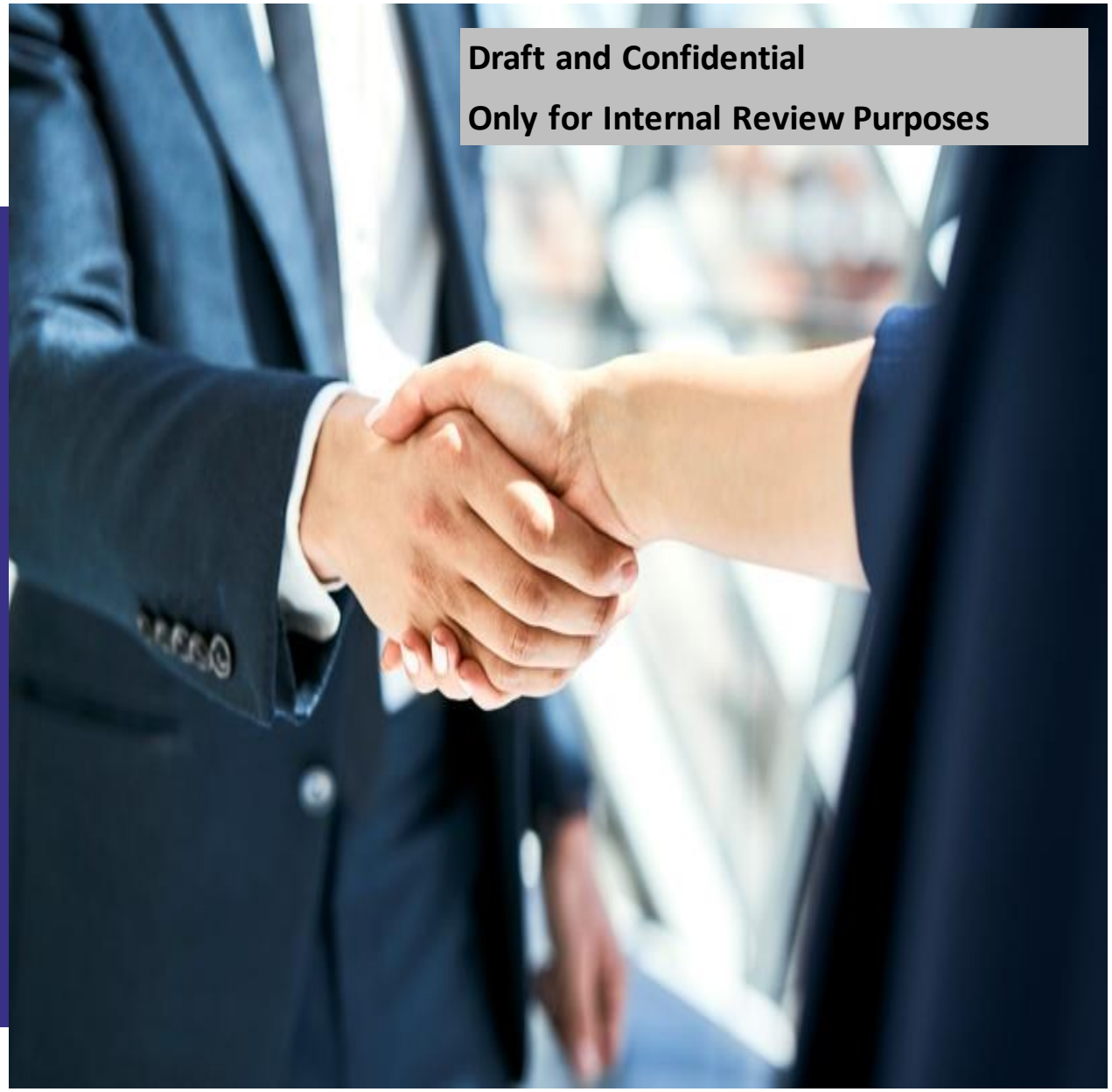
NATHEALTH®
Healthcare Federation of India

Realizing the full potential of MedTech Industry in India 2.0

March 2024



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Only for Internal Review Purposes

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Device-led digital health to promote preventive health and extend care continuum, especially in non-metros

Promote safe usage of medical devices supported by patient awareness, accreditation and skilling

Creating a conducive regulatory framework and supporting industry best practices

Section 1

MedTech Industry in India and mechanisms/investments needed to drive penetration of MedTech to the last mile

MedTech Industry lies at the fulcrum of Indian Healthcare ecosystem

Providers

Providing High Quality Care, Reducing Patient Side Effects, Delivering care as per new trends

Regulators

Ensuring care reaches to last income quintile and to last hamlet in India, Ensuring the OOPE don't lead to catastrophic expenditure and poverty

Digital healthcare

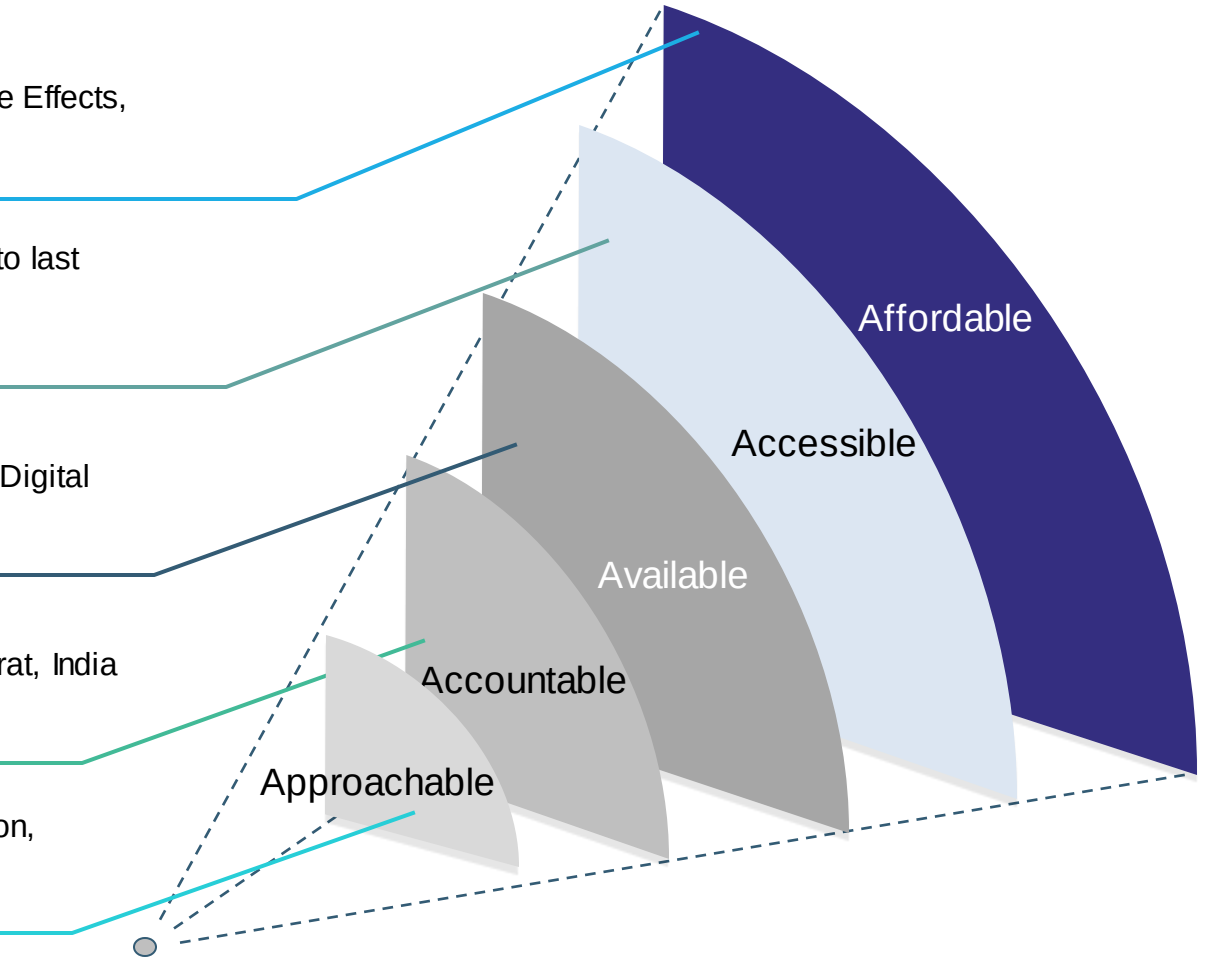
Medical Technology acts as the medium to deploy Digital Technologies; Force Multipliers

Economical / Political

Step towards Viksit Bharat 2047, Atmanirbhar Bharat, India helping define and shape Global Agenda

Skilling/capability

Importance of skilling, standardization, accreditation, capability building in MedTech Industry



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 indeed 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.**

High complexity OPD centres

- India has seen a significant growth in the **establishment and utilization of high complex OPD centers**,
  - ❑ driven by the increasing prevalence of chronic diseases
  - ❑ advancements in medical technology, and
  - ❑ rising demand for specialized healthcare services
- Multispecialty hospitals and healthcare chains have **expanded their OP services to include high complex OPD centers**.
- **By 2024**, the projected revenue is **estimated to reach INR US$23.41bn at is estimated toe grow at 7.27% CAGR**

POC testing

- POC testing is being increasingly adopted across healthcare settings (hospitals, clinics, PHCs, CHCs, and even in-home care settings)
- POC diagnostics market in India was valued at over **USD 400 million in 2020**
- The COVID-19 pandemic has further accelerated the adoption -**rapid antigen testing and SARS-CoV-2**
- Government initiatives such as the **NHM and Ayushman Bharat have played a crucial role** in promoting the use of POC
- E.g.: Glucometers (Roche, J&J), Rapid Diagnostics Tests(HIV, malaria, dengue,TB), Portable Hemoglobin Analyzers (HemoCue, Sysmex)

Preventive health checkups

- PHC is witnessing a gradual shift towards proactive healthcare management, **driven by increasing awareness about the importance of early detection and prevention of diseases.**
- Report by ICMR, the **prevalence of NCDs in India is on the rise, with an estimated 61.8 mn people affected by diabetes and 29.8 mn by hypertension.**
- PHC is low, particularly among rural and underserved populations
- E.g.: Master health checkups, corporate wellness program, government health initiatives (NHM, AB, NPCDCS)

Wearables

- Wearable technology has gained popularity in India, driven by **increasing health consciousness, growing smartphone penetration, and the availability of affordable** devices.
- Wearables encompass a wide range of devices, including **fitness trackers, smartwatches, wearable medical devices, and health monitoring accessories.**
- **Wearables market in India grew by 34% in 2023**

Source: Statistia, Grand View Research, ICMR,news articles and Pw C analysis
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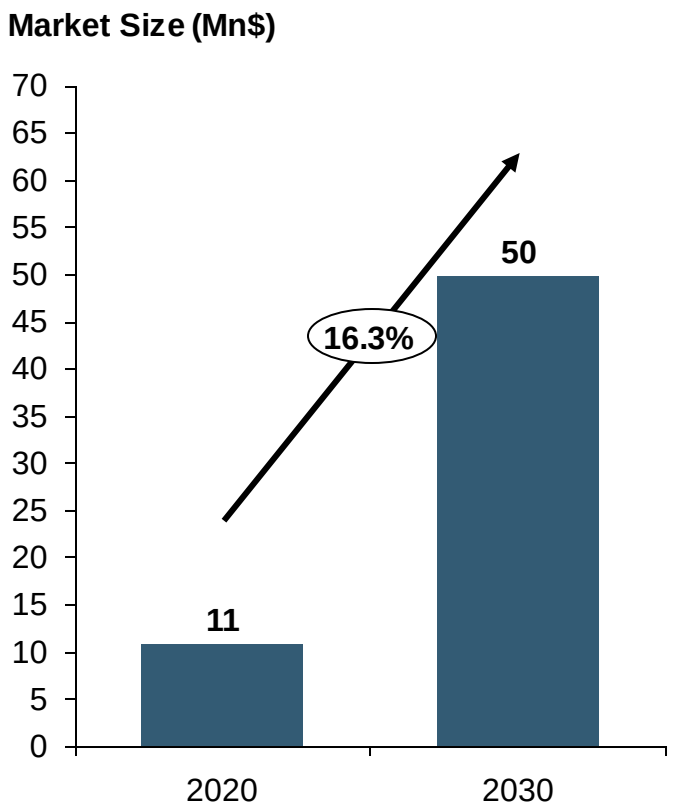
Indian MedTech Industry is currently valued at ~12bn$ and is expected to achieve ~50bn$ by 2030



Key Characteristics

- A **robust MedTech sector** is essential for empowering healthcare outcomes through improved access, quality, and innovation.
- The Indian medical device market, encompassing both domestic and export segments, has demonstrated steady growth, reaching an estimated value of approximately **USD 11.6 billion** by 2022
- **Import dependence remains high**, constituting ~70% of the total market, with **notable growth observed in the imports of disposables and consumables**.
- Exports from India have grown at ~**7.6%** from 2018 to 2022, with **implants being the fastest-growing category**.
- **India's per capita spend on medical devices remains significantly lower**
- India's expenditure on **Research and Development (R&D) in the medical technology sector lags behind** developed countries.
- Numerous opportunities exist across various sub-categories driven by market size, growth, import substitution, exports, and emphasis on domestic manufacturing, underscoring the potential for India's MedTech sector to achieve a **USD 50 billion valuation by 2030**.
- Governmental initiatives such as **'Make in India'** are pivotal in driving domestic manufacturing and innovation forward, laying a solid foundation for future growth.
- **Collaboration and innovation** are central to unlocking the sector's full potential
- India's MedTech industry can not only bridge healthcare accessibility gaps but also emerge as a global leader.

Source: Pw C analysis, Invest India, Statista
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India will have demand of $ 50 Bn worth medical devices to meet the needs of changing healthcare and growing services

India	Supply (2022)	Supply (2030)	CAGR
Production (worth in $Bn)	$ 7.6 billion	$ 50.5 billion	26.7%
Export to other countries from India	$ 3.4 billion	$18 billion	23.2%
In-house Country consumption	$ 4.2 billion (30%)	$ 32.5 billion (64%)*	29.1%
Import from other countries to India	$ 7.6 billion (70%)	$ 17.5 billion (36%)	10.9%
Annual demand of MedTech in India	**$ 11.8 billion**	**$ 50 billion**	

*Change driven by government initiative to become self-reliant and meet the growing demands

Medical devices or Med Tech can help by providing tele-consultation, tele-surgery and meet the growing needs of **1.75 million hospitalization beds by the end of 2025-** International Trade Administration

On average, each hospital acquired about 15–20 pieces of medical equipment for each staffed bed, which translates into a capital investment of around US$200–400,000/staffed bed

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**

Source: From $12B to $50B: Supercharging India's Medical Device Industry Growth, Healthcare & life science report by International Trade Administration & Medical technology industry in India report CII, A literature review : Medical devices inspection & maintenance, Canada
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While there are definitive drivers in the growth of Indian MedTech Industry…

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. With increase in ageing population, the demand for dental service such as implant and prosthetics will also increase

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

Source: World bank data, McKinsey report , BCG The New Indian: The Many Facets of a Changing Consumer, Forbes and Statista survey, and National health accounts 2021

…. The overall penetration / adoption of MedTech remains low in Care pathways

	Diabetes	CVD	Tuberculosis	Breast Cancer	Neurology	Nephrology	Orthopaedics	Auto-immune
USA	• ~2.4 million diabetic patients use continuous glucose monitor (CGM) • Hyperbaric oxygen therapy, Negative pressure wound therapy, Smart mat, etc. are used for the treatment of Diabetes foot ulcers (DFU).	• 35.5% surgeries are performed by robots • 30-40% patients use Implantable cardioverter defibrillator	• 75% patients are diagnosed with AI enabled devices for Tuberculosis	• AI-based technology is used for the pre-screening of Breast cancers in schools.	• AI/ML-enabled devices (compared to 2022- 15%) are expected to reach 30+% by 2024	• ~80,000 patients get their dialysis done by mobile devices. • 4 out of 10 surgeries are robotic	• 8 lakh knee transplants and over 4.5 lakh hip replacements are done in the USA every year	• 1 in 3 patients in USA uses wearable devices to track the autoimmune disorders
India	• 0.07 million patients uses CGM • DFU are treated using surgery, amputation and medication • Lifestyle modification and self-glucose monitoring is more prevalent	• Less than a thousand surgeries are done by robotics • Only 25 Implantable cardioverter defibrillators are used in a million population	• 25% of the tuberculosis diagnosis is done by Medical devices or AI.	• Very few patients are being diagnosed with the AI-based thermal detection pre-screening	• Neurological diseases are mostly treated using medication, lifestyle modification and surgeries	• Dialysis is mostly done at dialysis center or hospitals • Only 3-4 cities have robotic surgery facility available	• 1.5 lakh knee transplants are done every year. • Total hip replacement surgeries done is 3646 / lakh population annually	• It is usually controlled by medication and life-style modification

Sources: Pw C Analysis, WHO Data, Statista, World Bank, CDC
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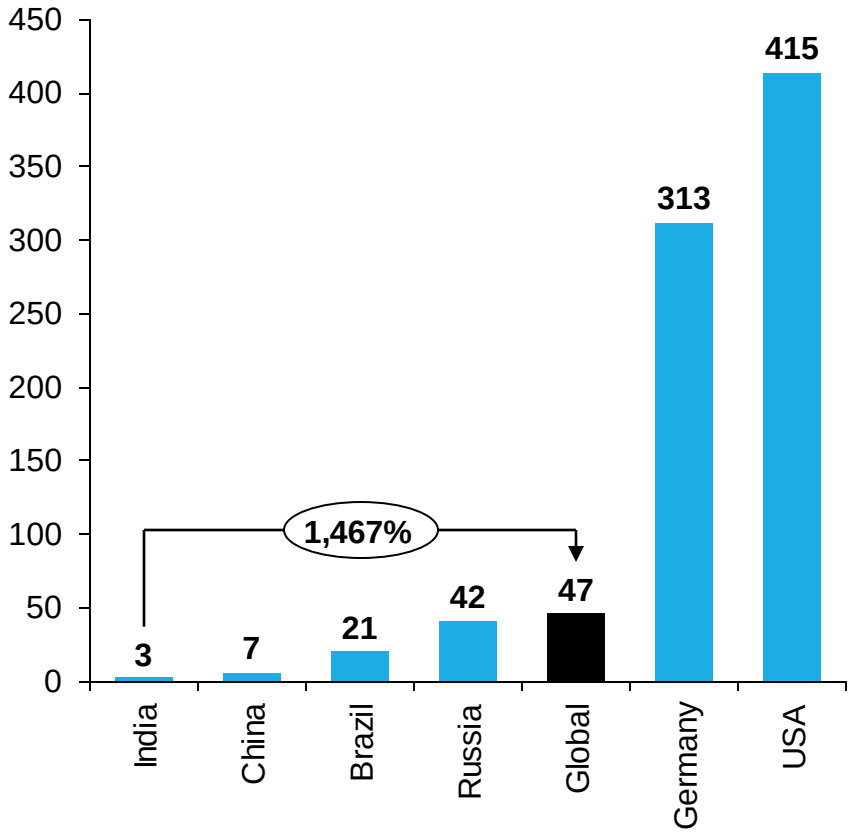
This is reflected in the lower per Capita Spending on Medical Devices in India as compared to other countries, leading to sub optimal health outcomes

Per Capita Spend on Medical Devices (USD)



Source: Strategy Document on NMC Policy 2023, DOP
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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

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

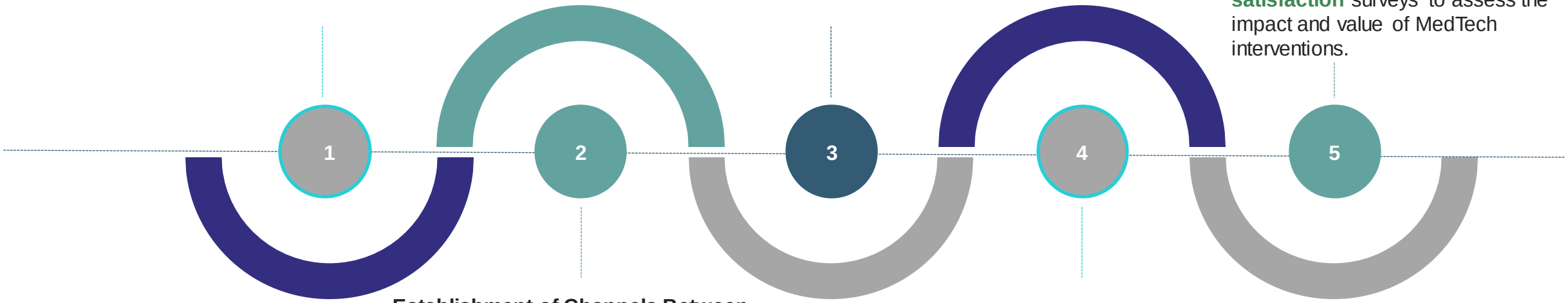
Source- International Trade Administration, CII

Development of STGs, formal channels of communication, interoperability, HTA assessments and Training programs can help expedite this transformation

Standardized Treatment Guidelines (STGs):. **Collaborate with medical associations, research institutions, and healthcare providers to create evidence-based guidelines.**

Interoperability and Compatibility: **A**doption of interoperable and **compatible medical technologies and systems that facilitate seamless integration and data exchange can help expedite adoption**

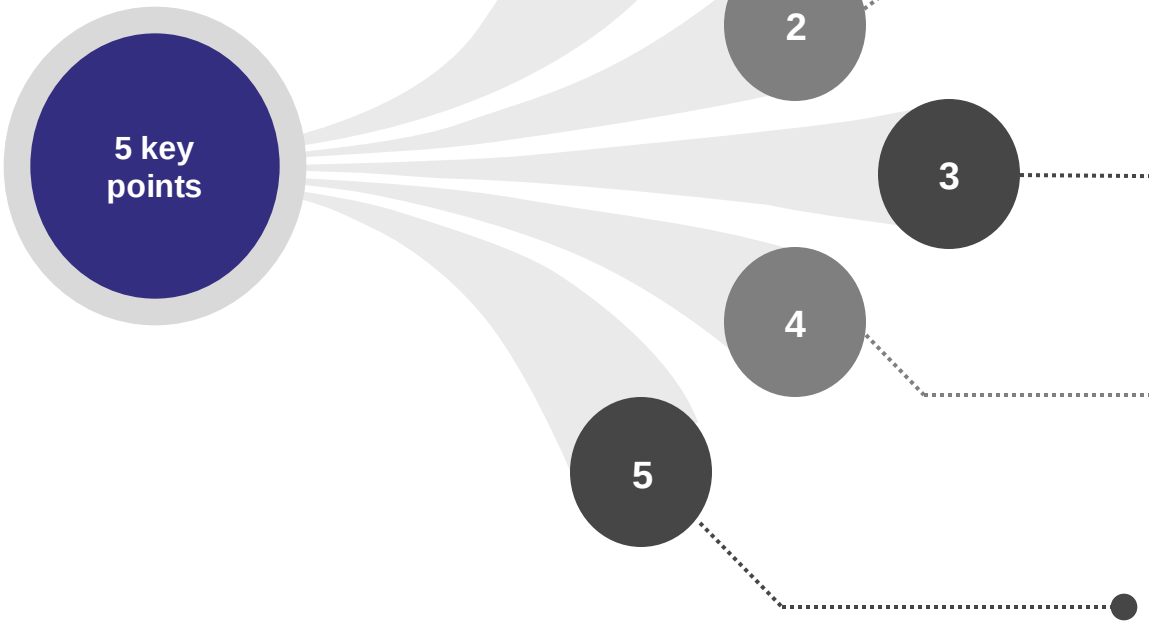
HTA: Establish mechanisms for technology assessment and evaluation to help healthcare providers make informed decisions .**Conduct comparative effectiveness studies, cost-benefit analyses, and user satisfaction** surveys to assess the impact and value of MedTech interventions.



Establishment of Channels Between Smaller and Larger Hospitals: Create channels for collaboration and **knowledge-sharing between smaller and larger hospitals to facilitate technology transfer, training, and capacity-building.** **Establish mentorship programs**, twinning arrangements, and telemedicine networks

Training and Education Programs: Provide training and education programs for healthcare professionals on the use, maintenance, and optimization of MedTech solutions. Offer **workshops, seminars, and online courses that cover topics such as device operation, patient monitoring, data management, and safety protocols.**

Expanding the insurance benefit package can help improve affordability and adoption of medical technology



Comprehensive Coverage for Outpatient Services: Expand insurance benefit packages to include comprehensive coverage for outpatient care, including diagnostics, consultations, medications, and procedures. Ensure that insurance plans provide adequate reimbursement for outpatient services

Specialized Coverage for Diagnostics in Oncology: Designate a specialized coverage category within insurance benefit packages for diagnostics in oncology. Include a **wide range of diagnostic tests and procedures specific to cancer detection, staging, monitoring, and treatment planning**

Streamlined Preauthorization Process:. Implement **electronic preauthorization systems, standardized criteria for approval, and fast-track pathways for urgent or time-sensitive cases.**

Provider Network Expansion: Expand the network of healthcare providers and diagnostic facilities covered **by insurance plans to improve access to outpatient care and diagnostics, particularly in underserved areas.**

Access to Advanced Diagnostics Technologies: Ensure access to advanced diagnostic technologies and modalities for cancer diagnosis and management through insurance coverage. **Include coverage for state-of-the-art imaging techniques (e.g., MRI, PET-CT), molecular diagnostic tests (e.g., next-generation sequencing), and innovative biomarker assays.**

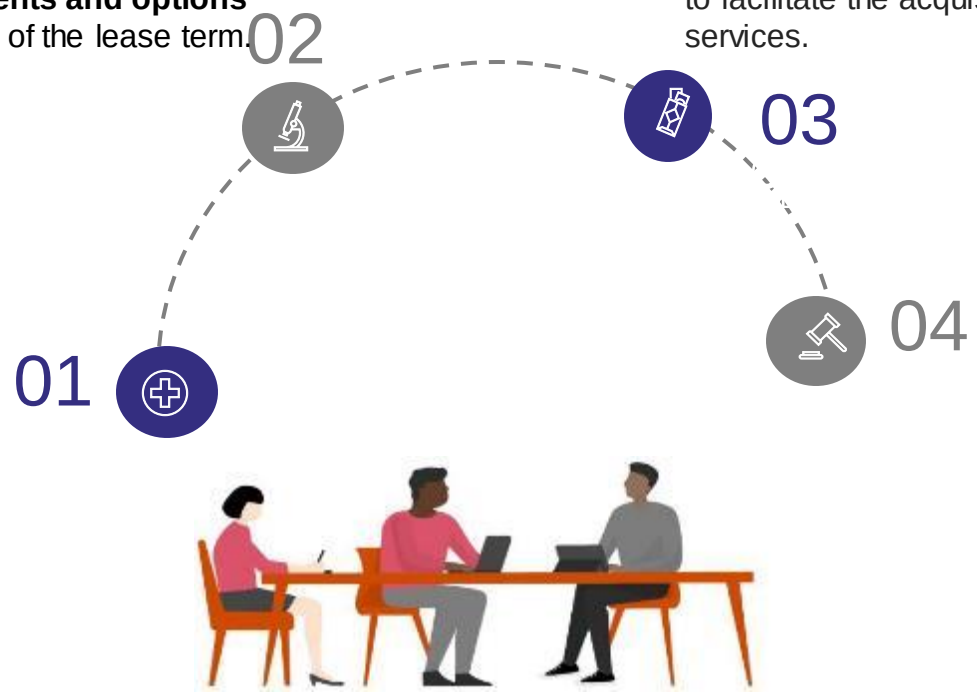
Innovative financing solutions can help providers adopt high capex MedTech Services

Leasing and Equipment Rental Programs:

- Introduce leasing and equipment rental programs **that allow healthcare providers to access state-of-the-art medical technology services** without the need for substantial upfront investment.
- Offer **lease-to-own options, operating leases, or equipment rental agreements with fixed monthly payments and options for equipment** upgrades or buyouts at the end of the lease term.

Vendor Financing and Supplier Credit:

- **Collaborate with medical equipment suppliers, manufacturers, and distributors to provide vendor financing** and supplier credit arrangements to healthcare providers.
- **Negotiate favourable financing terms, extended payment terms, and deferred payment options with equipment** vendors to facilitate the acquisition of high capex medical technology services.



Flexible Financing Solutions:

- Develop flexible financing solutions tailored to the unique needs and financial constraints of healthcare providers **seeking to invest in high capital expenditure (capex) medical technology services such as radiology equipment, CT scanners, and** MRI machines.
- Offer customized financing packages with adjustable repayment terms, **grace periods, and interest rates to accommodate budgetary constraints** and cash flow considerations.

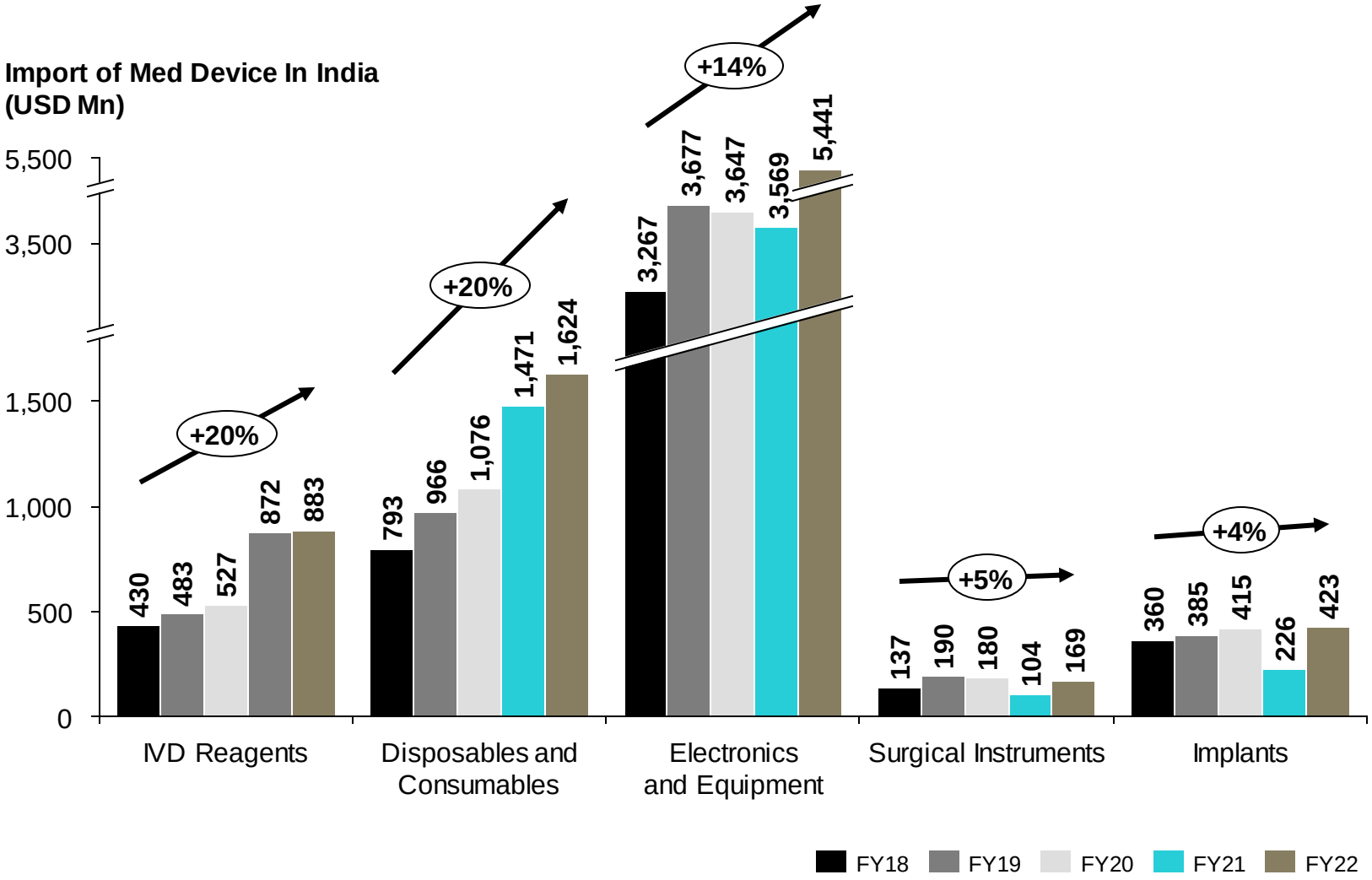
Government Subsidies and Grants:

- **Advocate for government subsidies, grants, and financial incentives to support healthcare providers in** acquiring high capex medical technology services.
- Lobby for funding programs, tax incentives, **or low-interest loans specifically earmarked for investments in medical equipment and infrastructure upgrades**, particularly in underserved or rural areas.

Section 2

Enhance “Make in India” to stimulate the ecosystem & manufacture for India and for the world (e.g., PLI and beyond) with a special focus on quality

Indian MedTech Industry is heavily import dependant, especially in high end products like electronics and Equipment



Source: PwC Analysis, Secondary Research
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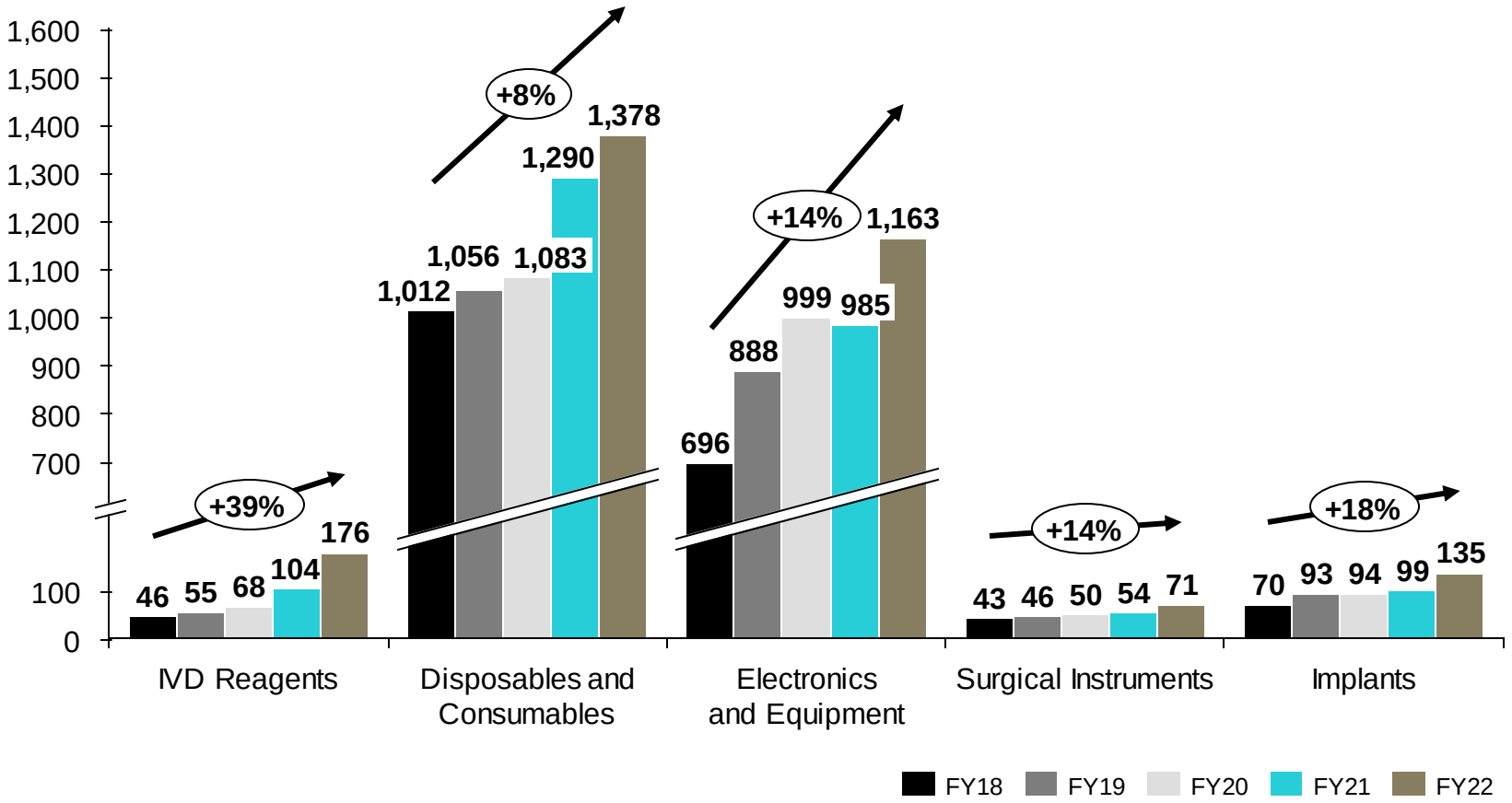
While the exports have risen, they are still considered sub optimal given the potential of industry

Export of Med Device From India (USD Mn)



Source: Pw C Analysis, Secondary Research

Multiple initiatives are being undertaken to make Industry Import neutral

Overall imports down 4% but shipments from Russia, China up: Govt data

Overall exports, meanwhile, increased 0.9 per cent, according to the data compiled by the commerce department

Interim Budget: MedTech industry urges govt action to cut import reliance

According to the Global Trade Research Initiative (GTRI) report on August 2023, the Indian medical devices industry has the potential to expand from $12 billion to $50 billion by 2030

India's exports rose to seven of the country's top 10 destinations — United Arab Emirates, Saudi Arabia, China, the UK, Australia, Singapore, and the Netherlands – in the first nine months of the current financial year (FY24). Overall exports, meanwhile, increased 0.9 per cent, according to the data compiled by the commerce department. Of India's top 10 import partners, inbound shipments from Russia, Switzerland, China, and South Korea saw growth during April-December, at a time when the country's overall inbound shipments dipped by 4 per cent compared to a year earlier.

Dr Jitendra Sharma Managing Director and Chief Executive Officer Andhra Pradesh MedTech Zone (AMTZ) said, "For the first time, medical device imports contracted by 4% and export grew 14% in 2023. If this trend continues, India can be import neutral by 2029.

Indian medtech industry urges govt action to reduce import dependency

According to the Global Trade Research Initiative (GTRI) report from August 2023, the Indian medical devices industry has the potential to expand from $12 billion today to $50 billion by 2030

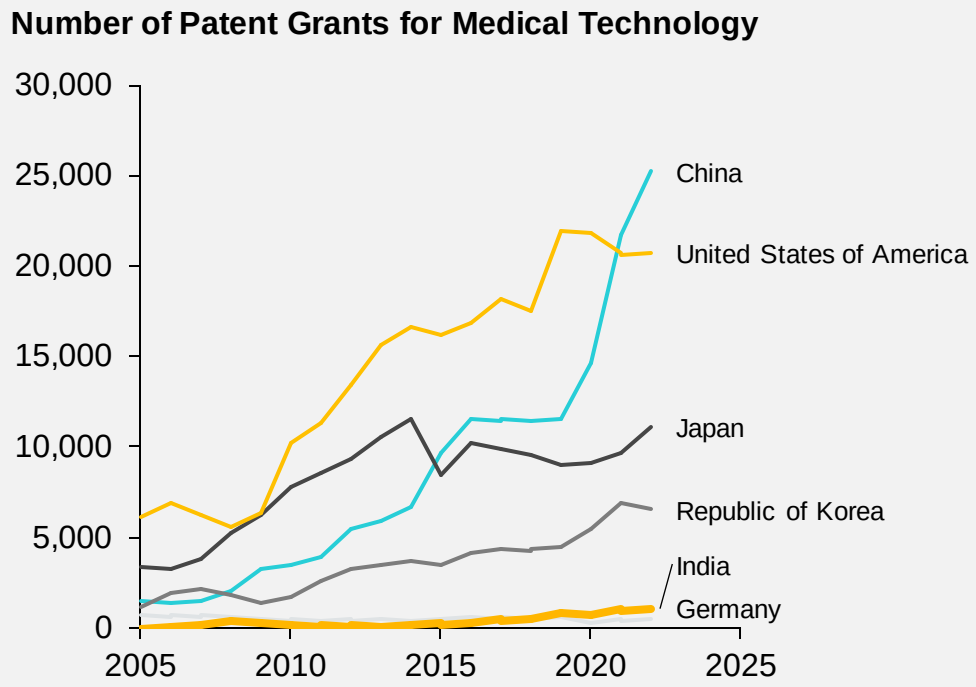
Source: New spaper snippets

Low domestic manufacturing is cited due to a multitude of reasons like Supply Chain issues; Domestic Demand; Capability and Skill Sets

Domestic Demand	Rising healthcare costs Disease	Regulatory Challenges	Cybersecurity concerns
• Increasing Healthcare Expenditure • Growing Aging Population • Technological Advancements • Rising Incidence of Chronic Disorder • Government Initiatives and Policies • Increasing Product Maturity leading to increased utilization and uptake • Increasing Demand (due to population, insurance penetration	• Cost for treatment is high • Treatment done by MedTech Devices isn't covered under the traditional insurance coverage	• Unregulated Environment • FDA evaluation process for the new devices is lengthy, expensive, and cumbersome. It becomes difficult for the startups to get the approval	• Device manufacturers facing concerns about patient privacy and protection per HIPAA, making the device costly. • Higher regulatory concern

Source: PwC analysis, Secondary research, Survey

The low innovation is reflected in the number of patents granted in Medical Technology

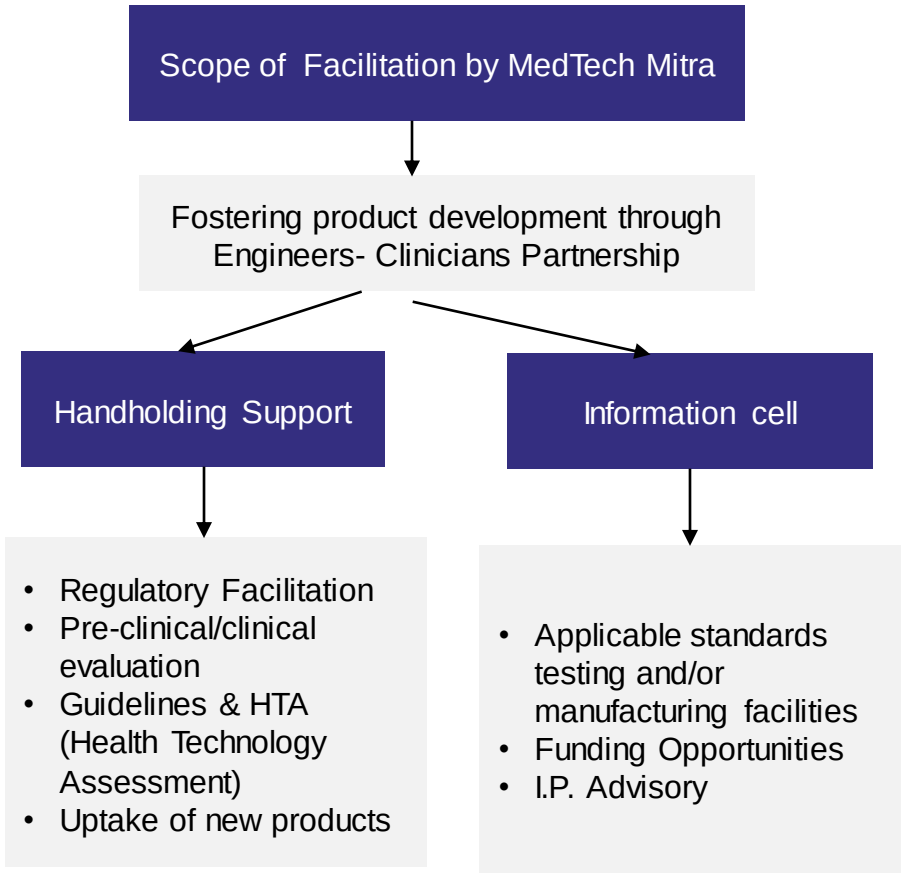


- The annual number of patents granted to India in Medical Technology has successfully increased in the last 15 years
  - <200 in 2007 to >1000 in 2022
- They still account for <1.5% of total worldwide patents
  - >80K Patent worldwide in 2022

Source: WIPO statistics database

Multiple initiatives like MedTech Mitra have been undertaken to provide a collaborative ecosystem for stakeholders for innovation, research and manufacturing

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



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	• 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	• 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	• ICMR-Intent (Indian Clinical Trial & Education Network)- Pan India network f 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 data
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National Medical device policy 2023 also envisages growth in domestic manufacturing

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..

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.***

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.**

Source: Public Information Bureau

The PLI scheme is a result of wide-ranging deliberations on India's dependence on critical resources, risk to supply chain bottlenecks and the Industry's global competitiveness

The success of this inaugural scheme led the government to launch the Rs. 15,000 crore PLI-II scheme which envisaged to increase our cost competitiveness for medicines and medical products in the international market".

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.

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

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.

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

Source: Public Information Bureau

Support from the government to strengthen domestic manufacturing via PLI scheme highlights segments with investment potential

	Segments considered for PLI scheme				
	Cancer Care / Radiotherapy Medical devices	**Radiology & Imaging Medical devices & Nuclear Imaging devices**	**Anesthesia & Cardio-respiratory medical devices & Renal care medical devices**	**All implants including implantable electronic devices**	**IVD device manufacturing**
Incentives offered & applications approved	• 5% incentive on minimum incremental sales of manufactured goods for coming 5 financial years starting from FY2022-23 • Total maximum incentive of INR 120 crores per applicant within the target segment • As of now, total of 21 applications approved				• Total incentive ceiling of INR 60 Cr for each applicant • 5 applications approved
Companies benefited	PANACEA: Linear Accelerator (LINAC) ; Rotation-al Cobalt Machine	SIEMENS Healthineers: CT scan, MRI Allengers: CT scan, MRI, X-ray, Ultrasound, Cath lab, Mammography, C – Arm, BPL Medical Technologies: X-ray, Ultrasound, C –Arm TRIVITRON HEALTHCARE: X-ray, Ultrasound, C –Arm PHILIPS: CT scan, MRI, X-ray, Ultrasound, Cath lab, Mammography, C – Arm, GE HealthCare: CT scan, MRI, Ultrasound, Cath lab,	MICROTEK: Anesthesia Unit Ventilators, Dialyzer & Oxygen Concentrators, DECK MOUNT POLYMED: Anesthesia Unit Ventilators, NIPRO: Dialyzer and renal care products BPL Medical Technologies: Anesthesia Unit Ventilators, ALLIED MEDICAL: Anesthesia Unit Ventilators, Oxygen concentrators PHILIPS OMRON: Anesthesia Unit Ventilators, INDOVASIVE: Blood pressure monitor Urology products	SMT: Heart Valves, Stents, PTCA Balloon, Catheter and Heart Occluders Innvolution: Stents, PTCA Balloon, Catheter ENVISION SCIENTIFIC: Heart Valves, Stents, PTCA Balloon, Catheter and Heart Occluders Meril: Hip Implants, Knee Implants and other Product Trauma Implant Heart Valves, Stents, PTCA Balloon, Catheter and Heart Occluders BIO INDIA: Hernia Surgical Mesh Implants, Staplers, Clips & Cutter	TRANSASIA No.1 Diagnostic Company in India TRIVITRON HEALTHCARE AGAPPE Premier Medical Corporation Private Limited
Allocated budget	**1,206 Cr INR**				**164 Cr INR**
Actuals	**1,050 Cr INR (as of September 2022)**				**100 Cr INR**

Source: Pw C Analysis, Secondary Research
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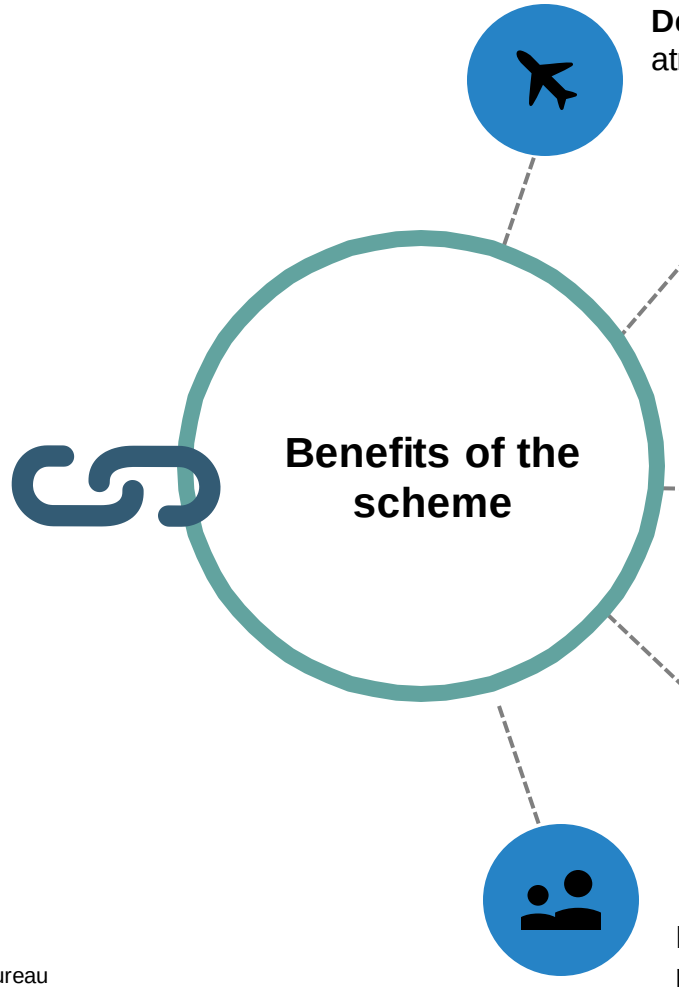
PRIP (Promotion of Research and Innovation in Pharma MedTech Sector) scheme can further help promote innovation and research



Development of Research Infrastructure- Building a world class research atmosphere at NIPERs and other institutes

Industry-academia linkages by promoting collaboration between Private sector and Govt. institutes

Focus on certain priority areas which will help India's pharma industry leapfrog and radically strengthen its position in the world market

Launching of **commercially viable products** which will accelerate the growth of Indian pharmaceutical sector by increased revenue and creating employment opportunities.

Development of affordable, accessible solution for primary area of health concern thus reducing health care burden.

Source: Public Information Bureau

A multitude of other strategies have also been adopted

Regularity Streamlined

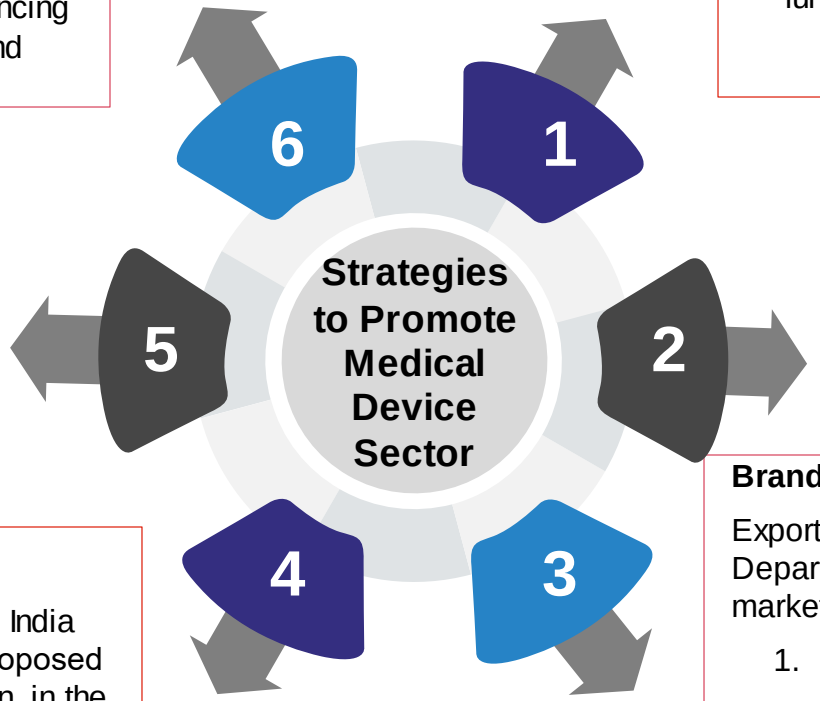
- "**Single Window Clearance System**' for Licensing of Medical Devices coopting all the stakeholder departments / organizations such as AERB, MeitY, DAHD, etc, enhancing the Role of Indian Standards like BIS and designing a coherent pricing regulation

Attracting Investors in the Sector

- Make in India, Ayushman Bharat program, Heal-in-India, Start-up mission, the policy encourages private investments, series of funding from Venture Capitalists, and PPP.

Enabling Infrasturcture

- The establishment and strengthening of large medical device parks, clusters equipped with world class common infrastructure facilities in proximity to economic zones with requisite logistics connectivity as envisioned under the **National Industrial Corridor Program**



Human Resource Development

1. Leverage the available resources in **Ministry of Skill Development and Entrepreneurship**
2. Support dedicated multidisciplinary courses for medical devices in existing institutions

Facilitating R&D and Innovations

- Promote Research & Development in India and complement the Department's proposed National Policy on R&D and Innovation in the Pharma- MedTech Sector in India. Establishing Centers of Excellence in academic and research institutions, innovation hubs**, 'plug and play'** infrastructures and support to start-ups

Brand Positioning and Awareness creation

Export Promotion Council for the sector under the Department which will be an enabler to deal with various market access issues:

1. Initiate studies and projects for learning from best global practices of manufacturing and skilling system
2. Forums to bring together various stakeholders for sharing knowledge and build strong networks across the sector.
3. Develop partnerships with foreign academic/industry organizations

Source: Public Information Bureau

Going forward, regulatory conformity to essential principles of safety and robust post market surveillance, can help drive in innovation in the MedTech Industry and stimulate exports

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

Recommendations

- 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

Source- FICCI: **Position Paper on Standards for Medical Devices and IVDs**

Increased allocation and spend on R&D can help improve innovation and product design, manufacturing outcomes

Enhanced Funding for R&D:

Increase funding and incentives for research and development (R&D) initiatives in the science and technology sector. **Encourage collaboration between government, industry, and academic institutions to foster innovation and accelerate** technological advancements.

Technology Transfer and Collaboration:

Facilitate technology transfer agreements and collaborations between research institutions, industry players, and startups. **Create platforms and mechanisms for knowledge exchange, technology licensing, and collaborative R&D projects** to leverage synergies and accelerate innovation.

Tax Benefits for Technology Investments:

Introduce tax benefits and incentives for companies investing in technology infrastructure, equipment, and talent development. Create a conducive tax environment to stimulate private sector investment in science and technology.

Promotion of IT Benefits:

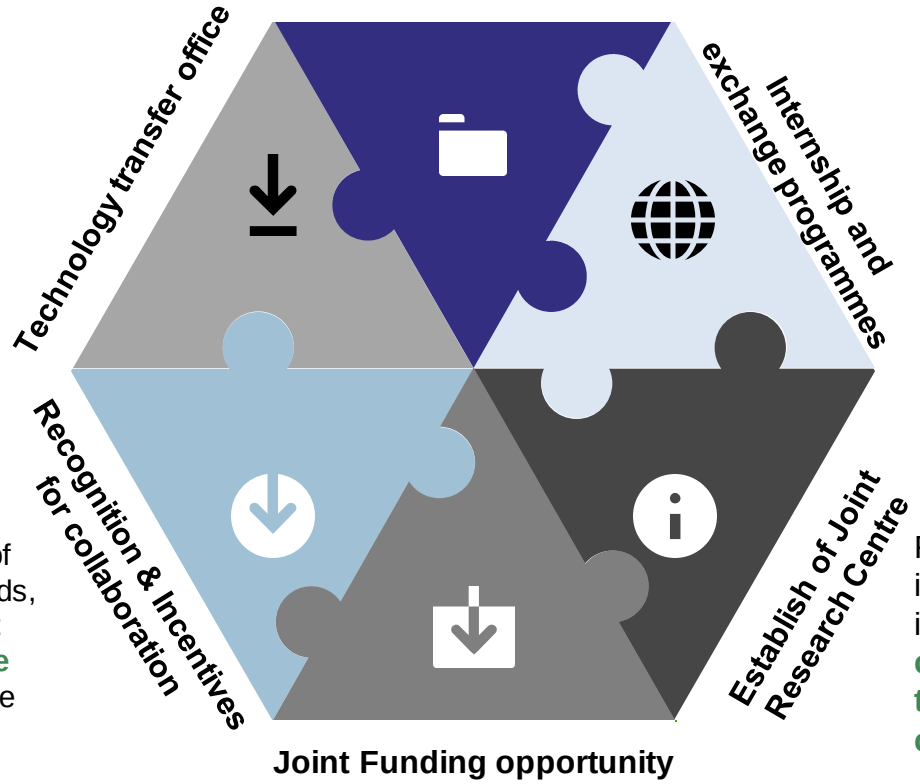
Raise awareness about the benefits of Information Technology (IT) **adoption and digitalization across various sectors. Provide training and capacity-building programs to facilitate the adoption of digital technologies and** IT solutions, particularly among small and medium-sized enterprises (SMEs).

Support for Startups and SMEs:

Provide **targeted support and funding opportunities for startups and SMEs engaged in technology-driven** sectors. Offer grants, subsidies, and incubation support to nurture innovative ideas, scale up technology ventures, and foster

Industry Academia Collaboration is critical for grass root development and scale up

Strengthen the capacity of technology transfer offices within academic institutions to facilitate the **commercialization of research findings and intellectual property.** Streamline the process of technology licensing, patenting, and spin-off formation to expedite the transfer of innovations to the market.



Develop internship and exchange programs that enable students and faculty members to gain practical experience in industry settings. **Encourage industry professionals to serve as guest lecturers, mentors, or advisors in academic institutions, providing valuable insights** and guidance to students.

Recognize and reward successful examples of industry-academia collaboration through awards, accolades, and incentive programs. **Highlight case studies and success stories to inspire other stakeholders to engage in** collaborative initiatives.

Foster the creation of joint research centers and innovation hubs where industry partners and academic institutions can collaborate on research projects. These **centers can facilitate knowledge exchange, technology transfer, and interdisciplinary collaboration.**

Create joint funding mechanisms and grant programs to support collaborative research projects between industry and academia. Provide financial incentives **and matching grants to encourage industry investment in research and development activities conducted in partnership** with academic institutions.

Multiple other building blocks can also help strengthen the existing and new manufacturers (1/2)

01

Technology Upgradation & Modernization

Encourage existing manufacturers to **invest in technology upgradation, automation, and modernization of production processes** to improve efficiency, quality, and competitiveness. Provide incentives, subsidies, and grants to support investments in new equipment, machinery, and digital technologies.

02

Product diversity & Innovation

Encourage existing manufacturers to diversify their product offerings and explore new market opportunities through innovation and product development. **Provide support for research and development (R&D) activities, technology transfer, and collaboration with research institutions or startups.**

03

Supply chain Optimization

Encourage existing manufacturers to optimize their supply chains, **streamline operations, and enhance collaboration with suppliers, distributors, and logistics partners. Facilitate networking opportunities, industry clusters, and supply chain** consortia to promote collaboration and efficiency gains.

04

Policy advocacy & Stakeholder engagement

Advocate for policies and regulations that support the growth and competitiveness of existing manufacturers. **Engage with industry associations, chambers of commerce, and government agencies to identify challenges**, address barriers, and advocate for supportive policies.

05

Access to finance & Investment support

Provide access to finance, credit facilities, and investment support for existing manufacturers to **fund expansion, diversification, and technology upgrades.** Create financial incentives, loan guarantees, and venture capital funds tailored to the needs of manufacturing enterprises.

Multiple other building blocks can also help strengthen the existing and new manufacturers (2/2)

Strategic planning &Forecasting

- **Utilize data analytics, market research, and** stakeholder consultations to inform procurement decisions and identify potential gaps or opportunities.

Procurement contract

- **Establish long-term procurement contracts and agreements with** reliable suppliers and manufacturers to ensure a steady and uninterrupted supply of essential goods and services.
- **Negotiate favorable terms and conditions that promote competitiveness**, quality, and innovation.

Public & Private partnership

- Foster collaboration between the public and private sectors through **PPPs to address infrastructure development, public service delivery,** and other procurement needs. Leverage private sector expertise, resources, and efficiencies to enhance the effectiveness and efficiency of procurement processes.

Innovation Procurement

- Encourage innovation procurement practices that prioritize the adoption of innovative technologies, solutions**, and products that address specific needs or challenges**. Provide incentives, funding, and technical assistance to support pilot projects, demonstrations, and technology adoption initiatives.
- **Bring inclusion and diversity** in supply chains

Capacity building

- Invest in **capacity building, training, and skill development programs for procurement professionals** to enhance their knowledge, expertise, and capabilities.
- Provide training on **best practices, ethical standards, and compliance requirements** to improve procurement governance and performance.

Section 3

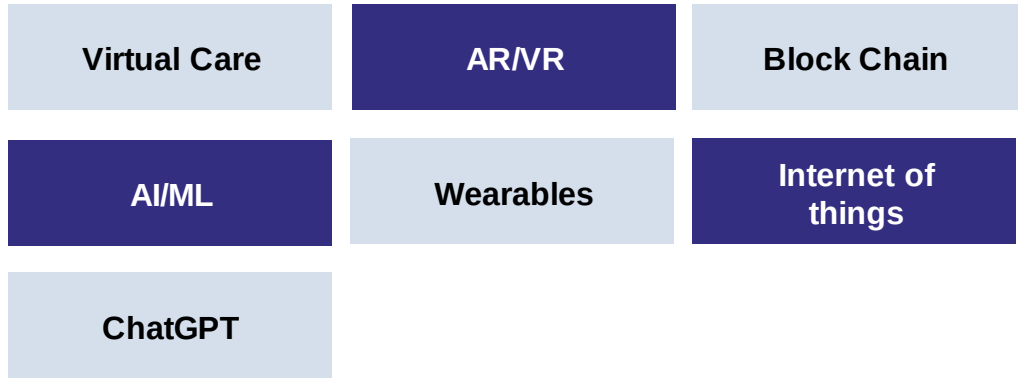
Device-led digital health to promote preventive health and extend care continuum, especially in non-metros

Digital Health has the potential to leverage the digital technologies to improve the healthcare outcomes

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



Source: WHO global strategy 2020-25 and A digital pill for revolutionizing healthcare, BCG report
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Digital health can eliminate the gaps in the care delivery

Healthcare space without digital intervention

Patient

Issues

- Transportation cost
- Waiting time
- Loss of previous health record
- OOPE expenditure (13.8% medical inflation in 2021)

Hospital

Issues

- Time consuming, hence ignored
- Overdosage, irregularity in medicine consumption
- Lack of manpower (Physician = 0.7/1000 people)

Diagnosis, treatment

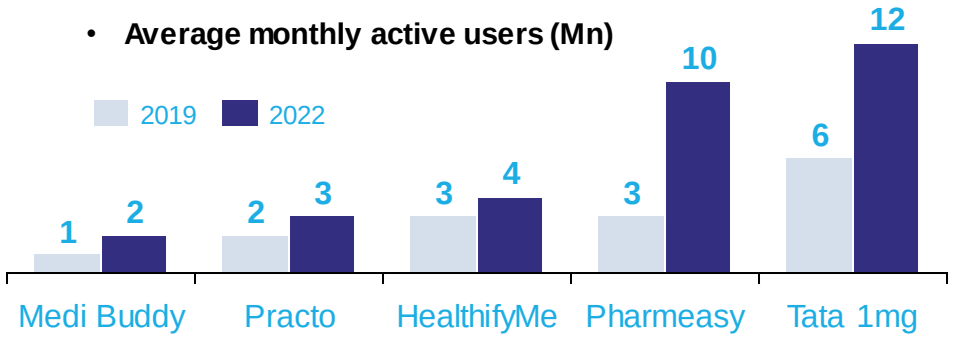
Issues

- Very few opt for rehabilitation services
- Loss of income
- Unemployment
- Social and mental issues

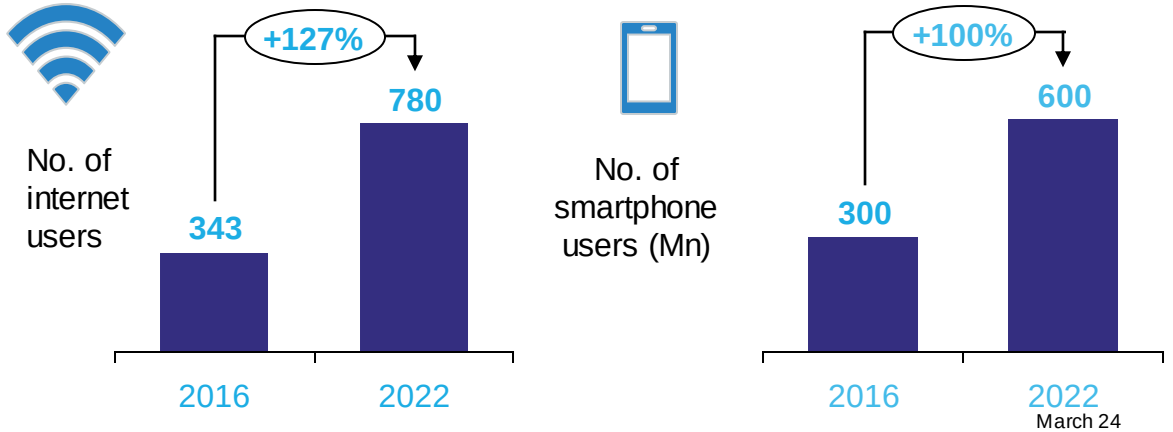
Rehabilitation services

Digital health penetration in India

- E- sanjeevani (consultation) has served 100 Mn by Jan 23
- More than 52.5 Cr ABHA ID created by 6th February 24
- Health claim exchange process also digitalised
- **Average monthly active users (Mn)**

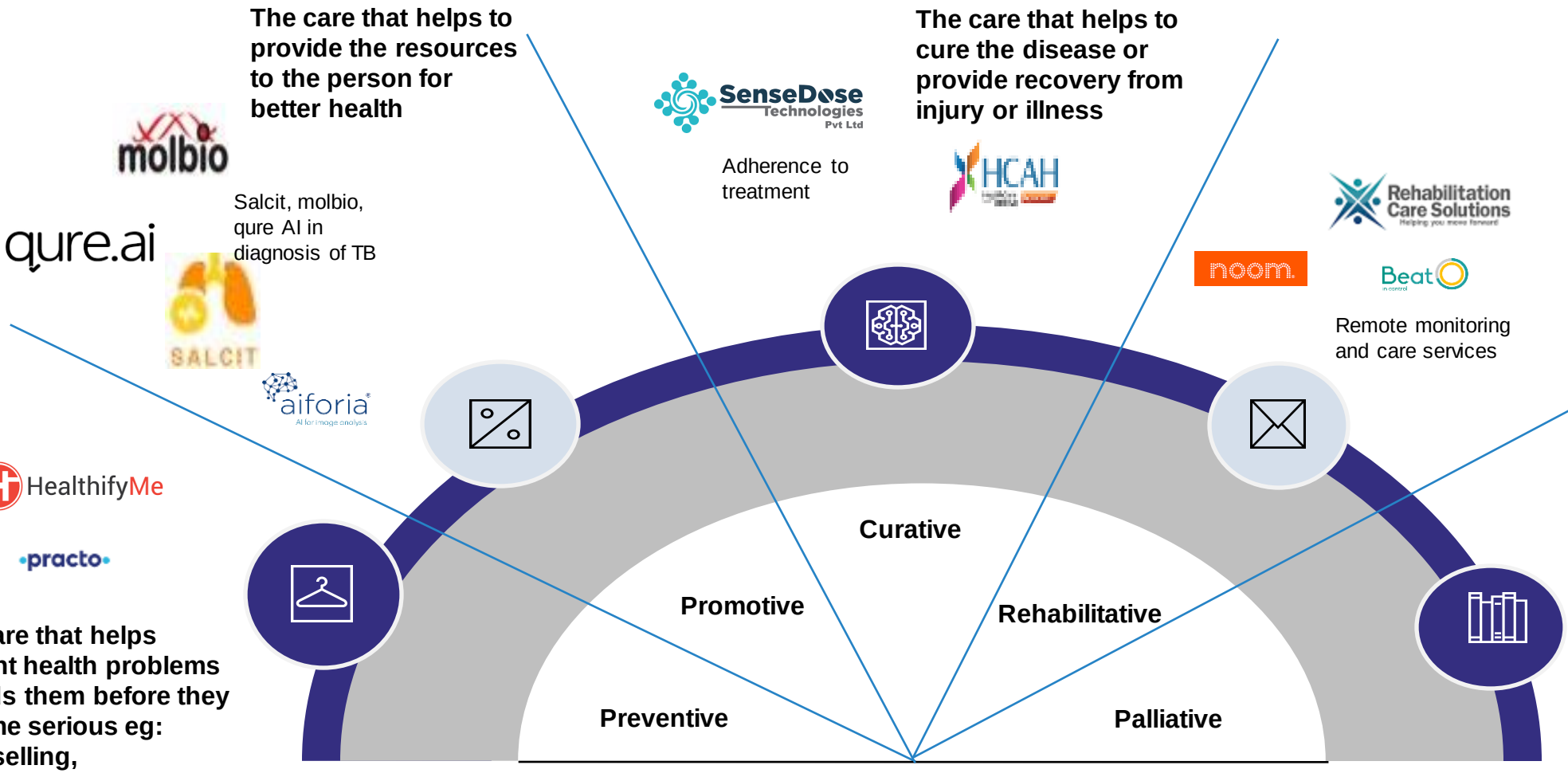


Factors responsible for growth of digital health



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

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



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
qure.ai	Tuberculosis	Artificial intelligence	Yes	Yes	Yes	Mass Screening	Primary	12+ countries	Yes	No	90% sensitivity	Absence of radiologist
Swaasa	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
HealthCube SMART DIAGNOSTICS STARTS HERE	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
moskeet Smart Mosquito Surveillance	Vector borne disease	Internet of things	Yes	NA	Yes	Surveillances	Primary	USA & South Africa	Yes	Yes	NA	Not required

Light blue filling means the category is well fulfilled by them while dark blue means they need to further grow in the areas

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

Source: Websites of various organisation

Major players from various segments and their portfolio to expand in market

	Players*	Market share	Bouquet of services	Collaboration/ Merger/ Acquisition	Investments
E- Pharmacy	TATA 1mg	FY 2022- 23 19% To 31%	Teleconsultation Health & Wellness E- Diagnostics (owned 15 labs)	SBI, PATANJALI, TATA DIGITAL, famhealth, Dr Lal PathLabs, MAHAJAN IMAGING, Max Bupa Health Insurance	Tata Digital had made an investment commitment of nearly Rs 100 Cr in 1mg
	netmeds.com India Ki Pharmacy	11% To 14%	Health & Wellness E- Diagnostics (owned 40 labs)	ZEE5 1- month free subscription to netmeds users Reliance Industries Limited Bought major stakes in the organization	Reliance Ltd bought 60% stakes in Indian digital pharma marketplace Netmeds for Rs 620 Cr
E- Diagnostics	Healthians	The Revenue increase 70% Year on year, observed 150% to 285% growth in tier-1 and tier- 2 (2021-22)	E- Diagnostics, 12 labs across the country	SIEMENS, Abbott, BECKMAN COULTER Technology partners	Healthians raises $ 54 Mn from WestBridge, Trifecta claiming its presence in 140 cities
Home care	HCAH HealthCare atHOME By your side	Increase 150 beds to 1500 beds for transition care, from the funds received from ABC world	Track health, doctor's insights, adherence to treatment Online drug delivery	Manipal Cigna Health Insurance Insurance organization to reduce OOPE RPG Digital health platform bought for geriatric care Critinext Enhance critical care	Singapore based ABC World Asia invested Rs 112 Cr in HCAH

*This is an illustrative slide on digital health business of various players

Source- The economics times, Websites of the major players and Indian Journal of Pharmacology: The rise of E- Pharmacy in India
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Government is leading a digital health initiative to ensure healthcare accessibility & affordability

Arogya Setu

COVID contact tracing, self- assessment & real- time advisories to citizens

Aarogya Setu

218Mn+
Total Installs

40 Days
First 100 Mn+ Installed

E- Sanjeevani OPD

National telemedicine program to provide primary care to remote areas

eSanjeevaniOPD
STAY HOME OPD

100 Mn+
Patient served

200k+
Providers Onboarded

CO-WIN

Easy vaccine administration- find vaccine centres, book slots & receive digital certificates

Co-WIN
Winning Over Covid-19

10 Mn+
Registered citizens

2 Bn+
Total vaccine administered

PM- JAY

Health insurance scheme to provide free secondary & tertiary care for EWS*

प्रधानमंत्री जन आरोग्य योजना
आयुष्मान भारत
PM-JAY

500 Mn+
Beneficiaries

INR 5lakhs
Insurance covered per family

*Economically w eaker section

Ayushman Bharat Digital Mission

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

Source: A digital Pill for Revolutionizing Healthcare, BCG report
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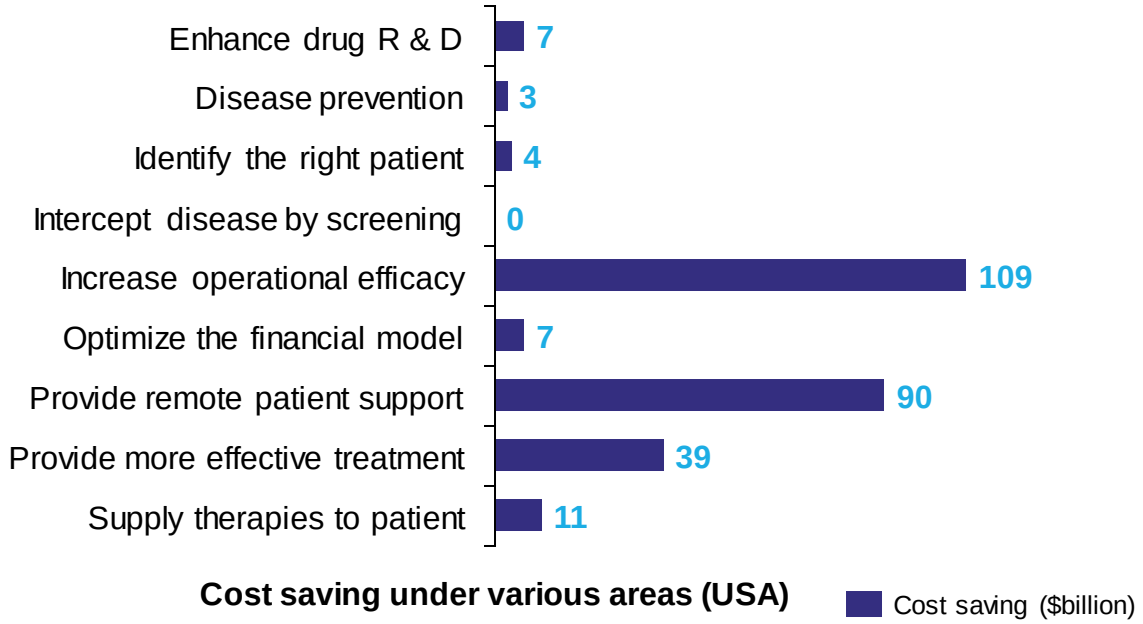
Real world evidence data has highlighted the improvement in outcomes using digital technologies

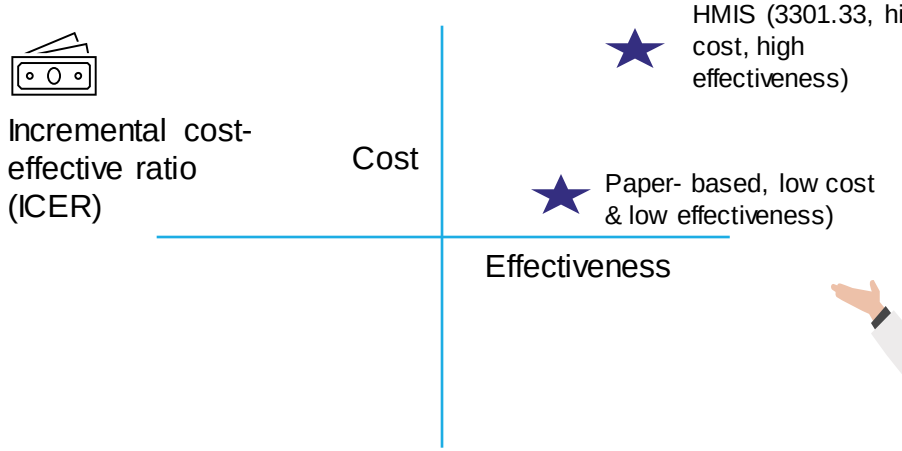
Care- delivery pool represents ~55% of the direct cost- saving potential associated with digital technologies (USA)



- One of the primary value propositions offered by digital health technologies is healthcare cost reduction.
- **Based on 2018 healthcare spend information, we estimate that digital health interventions alone have the potential to save the US healthcare system nearly $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.



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

Source- Mckinsey report on Health tech in the fast lane: What is fueling investors excitement? And Economic evaluation of hospital management information system in Tamil Nadu, India Realizing the full potential of MedTech Industry in India 2.0

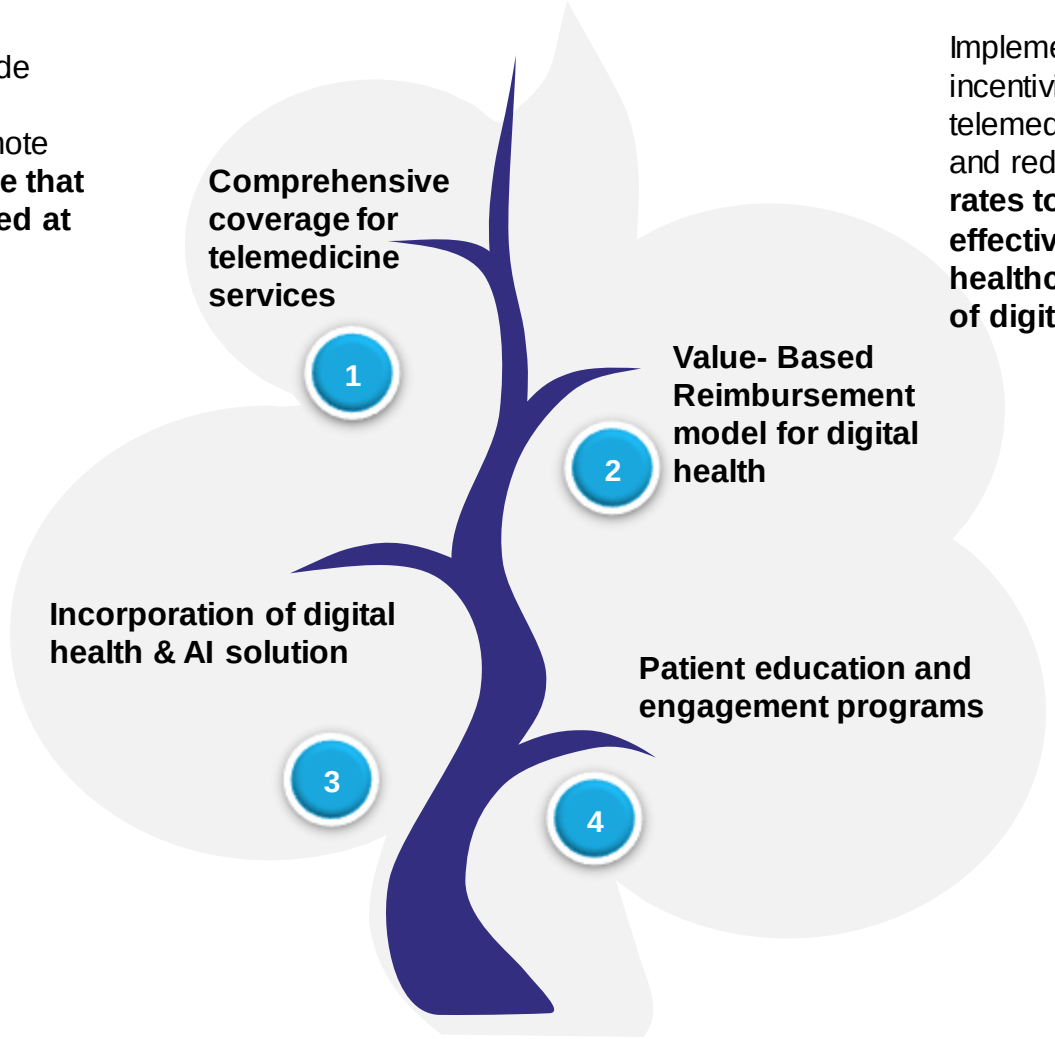
Adoption of these technologies can help deliver new forms of care as seen in India

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

Source: Website of various organization

Going forward, to help drive in the adoption of digital led healthcare, insurance schemes should include these services delivered via digital technologies

Expand insurance benefit packages to include comprehensive coverage for telemedicine services, including virtual consultations, remote monitoring, and telehealth platforms**. Ensure that telemedicine consultations are reimbursed at par with in-person visits to encourage utilization and adoption by healthcare providers and patients.**



Implement value-based reimbursement models that incentivize the use of digital health technologies and telemedicine services to improve patient outcomes and reduce healthcare costs. **Tie reimbursement rates to performance metrics such as clinical effectiveness, patient satisfaction, and healthcare utilization to encourage the adoption of digital health solutions**

Incorporation of AI and Digital Health Solutions into **insurance benefit packages to improve diagnostic accuracy, treatment outcomes, and patient care. Include coverage for AI-powered medical imaging analysis, predictive analytics,** remote patient monitoring devices, and digital therapeutics 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. **Provide resources, information, and support to empower patients to take advantage of remote healthcare services, manage their health effectively, and navigate the digital health landscape**

Leverage Capabilities in SIMD and SAMD at the Global Stage

International collaboration & Partnership

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. **Facilitate knowledge exchange, joint research projects, and collaborative initiatives with global counterparts to drive innovation.**

Participation in International Standard Development

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**. Engage with organizations such as the International Medical Device Regulators Forum.

Promotion of regulatory convergence

Advocate for regulatory convergence and harmonization initiatives **to facilitate market access and regulatory compliance for SIMD and SAMD products on a global scale.** Collaborate with regulatory authorities, industry associations, and other stakeholders to streamline regulatory pathways.

Global market expansion & export

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.**

Establish formal channel of linkage between smaller & larger hospitals

Telemedicine and Virtual Consultations: 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. **Provide training, technical support, and telehealth infrastructure to facilitate virtual collaborations and multidisciplinary consultations**

Collaborative Research and Quality Improvement Initiatives: Foster collaborative research and quality **improvement initiatives between smaller hospitals, medical colleges, and quaternary care centers to address common clinical challenges, share best practices, and improve patient outcomes.** Support joint research projects, clinical trials, and quality improvement programs that leverage the expertise and resources of all stakeholders.

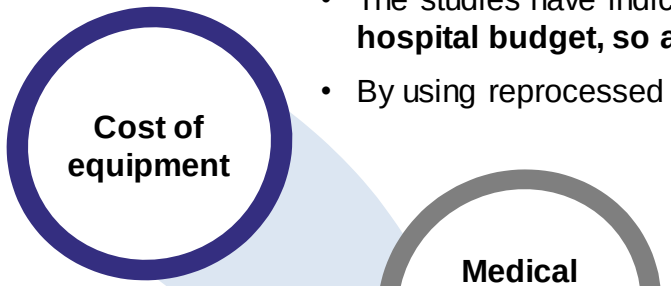
Establishment of Referral Networks: Create formal referral networks and channels of linkage between smaller hospitals, medical colleges, and quaternary care centers to facilitate seamless patient transfers, consultations, and referrals. **Develop standardized protocols, communication pathways, and electronic referral systems to streamline the process and ensure continuity of care.**

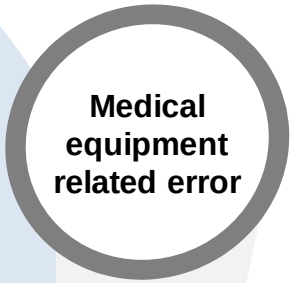
Clinical Training and Mentorship Programs: Develop clinical training and mentorship programs that enable healthcare professionals from smaller hospitals to **gain hands-on experience and specialized training at larger hospitals and quaternary care centers. Facilitate structured rotations, observerships, and continuing medical education (CME) opportunities to enhance skills and knowledge transfer.**

Section 4

Promote safe usage of medical devices supported by patient awareness, accreditation and skilling

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





- The studies have indicated that annual medical equipment maintenance and management **cost is approximately 1% of the total hospital budget, so a 500-bed hospital spends typically around $5 million/year**
- By using reprocessed devices, hospitals **lower their costs for medical devices by 25 to 40 %**

- Statistics accumulated by The Joint Commission (TJC) show **medical equipment-related "sentinel events" is typically among the top ten medical errors**
- Therefore, hospitals and healthcare organizations must ensure that their critical medical devices are safe, accurate, reliable and operating at the required level of performance

Regular maintenance of medical device for prolong life of device

Maintenance of medical devices & Patient safety: Government spends

Medical devices to get better maintenance in view of patient safety

As per reports there were a total of 756,000 pieces of equipment in 29,115 government medical institutions. **However, 4,560 medical devices are not working**

The **Centre had spent Rs113 crore in 2016-17 on maintenance of 4,560 medical devices** which were not functional in various public hospitals.

Source: A literature review : Medical devices inspection & maintenance, Canada , Association of medical Devices & Mint New spaper
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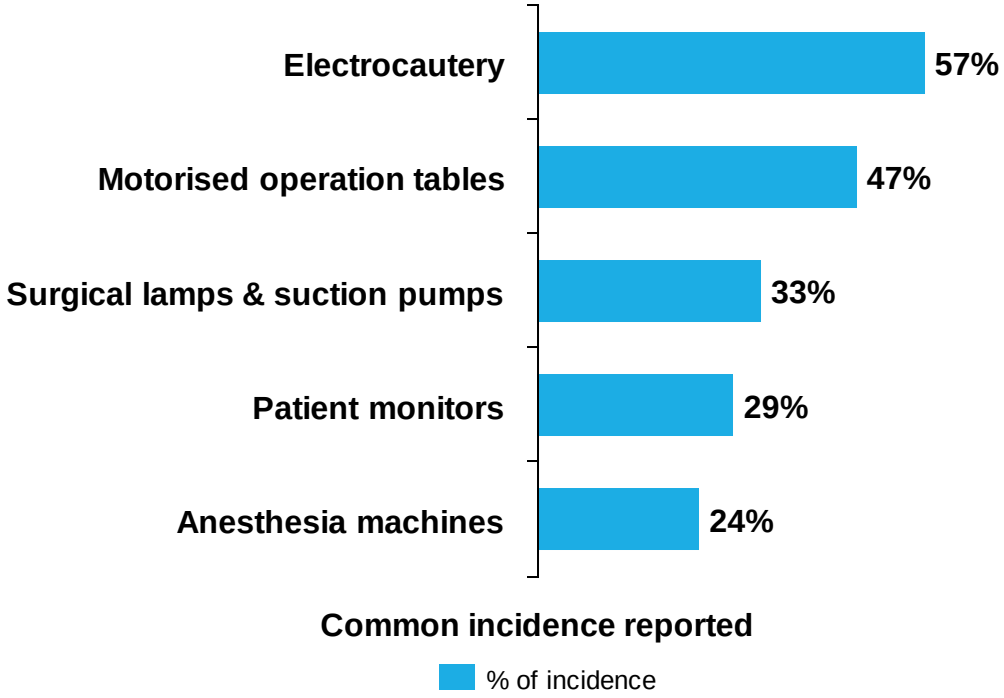
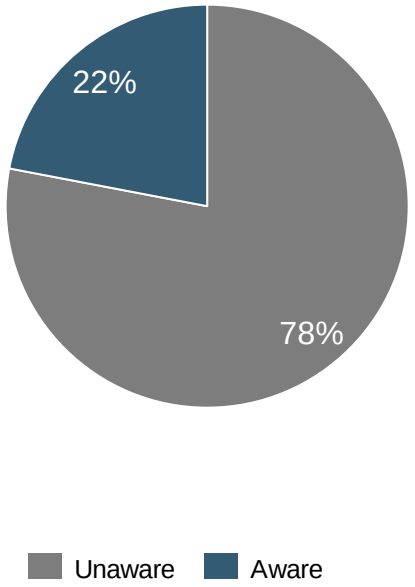
Need for regular maintenance of equipment's (AMC & CMC) and patient safety - Equipment in range of 13% to 34% were found dysfunctional across states

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



Awareness related to electrical safety testing procedure for medical equipment



As per The Joint Commission, the total number of medical equipment related incidents during the period of **January 1995 to September 2009 is only 125 or 1.9% of the total 6,428** sentinel events for all *The Joint Commission accredited hospitals. The number is less due to lack of reporting.*

Source: National efforts to improve healthcare technology management and medical devices safety in India
Evidence- based maintenance Part 3, Enhancing patient safety using Failure code analysis
Realizing the full potential of MedTech Industry in India 2.0
PwC

Failure of regular maintenance of medical devices directly affects patient safety

Device type	Selected advisories, alerts, and warnings	Notes and recommendations for safer device use
Infusion devices	• Sentinel event alert: • Tubing misconnections • Advisory: Smart infusion • pump technology	• A total of 30%-60% of all harmful intravenous medication errors are directly associated with infusion pumps Eliminate standard Luer-connection syringes for the administration of oral medications and enteral feedings. • Use distinct and dedicated infusion pumps for different applications (eg, epidural vs intravenous) 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
Patient monitors and alarms	• Top 10 hazards of 201026 • NCPS 2009 Advisory • AD09-09 “Alarms on • bedside physiological • monitors” • Advisory: Alarms on • bedside physiological • monitors	• 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

Source: Medical devices and patient safety , Elizabeth Mattox
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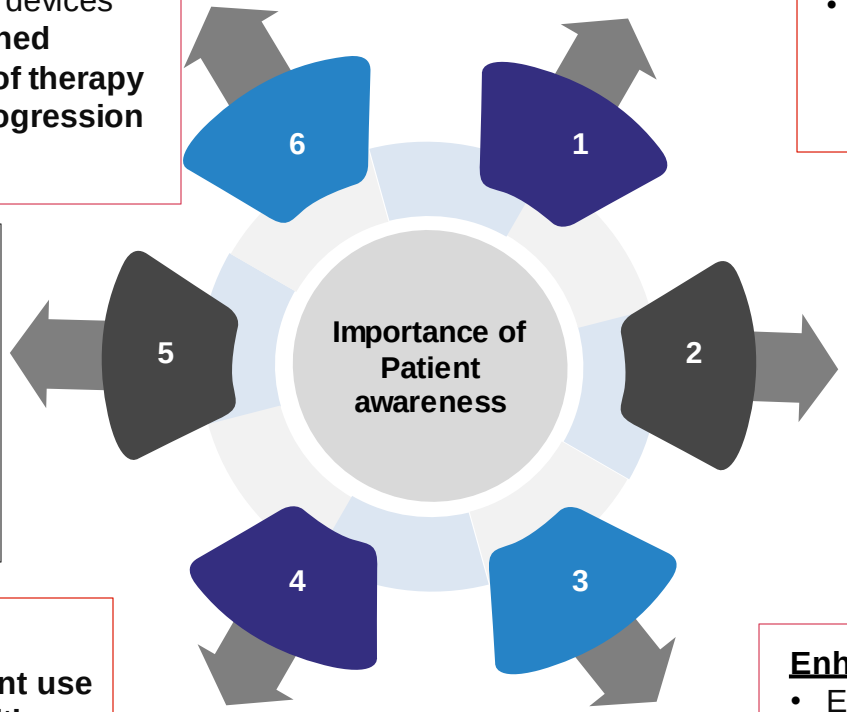
Patient awareness plays a critical role in ensuring safe and effective usage of medical devices

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. This **sustained compliance enhances the effectiveness of therapy and reduces the likelihood of disease progression or complications.**

Empowerment of self management
Awareness empowers patients to take an active role in their healthcare and promotes self-management of chronic conditions. With proper education, individuals can **confidently use medical devices as part of their daily treatment regimen**, leading to improved quality of life and overall well-being.

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. Patients who are knowledgeable about their medical devices are less likely to require additional medical interventions or hospitalizations due to complications arising from improper usage.



Optimal treatment outcomes
- Patient awareness enables individuals to understand the **proper usage and benefits of medical devices, leading to better treatment outcomes**.
- *For example, correct inhaler technique ensures that patients receive the prescribed dose of medication to manage respiratory conditions effectively.*

Prevention of adverse events
- Awareness of device usage guidelines helps patients **avoid potential complications or adverse events** associated with improper usage.
- *For instance, incorrect administration of insulin via pumps can lead to fluctuations in blood sugar levels, posing risks of hypoglycemia or hyperglycemia.*

Enhanced disease management
- Educated patients are better equipped to manage their medical conditions by using devices correctly. Proper use of insulin pumps, for instance, allows individuals with diabetes to maintain stable blood glucose levels, **reducing the risk of long-term complications.**

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, emerging technologies, and regulatory changes.

Regulatory Framework

- The Medical Devices Rules, 2017, issued by the Central Drugs Standard Control Organization (CDSCO), govern the manufacture, import, distribution, and sale of medical devices in India.
- ***The rules mandate that medical devices comply with specified standards and quality requirements***

Quality Assurance and Audits

- Healthcare facilities implement quality assurance programs to monitor and evaluate equipment maintenance processes.
- ***Internal audits and periodic inspections help identify areas for improvement*** and ensure adherence to maintenance protocols.

Maintenance Requirements

- Healthcare facilities are responsible for ensuring that medical devices are properly maintained to prevent malfunctions or breakdowns that could compromise patient care.
- ***Regular maintenance schedules are recommended for all medical equipment based on manufacturer guidelines and usage patterns.***

Adherence to Standards

- Medical equipment ***maintenance practices adhere to national and international standards*** such as ISO 13485 and ISO 14971
- Compliance with standards ensures the quality, reliability, and safety of medical devices throughout their lifecycle.

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.
- These contracts may include provisions for preventive maintenance, corrective maintenance, and emergency repair services.

Documentation and Record-keeping

- Healthcare facilities maintain detailed records of equipment maintenance activities, including service logs, maintenance schedules, and repair histories.
- ***Accurate documentation ensures compliance with regulatory requirements and facilitates audits and inspections.***

Training and Education

- Healthcare personnel responsible for operating and maintaining medical equipment receive training and education on device usage, maintenance protocols, and troubleshooting techniques.
- Training programs may be ***organized by equipment manufacturers, healthcare institutions, or professional associations.***

Principles to this quality regimen are also highlighted in different public Policy frameworks

1	**Quality:** To ensure the quality of the products manufactured in the country to be given utmost importance and more focus in order to enhance global positioning, acceptability and competitiveness.
2	**Research and Innovation**: To create an eco-system in tune with evolving times and needs to encourage and sustain the innovation in the Sector, such as technology driven medical devices with miniaturization /nano-technology / telecommunication technologies / IoTs & AI and precision and Individualized care for preventive, promotive, diagnostic, curative care.
3	**Access & Universality**: To strongly advocate for universal access to good quality Medical Devices for ensuring quality healthcare services to all at all ages, by responding to and aligning with public health strategies
4	**Security**: To ensure the Medical Devices Security (on par with Drug and food security of the country), by development of strong local manufacturing capabilities including for components and ancillary industry and to develop a resilient supply chain for inputs or raw materials, with optimal level of external dependency
5	**Preventive & Promotive Health:** To make people more aware and vigilant, enabling them to lead a healthier lifestyle by achieving extensive application of medical devices in early screening and diagnosis for early detection / prevention and management of diseases.
6	**Affordability**: To enhance the domestic manufacturing capacity and capability for newer technologies, so as to make the medical devices affordable and thereby, reducing the out-of-pocket expenditure on diagnostics, thus reducing the lifetime cost of disease burden.
7	**Patient centered & Quality Care**: To improve the quality of care by improving clinical outcomes and convenience of the patients, through early diagnosis of diseases and increased accuracy in treatment
8	**Skilled manpower**: To facilitate the future-ready skilled manpower aligned to the multi-disciplinary nature of medical device technologies

Source: Public Information Bureau

Strategies to channelise the process and improve the affordability and quality of patient care through well- maintained and better-quality medical device

Regulatory streamlining	Enabling Infrastructure	Facilitating R&D and Innovation	Accelerating Investment	Human resource development	Brand positioning & Awareness creation
To make it easier to do research and business while balancing patient safety and product innovation, a **"Single Window Clearance** System" for licensing medical devices will be created.	1.Large medical device parks with world-class infrastructure facilities will be established, near economic zones. Envisioned under the **National Industrial Corridor Program** and the proposed **National Logistics Policy** 2021 under the ambit of PM **Gati Shakti**	Aims at establishing Centers of Excellence in academic and research institutions, innovation hubs**, 'plug and play' infrastructures and support to start-ups.**	The policy encourages private investment and **Public-Private Partnerships (PPP)** to complement existing schemes such as **Make in India**, **Ayushman Bharat program**, Heal-in-India, and Start-up mission.	The policy aims to ensure a **skilled workforce in the medical device sector** by providing skilling, reskilling and upskilling programs through the Ministry of Skill Development and Entrepreneurship**.**	The policy envisages the creation of a **dedicated Export Promotion Council** for the sector which will be an enabler to deal with various market access issues.

Source: Public Information Bureau

Different organizations are offering courses in upskilling for medical devices domain

Organizations	Background	Key role	Offerings	Courses/training offered - Illustrative
Andhra Pradesh MedTech Zone (AMTZ)	AMTZ is India's first and only dedicated medical technology manufacturing zone, established to promote indigenous manufacturing of medical devices.	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.	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.	
National Skill Development Corporation (NSDC)	NSDC is a public-private partnership organization mandated with skill development initiatives across various sectors, including healthcare	NSDC collaborates with skill councils, training providers, and industry stakeholders to develop skilling programs, curriculum frameworks, and certification standards for medical device usage.	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.	Technical Intern Training Program
National Health Systems Resource Centre (NHSRC)	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.	NHSRC plays a role in promoting the safe usage of medical devices by developing training modules, guidelines, and protocols for healthcare providers.	The center conducts ***training programs, workshops, and knowledge-sharing sessions*** on medical device management, maintenance, and quality assurance to improve healthcare service delivery.	
National Health and Paramedical Council	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.	The council establishes competency standards, conducts examinations, and grants certifications to individuals demonstrating proficiency in medical device usage.	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.	• Medical Device Regulatory Affairs • Medical Device Design and Development • Biomedical Instrumentation

Source: Websites of various organisation

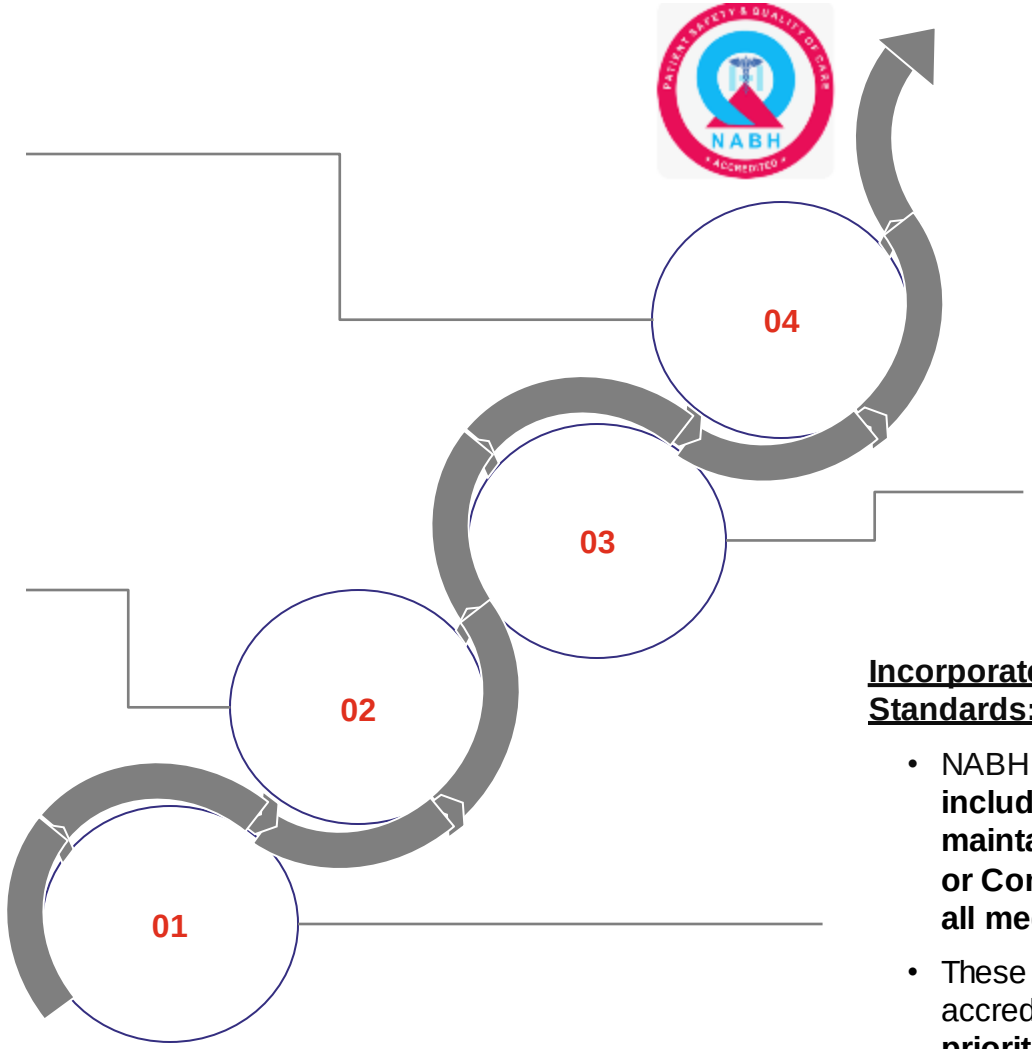
Going forward, inclusion of AMC / CMC regimen in NABH standards can help drive in its adoption and make it more objective

Implement Monitoring Mechanisms:

- **Establish mechanisms for monitoring compliance** with AMC/CMC requirements during the accreditation process.
- **Conduct periodic audits or inspections** to verify the existence and validity of maintenance contracts and assess adherence to contractual terms and conditions.

Specify Criteria for Valid Contracts:

- **Define specific criteria** that AMC/CMC contracts must meet to be considered valid within the accreditation standards.
- Criteria may include **provisions for periodic servicing intervals, response times for repairs, qualifications of service providers**, and coverage of essential components.



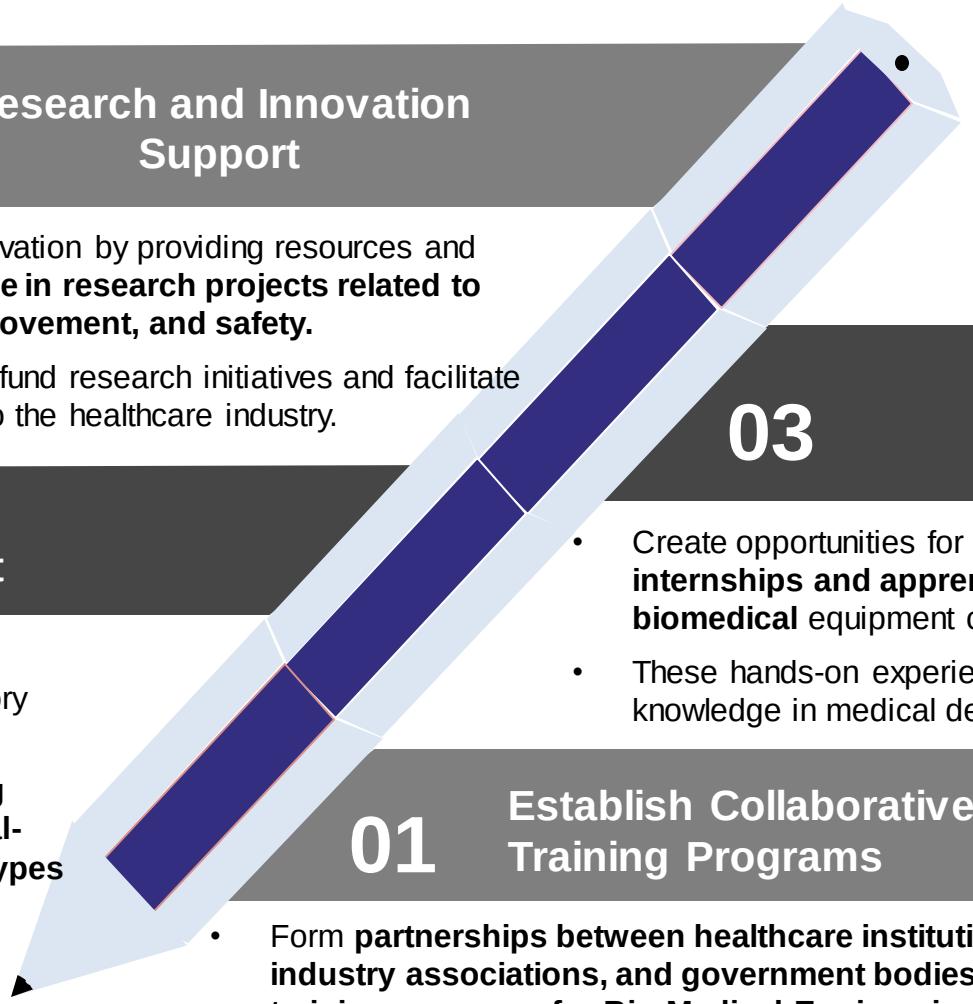
Ensure Compliance with Manufacturer Guidelines:

- 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.
- Emphasize **the importance of using authorized service providers and genuine spare parts to maintain device functionality and safety.**

Incorporate AMC/CMC Requirements into Accreditation Standards:

- NABH should revise its **accreditation standards to include the requirement for healthcare facilities to maintain valid Annual Maintenance Contracts (AMC) or Comprehensive Maintenance Contracts (CMC) for all medical devices.**
- These contracts should be deemed essential for accreditation, ensuring **that healthcare facilities prioritize the regular maintenance** and servicing of their medical equipment.

From a supply side perspectives, joint initiatives can be undertaken for bio – Medical Engineering training



04 Research and Innovation Support

- 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.**
- Collaborate with industry partners to fund research initiatives and facilitate technology transfer from academia to the healthcare industry.

03 Internship and Apprenticeship Opportunities

- Create opportunities for **BME students to participate in internships and apprenticeships at healthcare facilities, biomedical** equipment companies, and research laboratories.
- These hands-on experiences will enhance their skills and knowledge in medical device maintenance and troubleshooting.

02 Curriculum Development

- 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 in servicing various types of medical equipment.**

01 Establish Collaborative Training Programs

- Form **partnerships between healthcare institutions, universities, industry associations, and government bodies to develop collaborative training programs for Bio-Medical Engineering (BME) students.**
- These programs should provide **comprehensive training in the installation, maintenance, repair, and safe operation of medical devices.**

Patient awareness initiatives are likely to have a long and sustainable impact

- Encourage healthcare providers to play an active role in educating patients about **medical device safety during consultations, follow-up appointments, and hospital stays.**
- Provide training to healthcare professionals on how to communicate **effectively with patients about device usage and safety concerns.**

Engage healthcare providers

Educational Campaigns

- Launch comprehensive educational campaigns to **raise awareness among patients about the safe and proper usage of medical devices.**
- Provide information on how to use devices correctly, **potential risks associated with misuse, and steps to take in case of device malfunctions or adverse events**.

Health Literacy Programs

Accessible Information Resources

- Implement health literacy programs in healthcare **settings to empower patients with the knowledge and skills needed to navigate medical device usage effectively.**
- Offer interactive workshops and training sessions to improve patients' understanding of device functionalities, **maintenance requirements, and potential risks.**

- Develop easily accessible information resources such as **brochures, pamphlets, and online portals with detailed instructions and safety guidelines for various medical devices.**
- Ensure that these resources are available in multiple languages and formats **to cater to diverse patient populations**.

Section 5

Creating a conducive regulatory framework and supporting industry best practices

WHO cites various pricing models to accommodate the diverse needs and economic capacities of its member countries

Tiered Pricing:
- WHO implements tiered pricing to offer its products and services at different price points based on the economic status of member countries.
- Lower-income countries receive products or services at subsidized or discounted rates, while higher-income countries pay higher prices to reflect their greater economic capacity.

Cost Recovery Pricing:
- Under this model, WHO charges member countries fees to recover the costs associated with providing specific products or services.
- The fees are structured to cover production, distribution, and administrative expenses incurred by WHO in delivering the product or service.

Donation-Based Pricing:
- WHO may provide certain products or services free of charge to member countries through donations from governments, philanthropic organizations, or other sources.
- This pricing model is commonly used for emergency relief efforts, humanitarian aid programs, and disease control initiatives.

Subscription-Based Pricing:
- WHO may offer subscription-based pricing for access to specific services, publications, or databases on a recurring basis.
- Member countries pay an annual or periodic subscription fee to access WHO's resources and expertise in areas such as disease surveillance, health data analysis, and technical assistance.

Per-Unit Pricing:
- In some cases, WHO may charge member countries on a per-unit basis for certain products or services, such as vaccines, diagnostic tests, or medical devices.
- The price per unit may vary depending on factors such as volume discounts, negotiated agreements, and cost-sharing arrangements.

Flexible Financing Options:
- WHO may offer flexible financing options to member countries, such as installment payments, deferred payments, or financing arrangements tailored to their budgetary constraints.
- These options help ensure that countries can access WHO's products and services without facing undue financial burden.

Value-Based Pricing:
- WHO may adopt value-based pricing for innovative products or services that offer significant health benefits or cost savings to member countries.
- The price is determined based on the perceived value of the product or service in terms of its impact on population health outcomes, disease prevention, or healthcare cost-effectiveness.

Source: WHO

Value-based procurement (VBP) is a strategy increasingly adopted by governments and healthcare organizations 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.

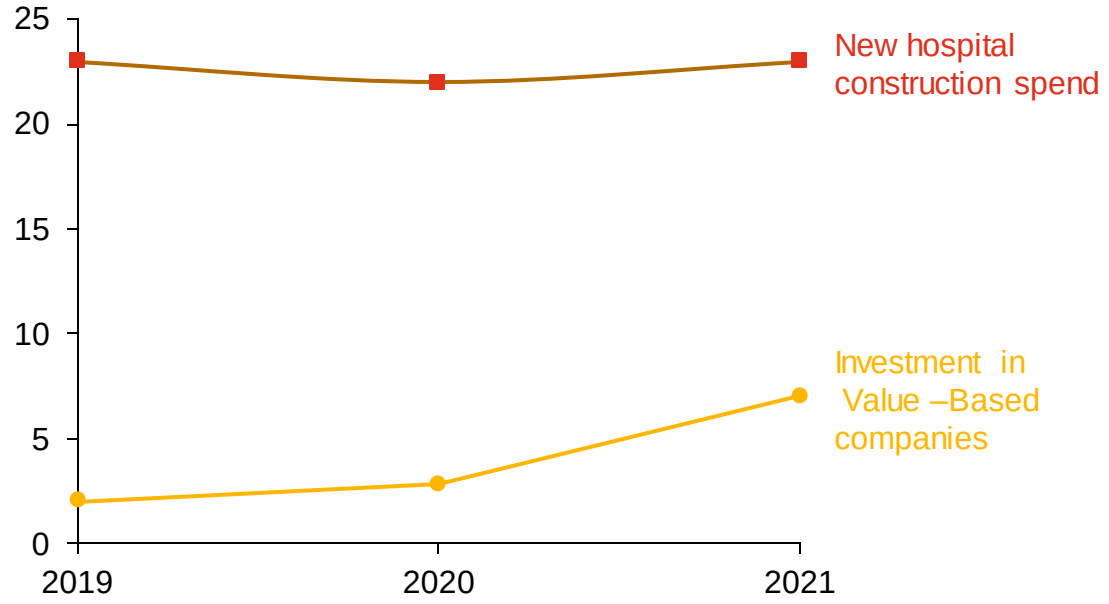
Source: Nathealth report, Value Based Procurement in MedTech 2022, VBHC policy document 2022

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.**

Source: Mckinsey report on investing in new era of value- Based care & BCG report on value- Based care: opportunity expand
Realizing the full potential of MedTech Industry in India 2.0
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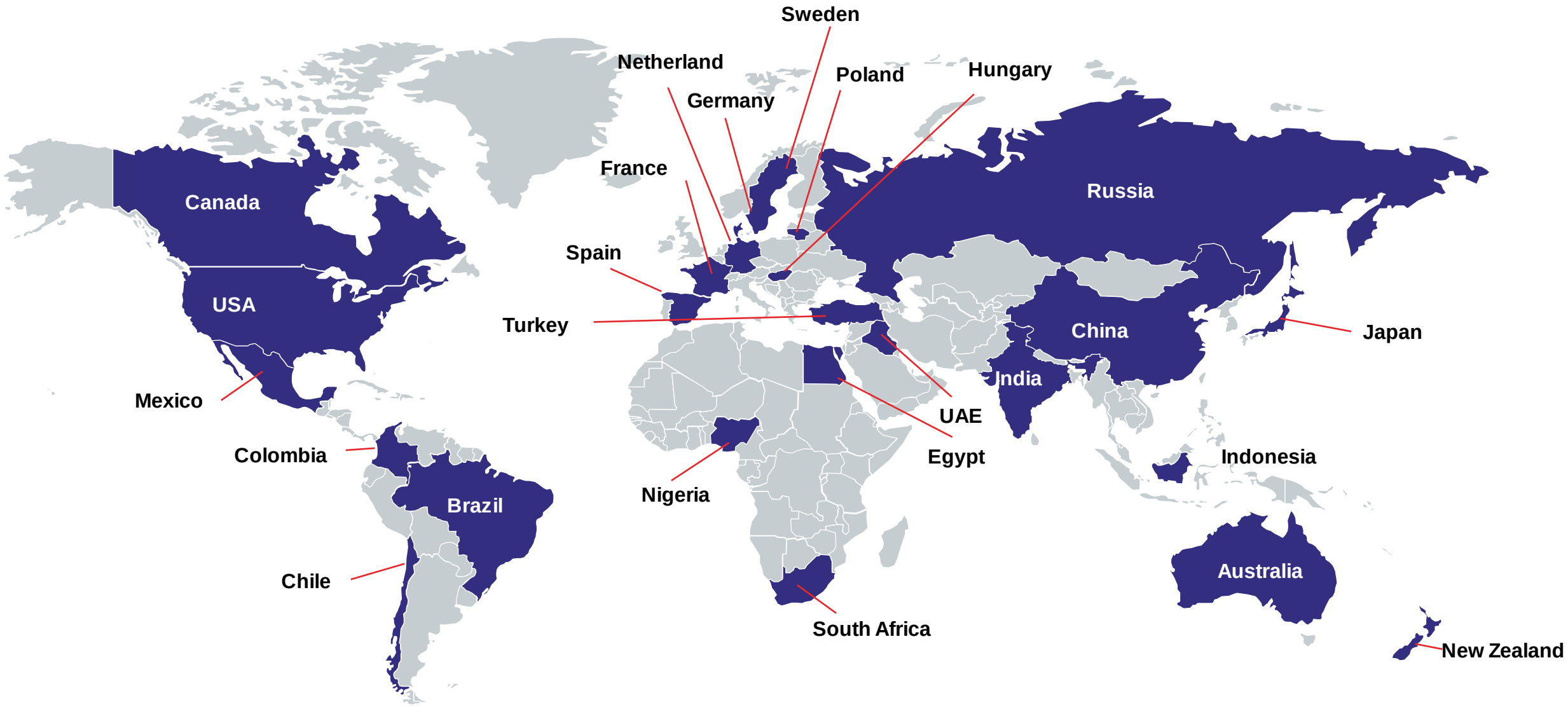
Countries that have adopted the Value Based Care in the world



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

Sweden is the best example for Value Based Care & the healthcare efficiency they bought after the implementation

The EIU (The Economist Intelligence Unit) assessed 25 countries globally on Value Based Care under 4 major criteria as listed. The study was commissioned by Medtronic, a global technology and medical devices company (2016)

Criteria for evaluation of Value Based Care under EIU

- ***Enabling context, policy & institutions for value in healthcare***
  - *Coverage of population*
  - *Stakeholder support*
  - *Health technology assessment*
  - *Policy*
- ***Measuring outcomes & costs***
  - *Patient registries*
  - *EMR/HER*
  - *Patient treatment cost*
- ***Integrated & patient focused care***
  - *Care pathway focus*
- ***Outcome based payment approach***
  - *Existence of mechanism for de-investment*

Score sheet of 25 countries evaluated under Value- Based Care delivery

Appendix C:
Table of country scores

	Unit	Sweden	India
1) Enabling context, policy and institutions for value in healthcare			
1.1) Health coverage of the population	0-4	4	0
1.2) High-level policy or plan	Y/N	N	N
1.3) Presence of enabling elements for value-based healthcare	0-3	3	1
1.4) Other stakeholder support	Y/N	Y	N
1.5) Health professional education and training in VBHC	0-2	0	0
1.6) Existence and independence of health technology assessment (HTA) organisation(s)	0-2	2	1
1.7) Evidence-based guidelines for healthcare	0-4	4	2
1.8) Support for addressing knowledge gaps	0-2	2	2

Lessons from Sweden

- Advanced & interconnected system of EHR
- Quality of health registries
- Predictive analytics, AI & ML
- Empowered patient through digitalization

Bundle payment: Ortho Choice

A small portion of the bundled payment, around 3.2%, is withheld and paid retroactively only if the provider meets previously agreed outcome goals.(care, complication)

Source: The Economist Intelligence Unit, report & Sweden reaching the next level report, 2019

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

Benefits observed after Value Based Care implementation

30.1% Fewer inpatient admissions for Value-Based Care in 2022 **Saving 214,000 admissions**	**7.1%** Fewer admission **Saving 50,000 admissions or 353,000 inpatient days**	**12.7%** Fewer Emergency visits **Saving 146,000 visits**

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

Source: Humana 10th annual report 2023

Sweden outstands along with other 5 countries to have implemented Value- Based Care & received benefits

Benefits received after implementing Value- Based Care

Clinician Engagement

- The cornerstone of Value-Based health care is broad and active engagement on the part of the clinical community
- ***For example, the international study of 13 disease registries in five countries revealed that the improvement in health outcomes is greatest when clinicians themselves are responsible both for collecting and interpreting data and for leading efforts aimed at clinical improvement***

National Infrastructure

- Clinician engagement can be greatly facilitated and supported by the existence of ***common standards for tracking diagnoses, treatments, outcomes, and costs at the patient level; a limited number of shared IT platforms; and a common legal framework regulating the use of patient data***

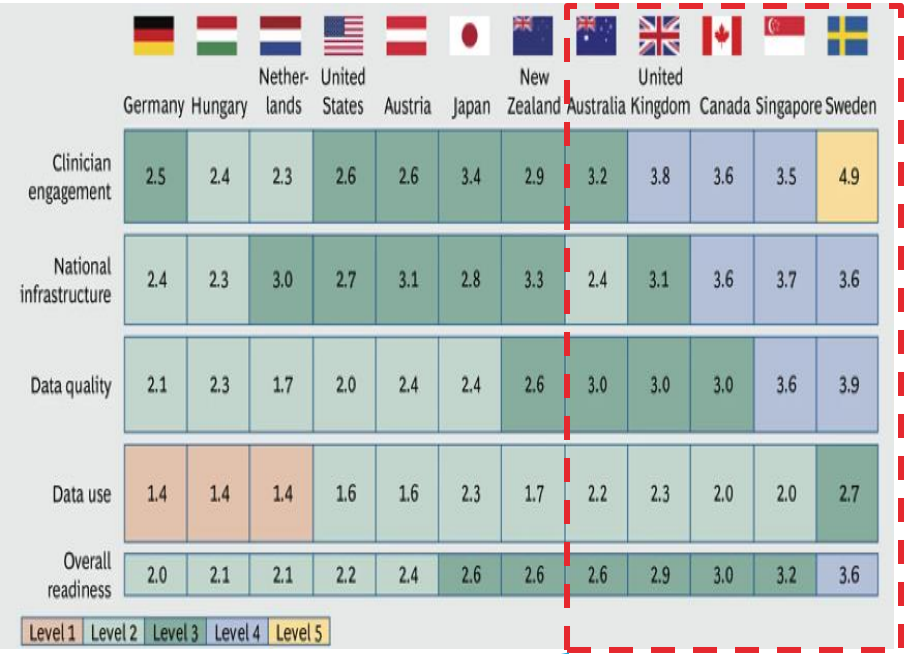
High-Quality Data

- Value-Based health care is a **data-driven approach for improving the quality of care**

Outcome-Based Incentives

- When such incentives are in place, the system itself ***drives changes in the ways clinicians practice, payers reimburse, and suppliers of drugs and medical devices develop and deliver products and services***

Comparative between various countries for Value Based Care on 5 parameters



Level 5 is the reached by Sweden in active engagement of clinicians in Value Based Care whereas Singapore, Canada & UK are also progressing to achieve the level

Source: Value- Based care assessment report by BCG
Realizing the full potential of MedTech Industry in India 2.0
PwC

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

Public awareness & education

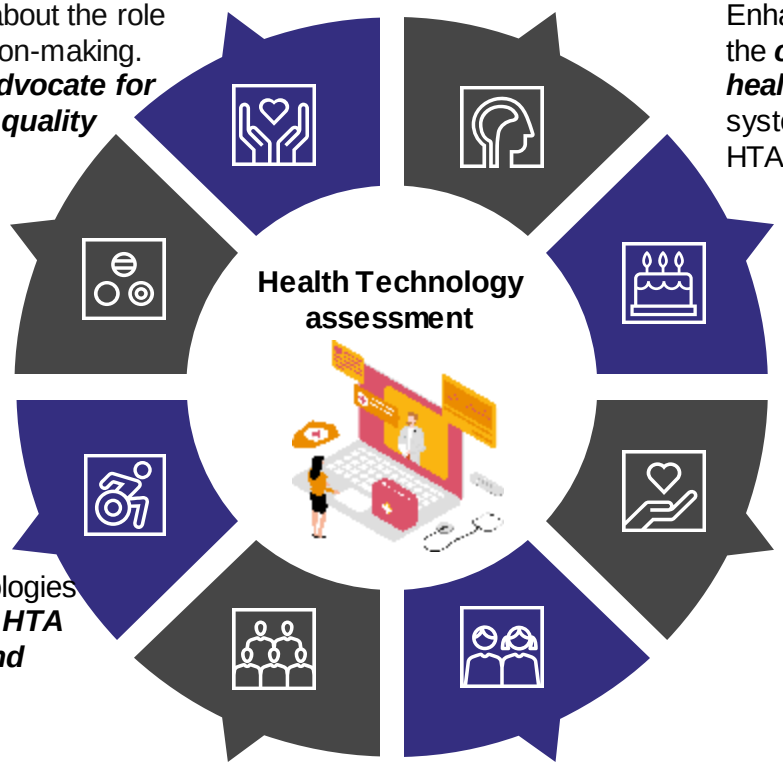
Enhance public awareness and education about the role and importance of HTA in healthcare decision-making. ***Empower patients and communities to advocate for evidence-based and equitable access to quality healthcare.***

Integration with Decision-Making

Integrate HTA findings into ***healthcare decision-making processes at various levels, including formulary decisions, reimbursement policies, and priority-setting exercises***. Ensure that HTA recommendations are effectively communicated and utilized by decision-makers.

Adaptive HTA framework

Develop an adaptive HTA framework that allows for continuous monitoring and evaluation of health technologies post-implementation. This enables ***timely updates to HTA recommendations based on emerging evidence and evolving healthcare needs.***



Comprehensive Data Collection and Analysis

Enhance data collection mechanisms to gather robust evidence on the ***clinical effectiveness, safety, and cost-effectiveness of health technologies***. This includes conducting rigorous systematic reviews, clinical trials, and real-world studies to inform HTA decisions.

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. This ensures that HTA decisions reflect the needs and priorities of patients and communities.

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***. This involves evaluating whether the introduction of a technology exacerbates or reduces existing health inequalities.

Capacity building and collaboration

Invest in building capacity for HTA within relevant institutions and stakeholders, including training programs, technical assistance, and knowledge-sharing initiatives. Collaborate with international HTA agencies and networks to leverage expertise and best practices.

Stakeholder engagement and transparency

Promote stakeholder engagement and transparency throughout the HTA process, ***including involvement of patients, healthcare providers, policymakers, and industry representatives***. This fosters greater accountability, legitimacy, and acceptance of HTA decisions.

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 GST[1] (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)

Recommendations[2]

- **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.

Source: 1. Notification No. 9/2017- Integrated Tax (Rate) dated 28 June 2017, healthcare services in India are exempt vide entry no 77; 2. A study on embedded taxes in the healthcare sector of India NATHEALTH – EY **March 2022**

THANK YOU

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Names in no particular order

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Mangsuli Dileep	Siemens
Ravi Valia	Medtronic
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