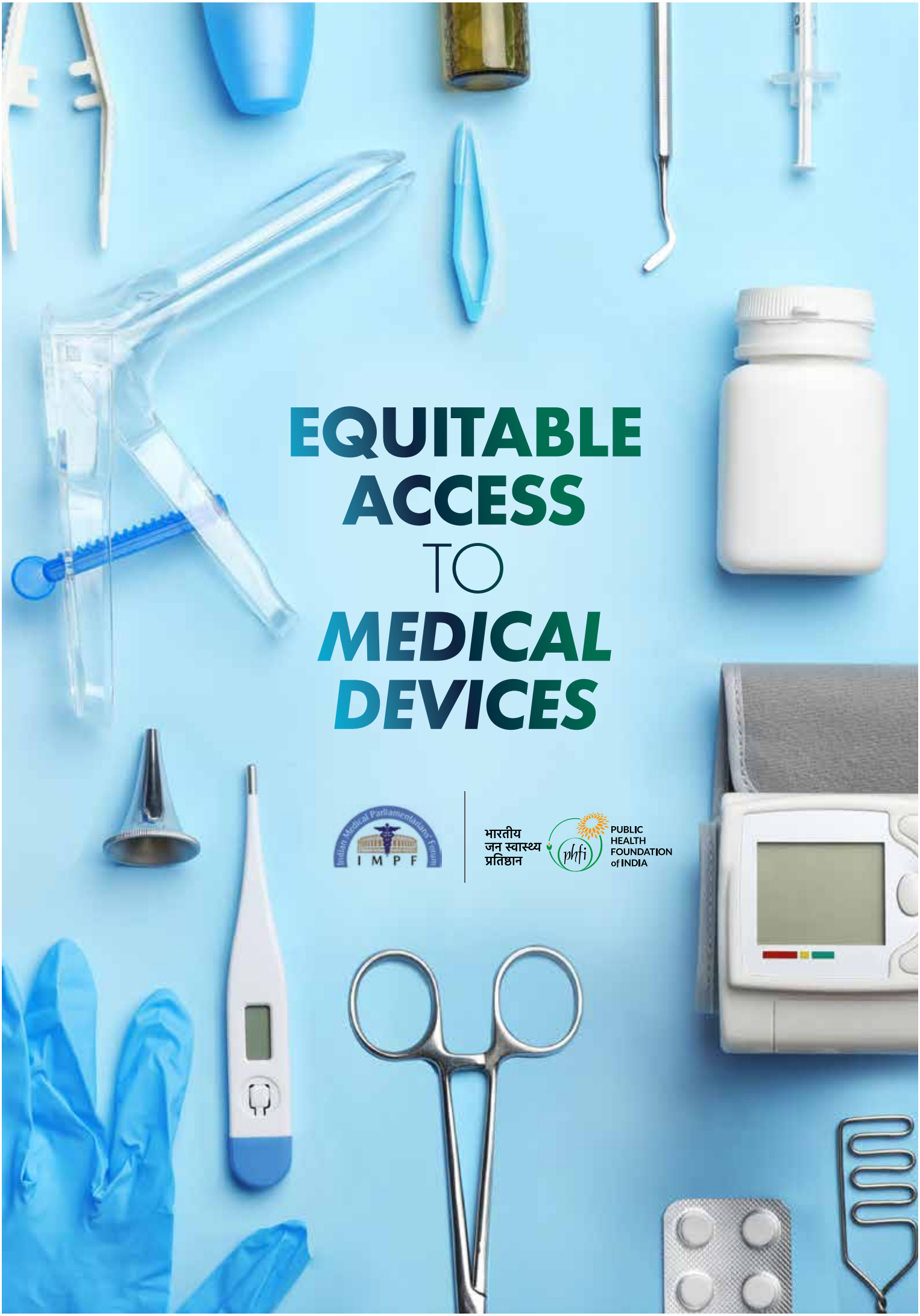
EQUITABLE ACCESS TO MEDICAL DEVICES



Indian Medical Parliamentarians' Forum
IMPF

भारतीय जन स्वास्थ्य प्रतिष्ठान
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PUBLIC HEALTH FOUNDATION of INDIA

REPORT ON

EQUITABLE ACCESS *TO* MEDICAL DEVICES

BY

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Public Health Foundation of India (PHFI) & Indian Medical Parliamentarians' Forum (IMPF)

Equitable Access to Medical Devices - India: A Report

March 2023

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Published by:

Vinod Bhanu, Executive Director CLRA for IMPF, New Delhi. Centre for Legislative Research and Advocacy (CLRA), an organization specializing in parliamentary affairs and legislative advocacy, is the hosting/implementing organization of the IMPF.

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FOREWORD

Ensuring Equitable Access to Critical Medical Technologies for Indian Citizens

India is amongst the top 20 markets for medical devices in terms of demand, but the domestic industry is still nascent, and the segment continues to be dependent on imports. The country currently relies on imports of advanced medical technologies such as cancer diagnostics, medical imaging tools, ultrasonic scans, high-value implantable cardiology devices like long durable heart valves and pacemakers, hearing aids and orthopaedic implants. The country is at a very early stage of developing cutting-edge medical technologies.

For sustainable development of the medical devices industry and safeguarding the interests of patients, India needs to actively reflect and work towards addressing the need for timely availability of crucial life-saving medical technologies to citizens, without any discrimination, to deliver better patient outcomes, and also to keep our medical faculty and students updated on the latest medical technologies.

Recognising this imperative, the Government of India (GoI) has launched several measures to make a leading manufacturing hub of medical devices for domestic and international markets as part of its vision of delivering Affordable and Universal Healthcare for All. GoI commenced various initiatives to strengthen the medical devices sector, emphasising research and development (R&D) and 100% FDI for medical devices to boost the market.

While international companies operating in India are a source of highly advanced medical technologies, local companies have a significant presence in the consumables and disposables segment. Therefore, the interplay between international and domestic players is vital to realising the country's vision of becoming a global hub for various medical technologies and devices.

The Public Health Foundation of India (PHFI), one of the country's pre-eminent think tanks focused on public health, has collaborated with the Indian Medical Parliamentarians' Forum (IMPF) to research and draft a compelling report on the theme, Ensuring Equitable Access to Critical Medical Technologies for Indian Citizens.

The report seeks to build evidence-based pathways for policymakers and other stakeholders to ensure the country delivers equitable access to critical care medical devices. Key aspects of the study include analysing the prevalent regulatory framework for medical devices in India, gauging demand for high-end medical devices, evaluating the procurement process, examining the cost efficacy of newer medical devices, evaluating how health technology assessment (HTA) is being utilised worldwide, and reviewing the implementation of emerging procurement processes such as value-based procurement (VBP).

We sincerely hope this report facilitates an open, engaging dialogue between Executives, Legislators, Medical Practitioners, Industry Leaders, and business chambers on this vital policy matter for enabling a fast-growing, robust, innovative medical device ecosystem in India.

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ACKNOWLEDGEMENTS

We would like to express our sincere gratitude and appreciation for all the people who have contributed to this report, whether through individual inputs, suggestions, editing, or simply answering the questions of the research team.

Individual thanks must go to the three distinguished public health scholars at Public Health Foundation of India (PHFI) who co-authored the report – Dr. Preeti Kumar, Dr. Senthil Ganesh, Dr. Sakthi Selvaraj and Ms. Puja Natarajan. Our heartfelt thanks to Professor K. Srinath Reddy, Honorary Distinguished Professor and Goodwill Ambassador of PHFI for Public Health Partnerships, for constantly guiding us with his invaluable inputs and suggestions on refining the report.

We would also like to thank the Indian Medical Parliamentarians' Forum (IMPF) for their steadfast support and encouragement in putting this study together.

EXECUTIVE SUMMARY

Equitable Access to Medical Devices

The COVID-19 pandemic highlighted the inadequate availability of essential medical devices in India during a time of intense demand. However, medical devices still need to be made available even otherwise, both in terms of availability and affordability. This inaccessibility stems from procurement-related hurdles in public health systems, inadequate or absent manufacturing capability in the country for high-end medical devices, and the high cost of importing medical devices.

This document examines medical devices in terms of their definition, regulation, pricing, demand, and procurement. It also explores how newer medical devices are evaluated on their cost effectiveness and health technology assessment and the various procurement practices adopted by different health systems.

India's robust pharmaceutical industry accounts for 20% of the global market for generic drugs, biosimilars and low-cost vaccines and continues to grow. However, the country's medical device industry is relatively nascent. While India is the world's 20th largest medical device market, it constitutes less than 1.6% of the global industry – having built capacity primarily in high-volume, low-value devices such as surgical gloves, urinary catheters and other disposables. Most high-value devices such as cardiac stents, respiratory support equipment and dialysis machines – which often turn out to be life-saving interventions – continue to be imported at high costs, affecting their accessibility and affordability.

The cost aspect remains an area of concern, given the fact that out-of-pocket expenditure (OOPE) represents around 60% of total healthcare expenses in India. At such high rates, the need for a single high-end medical device in a life-threatening situation may push most families into poverty. Developing and manufacturing these vital devices domestically would reduce the cost and risk of such catastrophic OOPE. Efforts have been made at the policy level to promote greenfield projects, focusing on attaining self-sufficiency in key medical devices. The Production Linked Incentive scheme (PLI) for medical devices, rolled out with an outlay of ₹18420 crores under the Make in India program, is designed to promote domestic manufacturing and position the country as a global industry hub.

The recently published approach paper on the draft National Medical Devices Policy 2022 envisages India becoming one of the top 5 global medical devices manufacturing hubs by 2047 and being home to the top 25 MedTech $Bn companies. The approach paper estimates that the country will capture a 10-12% share of the global medical devices market sector by 2047.

This report outlines a roadmap for achieving these ambitious targets while addressing the key objectives of access, equality, universality, affordability, patient control and quality care, as well as preventive and promotive health and health security. For India to realize these goals, ensuring quality standards, device safety, streamlined regulations, industry competitiveness through fiscal and financial support, infrastructure development, R&D and innovation, and human resource development will be vital.

The significant gap in the availability of medical devices between the public and private healthcare segments remains a major concern regarding providing equitable access to newer and improved medical devices. The Global Tender Enquiry (GTE) procurement process followed by the public health sector in India is designed to promote local manufacturing. However, the bureaucratic process associated with imports of devices that are not available locally often results in longer wait times and procurement of approved, but not necessarily updated, devices for patients accessing the public health sector. On the other hand, the private health sector can negotiate and import devices independently and much faster, even as they pay a premium for the same. Streamlining the procurement process for the public health sector while at the same time promoting local manufacturing through incentives would ensure equity in the availability of medical devices.

In India, medical devices are segmented around a risk-based classification system that categorizes instruments into low to moderate, moderate to high and high-risk. For instance, devices such as tongue depressors and weighing scales are tagged low risk, while heat packs and bandages are designated low to moderate risk. At the other end of the spectrum, devices like dialysis machines are classified as medium to high risk, and implantable cardiac pacemakers come under the high-risk bracket. The country's regulatory framework is tailored accordingly, with low-risk devices earmarked under class A requiring registration and low-level manufacturing oversight. In contrast, high-risk devices, tagged under class D, entail more comprehensive regulatory measures. WHO has also adopted and recommended this classification system to other member countries.

A desk review of 45 studies – in India and overseas – was conducted to examine the cost-effectiveness and technology assessment of select high-risk medical devices used in cardiology and urology. The global and regional literature on select medical devices reviewed in the document indicates the cost savings and improved quality of life realized through utilising newer medical devices that can be quantified for large-scale adoption. Such tools could potentially allow health systems to effectively assess the economic and public health impact of a newly designed medical device and its added value to a healthcare system.

The literature clearly shows that renal dialysis in patients with renal failure poses significant out-of-pocket expenditure in most developing countries and that cheaper peritoneal dialysis is the preferred choice in many countries. Despite the high cost, dialysis remains a cost-effective solution for the public, considering the alternative is a renal transplant. While the information on other renal devices was sought, more data on cost-effectiveness and health technology evaluation must be available.

Among cardiac devices, it was observed that the newer and less invasive devices, although more expensive, are cost-effective in the long run due to lower mortality and reduced length of stay in the hospital. For example, a meta-analysis showed that less invasive devices like percutaneous ventricular assist devices (PVAD) and intra-aortic balloon pumps (IABP) were associated with lower costs and higher survival rates, as compared to more established extra-corporeal membrane oxygenation (ECHMO). Similar benefits emerged when comparing tissue-based surgical aortic valve replacement (SAVR) with a fully prosthetic valve regarding valve deterioration and mortality across all New York Heart Association (NYHA) functional classes.

Desk review showed that cost is a significant barrier to accessibility, along with device availability and supply chain practices. Lack of device availability in public health care services forces patients to turn to the private sector at high costs.

A secondary review was also undertaken to highlight emerging procurement processes – such as value-based procurement and those based on health technology assessment – being adopted in different countries that incorporate evidence-based decisions. These methods have been developed and tested to reduce wastage, ensure the availability of resources, and effectively mobilize resources for optimal health outcomes. Policy measures, such as reduced import duties on essential medical devices that are not manufactured in the country, and incentives to set up greenfield manufacturing projects locally, are the need of the hour.

For enhancing service delivery across the public health system, it is also imperative to institutionalize a streamlined process for efficient evaluation and accelerated adoption of newer medical devices developed in India. Studies examining the cost-effectiveness of medical devices for their indicated use cases, risk estimation of the underlying interventions, and robust health technology assessment must be promoted in public and private healthcare institutions. This, in turn, would lead to superior, informed policy-making and regulatory oversight.

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ABBREVIATIONS

ABDM	Ayushman Bharat Digital Mission
BMJ	British Medical Journal
CAGR	Compound Annal Growth Rate
CDSCO	Central Drugs Standard Control Organisation
CKD	Chronic Kidney Disease
CO	Cardiac Output
CRT	Cardiac Resynchronization Therapy
DALY	Disability Adjusted Life Years
DCA 1940	Drugs And Cosmetics Act 1940
DCGI	Drugs Controller General India
DoP	Department Of Pharmaceuticals
DPCO 2013	Drug Pricing Control Order 2013
DPIIT	Department Of Promotion Of Industry And Internal Trade
ECMO	Extra-Corporeal Membrane Oxygenation
ENT	Ear, Nose, & Throat
ESRD	End-Stage Renal Disease
EU	European Union
FDI	Foreign Direct Investment
GDP	Gross Domestic Product
GFR	Glomerular Filtration Rate
GFR 2017	General Financial Rules 2017
GTE	Global Tender Enquiry
HD	Hemodialysis
HLEG	High-Level Expert Group
HTA	Health Technology Assessment
IABP	Intra-Aortic Balloon Pump
ICER	Incremental Cost-Effectiveness Ratio
IGST	Integrated Goods And Services Tax
INR	Indian National Rupee
IP	Intellectual Property
ISO	International Organization For Standards
IVD	In-Vitro Diagnostics
LMIC	Low- And Middle-Income Countries
MDR 2017	Medical Devices Rule 2017
OOPE	Out of Pocket Expenditure
PD	Peritoneal Dialysis
PET	Positron Emission Tomography
PLI	Production Linked Initiatives
PM JAY	Pradhan Mantri Jan Arogya Yojana
QALY	Quality Adjusted Life Years
R&D	Research and Development
RRT	Renal Replacement Therapy
SAVR	Surgical Aortic Valve Replacement
SpO2	Saturation of Peripheral Oxygen
TAVI	Transcatheter Aortic Valve Implantation
TRIPS	Trade Related Intellectual Property Rights
UHC	Universal Health Coverage
UK	United Kingdom
USA	United States of America
USD	United States Dollar
VBP	Value Based Procurement
WHO	World Health Organization
WTP	Willingness to Pay

Introduction

Healthcare has been growing tremendously in India both in terms of revenue and size and has led to the generation of 4.5 million jobs in India. One of the key components of healthcare delivery through medical devices—can be found at every level of healthcare services ranging in complexity right from diagnosis to surgery to post-surgical care (Tiwari, 2019). However, India's total health budget is considerably lower at 3.5% of GDP than Brazil (8.9%), Russia (6.2%) and China (5.2%). Moreover, the public sector component of the healthcare spending has been around 1.28% the GDP, with the result that a significant cost of health care continues to be borne at the household level as Out of Pocket Expenditures (Sehgal & Bose, 2016) (NHSRC, 2022).

The COVID-19 pandemic, having brutally claimed millions of lives all over the globe over the last two years, has driven the realization of the value and importance of well-equipped and functional healthcare systems. This was made evident by the fact that across the country and the globe there was a shortage of ventilators, oxygen monitors, and hospital beds. These equipment or devices come under the category of medical devices and are required to ensure the wheels of healthcare systems are kept turning smoothly to provide adequate, quality based, effective care by equipping and assisting healthcare personnel in diagnosing, monitoring, and treating patients.

Access can be defined as continuous availability and affordability at public or private health facilities within a one hour walk for the population. When considering access to healthcare to achieve Universal Health Coverage (UHC) in India, access to medical devices needs to be an integral part of the approach. While the COVID-19 pandemic highlighted the inadequate availability of essential medical devices in India during a time of intense demand, medical devices remain inaccessible even otherwise - both in terms of availability and affordability. This inaccessibility stems for issues such as hurdles in the procurement process in public health systems, inadequate or absent manufacturing capability in the country and the high cost of importing medical devices into the country when required. Towards ensuring equitable access to medical devices in country, this document aims to examine the definition and regulation of medical devices in India, the demand for high-end medical devices in the country, and the process of procurement and importation of the devices. There is also an effort to look at how cost-effectiveness is being evaluated for newer medical devices as well as how health technology assessment is being utilized both in and outside the country. Further, implementation of newer procurement processes such as value-based procurement in different countries has also been reviewed.

Though the terms may seem similar, 'medicinal products' and 'medical devices' are two different aids that assist in health service delivery. While the precise definitions vary across countries, the difference between the two remains the same, viz., medicinal products or medicines have a "pharmacological, immunological or metabolic mode of action" while medical devices work through modes of action not belonging to those (Racchi & Govoni, 2016).

01

Medical Device Sector in India

In the last few decades, India has seen remarkable growth and progress in various sectors ranging from healthcare to agriculture. The pharmaceutical industry in India has also been growing by leaps and bounds during this time. The fall in mortality rates due to communicable diseases has been and can be accredited to the availability of the technological strides made in healthcare. The role of medical technology in healthcare delivery can be seen right from the initial stages of diagnosis to complex surgical and post-surgical therapeutics altogether leading to a longer and better quality of life. It has allowed for relatively shorter times in diagnosis and multiple alternatives to life threatening conditions (insulin pumps, pacemakers, defibrillators etc.) (Dang & Sharma, 2019). Though India is the 20th largest medical device market in the world, compared to the global medical device industry, the Indian contribution to the same is less than 1.6%. (Sehgal & Bose, 2016).

REGULATORY OVERVIEW

Regulation of medical devices is needed to ensure their quality, safety, and efficacy for use in the healthcare sector. Medical devices range from a simple pair of surgical gloves to sophisticated replacement hip joints. This diversity, even within a specific therapeutic category, requires a rigorous classification system and a robust regulatory system to monitor and regulate use.

DEFINITION OF A MEDICAL DEVICE

The WHO defines a medical device as the following in their Global Model Regulatory Framework for Medical Devices including In Vitro Diagnostic Medical Devices (WHO, 2017). Diagnosis, prevention, monitoring, treatment or alleviation of disease;

A medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- Investigation, replacement, modification or support of the anatomy or of a physiological process;
- Supporting or sustaining life;
- Control of conception;
- Disinfection of medical devices;
- Providing information by means of in vitro examination of specimens derived from the human body;

And which does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

This definition, suggested by WHO for member countries to adapt and adopt their local settings, has been generated by reviewing the existing definitions in member countries including that of India's Central Drugs Standard Control organisation (CDSCO) which had also updated its existing medical device regulations in 2017 as follows (MoHFW, 2020):

All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of –

- Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
- Diagnosis, monitoring, treatment, alleviation or assistance for any injury or disability;
- Investigation, replacement or modification or support of the anatomy or of a physiological process;
- Supporting or sustaining life;
- Disinfection of medical devices; and
- Control of conception.

Furthermore, a risk-based classification and regulation of medical system has also been proposed by the WHO to be adopted by the various countries as per their needs. The "risk" of a medical device is determined by many factors but not limited to level of invasiveness, duration of use (in/ outside of the body), useability, if the device incorporates human/ animal tissue or cells.

The regulation of medical devices in India is governed by the Drugs and Cosmetics Act (1940), its amendment in 2005, and its update in 2017 Medical Devices Rule (2017) which provides improved regulatory coverage of medical devices. Per the Medical Device Amendment Rules of 2020, all devices in India will be required to be registered in a phased manner over 42 months, beginning April 2020.

Additionally, an increased focus on conformance with international standards has been seen. A gazette notification by the MoHFW in October 2021[1] has given manufacturers, importers to obtain ISO 13485 certificate through voluntary registration. This has been updated by another notification in February 2022 (102 E) providing extension on the deadline due to the unforeseen impact of COVID-19 on the healthcare sector and the economy. Moreover, there has been a recent introduction of a draft bill in India that combines and expands on the medical device regulations. This draft bill, introduced in July 2022, has sections to elaborate on clinical trials, testing, appointment of officials and penalties for crimes[2].

The figure below illustrates the changes made to the Medical Devices Rules 2017 since its effective date in January 2018.

01. ISO 13485 - Gazette Notification This gazette modified paras 19B-E of the Medical Device Rules (MDR) (2017) to ensure conformance so ISO 13485 could be obtained. The applicant would provide an undertaking on or before November 2021, that they will obtain a ISO 13485 certificate in lieu of the certificate of compliance as previously required. Upon this, a provisional registration will be provided and valid upto 31 May2022 or ISO certification whichever is earlier. The deadline of 31 May 2022 was given as a grace period, after which failure to obtain conformance certificate would lead to cancellation of license without any notice.

02. Draft Drugs, Cosmetics and Medical Devices bill introduced on 08 July 2022.

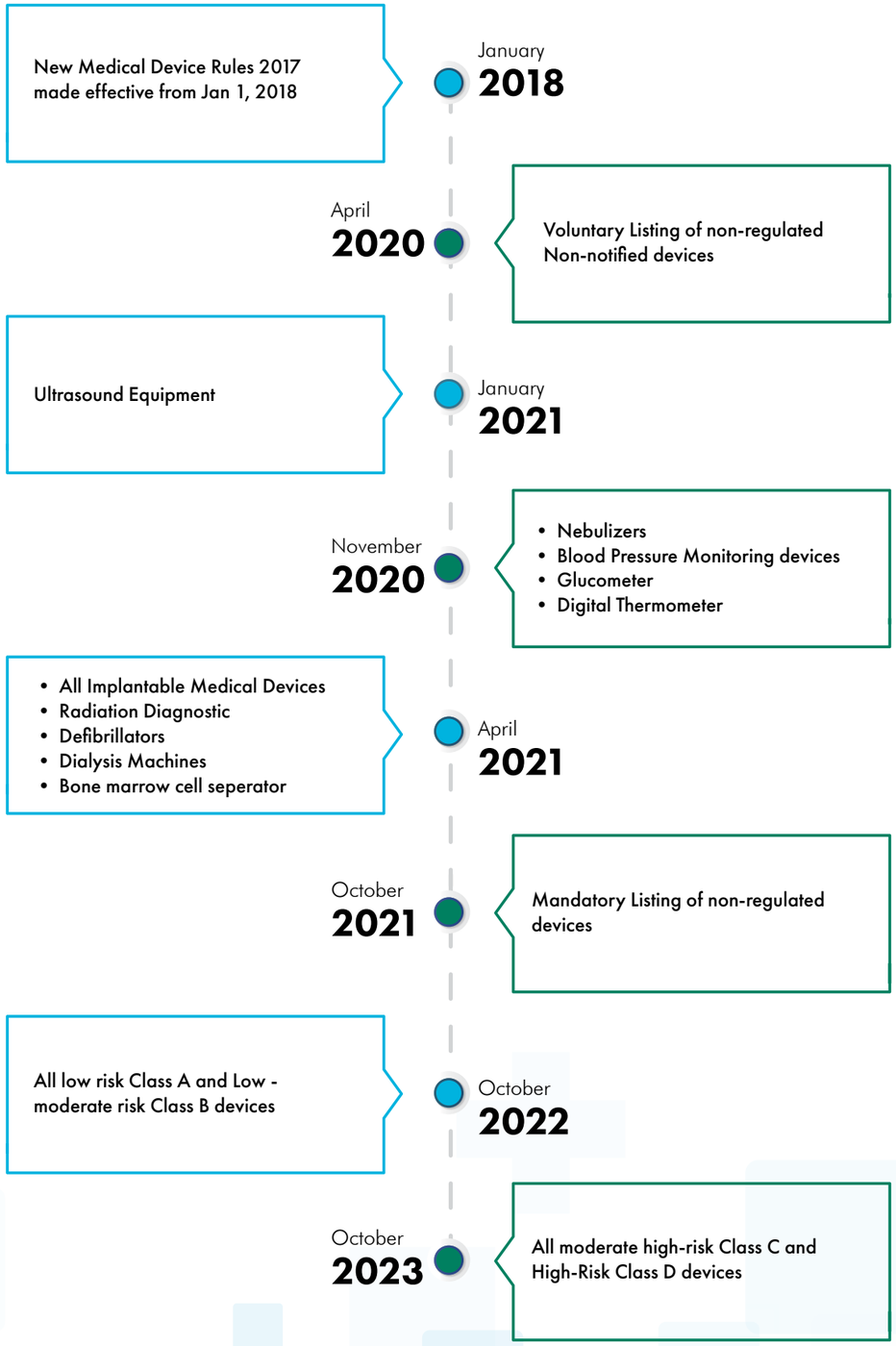

Figure 1: Medical Devices Regulation in India - an Overview (source: www.freyrsolutions.com)

DEVICE CLASSIFICATION (RISK CLASSIFICATION)

Medical devices span a diverse range of applications from the simplest of items used in practice (e.g., tongue depressors) to complex and intricate instruments that support physiologic functions of the body (e.g., cardiac pacemakers). This range of variation can be observed even within a specific therapeutic category and thus requires a different approach for categorization. The risk-based categorization has regulatory controls which are proportional to the "risk" category of the medical device. The risk of a medical device is determined by many factors including level of invasiveness, duration of use (in/outside the body), useability, if the device incorporates human/animal tissue or cells (World Health Organization, 2022).

This categorization has a twofold purpose: one, to allow end user (patient or health institution or healthcare professional) to understand how the devices are used and two, to create clarity among the regulators on how to set forth regulations to monitor them. Considering the two previous examples, while the tongue depressor, used in general clinical settings for non-invasive examination of the throat by medical professional, is in class A of low-risk devices, the cardiac pacemakers, an invasive device implanted by a trained cardiac surgeon, is in class D of highest risk.

The classification system used in India, updated in MDR – 2017 and updated frequently since then, has two level classification system where the devices are first categorized under their therapeutic category (e.g., cardiology, nephrology etc.) and then further classified based on their risk as mentioned in previous paragraph. India also has a separate therapeutic category for software which includes 60 devices as of 2020 (Drugs Controller General (India), 2017).

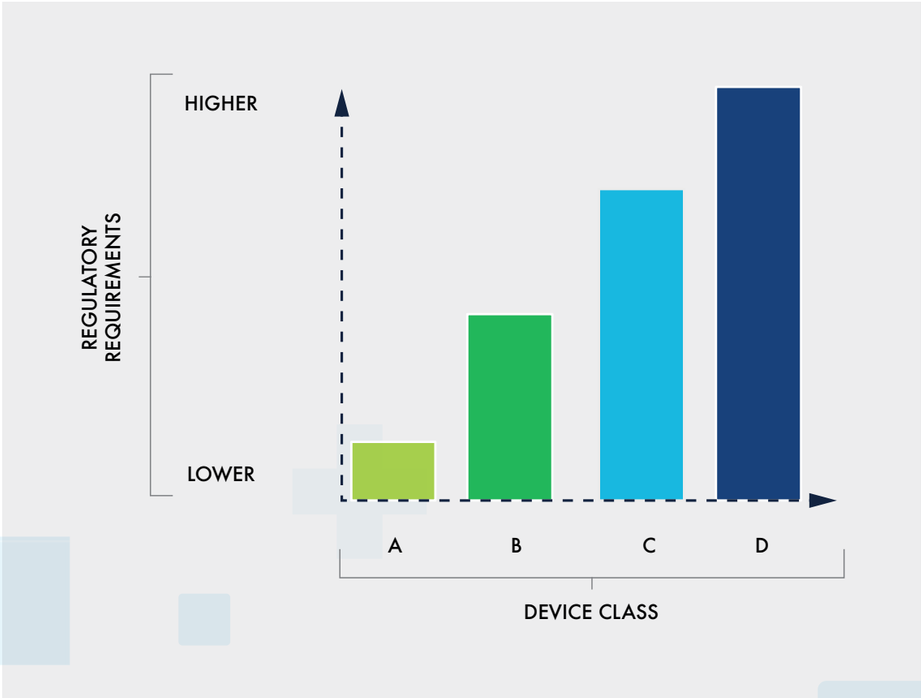

Figure 2: WHO device risk classification framework for regulatory scrutiny. (Source: WHO, 2022)

The table below gives an example each risk category of medical devices along with their intended usage and therapeutic group as per MDR 2017 and its updates.

Table 1: Medical device classification with examples. Modified from MDR-2017 Guidelines Sep 2020.

Risk Class	Risk Level	Device Example	Intended use	Therapeutic Group
A	Low	Tongue Depressor	A surgical instrument used to move the tongue to facilitate examination of surrounding organs and tissue	ENT
B	Low - Moderate	Exothermic heat therapy pack	A device intended to be applied to body surface to provide heat therapy to reduce muscle spasms and cramps and/or for joint and muscle stiffness and pain	Pain Management
C	Moderate – High	Automated Peritoneal Dialysis System	An active medical device intended to perform peritoneal dialysis.	Nephrology and renal care
D	High	Implantable pacemaker pulse generator	A device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart.	Cardiovascular

Table 2: Registration requirements based on Device Risk Classification. (Source: arogyalegal.com, 2021)

Class of Medical Device	Licensing Authority	Stipulated timeline for processing application	Deadline for obtaining license
Class A and B (import)	DCGI	Up to 9 months from the date of application	September 30, 2022
Class C and D (import)	DCGI	Up to 9 months from the date of application	September 30, 2023
Class A (manufacture)	State-level Licensing Authority	Up to 45 days from the date of application	September 30, 2022
Class B (manufacture)	State-level Licensing Authority	Up to 140 days from the date of application	September 30, 2022
Class C and D (manufacture)	DCGI	120-180 days (estimated)	September 30, 2023

The license application process and forms are included in the Medical Device Rules of 2017[3].
Chapter IV - Manufacture for Sale or for Distribution of Medical Devices
Chapter V - Import of Medical Devices

03. Sections 20-33 are allocated to Manufacture of Medical Devices for Sale or Distribution
Sections 34- 43 are allocated to Import Regulations of Medical Devices in. Medical Device Rules - 2017

MEDICAL DEVICE MARKET IN INDIA

The regulation of medical therapeutic drugs in India has been under the purview of the Drugs and Cosmetics Act since 1940 which has been amended several times over the past eight decades since its implementation. These amendments have been added to keep up with developments in the medical and healthcare sector to provide a regulatory overview on both, the manufacture and use of these therapeutic products. While high risk medical devices (now classes C and D) have been regulated under the 'notified' device category over the years, most of the low-risk devices (now under classes A and B) were 'non-notified' and were not under strict regulatory overview. The recent Medical Device Rules 2017 and the subsequent updates and guidelines released since then have brought all medical devices under the purview of regulatory authorities. This means that device manufacturers are now required to register the medical devices and their intended use and procure license for both their manufacture and import. This is inclusive of low-risk devices in classes A and B - which form a major share of the medical device manufactured in India.

The Indian medical devices industry is valued at 10.22 Bn USD as per the report published by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers (DoP, 2020), with exports valued at 2.51 Bn USD andthe domestic market standing at 7.71 Bn USD . A majority of this 7.71 Bn USD domestic market is serviced by imports valued at 5.60 Bn USD - which comprises 72% of the share. When compared to the Indian pharmaceutical market, the domestic market for medical devices is a third of its size and exports one tenths of its size. Although, the medical devices sector in India has a higher growth rate of 12-15% compared to the pharmaceutical sector's 10-12%,. it is understandable given that the Indian pharmaceutical industry has had over five decades to develop to a stage where it is the third-highest producer of pharmaceuticals (generics) in and has become an industry having a 42Billion Bn USD value spanning a massive 60% of the export of global vaccines to the USA and UK. This speaks of a solid infrastructure which has allowed the sector to make advances and grow (Jain, 2021).

The policy environment that enabled the development and growth of the pharmaceutical manufacture in India over the past five decades also needs to be looked into for comparison. Policy reforms in this sector have been aimed at improving access and affordability of medicines along with promoting domestic generic drug production. The key policy aspect that has been instrumental in promoting Indian pharmaceutical manufacturing industry has been The Indian Patent Act 1970 which allowed only process patents for pharmaceutical products i.e., granting of patent on the chemical process, resulting in the manufacture of a particular medicine but not on the product per se. This effectively allowed for the production of low-cost generic versions of existing patented medicines in India which were used both in domestic and export markets. However, in 2005, due to its obligations under the TRIPS (Trade Related Intellectual Property Rights) agreement, India shifted to a 'product patent' regime. Under this regime, firms with a new discovery are granted patents on the final product for a period of 20 years from the date of filing the patent application. Such a policy environment cannot be envisaged for the medical device market in India at present as medical devices, unlike pharmaceutical products, cannot be process patented in the first place, and, moreover, it would undermine India's TRIPS agreement.

While the medical device industry has been declared as a sunrise sector in 2014, it still majorly remains import based (Prasad, 2021) (EEPC India, -) (NITI Ayog, 2021). This has been attributed to the following reasons by the Pharma Bureau report. The medical device industry, compared to the pharmaceutical industry is more capital reliant, has longer gestation period, requires continuous induction of new technologies, training of health providers to adapt to the new technologies and a well-developed ecosystem and innovation cycle which is yet to be fully developed in India. Thus, the industry depends on imports up to an extent of 86%, while the domestic manufacturing is limited to surgical, cardiac stents and general medical devices and consumables that are high volume and low value production (DoP, 2020).

The medical device market in India (though import reliant) is ranked 4th highest market in Asia after Japan, China, and South Korea, and counts among the top 30 countries globally (DoP, 2020). This looks promising when considered with the fact that currently India constitutes only 1.5% of the global medical device market with 18% of the world population, indicating a huge potential local market for medical devices. To access this population dividend in the medical device market, India must ensure development of its tertiary healthcare sector, which is essential for the consumption of high-end medical devices. While generic pharmaceutical drugs can be utilized at all levels of the healthcare sector – from primary to tertiary,, and over-the-counter household market, both low and high-end medical devices require infrastructure in place for utilization. Moreover, the gap in potential demand combined with the surplus of low-end, low-value equipment manufacturers in India, leaves tremendous scope for the Indian medical device manufacturing to step up and take initiative to make India, not only self-reliant as a medical device manufacturer, but also as a major player in the global market of high-end medical devices. At present, there are about 750-800 manufacturers who fall in one of the following three categories: MNC with an Indian presence manufacturing moderate risk products; local manufacturer responsible for manufacturing low end products; MNC manufacturing high end products. The manufacturers producing low end products or high-volume, low-cost parts of devices form a major part of producers, but the revenue generated by exports by these are significantly less than those of global MNCs with a presence in India.

Segment-wise import of medical decices (2019-2020)

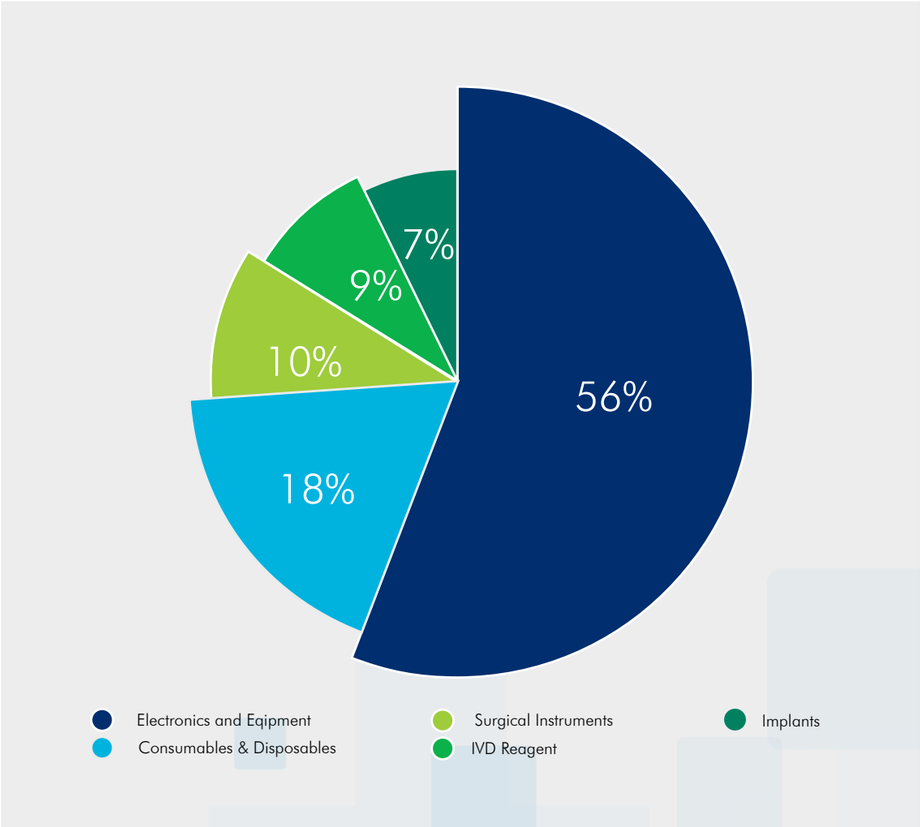

Figure 3: Segment-wise import of medical devices in India 2019-2020. Source: DGCIS

The medical device sector in India has been growing steadily at 15% for the last 3 years. With the healthcare sector in India being valued at 128 Bn USD and projected to expand by about 12% in the next 4 years, the Indian government has created initiatives like PLI (production linked incentives), manufacturing clusters to boost production and attract foreign direct investment. During 2019-2020imports were valued at a massive 1.77 Bn USD vs exports at 0.99 Bn USD. However, the CAGR of exports has increased to reach 10.22% over import CAGR at 5.89% (NITI Ayog, 2021).

Export and Import trends of medical devices in India USD billion

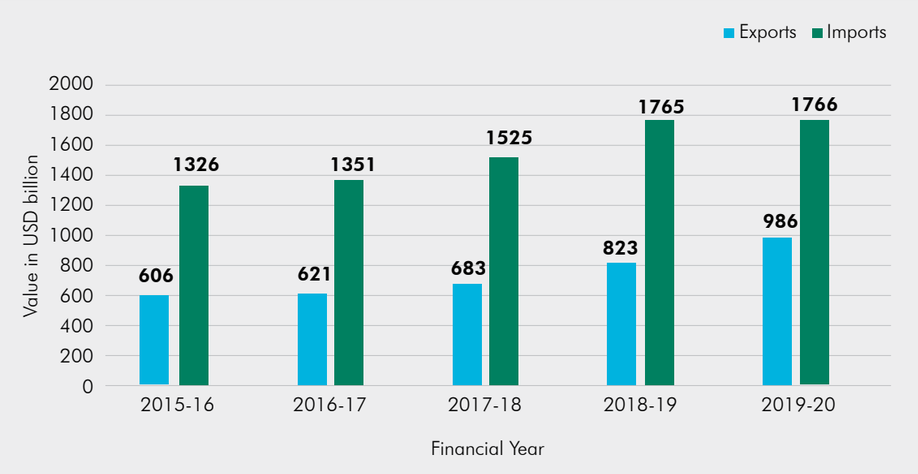

Figure 4: Export and import trends of Medical Devices in India in USD billion. Data Source: Investments in healthcare – NITI Ayog report 2021 (NITI Ayog, 2021)

The figure above shows the value of medical device imports being over double the value of exports. This is the case despite strict import restrictions, like the GTE, enforced to ensure a higher reliance on Indian made products including medical devices. There appears to be an increase in the import revenue valued at INR 43,365.9 Cr the year 2018-19 from INR 35,016 Cr during 2017-18. In contrast to this, the export sector of the Indian medical device market stood at much lower values valued at INR 13,034.95 Cr for the years of 2017-18 at INR 13,034.95 Cr and is projected to be around INR 20,935.1 Cr for the years 2021-22respectively. Manufacturing, on the other hand, was at even lesser level compared to the two categories of import and export (NITI Ayog, 2021).

The data also shows that the majority of import of medical devices in India belong to Classes C and D - or moderate to high-risk devices that are used in high value healthcare interventions like dialysis, pacemakers, and prosthetic heart valves. Whereas the Indian device manufacturing is concentrated in low-value and high-volume devices belonging to classes A and B. A study examining the patents filed in India between 2005-2014 found that as per the annual report of the Indian Patent Office, 2,03,509 patents were filed during the study period, of which, patents for medical devices constituted around 2% (4713). The majority (80%) of the patents filed belong to foreign-origin patents filed by countries for marketing needs -with the USA dominating at 41%, followed by Europe at 9%with Germany at 5% and Japan at 4%. This trend seems to be declining a little over the years—though the exact numbers are not available—indicating a reducing foreign presence in patents in India. Despite that, the foreign share of patents is significantly higher (Markan & Verma, 2017). The distribution of medical devices is as follows: medical instruments and appliances (34%), diagnostic imaging devices (31%), consumables and implants (19%), and patient aids and others (16%) (Manu & Anand, 2022).

At present, India not only lacks the manufacturing capacity, but also a healthcare system capable of providing universal care to the population, resulting in limited access to medical devices through a lack of access to the healthcare service or intervention. This is reflected in the stagnating financial allocations to the public health sector. According to the latest National Health Accounts, the health expenditure has declined. The government health expenditure was 1.35 % of the GDP in fiscal year 2017-2018 and fell to 1.28% of the GDP for the year 2018-2019 (NHSRC, 2022). As per the same report, the Out-of-Pocket Expenditure (OOPE) as share of the total health expenditure has also seen a slight fall since 2017-18, from 48.8% to a slightly lower 48.2% (NHSRC, 2021) (NHSRC, 2021). This shows that, still, nearly half of the total health expenditure is being taken up by the households, leading to a higher risk of catastrophic health expenditure and impoverishment. Since primary and secondary healthcare services are largely availed through the OOPE, expensive medical device interventions—that are usually lifesaving and reduce chances of disability —may not be accessible through OOPE, even if made available in large scale in India. This requires government intervention in the form of providing either the medical devices through the public health sector, or through reimbursement of services availed from the private sector. The PM-JAY insurance program aims to cover this aspect of healthcare services.

The High-Level Expert Group (HLEG) Report on Universal Health Coverage (UHC) for India Instituted by the Planning Commission of India and prepared by Public Health Foundation of India (PHFI) had recommended a minimum of 5% government investment in public health to achieve the goals of UHC (HLEG, 2011). This is reflected in the National Health Policy's objective of increasing public expenditure on healthcare in India. The Government has, since, expanded pharmaceutical reach and accessibility in the country through the Jan Aushadi Scheme, where generic medicines are provided at lower costs in numerous Jan Aushadi stores throughout India. Such schemes have also been instituted by various State governments locally. It would be beneficial for the people who approach public healthcare facilities, if the Indian Government and the State Governments were able to introduce such a scheme for availing cost-effective options for medical devices—both by the patients and their healthcare service providers—for their various healthcare needs. Although majority of OOPE goes towards availing primary and secondary interventions, high-end class 3 and 4 medical devices pose a significant financial burden to the average person, leading to catastrophic OOPE among the smaller sections of people who might need them. If there are cost-effective options, either through the public healthcare services, or through outlets that cater the private sector, such catastrophic OOPE and resulting economic ruin of the patient can be avoided.

The government has outlined initiatives—both short and long-term initiatives—with a vision of making India self-reliant. To boost the local manufacture of medical devices in India, medical device parks with a funding of INR 400 Cr have been outlaid by the government through their Production Linked Incentive Scheme, under schemes like Make in India and Atmanirhbhar Bharat Abhiyaan, by providing financial incentives to manufacturing units based on minimum threshold of production and sale of medical devices, while also supporting research and development by including expenses there in as investment - as long as the process is documented and approvals taken (DoP, 2022). Some key observations from the PLI Scheme are given below:

- The PLI aims to promote greenfield projects helping existing and new manufacturers to set up new manufacturing systems in India for the manufacture of medical devices.
- Medical device manufacture parks to "plug and play" with custom manufacture environment
- Allows 100% Foreign Direct Investment (FDI) to promote large-scale investment.
- It targets four key segments of high-value and low volume devices that require significant investments in R&D to stay relevant in the market, viz.,:
  - Cancer care / Radiotherapy medical devices
  - Radiology & Imaging medical devices and nuclear imaging devices
  - Anesthetics & Cardio-respiratory medical devices including catheters of cardio-respiratory category and renal care medical care devices
  - All implants including implantable electronic devices

The recently published approach paper on draft National Medical Device Policy 2022 (draft NMDP-2022) envisages that by 2047,

- India will be one amongst Top 5 Global manufacturing hubs in terms of value and technology for Medical Devices
- India will be home to 25 MedTech Bn USD companies and home & originator to 25 high-end futuristic technologies in MedTech
- India will emerge as champion in critical components, cancer diagnostics, medical imaging, ultrasonic scans, molecular imaging, & PCR technologies
- India will achieve 10-12% Global Market Share of Medical Devices sector to arrive at a $100-300 Bn USD industry
- India will have about 50 medical Device Clusters across India for faster clinical testing of Medical Devices to boost product development and innovation.

The draft NMDP-2022 aims to lay down a roadmap to achieve these targets, while making sure the key objectives of access, equality, universality, affordability, patient control and quality care, preventive and promotive health and security are covered thoroughly by focusing on key aspects of regulation. These aspects cover quality standards and safety of devices, regulatory streamlining, building competitiveness through fiscal and financial support, infrastructure development, facilitating R&D and innovation, human resource development and awareness creation and brand positioning (Dept of Pharmaceuticals, 2022). Although it should be stressed that, despite the availability of multiple sources of information (primary, secondary, and tertiary)[4] regarding the medical device market, there appears to be no standardized and universal data collection of this sector, leading to discrepancies and differences in figures regarding the classification, size, and distribution of medical devices.

MEDICAL TOURISM AND MEDICAL DEVICES

While the growth of medical tourism is valued at around 5 Bn USD and is projected to grow to 9 Bn USD or higher, the exact statistic about the medical tourism seems vague. (NITI Ayog, 2021). These numbers are further corroborated by the increase in medical tourism visas granted by the government to foreign nationals. Tourist visas for medical purposes remain at a consistent third place through the years. The geographic locale from where the influx of medical visa seekers arrive in India varies by region globally across nations and increases the burden on an already overtaxed Indian healthcare system and services. An analysis of visas depicted the percentage increase in number of visas granted has increased from 6.1% in 2018 to 6.8% in 2022 (Ministry of Tourism, 2022; Ministry of Tourism, 2019).

Based on the rise in the medical tourism visa statistics, those arriving to seek medical care can be counted amongst those being able to afford healthcare services provided in the country. The NITI Aayog anticipates this growth to be bolstered by the use of high-end medical devices and the interventions thereof, but such an unbalanced growth has the risk of making the same devices and interventions unaffordable for the Indian patients. Efforts should be taken so that Indian patients too, regardless of their socio-economic status, are able to afford life-saving healthcare interventions using high-end medical devices (NITI Ayog, 2021).

Medical Devices, ranging from simple and complex, in terms of usage as well as technical complexity, are used in surgery, diagnosis, assistance etc. and are, thus, priced to reflect the same by the manufacturer. While the previously 'notified' medical devices and pharmaceutical drugs were under the Drug Pricing Control Order 2013 (DPCO 2013) since 2014, the government has, with the removal of 'non-notified' devices category, brought all medical devices under the DPCO as of 2020. The government has made this move in order to better regulate and direct the development of the industry to achieve growth while addressing the healthcare needs of the country.

MEDICAL DEVICE IMPORTS

Since imports are such a large part of this sector, it is ideal to understand the import process, requirements, and barriers to the same. It is also crucial to understand how the usage of these devices is distributed between the public and private sector healthcare. Imports procured by the public institutions, i.e., the government hospitals, statutory medical instructions, or any entity that comes under government supervision, can procure items, services, goods, etc. from outside of India, or a foreign country, and needs to adhere to the government process for the same via an open tender system called Global Tender Enquiry (GTE). But, before a Central Government institution can procure medical devices through imports, they need to ensure no local manufacturer or supplier is available for the required products/ services/ goods. The institution also has to have a tender value above INR 200 Cr to be able to procure imports through the GTE.

04. Primary sources information published on Indian government websites not limited to official orders, amendments.
Secondary sources are peer reviewed articles and articles published on journals.
Tertiary sources are websites, other links that appear on an internet search like news articles etc.

PUBLIC PROCUREMENT PROCESS

The procurement process for public health institutions is usually via internal procurement from vendors within or outside their state. If the tender value is more than INR 200 Cr and there are no manufacturers available to supply within India, a process a called Global Tender Enquiry (GTE) has been set up to ensure necessary services, goods, etc. are available. Moreover, in case of medical devices that the MoHFW feels are not manufactured in India and are essential for providing healthcare services in the country, the ministry can request the Ministry of Finance to exempt these select devices from the GTE requirements, thus allowing tenders of value less than INR 200 Cr. to be floated. This list was updated most recently in January to July of 2022 to include up to 371 medical devices which were exempt from the GTE restrictions until 31st March, 2023 (Department of Expenditure, 2022).

As seen earlier, there is significant import of medical devices into the country, especially in the risk classes of C and D. Thus, there is a need to understand the process of GTE, the devices exempt from it at present, and key challenges associated with it.

GLOBAL TENDER ENQUIRY (GTE)

The foundation of public financed tendering in India is based on equity, non-discrimination, and transparency. The General Financial Rules 2017 (GFR 2017) are mandatorily applicable to all Central Government Ministries & Departments. The GFRs are a compilation of rules and orders of the Government of India to be followed by all while dealing with matters involving public finances. These were first issued in 1947 to bring the then existing financial orders and instructions in one single place and have been modified sever times over the course in 1963, 2005 and 2017.

The framework for Global Tender Enquiry (GTE) is provided by the GFR 2017 and is relevant to the context of medical devices, as most of the imports are of high-risk and high-value -medical devices which require significant capital to be invested in research and development and manufacture within the country. Currently research institutions and government run public healthcare institutions are required to go through a rigorous process of applications and approvals before they can float a GTE tender for import of medical devices. This is done to ensure that locally manufactured goods remain cost-effective and relevant (Dept. of Public Enterprises, 2021). These tenders are required to be displayed in newspapers or online advertisements to invite vendors to submit bids within a stipulated time and the bid with the least value is selected with conditions to deliver and penalties for non-delivery.

It should be noted that while GFR 2017 is applicable to Central Government ministries and the departments under them, the State Government Ministries, and departments there in are not bound by GFRs and are free to formulate their own rules and regulations. States such as Kerala, Gujarat, West Bengal, Rajasthan, and New Delhi, have well-defined procurement systems in place with e-tenders and up to date information available on their websites. Also, private enterprises providing healthcare and research in India are also free to procure their medical devices though channels that are profitable to them.

CHALLENGES WITH GTE

Though GTE has been viewed as a favorable method to enhance availability of medical/ health devices and improve availability of health services, certain challenges perceived with GTE are mentioned below:

Information spread out over multiple government websites

Typically, multiple Ministries and Departments are involved in the GTE process, such as the Ministry of Health and Family Welfare, Department of promotion for Industry and internal trade (DPIIT), Department of Pharmaceuticals to name a few. Though extensive and documented information is available, lack of awareness among users and availability across multiple websites makes it difficult to retrieve information. Further, as these documents and information are not linked to each other, much effort is required to collate complete information and ensure continuity and comprehension of information available.

GTE Process

The process of floating GTE is exhaustive with rules, regulations and approvals to ensure that the option is not misused. There was a recent introduction of a tender limit of 200 INR Cr ceiling amount, to encourage local manufacturers and manufacturing (for which capacity is being built)[5]. The exemption is only for select medical devices that are updated regularly based on the needs and requirements. Further, the tender bids typically favor the tender with a low cost (L1) to cut costs. While quality control and bid security are key things to consider while floating tenders and accepting bids, this is more so in the case of medical devices where patient health and safety is a concern. There is need for a balancing act between relaxation of rules to facilitate local manufacture and rigorousness of regulations to ensure quality of medical devices supplied to the hospitals[6].

05. Per NITI Ayog report – Investment Opportunities in India's Healthcare Sector (2021) , the Government has initiated several schemes to boost medical devices manufacturing initiative schemes. (NITI Ayog, 2021)

06. Judgement was delivered on 12 July 2022 in a case where the petitioner cited violation of the Startup and MSME rules and the Constitutional rule 14 and 19 to imply due process for selection was not followed. This they reiterated, led to rejection of their bids, in 2 cardiac medical device tenders placed by the hospital. In passing the judgement the judges noted that the death of around 218 people due to stents at the Rajiv Gandhi super specialty hospital in Delhi, caused them to not relax the criteria for Startup and MSME's.

02 Methodology

A literature review of medical devices, particularly those imported to India under exemption from GTE process, was undertaken to understand the status, importance, and usage of these medical devices in India and in select other countries. Such an effort to obtain and document information on medical devices in India has been taken only recently and relevant information is mostly available only through accessible government sources.

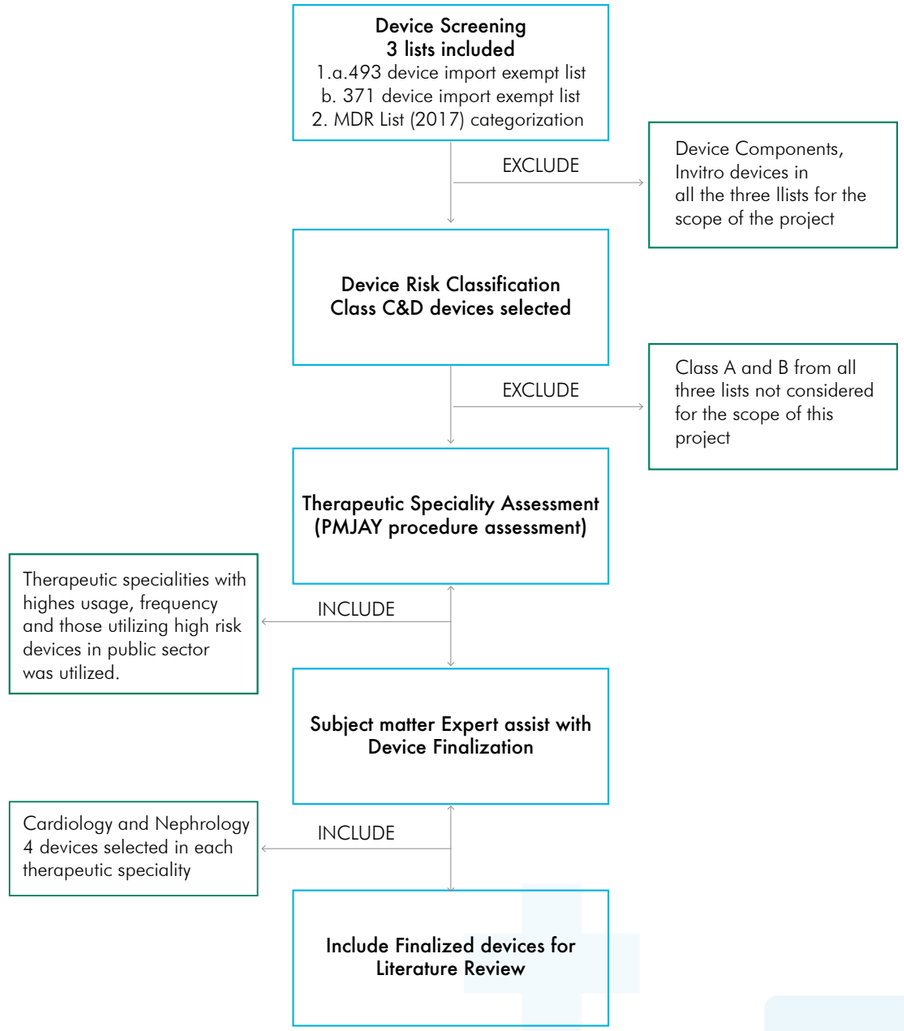

Figure 5: Selection process for medical devices for literature review

STEP 1 – DEVICE SCREENING

The list of medical devices exempt from GTE process was first published in January 2020 to include 128 devices. This was later updated in February and July of 202 to include a total of 371 devices in the latest list. This list was selected as it indicates that these medical devices are very much in need while there is little or no local manufacture of the same.

STEP 2 – DEVICE RISK CLASSIFICATION

The selected list of devices was then classified as per their therapeutic category and their risk class based on the CDSCO device categorization methodology elaborated in earlier sections of this document. Out of the devices in the three lists, some were uncategorizable due to inadequate device description and were excluded.

EXCLUSION CRITERIA

- Devices of Risk Classes A and B
- Device components that are part of a larger device
- Diagnostics and in vitro devices[7]
- Devices with inadequate information for assigning risk class

INCLUSION CRITERIA

- Devices of Risk Classes C & D

STEP 3 – THERAPEUTIC SPECIALTY ASSESSMENT (INPATIENT CARE UTILIZATION) UNDER PM-JAY

The healthcare setup in India is heterogenous with both hospital care and ambulatory healthcare divided between public sector and private sector. The private sector healthcare institutions in the country (hospitals, standalone clinics) have burgeoned in both size and numbers over the last few decades. Though the private healthcare sector is extremely diverse in terms of quality of healthcare services, many institutions have the supporting infrastructure to provide the quality care that seems to meet the expectations of the masses (Sembiah, Paul, Dasgupta, & Bandyopadhyay, 2018). Moreover, the majority of the beds, doctors, and services provided (inpatient and outpatient) are concentrated in the private healthcare sector.

These private healthcare hospitals are largely in Tier 1 or Tier 2 cities where people have better access to available health services. Before 2000's, utilization of healthcare services leaned towards the public sector, however, over the past two decades, the private sector has come to dominate the healthcare sector through increased patient footfall for outpatient and hospital care with corresponding higher revenues. A probable reason for this could be that despite proving expensive when compared to the public healthcare services, the quality of service must be good enough to justify the prices, which drives even those in the poorest sections of India to private care (Anand & Thampi, 2020). Though there were smaller clinics and hospitals before 2009, there was an increase in the services provided by the private sector since the 2009 influenza in India and in a sense, this could be said to be a starting point of turn towards the private sector in India (Kumar & Quinn, 2012).

The government goes to great lengths to ensure all patients can avail healthcare services by providing subsidies, reimbursements, and other support. (NITI Ayog, 2021). Over the last few decades, due to many reasons, achieving goals in healthcare, especially in low- and middle-income countries, seems unrealistic. Value based healthcare is an option which is gaining acceptance these days. (www.apacmed.org, 2022) According to a working paper by the NHA, 60% of mortality is due to poor quality of care and 40% due to lack of access. This has resulted in about 8 million deaths worldwide in LMIC in 2015. If we focus on India, the main idea behind introducing a national health reimbursement/ health scheme was to ensure health access can penetrate all levels of socio-economic populace from all walks.

The Government introduced 2 initiatives in the health sector i.e., Health and Wellness Center and the National Health Protection Scheme under the Ayushman Bharat (AB) Program. This nationwide health protection initiative is called the AB-PMJAY. (Ministry of Finance, 2018) . It is essentially a nationwide health insurance program aimed at providing procedures at no cost to make them accessible while ensuring affordability to those currently unable to. At present under this initiative, a cover of 5 Lakh INR is provided for all levels of hospitalization (i.e., primary, secondary, and tertiary) to 10.74 Crore poor and vulnerable families. Under PM-JAY an approximate 20,761 public and private hospitals have been empaneled across the country to provide inpatient services to the beneficiaries. Close to 88 lakh cases worth Rs. 12,169 Cr INR have been documented so far (Kumar R. , 2020).

Reports from the Pradhan Mantri Jan Arogya Yojana (PM-JAY) were used to observe trends in both public and private health sector partnership, to understand health sector performance and analyze it within Indian context. The PM- JAY data also gave insights regarding the percentage occurrence in different states and specialties. Overall, general surgery and general medicine are seen in varying percentages all over the country[8].

The PM- JAY data was then analyzed in parallel to understand specialty procedure occurrence frequency from where the devices pertaining to each specialty were selected. Overall, general surgery and general medicine are seen in varying percentages all over the country (Kumar R. , 2020). These procedures were analyzed to understand which disease burden were more prevalent in India, specialty wise allocation of resources, as well as no. of procedures within each specialty. Similarly, Orthopedics, Urology (or nephrology - renal diseases overall), and Oncology were selected as the number of procedures among the highest among other specialties.

INCLUSION CRITERIA (FOR THERAPEUTIC SPECIALTIES)

- Specialties (correlating prevalence of disease burden in India) with high number of costly procedures (to usage - high end medical devices)
- Increased number of imports of devices used within these procedures

EXCLUSION CRITERIA

- Devices published prior
- Accessories and Components of a device i.e., dialysate is a part of dialysis machine

The selected Class C and D class medical devices in Renal Category (Nephrology & Urology) and Cardiology (Cardiovascular & Intensive Care) were listed and a domain expert helped to identify the most common and critical devices used in both public and private sector. Included in the cardiology section was also the intensive care hemodynamic monitoring medical devices based on the critical nature of their use during high-risk surgeries among all therapeutic segments.

07. The authors recognize that not including diagnostics could prove to be a limitation of the study, but the idea to understand "equitable access" is seen as medical devices which directly assist with an increase in QALY or DALY or surgical intervention needing medical device assistance instead of diagnosis

08. An excel spreadsheet was created to translate the available data into a visual representation to identify state wise scenario to understand past trends as well as to understand how the future would look like. Since direct medical device usage data is sparse in India, the idea to infer the presence and or usage of medical devices by tracking the number of procedures occurring in the specialty wise was deemed suitable path to carry the research forward.

STEP 4 – EXPERT OPINION ON DEVICES

A list of low-volume and high-risk devices was prepared by combining both the MDR list and the import exempt device list under two therapeutic areas of nephrology and cardiology. These medical devices under nephrology and cardiology were further classified under Class C and D based on risk-classification and shortlisted and expert opinion was sought for each device regarding frequency of usage in both public and private sector institutions. The list of medical devices was then further pruned based on their usage in terms of case percentage load undertaken by the public institution, public contribution (financial) and interventions performed.

The selected Class C and D class medical devices in Renal Category (Nephrology/ Urology) and Cardiology were listed and a domain expert helped to identify the most common and critical devices used in both public and private sector.

STEP 5 – FINALIZING DEVICE LIST

NEPHROLOGY MEDICAL DEVICES[9]

- Automated peritoneal dialysis system
- Hemodialyzer reprocessing system
- Reverse Osmosis Unit (for dialysis)
- Kidney donor-organ preservation/transport system

CARDIOLOGY MEDICAL DEVICES[10]

- Pacemaker (& Components)
- Bypass Machine
- Intra-Aortic Balloon Pump (IABP)
- Heart Valve
- Peri-operative hemodynamic monitoring devices

09. The lists of 371 and MDR have device components listed as devices as well. While they are devices, by itself they do not contribute significantly. See Annexure for the device components.

10. Of the medical devices exempted from GTE for importation to India, cardiac medical devices, appear to a significant share. Moreover, unlike medical devices belonging to most other large volume specialties, cardiac devices are predominantly of higher risk device classes of C and D. When examined individually, the medical devices imported under cardiac specialty come under two major categories, implantable cardiac care devices, such as pacemakers, defibrillators and prosthetic valves, and diagnostic and surgical tools such as transesophageal echocardiographs

03 Literature Review

Though there is a large volume of literature on medical devices, both globally and within India, most of these are from a clinical perspective examining their efficacy, post-operative morbidity and mortality and survival rates. There are fewer studies examining procurement of medical devices from a policy perspective and the effect of procurement policies on availability, accessibility, affordability and the cost-effectiveness of these medical devices. A literature review was conducted to collate relevant information on these aspects of medical devices both in India and abroad. The medical devices from the following two therapeutic specialties were selected based on their majority share in the GTE exempt list as discussed earlier.

- Cardiology (Cardiovascular + Intensive Care)
- Renal (Nephrology + Urology)

The device selection process has been demonstrated in detail in the previous sections. A search was conducted on PubMed and Google Scholar using these device names as key words along with the following search terms: (medical devices) OR (implants) AND (cardiology) OR (cardiac) OR (heart) AND ((India) OR (southeast Asia)) AND (cost effectiveness) OR (technology assessment)). Similar search was conducted for the renal medical devices with (Renal OR Nephrology OR Urology) key words, and these searches were repeated without the geographic localization terms for a global search. A total of 744 results were obtained using the search terms of which 77 were selected for further evaluation by title which was further cut down to 30 by reviewing the abstracts. These studies were thoroughly reviewed further to meet the following inclusion and exclusion criteria:

INCLUSION CRITERIA:

- Studies related to accessibility, availability, cost-effectiveness of the selected medical devices
- Studies published in English language
- Studies conducted in adult population
- Studies published between 2011-2021

EXCLUSION CRITERIA:

- Clinical studies of medical devices examining indications, efficacy, survival rates etc.

Since literature on the cost-effectiveness and procurement of medical devices in India were scarce owing to the nascent nature of the industry in the country, literature on such studies globally were also considered. It should be noted that most of the current literature on procurement, cost-effectiveness and health technology assessment are published in developed countries such as those in European Union and USA. Effort was made to select studies from other countries with similar socio-economic profiles as that of India in terms of healthcare such as those from South American countries and South-East Asian countries. The literature selection process has been outlined in the figure below (Fig. 6).

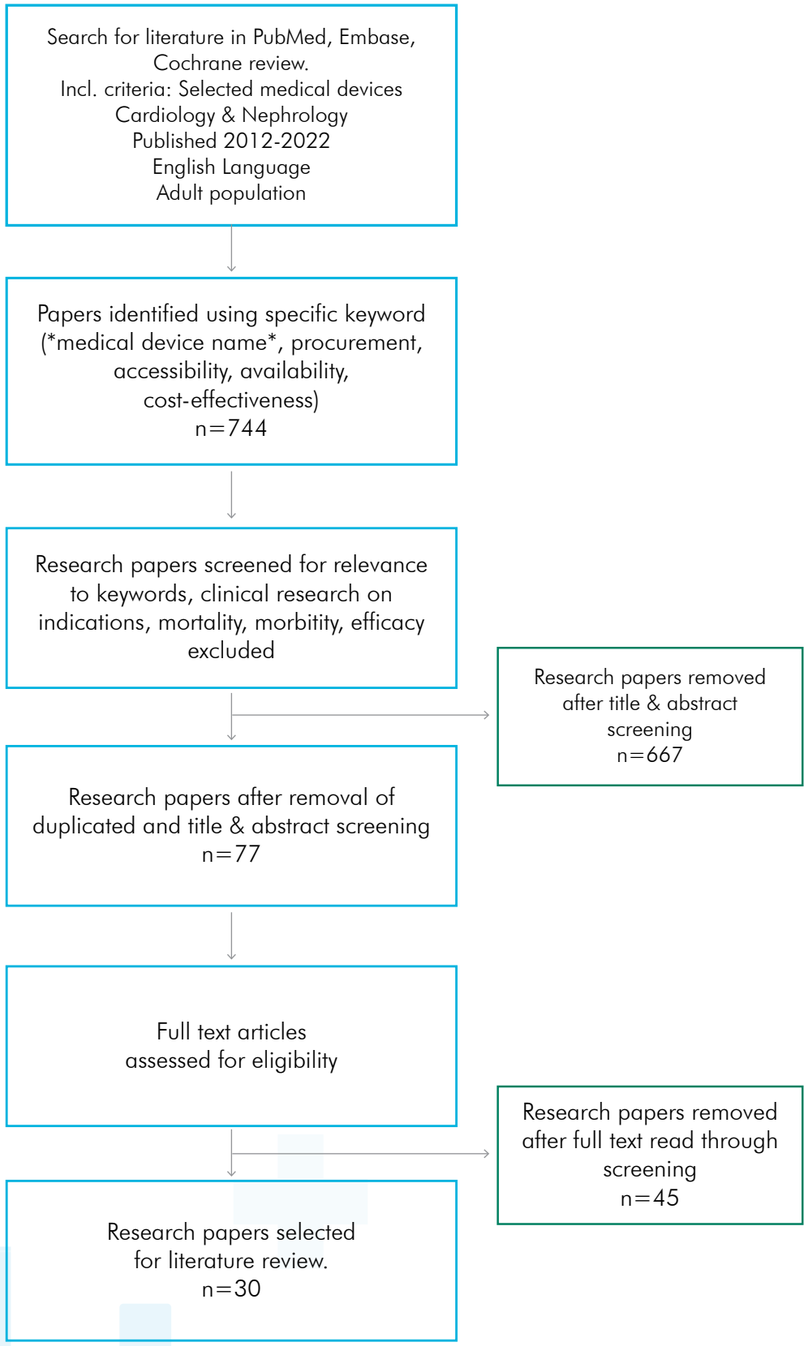

Figure 6: Document selection process for the literature review conducted

LITERATURE ON UROLOGY AND NEPHROLOGY MEDICAL DEVICES

Chronic kidney disease (CKD) is defined as kidney damage or glomerular filtration rate (GFR) of< 60 mL/ 1.73m for 3 months or more and if this reaches <15mL/ 1.73 m it is classified as CKD stage 5 or ESRD (Moosa, Meyers, Gottlich, & Naicke, 2016).

As of 2008, of 1.75 million patients across the world, were choosing dialysis as renal replacement therapy. Of which, hemodialysis was 89% (1.55 million); peritoneal dialysis 1% (197 000) patients were on peritoneal dialysis (PD). Further analysis revealed a majority 59% are from developing countries and the rest 41% from developed countries. In the case of HD, the percentages were even higher with 62% in developed countries and the remaining 38% in developing countries (Karopadi, Mason, Rettore, & Ronco, 2013).

According to WHO, by 2012, around 220 million people all over the world would be suffering from CKD. While kidney transplant ideally gives a longer and more promising quality of life, dialysis seems to be the more utilized option. Of these, the more cost-effective option of Peritoneal dialysis (PD) is preferred than an in-patient hemodialysis which requires frequent visits to hospital adding other non-medical charges making it an expensive option (Bavanandan & Ahmad, 2015). This is relevant as only a few countries are equipped with the health system, capabilities, and personnel able to tackle this disease causing an already strained healthcare systems like India to suffer.

As with most other developed countries, the cost of Hemodialysis (HD) USD 30,000 is more than peritoneal dialysis (PD) USD 13,000. Hemodialysis resulted in the highest direct and overall costs; in indirect costs it was peritoneal dialysis followed by nocturnal home dialysis. The time spent during dialysis and expensive hospital setting resulted in increased healthcare costs. On the contrary, the PD resulted in comparatively low cost both in the initial years and the follow up years (Wong, et al., 2019). PD remains popular only in certain countries which have a PD first policy like Hong Kong, Mexico, and New Zealand (Karopadia, Antony, Subhramanyam, & Nayak, 2013). In comparison, PD is almost entirely shouldered by the public sector in Malaysia and under 1% (0.92%) is treated by private sector (Ismail, Manaf, Abdul Gafor, Zaher, & Nur Ibrahim, 2019).

In a Hong-Kong based study, done to assess the direct (treatment + machine rental, dialysis access surgery, hospital stay, annual OOP costs), indirect costs or to summarize the cost effectiveness. Dialysis devices which were procured at rent came at 5000-6000 HKD. Despite the high costs dialysis remains a cost-effective solution to the public considering that the alternative is kidney transplantation. The Hong-Kong healthcare authority, like the Indian healthcare initiatives like PM-JAY, provide free RRT treatments with small co-payments to access health network and dialysis.

The LMIC countries are more susceptible to deaths because of CKD as both the incidence and the resulting death is high. A study conducted in India, reported only 900 nephrologists with 55000 patients and 5,500 dialysis centers (Shrestha, Gautam, Mishra, Virani, & Dhungana, 2021). Though Government has taken actions to ensure higher access to treatment, dialysis as a mode of therapy remains inaccessible to millions in India. Though the study assessed direct and Indirect costs of dialysis both in public and private facilities. A total of 835 patients comprising of in (n=10 sites, 540) North Kerala and South Kerala (n=5 sites, 295) consented to the study. An observation of more people preferring to go to private centers to get dialysis emerges from the study. Despite subsidies, people still spend out of their pockets resulting in discontinuation of dialysis due to lack of funds. This indirectly results in a reduced access to treatment by dialysis machine (medical device), especially with already low number patient footfall (per the study) (Bradshaw, et al., 2018).

There is comparatively little literature available on screening for kidney donor-organ preservation/ transport system as a device. Reverse osmosis is a process, as well as a unit, which is used in dialysis machines which has a noted lack of research available. Available research on reverse osmosis did not provide information relevant to the area of investigation i.e., medical device with a focus on cost effectiveness or focusing on procurement.

LITERATURE ON CARDIOVASCULAR MEDICAL DEVICES

As per the Global Burden of Disease study and the India State-level Disease Burden initiative, as of 2016, there has been a 85% increase (from 15.2% to 28.1%) in deaths due to cardiovascular diseases in India since 1990 and a corresponding increase of DALYs by 104% (from 6.9 to 14.1) (Collaborators, 2018) According to the study of the 28.1% share of deaths due to cardiovascular causes, 17.1% is due to ischemic heart disease, 1.1% due to rheumatic heart disease, 0.21% due to atrial fibrillation and 0.12% due to cardiomyopathies and myocarditis. Cardiac interventions such as implantable pacemakers (fibrillation and arrhythmias), coronary artery stent (ischemic heart diseases); intra-aortic balloon pump (cardiomyopathies) and through open heart surgeries with extra-corporeal circulation are globally accepted practices for reducing morbidity and mortality due to cardiovascular diseases. One common factor among all of the above cardiac interventions that both improve mortality rates and DALYs in the population is their dependency on the availability of medical devices to perform the requisite procedures. A systematic review and economic evaluation of using dual chamber pacemakers in treating bradycardia due to sick sinus syndrome conducted in the UK on literature from both UK and non-UK countries in 2015 found that dual chamber pacemakers had a cost-effectiveness of over 70% at a willing-to-pay (WTP) threshold of either £20,000 or £30,000 as compared to single chamber pacemakers in such patients. This was calculated after accounting for improved QALY and the similarity in the mortality rates due to strokes and heart failure complications in dual chamber pacemakers as compared to single channel pacemakers (Edwards, Karner, Trevor, Wakefield, & Salih, 2015). A 2014 Danish study using the DANPACE (Danish Dual chamber pacing in Sick Sinus syndrome) study found similar cost-effectiveness of dual chamber pacing of 41-70% at a WTP threshold of £20,000 and 50-70% at a WTP threshold of £30,000 (Oddershede, et al., 2014). This study was included in the systematic review mentioned above.

A British Medical Journal (BMJ) educational article on the cost-effectiveness of cardiac resynchronization therapy (CRT) using implantable pacemakers with or without inbuilt defibrillators, as compared to conventional pacing, published in 2012 summarizes previously published health-technology assessment papers in their use in cases of heart failure, sick sinus syndrome, atrial defibrillation. This article shows that CRT have an incremental cost-effectiveness ratio (ICER) below $50,000/QALY – a value proposed as threshold of healthcare attractiveness in the USA – when considering the patient's lifetime as the time horizon, rather than the period of the clinical trial (Boriani, Diemberger, Biffi, & Martignani, 2012).

Another cost-effectiveness analysis of CRT using implantable pacemakers using clinical data of patients with systolic heart failure (NYHA II-IV) in the Brazilian public health system using a Markov process decision-analytical model demonstrated an ICER of CRT with pacing alone (CRT-P) as $15,724/QALY and of CRT with defibrillator (CRT-D) as $36,940/QALY over conventional therapy (Bertoldi, Rohde, Zimerman, Pimental, & Polanczyk, 2013). Based on these results the authors conclude that CRT-P can be cost-effective from the perspective of the country's healthcare system while CRT-D was well above the WTP threshold, where WTP was calculated using the World Health Organization (WHO) suggested value of three times the gross domestic product per capita.

A meta-analysis performed in 2014 on the global literature on cost-effectiveness of percutaneous ventricular assist devices (PVAD) and intra-aortic balloon pump (IABP) used six studies to determine that these devices perform at a lower cost and with higher survival rates in cases of cardiogenic shock than devices that require more invasive implantation such as extra-corporeal membrane oxygenation (ECMO) (Maini, Scotti, & Gregory, 2014). However, in these cases, it should be noted that the device is expected to perform for a shorter duration while the patient's heart recovers. A similar cost-effectiveness, in terms of shortened length of stay and improved survival rates, was also found in the use of the PVAD in patients undergoing percutaneous coronary intervention. However, the authors note that the studies selected were not randomized but, at the same time, point out the difficulty in setting up randomization in such high-risk patients.

Similarly, a health technology assessment systematic review published by Health Quality Ontario on percutaneous ventricular assist devices such as the intra-aortic balloon pump (IABP) and the PVAD demonstrated that the latter is associated with higher costs but fewer QALY than the established IABP (Health Quality Ontario, 2017) A similar study comparing these two devices among the European and American patients also demonstrated improved QALY and lower costs when using the PVAD as compared to the IABP in high-risk per-cutaneous coronary intervention patients (Roos, et al., 2013).

Guidelines currently indicate the use of surgical aortic valve replacement (SAVR) to treat severe cases of aortic stenosis in low- to medium-risk patients. An economic simulation model to estimate long-term healthcare costs associated with tissue valve relative to mechanical SAVR used literature-based epidemiologic and cost inputs to calculate annual expenditures related to SAVR for up to 25 years after initial surgery. They found the expected net discounted savings per patient receiving tissue SAVR, relative to mechanical SAVR, at ages 45, 55, and 65 years were $12,266, $15,462, and $16201, respectively (in USD) over a 25-year horizon (CI 95%). And the estimated per patient cost difference (relative to mechanical SAVR) of reoperation over 25 years for a 45-year-old tissue SAVR patient ($16201) were offset by expected savings on anticoagulation monitoring ($26257) over the same period. Significant long-term savings were also found with tissue SAVR in the three age cohorts in a sensitivity analysis (Nguyen, Walker, Gunnarsson, Moor, & Keuffel, 2021). Moreover, a multicenter, prospective study of 689 patients receiving bovine tissue SAVR over a period of five years showed reduction in structural valve deterioration and mortality across all NYHA functional classes (Bavaria, et al., 2021).

A systematic review analyzing papers from Iran, USA, and France on the cost-effectiveness of mechanical heart valve over bio-prosthetic valves published between 1990 and 2019 found higher cost per QALY to be higher for the mechanical valve in all three nations. Although the ICER values were lower in Iran compared to the other two countries, which the authors argued was due to the lower medical tariffs in Iran than in USA and France (Azari, et al., 2020). Another cost-effectiveness study conducted in Singapore healthcare system on the use of transcatheter aortic valve implantation (TAVI) as compared to the conventional surgical aortic valve replacement (SAVR) demonstrated an ICER of S$33,833/QALY over eight years for TAVI. With the Singaporean willingness-to-pay threshold calculated as S$73,167/QALY, the authors concluded TAVI to be a cost-effective option over SAVR (Kuntjoro, et al., 2020). A similar study of cost-effectiveness of TAVI over SAVR in patients with aortic stenosis in Japan evaluating the QALYs with over 100,000 simulations found that among inoperable patients, the ICER for TAVI compared with medical therapy was nearly 4 billion yen per QALY, while the same for operable patients over SAVR was slightly over 7.5 billion yen per QALY, suggesting that TAVI having the cost-effectiveness for inoperable patients but not for operable patients (Kodera, Kiyosue, Ando, & Komuro, 2018). Another recent study that combined the data from PARTNER 3 trial (Placement of Aortic Transcatheter Valve Trial, which found even low risk patients up for SAVR clinically benefit from TAVI) and the French national hospital claim database to inform a cost-utility model and examine the cost-effectiveness of TAVI in low-risk population found that TAVI with SAPIENT 3 valve prosthetic provides cost saving (€12742 per patient) and generates greater QALY (0.89 per patient) over SAVR (Gilard, et al., 2021).

Another study creating a national registry of heart failure and cardiac arrhythmia patients in India published in 2017 showed that 46% of the registered patients would potentially benefit from interventional cardiac procedures such as implantable pacemakers, cardiac resynchronization therapy and radio frequency ablation therapy. Of the registered patients, 25% would have benefited from the former two implantable devices (Vora, et al., 2017). The authors further argue that price reduction through centralized tender process, rather than price capping through inclusion in NLEM has resulted in such a significant increase in device accessibility.

Literature review on peri-operative hemodynamic monitoring, a critical component of high-risk cardiac surgeries, resulted in results mostly from the developed side of the global healthcare sector albeit with a few publications discussing the feasibility of such monitoring in low resource settings discussed below. The importance of peri-operative hemodynamic monitoring becomes apparent when considering the fact that 'cardiogenic shock' or hypo-perfusion at tissue level of end organs (like brain, kidneys, and liver) due to reduced cardiac output (CO), and resultant fall in systolic and mean arterial pressure, is a leading of cause of death during cardiac surgeries accounting for 2% to 6% of perioperative cardiac surgery deaths. The fact that such death due to peripheral hypoperfusion of tissues is preventable 90% of the time given timely intervention by the attending anesthesiologists or intensivists with application of vasopressors, fluid therapy, ionotropic drugs, and implementation of existing cardiac shock protocols given an early detection of the event gives credence to the value of peri-operative hemodynamic monitoring in all cardiac surgery cases amongst other intensive care cases (Masud, Gheewala, Giesecke, Suarez, & Ratani, 2020) (Reynolds & Hochman, 2008). While clinical factors like cold extremities, lower limb edema, prolonged capillary refilling time under the nail beds are indicators of peripheral hypoperfusion in surgical and intensive care settings, these features manifest quite late in the development of the cardiogenic shock to provide adequate window for life-saving interventions to occur. And while peripheral monitoring devices like external blood pressure monitoring, digital pulse oximeter of SpO2 and endo-tracheal CO monitoring provide earlier alert to the impeding hypoperfusion, the earliest – and current gold standard – of warnings is provided by intra-arterial blood pressure and blood oxygenation monitoring among other cardiac parameters using invasive intra-arterial catheters measuring transpulmonary thermodilution (Chioncel, et al., 2020). However, it has been difficult to measure the cost-effectiveness of such a monitoring mechanism as these early warning devices are only as useful as the therapeutic interventions that follow said early warning which is subjective and dependent on human interpretation and action in spite of existing therapeutic protocols (De Backer, et al., 2018).

However, of late, there has been incorporation of minimally invasive or non-invasive methods of monitoring cardiac output as a safer alternative to intra-arterial catheter-based measurement which is highly invasive and risky with adverse effects including death due to pulmonary embolism. These non- or minimally invasive means of measurement of cardiac output use algorithm-based methods like pulse contour analysis, thoracic bioreactance, doppler ultrasound cardiac output monitoring. While these options provide a safer and cheaper option for hemodynamic monitoring in resource poor settings when compared to invasive cardiac output monitoring devices discussed earlier, they are not yet gold standard with their accuracy still being developed and evaluated (Sivakorn, Schultz, & Dondorp, 2021). Moreover, the more modern equipment and the requisite training of the healthcare personnel for specific devices and their development may also present an accessibility barrier in remote areas of the country. The current less-invasive methods of intra-operative and peri-operative hemodynamic monitoring mechanisms require a central venous access, along with a peripheral arterial access rather than a central pulmonary artery access, and in some cases requiring only a peripheral arterial access. The continuous non-invasive monitoring technology available at present include devices that require either an arm cuff and a finger cuff or just a pair of finger cuffs that are inflated and deflated based on prior calibration of the device with patient parameters such as their body weight, blood pressure, heart rate and further assisted by predictive algorithms to monitor peripheral arterial blood pressure to calculate real-time continuous hemodynamic parameters such as cardiac output, central venous and arterial pressures and peripheral perfusion. In a review comparing the results of ten studies, including a total of 365 patients, that compared non-invasive finger cuff cardiac output monitoring device to the pulmonary artery catheterization method showed that the finger cuff monitoring device, although fairly close in estimating the CO, was not clinically interchangeable with the current gold standard in cardiac output monitoring (Ameloot, Palmers, & Malbrain, 2015). While non-invasive methods of cardiac output monitoring are yet to be as precise as the invasive pulmonary artery catheterization method, their inherent advantages of reduced invasiveness, decreased chance of infections, ease of application points to a need to develop standardized evaluation criteria for such non-invasive hemodynamic monitoring devices (Bodys-Pwlka, Kusztal, Boszko, Glowczynska, & Grabowski, 2021). While the above discussion focused on cardiac parameter monitoring in the case of cardiac surgeries, such monitoring is essential in other medical and surgical scenarios as well. The WHO clinical management of COVID-19 guidelines also mentions the importance of monitoring cardiac parameters such as variations in systolic pressure, pulse pressure, inferior vena cava size, or stroke volume in response to changes in intrathoracic pressure during mechanical ventilation in critically ill COVID-19 patients (WHO, 2022).

A pattern emerges from the medical device interventions seen above in both nephrology and cardiology, and other specialties, that the cost is a significant determining factor whether a device and the health treatment is accessible or not. Moreover, newer, and less invasive medical devices are continuously being developed and introduced in the market and existing devices are also being improved upon. There is a need for a standardized evaluation of these improved and newer devices and their adoption in the public health sector for the patients to reap the benefits of these developments. However, there is also significant lack of published research on the cost and procurement aspect of existing medical devices in India at the moment. Studies examining the cost-effectiveness of medical devices for their indicated use cases, risk estimation of medical device interventions, and robust health technology assessments (HTA) need to be promoted in both public and private healthcare institutions which could in turn help advice policy and regulatory decisions on the matter in the future. Medical devices, regardless of their complexity, need to function optimally and are a necessity to ensure good health outcomes and are the benchmark of a good health system. When presented with a lack of it, it not only leads to poor outcomes, but it also increases the risk of the nation's health. Good healthcare service delivery relies heavily on the medical equipment or devices to function smoothly 24*7 and is directly proportionate to the accessibility and affordability of the medical devices.

04

Barriers to Accessibility

While access can be assessed against multiple parameters and the percentage extent of it can vary, the essential barriers to access can be divided into the following key points in order to enhance access to medical devices by institutions in the public health system in India and thus to enhance access to the healthcare services facilitated by these medical devices by the Indian population at large.

ECONOMIC BARRIERS

India's economic growth in recent years and steady rise in per capita GDP, a quarter of the global poor live in India and inequalities continue to exist in the population. There is higher access to healthcare in metro cities in contrast to rural areas, hospitals in non-metro areas go for cheaper devices or sometimes without the devices as well (Sharma, 2021).

DEVICE AVAILABILITY AND IMPACT

There have been instances where lack of device availability has resulted in patients turning toward private healthcare sector for health services. Longer wait times for healthcare services – crucial in life threatening or terminal diseases – can lead to patients not getting the treatment at all, thereby, again posing a barrier to access (LillyWhite, 2021).

PROCUREMENT PRACTICES (SUPPLY CHAIN)

While GTE and the GFRs 2017 aim to promote local manufacture of devices due to the increasing import duty on finished medical devices and thereby making them expensive in comparison, this process is complex and lengthy which might delay access to medical devices by the institutions and thereby the patients. Simplified and clear-cut procurement practices for the institutions under the government would shorten procurement times and ensure timely delivery of healthcare services.

POLICY SUPPORT

While the import duty on finished medical devices was at 5% until 2020, this has been raised to 7.5% since then. This along with the health cess ad valorem brings the total on medical devices up to 13.75%. With IGST included, this brings the total taxation on imported medical devices to 25-26% of their cost This has been done in order to promote local manufacture under the Make in India campaign by the government. While medical devices made with 50% local components attract a lower tax and higher priority while accepting bids as 'local supplier' goods with <20% local components lose this tag. The import duty on the raw materials needed to produce medical devices have been kept at a minimum of 5%. While these measures help promote the local industry by raising the price of imported finished medical devices, these costs are borne by the patient if they spend out-of-pocket on healthcare services. Such a high price may prove to be a barrier to access these medical devices at present to many patients. Efforts must be taken to ensure that these policy measures aimed at promoting local manufacture on the long term should not affect patients availing medical devices in the short run.

Though the TRIPS Agreement India has sought to refine the IP laws and acts to protect confidential information. Trade secrets and protection is still an upcoming area in India and not all patents are protected or accepted when it relates to drugs or devices. (Chaudhary Kapur & Ranjan, 2019).

Hence, both macro and micro changes are needed in the regulation and operation of medical devices in the country to ensure adequate policy framework can boost access to devices.

INTELLECTUAL PROPERTY

Patent application trends show that while Indian manufacturers are aware of the need for medical device innovation, this need not necessarily translate to an increase in presence of Indian-made medical devices. A reason for this could be because India is an exporter of low-end, high-volume devices which can be marketed and distributed off patents thereby having a low presence about patenting medical device innovation (Markan & Verma, 2017). In contrast to the pharmaceutical industry, the medical device market is capital intensive in R&D and manufacture, this has been discussed in earlier sections.

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Hence, both macro and micro changes are needed in the regulation and operation of medical devices in the country to ensure adequate policy framework can boost access to devices.

05 Best Procurement Practices observed around the globe

Reviewing procurement practices followed in other countries around the world will be useful for India to improve its procurement practices by either adopting or reworking these practices that have been shown to work in other countries.

China for example, a manufacturing hub exporting to USA and other countries has certain non-monetary incentives like reduced registration times, fast-track approval times for innovative medical devices acting as incentives for doing business, motivating manufacturers to come up with affordable devices. Additionally, corporate tax rates have also been reduced, and tax benefits can be availed if the organization is recognized as a medical device organization. India can adopt these measures and modify it to work within Indian legal framework (Sehgal & Bose, 2016).

Ireland, another major hub for exports of medical devices, through conducive policy environment, has transformed into a hub for LMIC high-end manufacturing of invasive devices along with R&D as well. Devices like lenses and diabetes devices, are manufactured by Irish companies, catering to a global market. The medical device companies that have a presence in Ireland have R&D sector and relate to the tertiary health and government sectors of the country, with a say in policy shaping (Vendotti, 2018) (Sehgal & Bose, 2016),

In a burgeoning economy like India, the widening socio-economic inequalities are reflected in healthcare utilization, where the poor largely access services from public healthcare facilities. Though the poor use public healthcare services more than the rich, the comparative lack of medical devices in the public sector facilities contribute to poorer access to life saving services. Based on global best practices, the following are two potentially viable long-term options for improving access to medical devices in the country

HEALTH TECHNOLOGY ASSESSMENT

HTA (Health Technology Assessment) is an evidence-based framework allowing for policy development and mostly pertains to understanding how economies around the world provide healthcare. Almost all developed and developing countries have some form of HTA. (Tarricone, et al., 2021). Health Technology assessment solely for medical devices require different level of oversight varying on a case-by-case basis due to differences in technology which may not always be linear for all medical devices[11]. Unlike medicines they require both procurement and maintenance costs. For a decentralized procurement scenario present in India, this could be highly useful in understanding the trends seen in local, state and nation wide allowing for a better or equitable access to devices thereby medical treatment (Tarricone, et al., 2021). This essentially translates to increased transparency, direct impact and a greater scope for tackling rising or unmet needs to ensure timely and equitable access to all classes of people.

India and Italy have a similar structure of split procurement system where in both have a centralized procurement but also decentralized procurement (Italy -21 states provinces) and India has a state wise procurement setup which is different. Having a robust HTA allows for priorities to be set solely based on evidence-based needs and not have any biases or blind spots, since qualitative and quantitative parameters can be set and achieved.

11. A consultation paper regarding HTA is ongoing in India. Ayushman Bharat Digital Mission(ABDM) has a draft consultation paper as of April 2022, that is set to be applicable to Medical devices, but primarily focuses on building a drug registry HTA https://abdm.gov.in

TRADITIONAL VS VALUE BASED PROCUREMENT

Typically, procurement focuses more on cost savings. Traditional or government procurement leans more on the lowest cost within the specified budget, while typically specifications are mentioned and vendors are vetted, there is an underlying cost threshold which is focused on. For the most part, this procurement system is the most accepted, not just in healthcare, but also in other industries, commercial or otherwise, there are some significant problems that can be foreseen theoretically or do occur practically.

Ideally, the traditional approach of a tender identifies a bid mostly with what has been anticipated and this is almost always the lowest cost which constraints other potentially well suited and qualified bids. Price based procurement typically fails to factor in other related costs like acquiring and maintenance costs. These limitations associated with traditional cost-based procurement of medical devices are conflicting interests, fragmented organizing amongst procurers as well as inadequate availability of information and insufficient documentation practices (Rahmmani, Karimi, Rezayatmaand, & Raeis, 2021).

Value is subjective and can hold varied meanings based on perspective, purpose of use, and which market it is desired to work in. In healthcare it could be deciphered as favorable outcomes to ensure patient quality of life, safety, or reduced cost of care or all of it. In a nutshell, VBP focuses on the spending reflects optimal quality than spending less and on the overall impact of the spending on health ecosystem.

ESCALATING COSTS

The rising costs of healthcare interventions could be a major factor in fewer people opting for health interventions. This is exacerbated by not only the actual health delivery costs and personnel costs, but also equipment procurement whose maintenance costs are rarely considered leading to increase in equipment downtime and increased load of patient footfall, where hospitals are unable to handle the same. (www.apacmed.org, 2022)

SILOS IN THE SYSTEM

In traditional procurement there could exist silos, where in concerned departments or entities may or may not interact with each other. This may create silos and reflect in the aspects of procurement. Ideally, different segments should work collaboratively with an osmosis of inputs given, absorbed, and implemented. It should also consider the patient outcomes, multiple stakeholder opinions and costs which may not be directly visible.

These could be tackled with a mindful use of VBP, as it could essentially ensure zero silos, and views health ecosystem as segments which are cohesive to ensure efficiency. It has the potential to provide advantages like:

- Total cost accountability and sustainable benefits over long term
- Impact focused solutions in all levels of hierarchy
- A transparent dialogue between different critical stakeholders i.e., policy makers, health industry, health providers, patients, procurers, payors.
- Long term cost accountability and sustainable benefits (www.apacmed.org, 2022)

In the global landscape, several nations in EU have implemented Value based procurement. The MEAT system in the policy itself in 2014 in EU directive 67, subsection3 (Contract award criteria) where the basis of price would be cost effectiveness approach and would be assessed on the qualitative, environmental and or social aspects. It has been steadily gaining support as it seeks to help the health system by aiming to address rising costs, and the variation in quality care. Ideally, the traditional approach of a tender identifies a bid mostly with what has been anticipated and this is almost always the lowest cost which constraints other potentially well suited and qualified bids, and potentially higher quality medical device/ equipment with higher survival rates or has marginally better outcomes. Price based procurement typically fails to factor in other related costs like acquiring costs and maintenance costs. These limitations associated with traditional cost-based procurement of medical devices are conflicting interests, fragmented organizing amongst procurers as well as inadequate availability of information and insufficient documentation practices. (Rahmmani, Karimi, Rezayatmaand, & Raeis, 2021) The critical success factors resulting in VBP implementation and sustained option as the go-to choose for all stakeholders involved. (www.apacmed.org, 2022)

Different case studies highlight some significant impact:

- VBP helped Denmark create individualized advanced treatment plan for patients and also allowed to automate manual processes around radiation therapy by reducing complications and poor prognosis of cancer patients by opting for strategic procurement of devices and a targeted treatment approach plan.
- In a case study done in Netherlands, an estimated 5,00,000 euro per year costs were cut through reducing the nursing cost and shortening the length of stay by a day, to allow for efficient patient monitoring. Through VBP, a digitally connected bed was connected and an alert sent to the nurse if any patient movement was detected (www.apacmed.org, 2022).

Though this type of procurement is a long-term goal for India, it is not recommended till a well-established framework can be implemented. Supporting elements, like HTA to document information and assess trends, will allow VBP to gain traction and make value-based decisions. Whereas, in developed nations, where associated HTA process is well documented VBP has been utilized as a tool to solve myriad problems in healthcare scenarios as seen in case studies above.

Closer home, in a case study in procuring a medical device in India i.e., PET scan, where senior management personnel assessed or forecasted the hospital needs to prepare a well-researched specification list. After which global tenders were invited, and a tender evaluation group provided clinical and technical expertise. This process led to the bids being evaluated on various levels like service, preference and usability, technical specifications, lifecycle costs. Ultimately decision was made to procure, PET scan from vendor which had all the required specifications and led to almost 50% increase of the hospital machine scan capacity (www.apacmed.org, 2022).

The VBP framework could be adapted in India to ensure Efficiency (Stakeholder benefits), improved patient outcomes, equipment lifecycle cost, access to care, long term sustainability of the solutions being implemented. One of the reasons the PM-JAY is considering Value based care is that the existing form of health coverage though aims at covering populace above below poverty line, the statistics on how much, how often and how satisfactory the other sections of population are covered remains vague or at best gives unsatisfactory answers. By keeping value at the center of all its decision-making activities, policies etc. Value based care will help refine a lot of avenues for PM-JAY allowing to reach to maximum people.

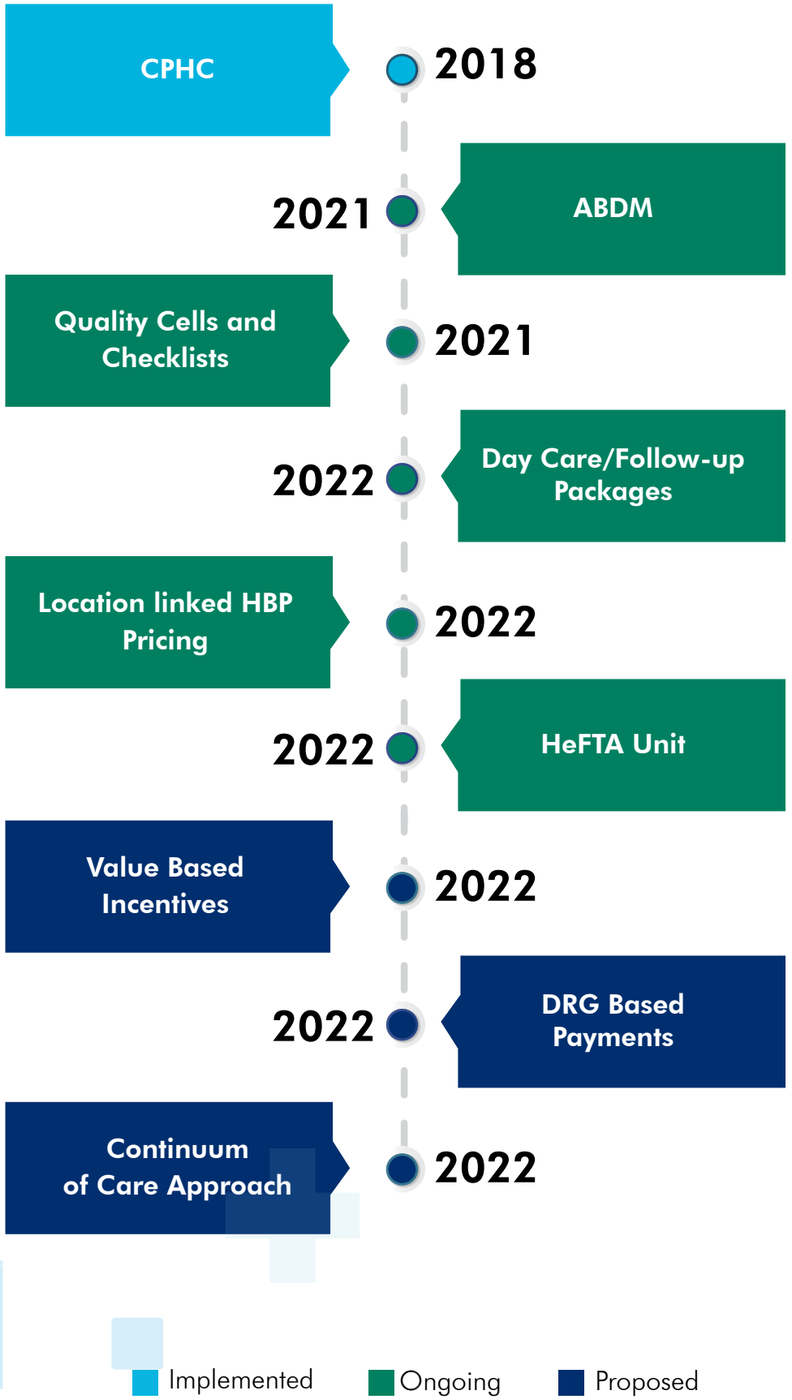

Figure 7: Value Based Procurement application in PM-JAY. (Source: NHA, 2022)

To summarize, some key observations from Value Based Procurement are:

- **Works in developed and some developing economies but developed economies have relatively faster uptake and implementation rates**
- **Could be applied in public and private healthcare, where public sector driven by government reforms, accelerated by policy and regulations.**
- **Can be used for a single service / product or could be suited for long-term complex solutions.**
- **Effective in different payment model systems i.e., Fee for Service and Diagnosis**

At present, there is both a state and central level procurement which, goes through multiple approval channels, increasing the time, money and resources involved miring it in various levels of bureaucracy. Ultimately, the end consumer, the patient, regardless of the healthcare sector they seek medical assistance from, gets affected.

Conclusion

The medical device industry is fast evolving with research, development and innovations improving both the variety of problems addressed by the medical devices and the quality of life of the patients receiving them. This has been made apparent by the inclusion of software as medical devices by the European Union, USA, and India. The need to have a planned agenda to outline regulation of medical devices, both locally manufactured and imported has been made evident by an acute lack of devices during the COVID-19 pandemic, which left the nation scrambling for access to medical devices that provide oxygen to those afflicted. Though the pandemic is almost at an end, the problems which had come to light still have not. The solutions to these are not straightforward and require patience, foresight, and adequate planning to implement policy changes, increase public healthcare budget, and effort by the government to help access to medical devices reach all levels of populace regardless metrics like geographic location, education, finance in order to ensure Universal Health Coverage in India.

Targeted research at a health system level focusing on procurement, availability, and cost-effectiveness of medical devices in both global and Indian medical space with practical and alternative suggestions on implementing them in a diverse and ever-growing economy like India is sparse. If done, such a systematic analysis would help achieve improved availability and accessibility of high risk and high value medical devices on a larger scale which would help in achieving the goal of universal health coverage (UHC) in a cost-effective manner. It would also help bridge a gap in analyzing and documenting the information available, thereby strengthening the HTA in India and allow the government to make informed decisions. This can only be achieved with large scale collaboration of policy makers, public health specialists, medical device sector overall and health system managers in sounding the demand for medical devices in India and globally and striving to achieve cost-effective practices in procurement and manufacture of these devices.

New initiatives by the government both in terms of building a robust infrastructure and enhancing the capacity of the health systems are bound to pay off. Initiatives like the Ayushman Bharat Digital Mission (ABDM) intend to have a singular IT platform to coalesce the data under multiple websites, provide information to the public, and help create a robust digital health information system. There is also a need to develop standardized testing protocols for the evaluation of newer medical devices that are being developed and introduced in the market. Such a system will ensure that newly introduced medical devices find their way to the healthcare practitioner and patients as early as possible while also ensuring that they are safer, more beneficial, and more cost-effective compared to existing medical devices and practices. For example, in the field of healthcare monitoring, as discussed in earlier sections of the report, there is an opportunity to shift from invasive to less-/non-invasive methods and from static to dynamic systems with the implementation of predictive technologies enabled through machine learning algorithms in the medical devices used for monitoring patient parameters in healthcare settings.

Although there has been significant effort to promote manufacture of medical devices in India, there is a significant lack of research on cost-effectiveness and health technology assessment of medical devices as interventions in the country which could further advice policy and regulatory decisions. While a capital-intensive industry that relies on expensive research and development like the medical device industry can benefit from foreign investment by MNCs with significant resources, there is need to ensure long-term availability of both capital and skilled human resource in the country to establish a robust medical device industry that could one day rival the pharmaceutical manufacturing industry in India in providing for the healthcare needs of not only this country, but also others.

Annexure

ANNEXURE 1
DEVICE RISK CLASSIFICATION

Under the medical device and IVD regulations, the Health Ministry of India has divided medical devices into the following four categories:

Class A (Low Risk)	Class B (Low Moderate Risk)	Class C (Moderate High Risk)	Class D (High Risk)
Medical devices such as surgical dressings, umbilical occlusion devices, bolster sutures, alcohol swabs, nasopharyngeal catheters and Y-connectors, as an accessory to perfusion sets etc. are included in this category.	Medical devices such as endoscopic forceps, vial adapters, suction cups and catheters, Sengstaken-Blakemo re tube, feeding tubes, gastrointestinal tubes etc. are included in this category.	Medical devices such as anesthesia conduction filter, introducer sheath, microcatheter, imaging catheter colonic stents, pancreatic instruments etc. are included	edical devices such as coronary stents, cardiac catherisation kits, cardiovascular, intravascular diagnostic catheters, occlusion catheters etc. are included in this category.

ANNEXURE 2
MEDICAL DEVICE RULE AMENDMENTS – KEY CHANGES

Table 3: Medical Device Rules Amendments overview. Adapted from information from gazette notifications

Date/Year	Changes
15 June 2017	Medical Device Rules introduced
22 February 2020	Registration Rules for medical devices (section 19A) introduced. Has five subsections
12 October 2021	Further amendments introduced (also called Third Amendment Rules) for ISO 13485 requirements
18 May 2022	Cancellation of license

ANNEXURE 3
GLOBAL TENDER ENQUIRY – KEY CHANGES

Table 4: Key changes in Global Tender Enquiry process. Adapted from data on https://pharmaceuticals.gov.in

Date	Official memorandum	Key change summarized
15 May 2020	OM. F12/17/ 2019 -PPD	• Introduction of GFR 161 iv subsection (b) introducing limit of 200 Cr INR
28 May 2020	F 12/17/ 2019 -PPD	• GTE will be applicable to goods, consultancy services, non-consulting services, works
27 Aug 2020	OM F. 20/1/2020 - PPD	• GTE to be submitted before 10th of every month; Format of GTE
09 Nov 2020	31026/36/2016-MD	• Definition of supplier (non-local, class 1 and class 2) ; non- local supplier • Verification of local content • Supersedes all previous versions of 31026/26/2016 memorandum
08 Jan 2021	OM F. 20/45/2020 - PPD	• Relaxation of GTE strictly for research institutes with the respective ministry as overseeing authority
16 Feb 2021	F.No.31026/361/2016-MD	• Recognition of DOP as the nodal department to make decisions regarding Medical devices • Definition of local supplier , requirements to be followed if local supplier costs more than 10 Cr INR
12 March 2021	OM F4/1/2021- PPD	• OM 12/17/2019 dated 15may20 not applicable for GTE where institutions had them with foreign import in place prior to 15 May 20 and need to fulfill them. • Applies to bids entered before 15 May 2020
11 June 2021	OM F4/1/2021- PPD	• Relaxation of GTE till 31 Oct 2021 for COVID-19 related procurement
07 Jul 2021		• Instructions on proposal requirements and filing format • Domestic tenders should be floated prior to GTE and must contain deliberations with DPIIT or relevant industrial bodies • 3-5 year procurement plan issued by DPIIT PPP must be published on the website prior to GTE proposal
03 Aug 2021	OM F. 4/1/2021- PPD	• OM F 12/17/2019 dated (October) not applicable to Original Equipment Manufacturers (OEM) / Original Part Manufacturers (OPM) • Methods to ensure accuracy and completeness of GTE application
09 Aug 2021	F. No DPE 7 (4)/2017- Fin	
Sep 2021	OM F. 4/1/2021 - PPD	• Services like AMC and auxiliary add on components for such equipment also exempt ie GTE not applicable
18 December 2021	F 31086/180/2021- PPD	• 493 Devices exempt from GTE
06 Jan 2022	No.F 4/1/2021-PPD	• Relaxation of the 161(iv) of GFR – procurement pertaining to GTE • Exemption of 128 devices mentioned in Annexure A of the memorandum
21 June 2022	No.F 4/1/2022-PPD (pt)	• Devices exempt narrowed down to 371 Medical Devices/ Equipment listed at Annexure-A department vide OMs No. F .12/17/2019-PPD dated 15.05 2020 & 28.05 2020 - GTEs. • This exemption will be valid for all the tenders issued after this date till 31 .$.2023.

ANNEXURE 4
PROCUREMENT – KEY CHANGES

Date	Order no.	Key changes
15 June 2017	PPO 4501/2/2017 - B.E- II	• PPO order 2017 issued and outlines • Definitions, Requirement of purchase preference, exemption of small purchases etcs
Revisions		
14 August 2017	P-45021/2/2017-BE-II	• Nodal department for implementing provisions of PPO relating goods and services relating to pharma sector
29 May 2019	P-45021/2/2017-BE-II	• Para 3 and 14 modified and 10 a added
04 June 2020	P-45021/2/2017-BE-II	• Partial modification of 2,3,5, 9 (a and b), 10b
16 Sep 2020	P-45021/2/2017-BE-II	• Para 23,5, 10 and 13 modified
Other order(s)		
18 May 2018	F. No 31026/36/2016- MD	• Percentage of minimum local content : manner of calculation of local content : purchase preference, verification of local content

ANNEXURE 5
DEVICE DISTRIBUTION IN EACH CLASS FROM 371 (EXAMPLES)

Category	Class				Total	List
	A	B	C	D		
Cardiology	0	0	21 + 13	6 + 1	41	371
Nephrology	0	0	1+2	0	3	

ANNEXURE 6
DEVICE DISTRIBUTION IN EACH CLASS FROM MDR LIST (EXAMPLES)

Category	Class				Total	List
	A	B	C	D		
Cardiology	1	18	11	7	37	MDR
Nephrology	2	13	22	2	39	

ANNEXURE 7
PUBLIC AND PRIVATE HOSPITAL DISTRIBUTION

Public Hospitals and Private Hospitals

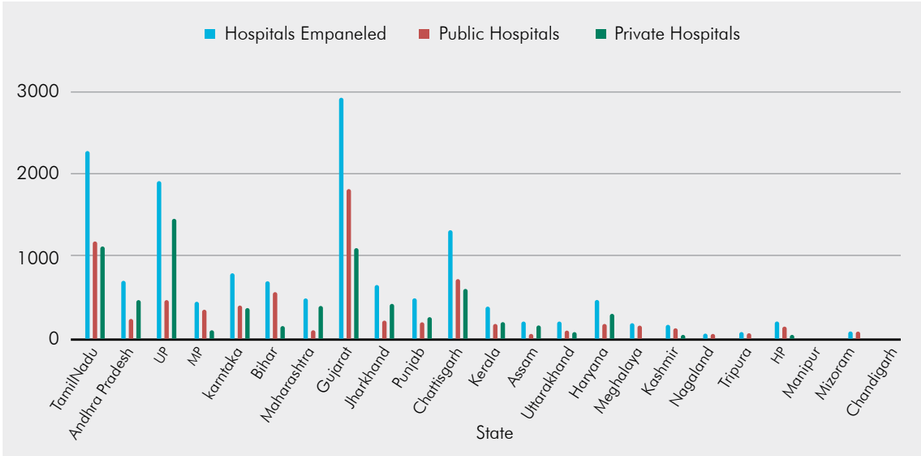

Figure 8: Distribution of Public and Private Hospitals in India. Source: PMJAY report 2019

ANNEXURE 8
GLOBAL EXAMPLES OF VBP

Table 5: Examples of value-based procurement worldwide.

Category	Type of Economy	Timeline	Type	Outcome	Assessment parameters
USA	Developed	2013	COQ()	Cost quality, Outcomes	• TCO • Product quality and patient outcomes
Norway, Finalad, Denmark	Developed	March 2013-April 2014	VABPRO	Value based Procurement and Social healthcare	• Outcomes (patient, user, commissioner) • Value (individual and subjective)
EU (Italy, Spain, Netherlands), UK	Developed	April 2014	STOPGO	Sustainable Technologies for Older people	• Patients' clinical outcomes • Performance level of technology • Population impacted
EU and Canada	Developed	March 2016	MEAT	Most Economically Advantageous Tendering	• Sequential evaluation of patient clinical outcomes divided by TCO • Patient user and safety experience • Innovation, sustainability and socio-economic impact
Ethiopia, Malawi, Zimbawe Tanzania, Kenya, Sudan Etc	Developing	July 2011 (Reform-2019; 2020)	VFM	Value for Money	• Economy (health services at lowest cost) • Efficient heath outcome contribution • Efficiency (maximize service alternative) • Equity (support needs of populace)

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