating common facilities, testing labs in medical parks, greenfield and brownfield clusters Envisioned under the National Industrial Corridor Program and the proposed National Logistics Policy 2021 under the ambit of PM Gati Shakti 	<ul style="list-style-type: none"> Establish Centers of Excellence in academic and research institutions, innovation hubs, 'plug and play' infrastructures and support to start-ups 	<ul style="list-style-type: none"> Ensure a skilled workforce in the medical device sector by providing skilling, reskilling and upskilling programs through the Ministry of Skill Development and entrepreneurship Create multidisciplinary courses for medical devices Develop partnership between academia and industry around new upcoming medical technologies 	<ul style="list-style-type: none"> Create a dedicated Export Promotion Council for the sector which will be an enabler to deal with various market access issues
Progress (Funding quoted basis Scheme for Strengthening of Medical Device)	<ul style="list-style-type: none"> The Single Window System now facilitates registration and licenses for medical devices 	<ul style="list-style-type: none"> Rs. 110 cr for MedTech cluster facilities + Rs. 180 cr for deepening supply chain and reducing reliance on imports 	<ul style="list-style-type: none"> Rs. 100 cr allocated for clinical studies for new medical devices 	<ul style="list-style-type: none"> SSMI has supported skilling in the MedTech sector, through partnerships with academic institutions Rs. 100 cr allocated towards workforce capacity and skilling 	<ul style="list-style-type: none"> Export Promotion Council for Medical Devices (EPC-MD) has been launched Rs. 10 cr MedTech promotion scheme

Regulatory conformity to essential principles of safety and robust post market surveillance

International Best Practices followed by Regulators

- **Conformance to Essential Principles** or General safety and Performance Requirements
- **Use of Standards is voluntary** in nature and manufacturers have the option to select alternative solutions, thereby leaving the decision around utilization or non-utilization of standards to them
- Manufacturers may use “consensus” standards, in whole or in part, or cite Manufacturer’s own specifications.



- **In view of the rapid innovation in the medical device industry, a prescriptive standard can result in innovation being stifled, and therefore ideally standards should only focus on the requirements necessary to ensure safety and essential performance of the device**
- Conformance to essential principles helps the manufacturer to innovate products of same intended use with different technologies and allows maximum freedom for technical development
- The regulatory bodies around the world are working towards regulatory convergence thereby aligning the technical regulations, standards and conformity assessment criteria for medical devices and moving towards single set of internationally harmonized criteria



“India’s economy is poised to become the third largest by FY28 with a GDP of \$5 trillion. The healthcare market in India is thoroughly engaging with a broad spectrum of opportunities with MedTech sector declared as the Sunrise sector. The world is eyeing India as a huge investment opportunity. With transformative policy reforms to bring in ease of doing business, impetus for attracting large investments and incentives to boost local manufacturing, India has the potential to become the hub for MedTech innovation and manufacturing for the world. A regulatory policy ecosystem that is harmonized with global standards and enhances ease of doing business will encourage more manufacturers to invest in India, giving a further boost to ‘Made in India MedTech’”

**- Chaitanya Sarawate, MD, Wipro GE Healthcare, and
President and CEO, GE HealthCare South Asia**

Rule-based governance, such as the Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act, strengthen compliance with standards for quality and ethics

The Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act

- PCPNDT was enacted in 1994 to address misuse of prenatal diagnostic techniques for sex determination, leading to sex-selective abortions
- The Act sets strict guidelines and legal requirements for the use and regulation of prenatal diagnostic techniques and machinery, such as ultrasound devices, ensuring these technologies are used ethically and responsibly:
 - Mandates audits and inspections of genetic counselling centres, genetic labs, and clinics to ensure compliance with the Act
 - Requires stringent code of conduct, including reporting and record-keeping practices to monitor the use of prenatal diagnostic techniques
 - Imposes severe penalties, including fines and imprisonment, for non-compliance and unethical practices
- Enforces compliance in MedTech by setting strict guidelines for the use of prenatal diagnostic techniques, thereby preventing misuse. Also ensures high ethical standards in the industry, which protects public health and enhances trust and integrity of domestic manufacturers within India, as well as globally.

A model for future MedTech regulation



- PCPNDT demonstrates the effectiveness of rule-based governance mechanisms in MedTech, providing a model for developing similar mechanisms in other areas of the MedTech sector to ensure compliance and maintain high standards for quality and ethics.
- Forms a template for the creation of comprehensive regulatory frameworks that develop a culture of accountability, transparency, and ethical standards in the development and utilization of medical technologies.

Recommendations (1/2)

Increased allocation and spend on R&D

- ❑ **Enhanced fund for R&D** : Expansion of existing scheme like PRIP to cover more no. of institutes and medical devices
- ❑ **Technology transfer & collaboration** agreements between research institutions, industry players, and startups. Create platforms and mechanisms for knowledge exchange, technology licensing, and collaborative R&D projects
- ❑ Introduce **tax benefits and incentives for companies investing in technology** infrastructure, equipment, and talent development.
- ❑ **G2G engagements for knowledge transfer and import of specialized materials** like semiconductors, imaging sensors, and specialized electronic assemblies

Building blocks for existing manufactures

- ❑ To invest in **technology upgradation, automation, and modernization** of production processes..
- ❑ Facilitate **export promotion initiatives and market expansion** strategies to help existing manufacturers access international markets and increase their global competitiveness.
- ❑ Encourage existing **manufacturers to optimize their supply chains**, streamline operations, and enhance collaboration with suppliers, distributors, and logistics partners.
- ❑ **Awareness related to PLI, SCALE committee initiatives** for manufacturing play key role along with ensuring scalability by Market Access Schemes.

Industry Academia Collaborations

- ❑ **Establishment of Joint Research Centers**
- ❑ Organize regular **conferences, workshops, and networking events** between industry professionals and academic researchers.
- ❑ **Internship and Exchange Programs** to encourage industry professionals to serve as guest lecturers, mentors, or advisors in academic institutions
- ❑ **Joint Funding Opportunities** to provide **financial incentives and matching grants** to encourage industry investment in research and development activities conducted in partnership with academic institutions.
- ❑ Strengthen the capacity of **Technology Transfer Offices (TTOs)** within academic institutions to facilitate the commercialization of research findings and intellectual property.

Recommendations (2/2)

Assured demand & Procurement

- ❑ Develop a comprehensive **strategy for assessing demand and forecasting procurement** needs..
- ❑ **Long-Term Procurement Contracts** to negotiate favorable terms and conditions that promote competitiveness, quality, and innovation. Preference should be given to Make In India suppliers
- ❑ **Public-Private Partnerships (PPPs)** to leverage private sector expertise, resources, and efficiencies to enhance the effectiveness and efficiency of procurement processes.
- ❑ Implement policies and incentives that prioritize the **procurement of goods and services from domestic suppliers** and manufacturers, particularly in strategic industries and critical sectors.

Global Standardization

- ❑ **Standards serving as a basis for technical regulations should be appropriate for use.**
 - International standards to be used (unless there is evidence that they would not achieve a defined public policy).
 - Use Performance Standards (instead of Design Standards).
- ❑ **The regulatory system to provide sufficient flexibility to reflect or respond to changes in the regulated environment, such as evolving science and technology.**
 - The use of parts of standards and/or combinations of standards to be acceptable for conformity assessment purposes.
 - The use of other objective evidence may be used in lieu of using any standard, even if there is an available standard, to demonstrate conformance to the essential principles.
- ❑ Introduction of **robust Post Market Surveillance** mechanism to affirm quality of the medical device as well as make improvements, if needed

03

Promoting Device Led Digital health adoption



Digital health tools enhance healthcare governance, optimize care delivery, and improve healthcare access through the integration of digital technologies

Digital Health Segment	Description and Potential Impact
Healthcare Delivery	<ul style="list-style-type: none"> Integration of digital tools such as telemedicine, EHRs, and mobile health apps enhances the provision of healthcare services Improved access to healthcare, especially in remote and underserved areas, leading to timely diagnosis and treatment.
POC	<ul style="list-style-type: none"> Technologies that enable healthcare professionals to deliver and document patient care efficiently at the PoC, improving accuracy and timeliness Enhanced patient care through real-time data capture and reduced errors in documentation.
Rule-Based Governance	<ul style="list-style-type: none"> Digital frameworks ensure compliance with healthcare regulations and standards, maintaining data integrity and security Increased trust in the healthcare system through transparent and secure data management.
Skilling & Training	<ul style="list-style-type: none"> Digital platforms are utilized to enhance healthcare professionals' skills through online courses, virtual simulations, and e-learning modules Continuous professional development and upskilling, leading to improved healthcare delivery.

Health Stack Component	Description and Potential Impact	The health stack also includes: <ul style="list-style-type: none"> Data Standards and Interoperability Security and Privacy Protocols Analytics and AI
Health IDs	<ul style="list-style-type: none"> Unique identifiers facilitate seamless access to health records across different providers Efficient patient identification and record management, enhancing continuity of care. 	
Electronic Health Records	<ul style="list-style-type: none"> Digital repositories of patients' medical histories enable easy information sharing and updating Improved coordination of care and reduced duplication of tests and procedures. 	
Telemedicine Platforms	<ul style="list-style-type: none"> Platforms support remote consultations, improving accessibility and convenience Increased healthcare access and reduced burden on physical healthcare facilities. 	
Health Data Analytics	<ul style="list-style-type: none"> Data analytics monitor, evaluate, and enhance healthcare services Data-driven decision-making leading to improved healthcare outcomes and resource allocation. 	

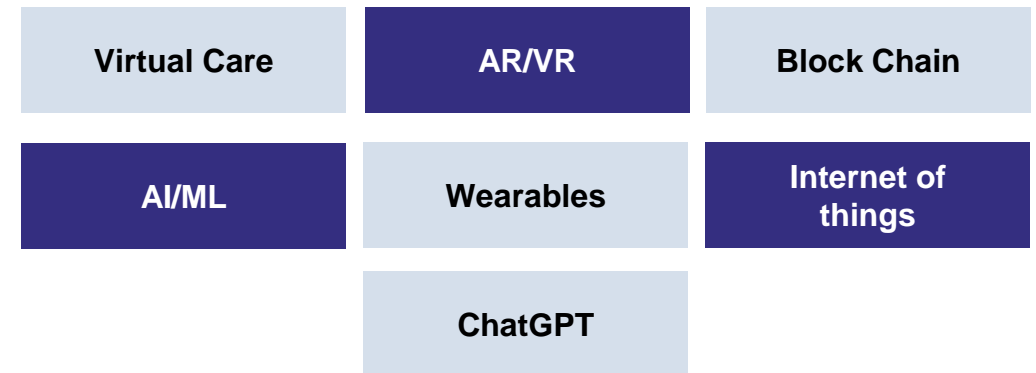
Areas of Improvement	Approaches
Enhanced Governance	Data-Driven Decision Making: Use analytics to inform policy and operational decisions. Transparency and Accountability: Implement robust data governance frameworks to ensure compliance and ethical use of data.
Optimized Care Delivery	Integrated Care: Use EHRs and HIE to provide a holistic view of patient health, enabling coordinated care. Personalized Treatment: Leverage AI and analytics to tailor treatments to individual patient needs.
Improved Access	Telemedicine and mHealth: Expand telemedicine services and mobile health applications to reach underserved populations. Affordable Solutions: Develop cost-effective digital health tools to make healthcare more accessible.

Digital Health has the potential to improve the healthcare outcomes exponentially

WHO definition, Global strategy 2020-25

- Digital health is understood to mean “**the field of knowledge and practice associated with the development and use of digital technologies to improve health**”.
- This definition encompasses eHealth, Digital health expands the concept of eHealth to include digital consumers, with a wider range of smart and connected devices.
- It also encompasses other uses of digital technologies for health such as the **Internet of Things, advanced computing, big data analytics, artificial intelligence including machine learning, and robotics.**

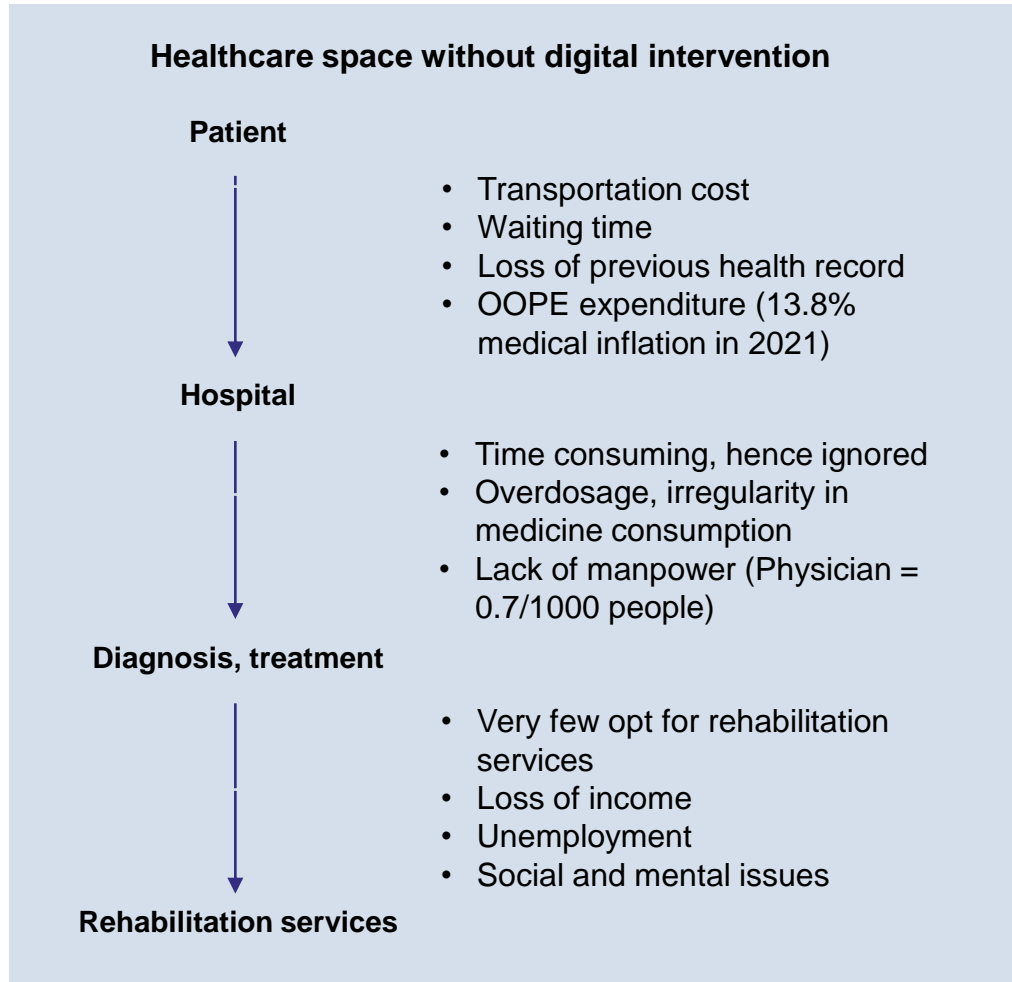
Emerging technologies act as enablers for the initiatives in digital healthcare ecosystem



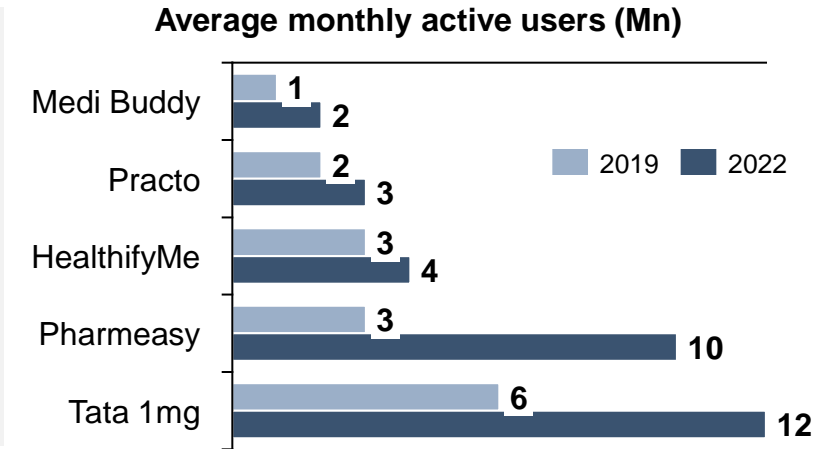
As per the survey, it has been perceived that **AI/ML & 3D printing will have a significant impact on MedTech.** Considering the growth, the top priorities are:

- 1) **Quality manufacturing & increase in utilization** in healthcare delivery system (63.6%)
- 2) **Strengthening healthcare infrastructure** for sustainable growth (45.5%)
- 3) Investing in **research & development** (36.4%)

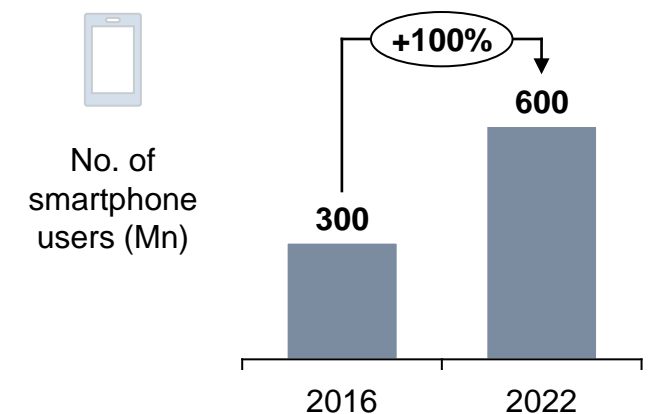
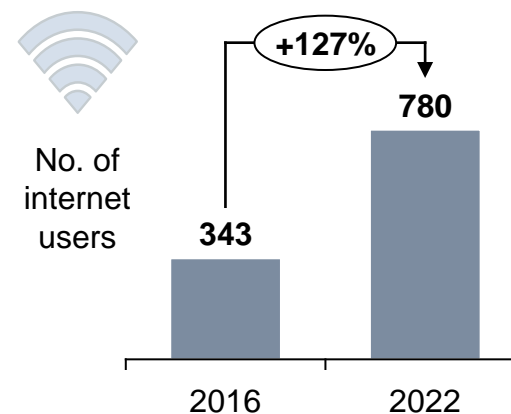
Digital health can eliminate the gaps in the care delivery



- E-Sanjeevani (consultation) has served 100 Mn (as of Jan 2023)
- More than 52.5 Cr ABHA ID created (as of 6th Feb 2024)
- Health claim exchange process also digitised

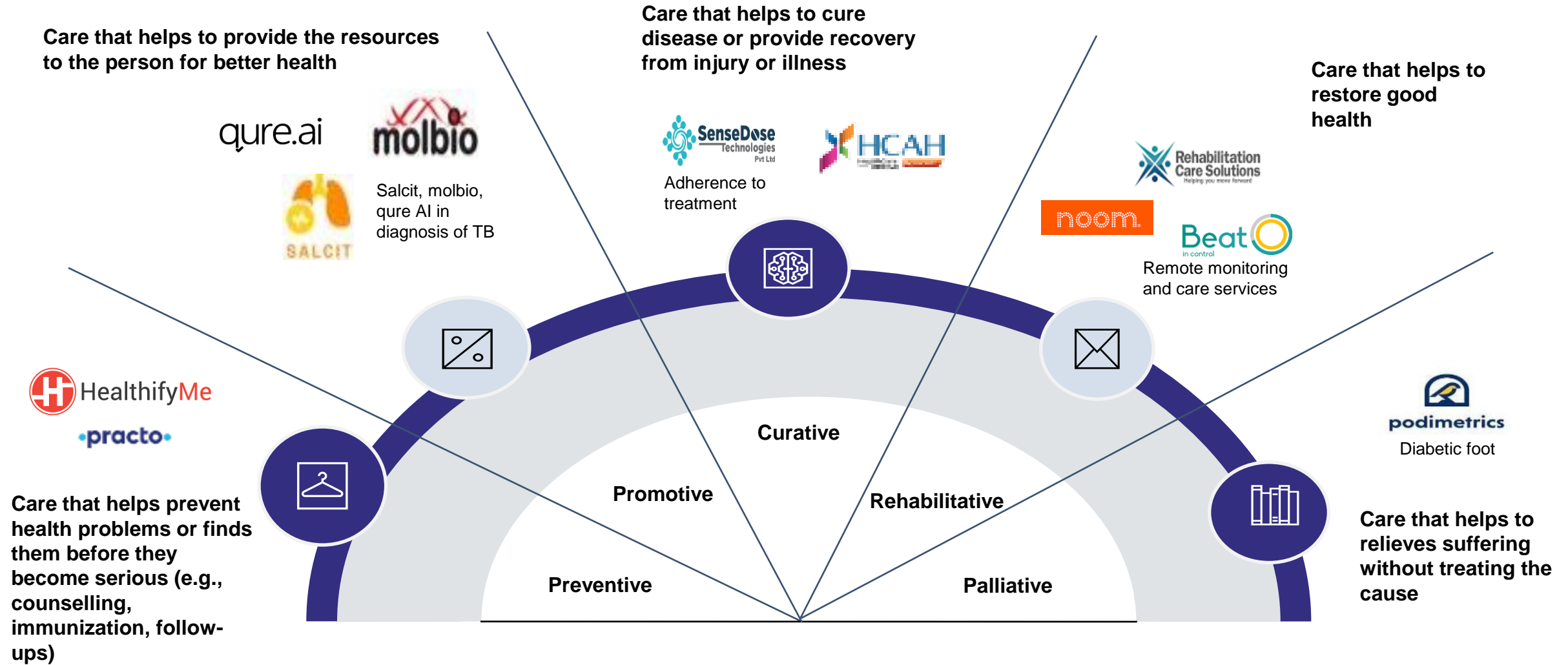


Factors responsible for growth of digital health










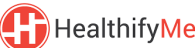






Source: A digital pill for revolutionizing healthcare, BCG report (Oct 2024), & PIB reports on ABHA ID

The role of Digital Health Technologies spans across the continuum of care







Source: Websites of various organization

Adoption of these technologies can help deliver new forms of care as seen in India

	Player Category	Core Offering	Preventive	Screening and Diagnosis	Treatment	Chronic management	Example
	E-pharmacy	Online medicine retail		✓	✓	✓	
	E-diagnostics	Home collection of samples and digital reports		✓		✓	
	Online consultation and Tele medicine	Voice/ Video consultation, remote ICU monitoring			✓	✓	
	Wellness and Personal Health	Fitness and healthy lifestyle	✓				
	Home health	Chronic skilled care at home				✓	
	Deep tech diagnostics	Use of AI/ ML for diagnostics		✓			
	Disease management	Use of AI/ ML for chronic disease management				✓	

Source: Website of various organization

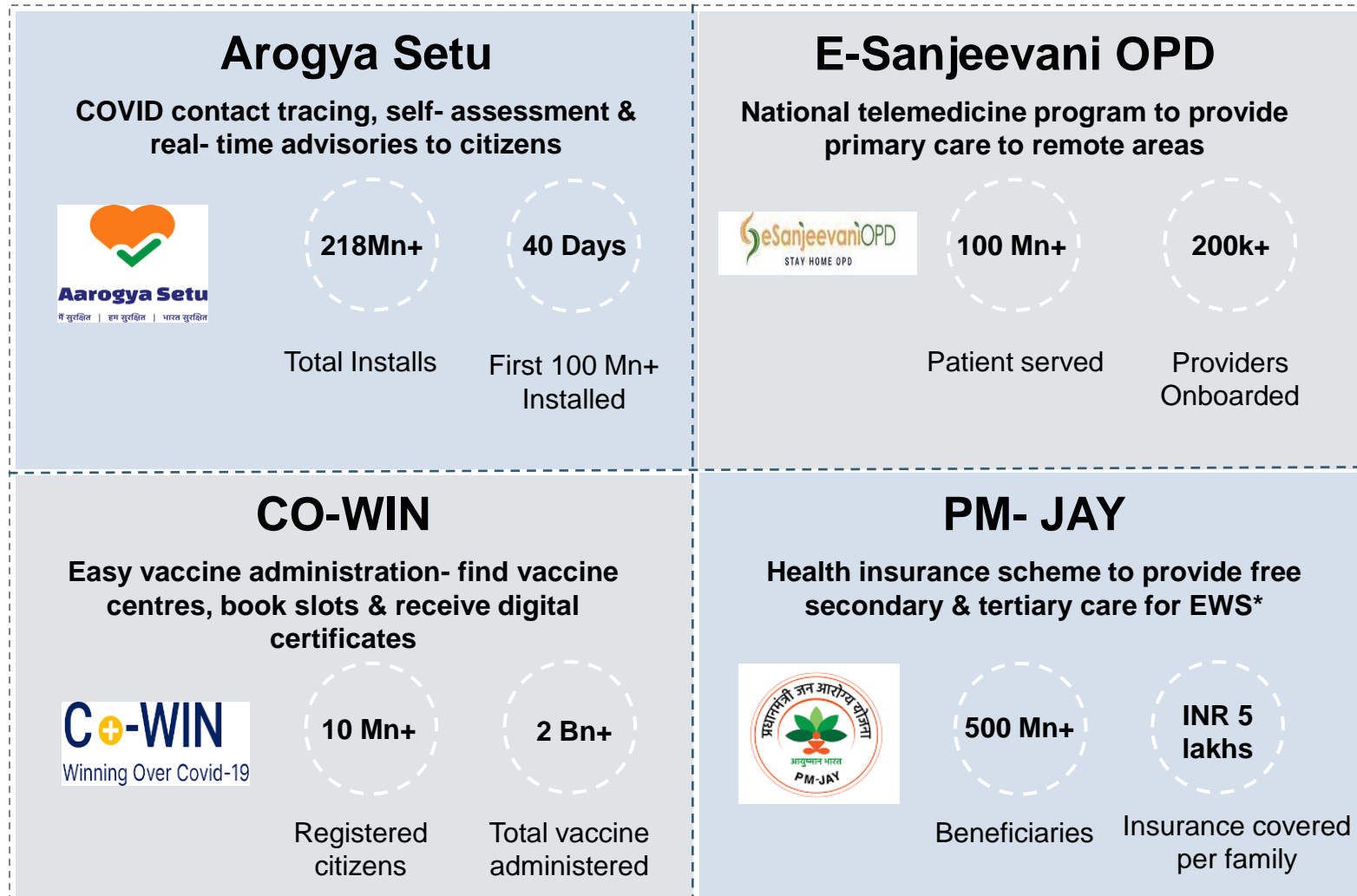
Some recent Digital Health innovations highlight the potential of digital health in addressing public health requirements

Organization	Disease covered	Technology	Remote access	Affordability	Data capture	Services	Level of care	India to world	Saves time	Self- test	Quality of result	Manpower
	Tuberculosis	Artificial intelligence	Yes	Yes	Yes	Mass Screening	Primary	12+ countries	Yes	No	90% sensitivity	Absence of radiologist
	Tuberculosis	Cough sound analysis	Yes	Rs. 5 / test	Yes	Screening	Primary	4+ country approvals	15 sec	Yes	90.36% sensitivity and 84.67% specificity	Radiologist not required
	Diagnosis / Lab test at PHC level	AI/ ML	Yes	Yes	Yes	Diagnosis	Primary	No	Provide 30+ test result in 15 min	PoC	90% -n92% sensitivity	ASHA workers
	Vector borne disease	Internet of things	Yes	NA	Yes	Surveillances	Primary	USA & South Africa	Yes	Yes	NA	Not required

Note: Light blue filling means the category is well-fulfilled, while grey means indicates areas where growth is needed

Most of the digital health solutions are scalable, affordable, accessible and providing the best delivery of care to the patients

Government is leading a digital health initiative to ensure healthcare accessibility & affordability



**Ayushman Bharat
Digital Mission**

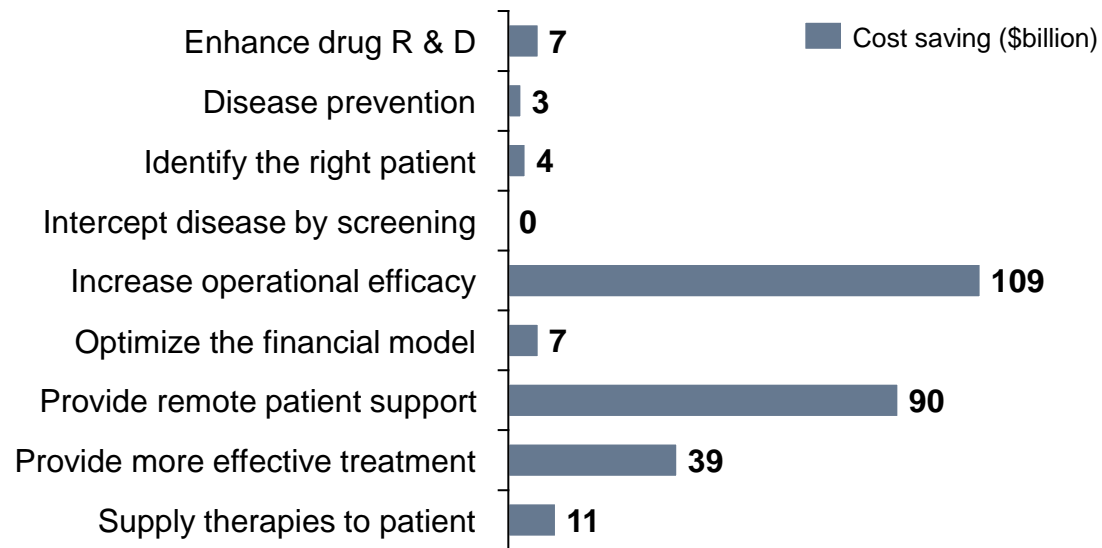
Bringing existing healthcare ecosystem online via unique digital IDs and digitizing all parts of the value chain

- 380Mn+ Health IDs created
- 20 Mn+ Health Facilities Registered
- 1.7 Mn+ Health Professional Registered

*Economically weaker section

Real world evidence data has highlighted the improvement in outcomes using digital technologies

Care delivery pool represents ~55% of the direct cost-saving potential associated with digital technologies (USA)



Cost saving in various areas (USA)

- One of the primary value propositions offered by digital health technologies is healthcare cost reduction.
- **Based on 2018 healthcare spend information, digital health interventions alone have the potential to save the US healthcare system an estimated \$500 billion if fully adopted.**

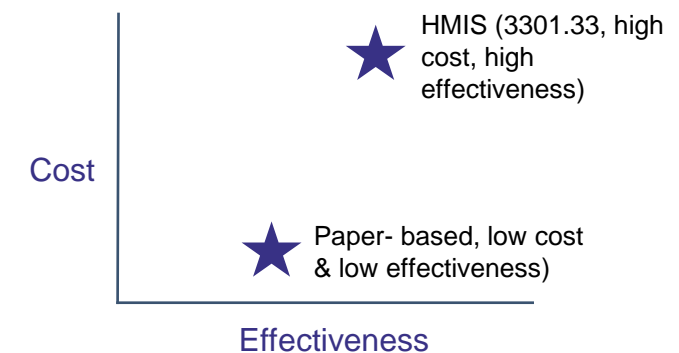
24 Government hospitals in Tamil Nadu were studied, 13 had HMIS. The data was compared to study the impact of adoption



New patient time taken to register was 0.86 second lower. For 100 patient, 22.76 min are saved each day.



Incremental cost-effective ratio (ICER)



Other benefits observed were:

1. Improvement in clinical flow
2. One-time registration
3. Increased computer literacy
4. Reduction in medical error
5. System transparency

Recommendations

Inclusion of services in Insurance package and allocating funds

- ❑ Expand insurance benefit packages to include **comprehensive coverage for telemedicine services**, including virtual consultations, remote monitoring, and telehealth platforms
- ❑ **Value- Based Reimbursement model for digital health** -Tie reimbursement rates to performance metrics such as clinical effectiveness, patient satisfaction, and healthcare utilization to encourage the adoption of digital health solutions
- ❑ To improve diagnostic accuracy, treatment outcomes, and patient care. **Include coverage for AI-powered medical imaging analysis**, predictive analytics etc. that complement traditional healthcare services
- ❑ Develop **patient education and engagement programs** to raise awareness about the benefits of telemedicine, AI, and digital health technologies covered by insurance benefit packages
- ❑ India must **ensure allocation of funds to boost digital infrastructure & capabilities** as per NMDP investing in 5G & IoMT will be the key in expansion of innovation

Leveraging capability of SIMD & SAMD

- ❑ **Foster collaboration between stakeholders in SIMD** (Software-Intensive Medical Devices) and **SAMD** (Software as a Medical Device) sectors to leverage collective expertise, resources, and capabilities
- ❑ Actively **participate in international standards development organizations** and regulatory forums to contribute to the establishment of global standards and regulatory frameworks for SIMD and SAMD
- ❑ Advocate for **regulatory convergence and harmonization** initiatives to facilitate market access and regulatory compliance for SIMD and SAMD products on a global scale and **formulating the regulatory framework for medical devices with software & AI**. Subsequently the regulatory reliance model can be incorporated into the guidelines
- ❑ Develop **targeted export strategies, participate in international trade fairs and exhibitions**, and establish distribution channels and partnerships in key markets to increase global competitiveness and market related to SIMD & SAMD

Linkage b/w smaller & Larger hospitals

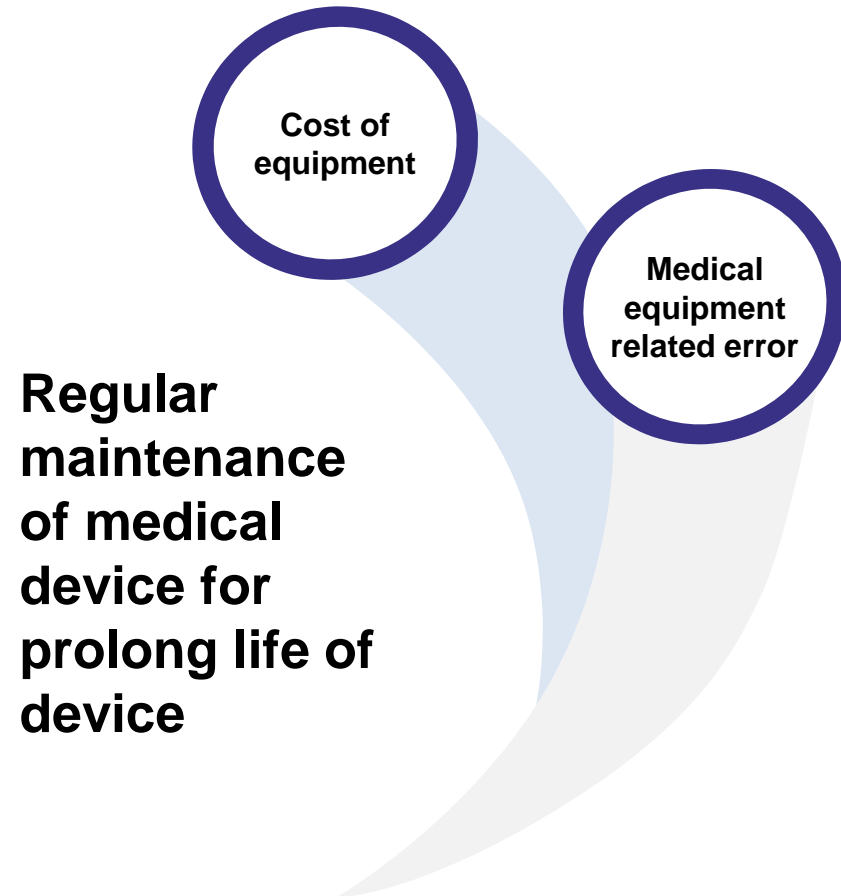
- ❑ Implement **telemedicine and virtual consultation platforms** to enable smaller hospitals to access specialist expertise and consultation services from larger hospitals and quaternary care centers remotely.
- ❑ Develop **standardized protocols, communication pathways, and electronic referral systems** to streamline the process and ensure continuity of care.
- ❑ **Collaborative Research and Quality Improvement Initiatives** to support joint research projects, clinical trials, and quality improvement programs that leverage the expertise and resources of all stakeholders.
- ❑ **Clinical Training and Mentorship Programs** to facilitate structured rotations, observerships, and continuing medical education (CME) opportunities to enhance skills and knowledge transfer.
- ❑ Expand **rule-based governance mechanisms** (such as PCPNDT) and the **single window clearance system** to ensure standardized quality and streamlined processes across businesses

04

Promoting Safe usage of Medical Devices



Need for regular maintenance of equipment's (AMC & CMC) and patient safety

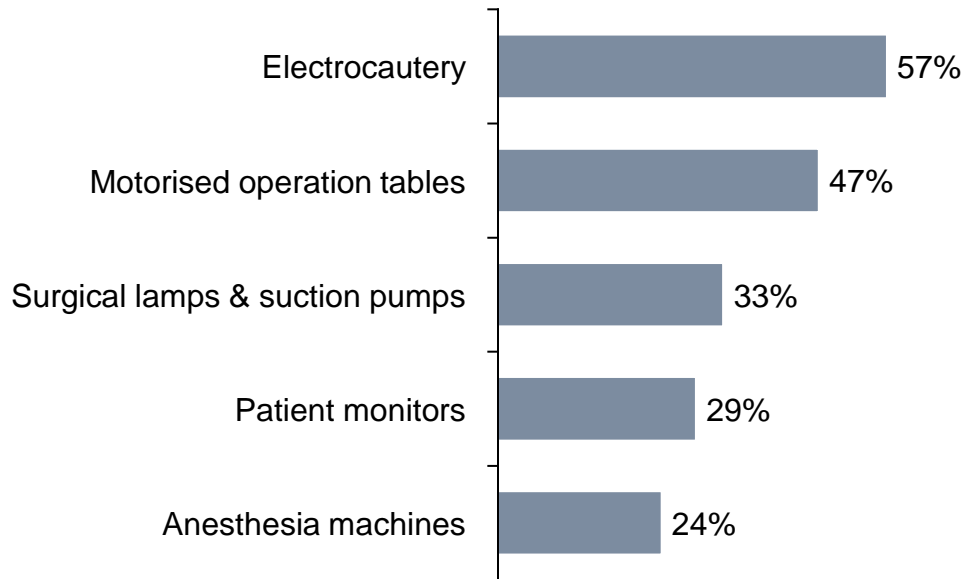


- Studies indicate that annual medical equipment maintenance and management **cost is approximately 1% of the total hospital budget**
- Statistics accumulated by The Joint Commission (TJC) show **medical equipment-related “sentinel events” is typically among the top ten medical errors** (i.e., unexpected occurrences involving death or serious physical or psychological injury, or the risk thereof).
- Therefore, hospitals and healthcare organizations must ensure that their critical medical devices are safe, accurate, reliable and operating at the required level of performance

Need for regular maintenance of equipment's (AMC & CMC) and patient safety - Equipment in range of 13% to 34% were found dysfunctional across states

Regular maintenance is needed since, 75% of the medical devices in India are imported and 30% are 'out of service'. **As identified by a recent study covering one of the largest public hospital in South India.**

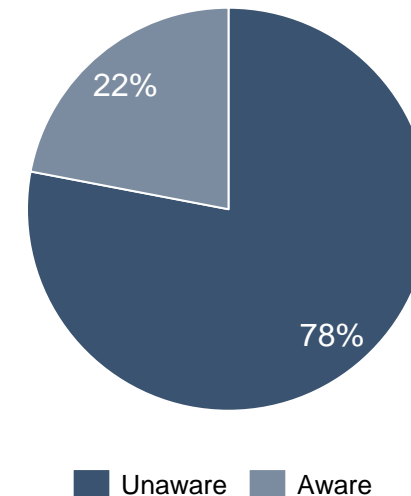
Common medical safety device incidence reported by clinicians in India



Common incidence reported

■ % of incidence

Awareness related to electrical safety testing procedure for medical equipment



Failure of regular maintenance of medical devices directly affects patient safety (Example Infusion Devices, Patient Monitors and Alarms)

Device type	Selected advisories, alerts, and warnings	Notes and recommendations for safer device use
<p>Infusion devices</p>	<ul style="list-style-type: none"> • Sentinel event alert: • Tubing misconnections • Advisory: Smart infusion pump technology 	<ul style="list-style-type: none"> • A total of 30%-60% of all harmful intravenous medication errors are directly associated with infusion pumps • Use distinct and dedicated infusion pumps for different applications (eg, epidural vs intravenous) <p>Promote the design of incompatible devices to physically prevent Misconnections. Use the data generated by infusion devices to monitor compliance with local policies and evaluate overrides from a systems perspective</p>
<p>Patient monitors and alarms</p>	<ul style="list-style-type: none"> • Top 10 hazards • NCPS 2009 Advisory • AD09-09 “Alarms on bedside physiological monitors” • Advisory: Alarms on bedside physiological Monitors 	<ul style="list-style-type: none"> • Regularly verify that bedside and central alarm volume settings are appropriate. Disable the ability to set alarms at less than acceptable levels for the specific setting • Identify and reduce causes of excessive false alarms; patient-sensor interface is an area where appropriate skin preparation and other actions can reduce false alarms • Review need for alarm enhancement or consolidation systems, particularly where the physical layout of the setting compromises the ability to hear, see, or otherwise detect alarms • Evaluate devices for logical, safe, and facility-appropriate alarm capabilities



Patient awareness plays a critical role in ensuring safe and effective usage of medical devices

1

Optimal treatment outcomes - Patient awareness enables individuals to understand the proper usage and benefits of medical devices, leading to better treatment outcomes.

2

Prevention of adverse events - Awareness of device usage guidelines helps patients avoid potential complications or adverse events associated with improper usage.

3

Enhanced disease management - Educated patients are better equipped to manage their medical conditions by using devices correctly

4

Reduced healthcare costs - Patient awareness contributes to the efficient use of medical resources and minimizes healthcare costs associated with preventable errors or misuse of devices

5

Empowerment of self management - Awareness empowers patients to take an active role in their healthcare and promotes self-management of chronic conditions

6

Long term device compliance - Patients who understand the importance of correct device usage are more likely to adhere to treatment protocols and continue using the prescribed devices consistently over the long term

The current equipment maintenance policy for medical devices in India primarily revolves around ensuring the safety, efficacy, and reliability

Continuous Improvement

- Healthcare institutions **continuously review and update their equipment maintenance policies and procedures** to incorporate best practices

Quality Assurance and Audits

- **Internal audits and periodic inspections help identify areas for improvement** and ensure adherence to maintenance protocols.

Adherence to Standards

- Medical equipment **maintenance practices adhere to national and international standards** such as ISO 13485 and ISO 14971

Documentation and Record-keeping

- **Accurate documentation ensures compliance with regulatory requirements and facilitates audits and inspections.**



Regulatory Framework

- The rules mandate that medical devices **comply with specified standards and quality requirements**

Maintenance Requirements

- **Regular maintenance schedules are recommended for all medical equipment based on manufacturer guidelines and usage patterns.**







Service Contracts

- Healthcare providers often enter into service **contracts with original equipment manufacturers (OEMs) or third-party maintenance providers** for the upkeep of medical devices.

Training and Education

- Training programs may be **organized by equipment manufacturers, healthcare institutions, or professional associations.**

Different organizations are offering courses in upskilling for medical devices domain

Organizations	Background	Key role	Offerings	Courses/training offered - Illustrative
<p>Andhra Pradesh MedTech Zone (AMTZ)</p> 	<p>AMTZ is India's first and only dedicated medical technology manufacturing zone, established to promote indigenous manufacturing of medical devices.</p>	<p>AMTZ plays a crucial role in skilling initiatives by providing specialized training programs for healthcare professionals, technicians, and engineers involved in medical device manufacturing and usage.</p>	<p>The zone offers state-of-the-art infrastructure, including laboratories, testing facilities, and training centers, to facilitate hands-on training and skill development in medical device technology.</p>	
<p>National Skill Development Corporation (NSDC)</p> 	<p>NSDC is a public-private partnership organization mandated with skill development initiatives across various sectors, including healthcare</p>	<p>NSDC collaborates with skill councils, training providers, and industry stakeholders to develop skilling programs, curriculum frameworks, and certification standards for medical device usage.</p>	<p>The corporation supports skill development projects and initiatives aimed at enhancing the employability of healthcare professionals and meeting the evolving needs of the healthcare sector.</p>	<p>Technical Intern Training Program</p>
<p>National Health Systems Resource Centre (NHSRC)</p> 	<p>NHSRC is a technical support institution under the National Health Mission (NHM), tasked with providing technical assistance and capacity-building support to state health departments and other stakeholders.</p>	<p>NHSRC plays a role in promoting the safe usage of medical devices by developing training modules, guidelines, and protocols for healthcare providers.</p>	<p>The center conducts training programs, workshops, and knowledge-sharing sessions on medical device management, maintenance, and quality assurance to improve healthcare service delivery.</p>	
<p>National Health and Paramedical Council</p> 	<p>It is a regulatory body responsible for setting standards, accrediting training institutions, and certifying healthcare professionals in various paramedical fields, including medical device operation and maintenance.</p>	<p>The council establishes competency standards, conducts examinations, and grants certifications to individuals demonstrating proficiency in medical device usage.</p>	<p>By ensuring that healthcare professionals meet prescribed competency standards, the council plays a crucial role in promoting the safe and effective usage of medical devices in healthcare settings.</p>	<ul style="list-style-type: none"> • Medical Device Regulatory Affairs • Medical Device Design and Development • Biomedical Instrumentation

Source: Websites of various organisation

Recommendations

Include of AMC / CMC regimen in regulatory and accreditation standards

- ❑ Establish **mechanisms for monitoring compliance** with AMC/CMC requirements during the accreditation process.
- ❑ Require healthcare facilities to adhere to **manufacturer guidelines when entering into AMC/CMC contracts**, ensuring that maintenance activities are performed according to the manufacturer's recommendations.
- ❑ Define **specific criteria that AMC/CMC contracts** must meet to be considered valid within the accreditation standards.
- ❑ **NABH to revise its accreditation standards** to include the requirement for healthcare facilities to maintain **valid AMC or CMC for all medical devices**.

Joint initiatives for bio – Medical Engineering training

- ❑ Form partnerships between healthcare institutions, universities, industry associations, and government bodies to **develop collaborative training programs for Bio-Medical Engineering (BME) students**.
- ❑ Work together to **design a curriculum** that aligns with industry standards and regulatory requirements for BME training. Incorporate practical, hands-on training modules that allow students to **gain real-world experience**
- ❑ Create opportunities for BME students to participate in **internships and apprenticeships** at healthcare facilities, biomedical equipment companies, and research laboratories.
- ❑ Foster a **culture of research and innovation** by providing resources and support for BME students to engage in research projects related to medical device development, improvement, and safety.

Linkage b/w smaller & Larger hospitals

- ❑ **Encourage healthcare providers** to play an active role in educating patients about medical device safety during consultations, follow-up appointments, and hospital stays.
- ❑ Implement **health literacy programs** in healthcare settings to empower patients with the knowledge and skills needed to navigate medical device usage effectively.
- ❑ Launch comprehensive **educational campaigns** to raise awareness among patients about the safe and proper usage of medical devices.
- ❑ Develop easily **accessible information resources** such as brochures, pamphlets, and online portals with detailed instructions and safety guidelines for various medical devices.

05

Regulatory framework for fostering industry best practices



From L1 to Vmax : Adopting Value-based procurement (VBP) to improve healthcare quality while controlling costs

What is VALUE?

While value can be specific to the product / solution, its market, its purpose of use, and its details can be defined differently to different procurers

VALUE is defined as the DESIRED OUTCOMES relative to the COST

Desired outcomes

- Improved patient care outcomes
- Improved patient and user safety
- Improved patient and user experience
- Reduced cost of care
- Quality and sustainability
- Manufacturer's life-cycle support



Costs

Costs incurred to procure the product / solution across its life-cycle:

- Transport, installation, training, operations, maintenance, upgrade, and disposal costs

What is Value Based procurement (VBP) ?

VBP entails making purchasing decisions that consider how a product or solution can best deliver the predefined outcomes and reduce the total cost of care, rather than focusing exclusively on purchasing a specific product at the lowest possible price

Diagnosis Related Groups (DRGs)

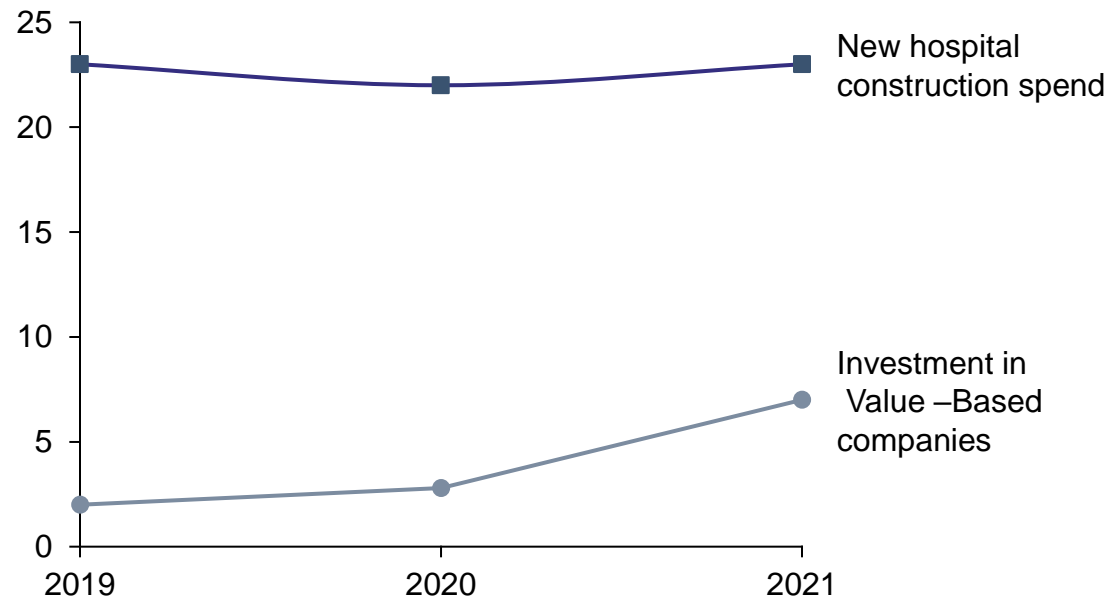
- DRGs are a patient classification system used to categorize hospital cases into groups that are clinically similar and consume similar hospital resources.
- This system helps **standardize payment rates for healthcare services based on the patient's diagnosis, treatment, and other relevant factors.**
- For example: **PMJAY is in the process of upgrading the system of reimbursing the providers** moving from a cruder to a much more refined value- driven approach, which accurately approximates the value of resources used to deliver services, as well as incentivize certain behavior and practices
- In the latest version of **HBP 2022, a differential pricing** system has been introduced
- This differentiates the payments to hospitals as per the city where the hospital is located and the specialty level (tertiary/ secondary)- two variables which determine hospital level drivers of resource use and cost. In the **next proposed iteration of pricing, as part of DRG reforms, the prices will be differentiated as per the clinical characteristics of the patient**, i.e., degree of severity, comorbidities, and complications.

Value- Based Care & the growing opportunities in the space

Value-Based Care is a form of reimbursement in **which payments to the healthcare providers for care delivery is made based on quality of care provided**. Under value-Based care model, healthcare providers are rewarded for **helping the patients to improve their health, which consequently reduces the effect of disease in the population in the long term**.

Value-based care investment inflows have grown faster than capital expenditure on new hospital construction

Annual new hospitals constructed Vs Value- Based care capital inflows, \$billion

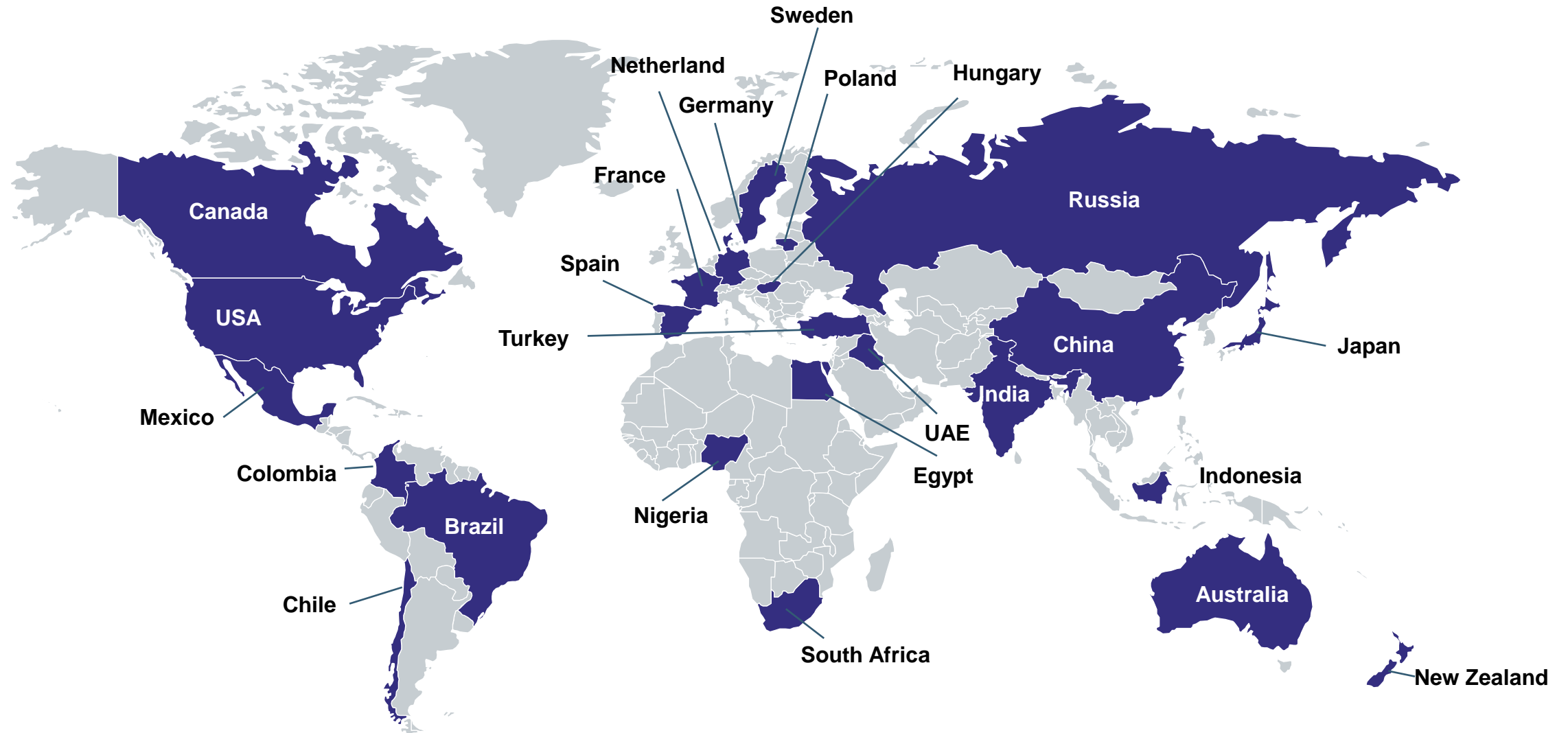


In July 2022, **Amazon announced a \$3.9 billion takeover of publicly listed One Medical**, a membership-based primary care practice. One Medical owns the Iora Health clinics, which provide comprehensive primary care services for Medicare patients, and **aims to move patients to a capitated reimbursement model**.

In April 2022, Optum announced its acquisition of Houston-based Kelsey-Seybold Clinic for around \$2 billion. **Kelsey-Seybold operates multispecialty care centers and also owns its own Medicare Advantage plan for seniors, KelseyCare Advantage**. The deal provided an exit for TPG Capital.

In May 2022, Humana and Welsh, Carson, Anderson & Stowe (WCAS) announced a reinvestment of \$1.2 billion in Center Well Senior Primary Care, **a network of Value-Based care clinics, to develop 100 new senior-focused primary care clinics by 2025**.

Countries that are increasingly adopting Value-Based Care / Procurement



Source: BCG report on progression on Value Based Care & The Economist Intelligence Unit Data

USA has observed reduction in emergency hospitalization, expenses & increase in patient adherence, satisfaction with Value Based Care

Comparative of Value Based Care after 10 years of implementation		
Areas	Non- Value Based Care	Value Based Care
Alignment with Value Based Provider	NA	70% individuals
Physician earning	Same	3.4 times higher
Overall Rating	3.3	3.9
Patient safety rating	2.8	3.8
Preventive screening (better health & lower cost for everyone)		
Breast cancer screening	69%	78%
Colorectal cancer	68%	76%
Savings	Increase expenses \$ 527	23.2%
Reduced insurance premiums	NA	Yes

Source: Humana 10th annual report 2023

Benefits observed after Value Based Care implementation

<p>30.1%</p> <p>Fewer inpatient admissions for Value-Based Care in 2022</p> <p>Saving 214,000 admissions</p>	<p>7.1%</p> <p>Fewer admission</p> <p>Saving 50,000 admissions or 353,000 inpatient days</p>	<p>12.7%</p> <p>Fewer Emergency visits</p> <p>Saving 146,000 visits</p>
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Hospitalization rate was lesser compared to Non- Value Based care patients

Comparison of preventive screening among Value-Based Care & Non-Value Based Care



Preventive screening was 17% higher in Value Based care patient

Health Technology Assessment can help strengthen effective analysis and adoption of health technologies in public programs

Public awareness & education

Enhance public awareness and education about the role and importance of HTA in healthcare decision-making.

Comprehensive Data Collection and Analysis

Enhance data collection mechanisms to gather robust evidence on the **clinical effectiveness, safety, and cost-effectiveness of health technologies**.

Integration with Decision-Making

Integrate HTA findings into **healthcare decision-making processes at various levels, including formulary decisions, reimbursement policies, and priority-setting exercises**.

Adaptive HTA framework

Develop an adaptive HTA framework that allows for **continuous monitoring and evaluation of health technologies post-implementation**.

Capacity building and collaboration

Invest in building capacity for HTA within relevant institutions and stakeholders, including training programs, technical assistance, and knowledge-sharing initiatives.

Stakeholder engagement and transparency

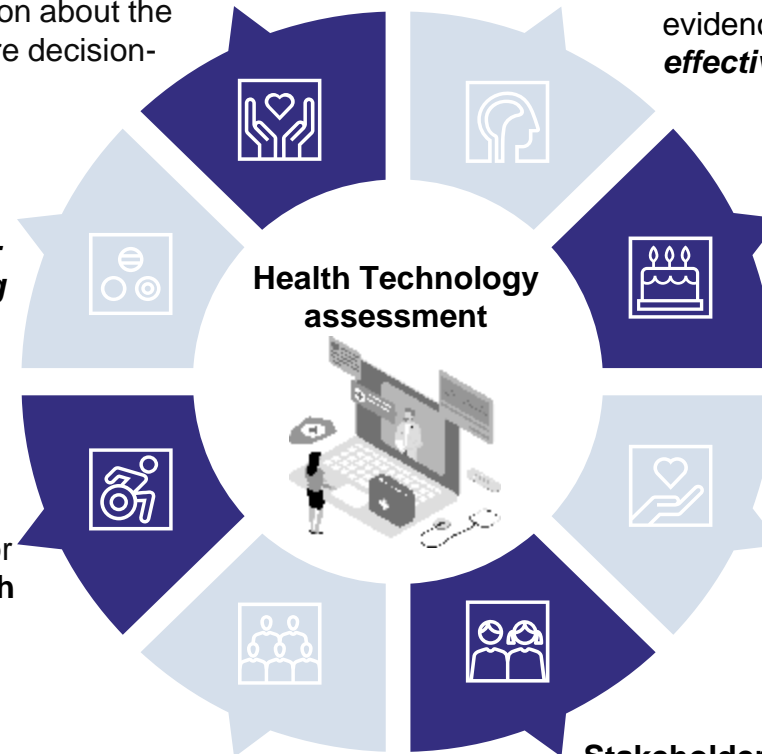
Promote stakeholder engagement and transparency throughout the HTA process, **including involvement of patients, healthcare providers, policymakers, and industry representatives**.

Incorporation of Patient-Centered Outcomes

Expand the scope of HTA to incorporate patient-centered outcomes, such as quality of life, patient preferences, and patient-reported outcomes.

Consideration of Equity Implication

Integrate equity considerations into HTA processes to assess the **impact of health technologies on different population groups, particularly vulnerable and marginalized communities**.



Going forward rationalization of the current GST structure on Healthcare can help utilize the input GST credit in the value chain

Current Landscape

- **Background:** Healthcare services on exemption list of GST¹ (The then rationale: To relieve majority of healthcare establishments, who would not come under the GST regime, from fulfilling a lot of GST related procedures like 'Registration' and 'filing of Returns')
- **Problem it ensues**
 - Restricted flow of input tax credit as most of the inputs procured by the healthcare establishments including medical equipment, consumables, labor and maintenance of medical equipment, rental services, housekeeping services, etc., bore the GST burden (average rate of 12%, accounting for ~), but these taxes could not be set off against the output tax liability
 - The blocked credit which remains unutilized in the value chain becomes a cost and gets passed on to the end user, raising the cost of healthcare services and thereby diluting the government objective of making India an affordable healthcare destination
 - Embedded taxes post GST account for ~6% of Hospital's total expenses in a year (Pre GST it was ~4.3%)
 - Average GST rate faced by hospitals on procuring their inputs is ~12%
 - Expenditure of GST bearing inputs total expenditure is ~43.5% (2020-21)

Recommendations²

- **Option 1** – Zero rating on healthcare services is proposed. This will cause no change in price to the consumers while reducing the burden of embedded taxes on healthcare service providers.
- **Option 2** – A suitable GST rate may be levied on output services for all private hospitals and an optional dual rate structure may be given for Government establishments. This will allow private hospitals to have partial passthrough of blocked input credit. Meanwhile, the consumers may not be impacted as the reduction in costs to the hospitals will offset the impact of the decided GST rate on the output level.
- **Option 3** – Employing a combination of above listed options.



About NATHEALTH NATHEALTH has been created with the vision to “Be the credible and unified voice in improving access and quality of healthcare”. Leading healthcare service providers, medical technology providers (devices & equipment), diagnostic service providers, health insurance companies, health education institutions, healthcare publishers and other stakeholders have come together to build it as a common platform to power the next wave of progress in Indian healthcare. NATHEALTH is an inclusive institution that has representation of small & medium hospitals and nursing homes. It is committed to working on its mission to encourage innovation, help bridge the skill and capacity gap, help shape policy & regulations and enable the environment to fund long term growth. NATHEALTH aims to help build a better and healthier future for both rural and urban India.

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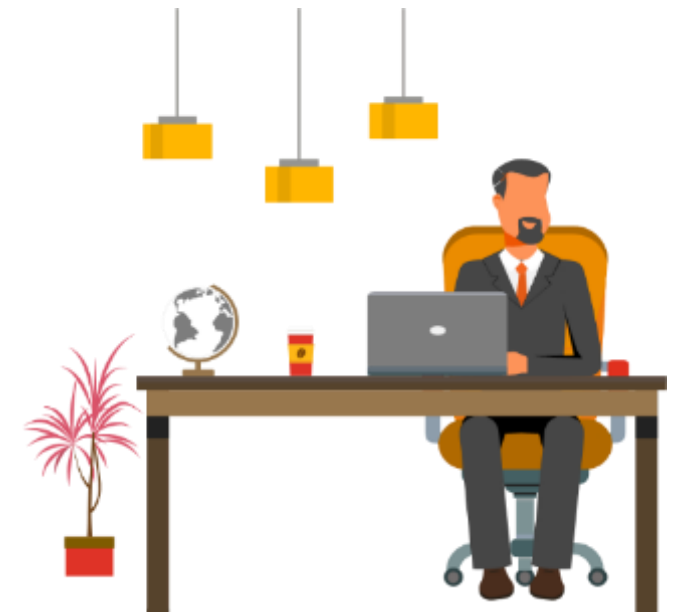
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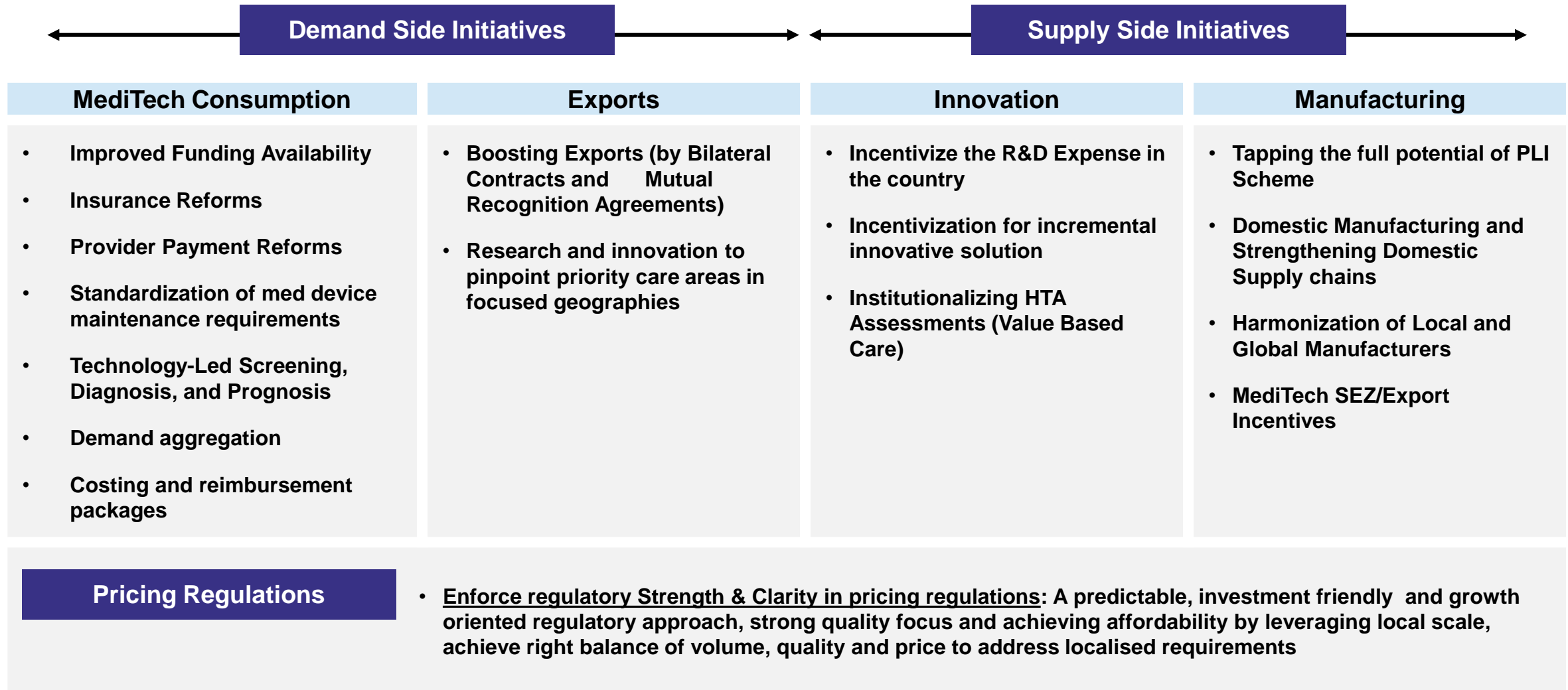
Industry Stakeholders	Organization
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Rajib Sen	Niti Aayog
Chaitanya Sarawate	GE
Mayank Rohatgi	Healthium
Jitendar sharma	AMTZ
Amit Chander	IFC



KEY RECOMMENDATIONS



Achieving the vision of 30Bn\$ industry by 2030 towards Viksit Bharat



Demand Side Initiatives

Improved Funding Availability to drive in utilization of MediTech Sector

(Via CAPEX subsidies across the value chain- equipment, components, sub-components, priority Sector Lending, low Interest Rate etc.)

Overcome roadblocks to accelerate infrastructure creation in both greenfield and brownfield models

[Report Health-Financing-PPP.pdf](#)

GST Reforms for increased Affordability

(5% GST on Healthcare and Reducing GST on Home Health Services and Health Insurance)

[NATHEALTH-and-EY-GST-Whitepaper.pdf](#)
[EY-Dialysis-Whitepaper](#)

Boosting Exports

(Favorable Bilateral Contracts, Mutual Recognition Agreements, Reinstatement of MEIS / higher incentives in RodTEP scheme)

Provider Payment Reforms^^

(Via increasing the strategic Purchasing of Healthcare Services and [Value Based Procurement](#))



Standardization of med device maintenance requirements to ensure adequate usage and delivering quality outcome

[Allied-Health-ProfessionalsNathealth](#)

Medical Device Led growth

Creating strong use cases for ABDM Adoption via Medical Devices and developing standards for SaMD and SiMD

[Digital-Governance-System-for-Ultrasound-Devices- Nathealth](#)
[Organ-Donation NatHealth](#)

^^ Inserted PDFs include details on NATHEALTH submission on Provider Payment Reforms and Scaling PMJAY

Supply Side Initiatives

Revamp the PLI Scheme

(PLI Scheme for devices, Components & sub-components in Greenfield & Brownfield manufacturer facilities)

Incentivize the R&D spend

(R&D incentives to be aligned with key component requirements for the industry and Via increasing income-tax weighted deduction on R&D expenses)

Domestic Manufacturing and Strengthening Domestic Supply chains

(Uniform implementation of PPO & Land Border Order in all States, Central Procurement Agencies & PPP projects; Supply Chain Resilience to deepen manufacturing and local content development; G2G support for technology transfer & sourcing of specialized raw material)

Harmonization of Standards

(Usage of International standards and Performance Standards (instead of Design Standards); Introduction of robust Post Market Surveillance mechanism to affirm quality of the medical devices)

MediTech SEZ to help boost manufacturing and Exports

(Favorable Import and Export provisions)

Strengthening the Incremental Innovations

(Value Based Procurement and providing incremental reimbursement rate for Frugal local innovations)

[Value-Based-Procurement-in-MedTech-Building-Blocks-for-Enabling-Implementation-in-India](#)

Improved HTA Landscape

(Via Increasing the number of Institutes doing HTA Studies from current 20 Government Institutes)

Projecting Meditech Regulatory Strength & Clarity

Demonstrate Real Demand at scale with Affordability creating local Market Gravitas

[PMJAY- NATHEALTH Recommendations](#)

Drive affordability through Public procurement also reward innovations that result in growing competitiveness of Meditech Sector resulting in “Make in India”

Enable private Enterprise and Investment for Meditech

Lower cost of capital (tax free bonds), incentivize bank lending and set up single window clearance for Meditech sector for all issues

Monitor market prices while growing Indian market to critical size, allow competition and grow local market appeal for investments.
[Collate emerging evidences](#) on price regulatory interventions and its long-term impact on sector.
Recommend that primary levers used for affordability are seen as PMJAY & Public procurement options

Incentivize Integrated omnichannel Healthcare Eco system

Build up continuum of care financing and an entire category of new healthcare infrastructure & consumer opportunity will present to Meditech

Credentialize Meditech Talent, Encourage Health outcome publishing and higher alignment between central & state policies including unlocking expensive private capital through a firm commitment to pay on time for all government procurements