Market Assessment of Medical Devices in India

By
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Under the Supervision and Guidance of

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DECLARATION BY STUDENT

I, **Manish Sardana** Enrolment No. IIHMR-U/02/2021-23/0314 hereby declare that this dissertation is titled **Market Assessment of Oncology Medical Devices in India.** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in thetext.

Name of Student: Manish Sardana

Date:

CERTIFICATE

This is to certify that the dissertation titled **Market Assessment of Oncology Medical Devices in India.** is a record of the research work undertaken by **Manish Sardana** in partial fulfillment of the requirements for the award of the degree MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidanceand supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Dr. Ashok Kumar Peepliwal	Dr. Saurabh Banerjee
Faculty Guide	School Dean
IIHMR University, Jaipur	IIHMR University, Jaipur
Date:	Date:

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Date:

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I would extend my vote of thanks to the Dr. Sudhinder singh Chouhan who gave me the guidance and support during my internship.

I hope that, in the future, I will be able to draw on my expertise and skillsto make a useful contribution to the industry.

Abstract

The report examines the topic of medical devices using secondary data sources and provides an overview of the Indian market for Oncology Medical Devices. This explains how the development and progress of this sector is taking place. The Oncology Medical Devices and Indian company's medical devices industry is growing, and their applications are an important component of the study. The market segmentation of Oncology Medical Devices demonstrates how much scope we have in this industry, which immediately corresponds with us and leads us to the question of how much we can investigate and where we stand in this field. The impact of COVID-19 outlines how the market has fluctuated and how the market has demonstrated its potential to influence business and present us with opportunities for expansion, allowing us to get entry to the healthcare system. The general trends of the Oncology Medical Devices market with future impact and trends for prediction of the growth of the Oncology Medical Devices in India is a general indicator that how fast this market is growing as the cost of Oncology Medical Devices is much higher as compared to Medicines and this also leads to the fact that as the population grows and the cost of treatment goes up, this also affects the Oncology Medical Devices market.

Introduction

Medical Devices for Oncology is defined as the field of medicine known as oncology is concerned with the identification and management of malignant illnesses. The phrase "medical device" can refer to any apparatus, tool, or piece of equipment that is used in human or animal medical procedures that has been specifically designed to analyse, treat, or prevent physiological disorders. One kind of medical equipment, oncology equipment, aids in the diagnosis of cancer patients and the mapping of the disease's severity. MRIs, PET scans, ultrasounds, and other imaging techniques are often used by oncologists to detect malignant diseases and tumours.

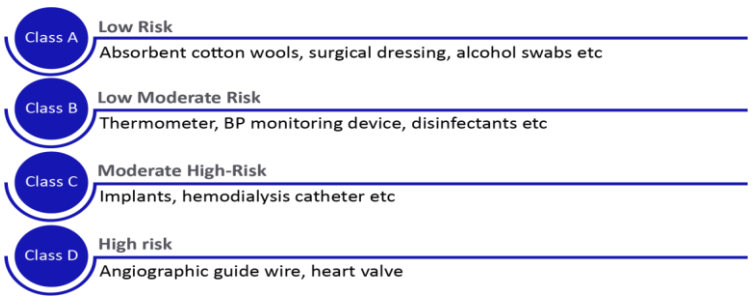
The 1940 Drugs and Cosmetics Act no longer regulates any medical devices; only those that have been specifically notified are. According to their intended use and risk class, the CDSCO published a list of 31 oncology medical devices in 2020. By October 2022, CDSCO licencing will be required for any medical devices that fall within Risk Classes A or B. A CDSCO licence is required for importers of oncology medical devices in order to sell their goods in India. The CDSCO website provides access to the whole list.

The registration link on the CDSCO website must be clicked by applicants in order to start the application process. While Class A and B devices are already required to have a licence starting in October 2022, Class C and D devices will follow the same pattern and be required to have a licence starting in October 2023.

The manufacturer and/or importer must abide by CDSCO standards and register the cancer medical device within the period offered after the device is notified on the CDSCO list in the case of products that were already on the market prior to the CDSCO notification.

Risk Classification System in India

The New Medical Rules of 2017 have divided all medical devices into four groups. These four groups—also known as Risk Classes—are shown in the following table.



A variety of factors affect the classification level of Oncology Medical Devices, such as-.

- The length of time the medical equipment is in touch with the body.
- The level of intrusion.
- Whether the medical equipment gives the patient energy or any medication.
- If the medical equipment is designed to affect the patient biologically.
- Local as opposed to systemic consequences (e.g., traditional as opposed to absorbable sutures)
- In the instance of a group of medical devices that meet all regulatory standards separately, the risk categorization for the group is determined by the owner's packaging and marketing goals.
- Any accessories aimed at helping a specific Oncology Medical Device function will be subject to the same regulatory practices as the main device.
- Any software that is not included in the Medical Device itself is referred to as standalone software and may be regarded to be encompassing a Medical Device. As a result, such independently developed software is classified as follows: • If the software drives or influences the usage of a separate medical equipment, its categorization is determined by the combination's desired objective.
- If the software is not dependent on any other medical equipment, it is categorized as an independent gadget under the classification standards.
- Standalone software is regarded as an active medical device.

MARKET SIZE

Large worldwide enterprises as well as small and medium-sized firms are present in India's medical device industry.

By 2020, it is expected that the Indian medical device industry would be worth US$ 12 billion, growing at a CAGR of 15%, or 2.5 times the global growth rate. India, which ranks as the fourth-largest market for medical devices in Asia behind Japan, China, and South Korea, is one of the top 20 global markets for medical devices.

The diagnostic imaging market is anticipated to grow at a CAGR of 13.5% from 2020 to 2025.

In FY22, India exported $2.90 billion worth of medical equipment, and by 2025, those exports are anticipated to reach $10 billion. to expand the exports of medical devices from the nation

The following efforts were started by the Ministry of Health and Family Welfare (MOHFW) and the Central Drugs Standard Control Organisation (CDSCO):

- Schedule MIII (draught guidelines on good manufacturing practices and facility requirements) should be re-examined and implemented.
- Export labeling system
- Clarification of clinical evaluation and adverse reporting
- To facilitate exports, the state licensing body will increase the validity of free sales certificates from two to five years.
- Make a list of producers who have export licenses for simple access to regulatory agencies throughout the world.

Literature Review:

Over the past ten years, India's healthcare industry has grown significantly. In many parts of the nation, access to high-quality, affordable healthcare is still a challenge, and the distribution of healthcare services is still uneven. Over this time, the market for medical devices has grown tremendously and is now necessary for all phases of the healthcare continuum. Although it has contributed to the accessibility and affordability of healthcare services, several ecosystem limitations have made it challenging to meet domestic demand domestically, leading to a significant reliance on imports.

The current dynamics of supply and demand support the potential and justification of medical device production in India. The Indian government's "Make in India" effort offers a chance for the market to assess its guiding principles, pinpoint key growth drivers, and consider potential routes for bringing about a sea change in the medical devices market.

To identify the main challenges and conditions needed to take advantage of the "Make in India."opportunity, NATHEALTH and Deloitte worked together to study the present environment and role of the medical devices industry. The findings of this study are the result of an in-depth investigation and numerous interviews with influential figures in the public and commercial healthcare sectors. 2016 Deloitte report (1)

The healthcare industry has developed into one of the largest in India in terms of revenue and jobs. It has added 4.7 million new direct jobs since 2016, growing at a CAG of 22%. Over 500,000 new jobs each year, or 2.7 million new jobs between 2017 and 22 in India, might be added by this sector.

Over the past two decades, the Indian healthcare sector has grown as a result of the prevalence of lifestyle diseases, an ageing population, a growing middle class, a focus on public-private partnerships, the quick adoption of digital technologies like telemedicine, as well as increased investor interest and increased FDI inflows. NitiAyog for 2016. (2)

In the 21st century, India's healthcare system has undergone substantial development. By continually increasing by 10%, this industry in India is expected to reach $280 billion by 2025. India only spent $75 per person on healthcare in 2016, compared to $9403, $3613, $420, and $1061 in the US, EU, China, and the global average. The $128 billion Indian healthcare industry is expected to expand at a 12 per cent yearly rate over the next four years.

Medical technology must now be a part of any emerging nation's healthcare system that is concerned with patient quality. These have a range of uses in the healthcare industry, including but not limited to screening and diagnosis, treatment and care, recovery, and monitoring. One of the top 20 markets in the world for medical devices is India. Given that it is expanding quickly—at a rate of 15% yearly—by 2025, it is predicted to reach $50 billion. In India, different items supplied in distinct market segments have varying market shares. The market is dominated by medical equipment and devices (34%) followed by diagnostic imaging equipment (31%), patient assistance and other non-medical items (19%). (3)

Essential materials needed for the prevention, detection, and treatment of COVID-19 are in low supply worldwide, and price speculation and increases may have had a detrimental impact on availability. This study found that the pricing of items acquired under government-driven contracts varied during the first pandemic reaction in Ecuador, which had the greatest fatality rates ever recorded in single 24 hours.

In order to determine the pertinent metrics for frequently purchased items, medical equipment, prescription medications, and other products, a statistical descriptive analysis was carried out. The three items with the biggest spending were face masks ($4.5 million), paracetamol ($2.2 million), and RTPCR kits. 2019 Ortiz-Parado (4)

India's current regulatory framework for medical devices is insufficient for a $6 billion industry. In India, there was no legislation governing medical equipment until recently. 22 medical devices are currently classified as "drugs" under the Drugs & Cosmetics Act (DCA), 1940 & Rules, and are handled accordingly.

In July 2016, the MoHFW published the first draughts of the Medical Device Rules. The second draught was made public in October 2016 following discussions with stakeholders and the industry. The industry was given time to adjust to the new Rules when the Medical Devices Rules, 2017—which were released by the MoHFW—indicatively stated that they will go into effect on January 1, 2018. The Rules make a clear distinction between medical devices and pharmaceuticals, which helps the business overcome some challenges. Even while the DCA still sees medical devices as drugs, the government need to work towards a total separation of medical devices and medicines, with each having its own set of laws.

The Global Harmonization Task Force (GHTF) rules for medical devices are generally followed by the Rules, which are following international standards. The Rules also address procedural issues, such as the necessity of routine renewal of manufacturing licenses and the elimination of the requirement for simultaneous submission of import permits and registrations. Monitoring the progress of license application processes is made easier by online technologies. Even while the new Rules are meant to fill in some of the gaps in the existing framework, they have caused confusion among medical device businesses. Consumer perception of electronics created in India is expected to change as the Indian market and manufacturers grow, and these rules should help to elevate product quality. (5)

The procedure for selecting medical devices required for diagnostic, therapeutic, or rehabilitative reasons owing to disease or clinical intervention was devised by the WHO Priority Medical Devices initiative beginning in 2011. Over time, there have been more diseases and medical conditions added to the list. The ultimate objective of the priority medical equipment lists is to serve as a reference for Member States in the preparation or revision of their national lists for the purpose of ensuring patient access, procurement, availability in

healthcare institutions, and appropriate use. Depending on their infrastructure, health workforce, financial resources, and local goals, countries and environments should alter these lists. This book contains the priority medical devices that WHO has developed over the past five years for the current epidemic. (WHO, 2020) (6)

Vital sign monitoring is provided by a wearable medical device. To monitor fitness and perform medical diagnostics, it is necessary to monitor one or more of the physiological vitals listed below as well as any others, including blood sugar level, blood pressure, pulse rate, electrocardiogram (ECG) patterns, respiration rate, and respiration efficiency (such as blood oxygen saturation). wearable medical technologies is a very helpful preventative technology as a result. Similar gadgets are now commonly accessible. They are not generally known in India despite their worth. Given that metropolitan areas have the biggest markets for these devices, this may be a result of insufficient knowledge. (Nanda, 2018) (7)

For the advancement of universal health care, the management of medical emergencies, and the promotion of healthier communities, access to high-quality, reasonably priced, and suitable health items is essential.

A broken ankle can be bandaged, HIV/AIDS can be identified, an artificial hip can be implanted, and any operation may be performed without the need of medical equipment, would not be conceivable. In addition to optometrists, dentists, and other healthcare professionals working in state-of-the-art medical facilities, laypeople at home, paramedics and clinicians in remote clinics, and patients receiving palliative care all use medical devices. These medical technologies are used to diagnose and treat both acute and long-term diseases, as well as to help people with impairments.

Approximately 2 million distinct types of medical devices and 7000 generic device groupings are available on the current global market. A medical device is any piece of equipment that the maker intended to be used for a medical purpose, either by itself or in conjunction with other items. This covers devices such as tools, implements, machinery, appliances, implants, reagents for use in vitro, software, materials, and other similar or related objects. (8)

Research Methodology

3.1 Research Question:

- How much do you prefer medical devices?
- On what extent medical devices make the surgery easy?

3.2 Objectives: to comprehend India's current medical device regulation system.

3.3 Hypotheses: A continuum of care approach that provides a framework for the deliveryof appropriate healthcare to population groups by way of an evidence-based, comprehensive, measurable, and patient-centric survey is required to address the rising burden of diabetes.

3.4 Material and Methods:

Study Design: Descriptive Type

Setting: It would be primary research, with the goal of compiling data from surveys, legal documents, regulatory documents, and reports that are already inexistence.

Study Population: Healthcare related domain individuals.

Sampling Technique: Non-Probability Convenient Sampling.

Sample source: Primary and Secondary research

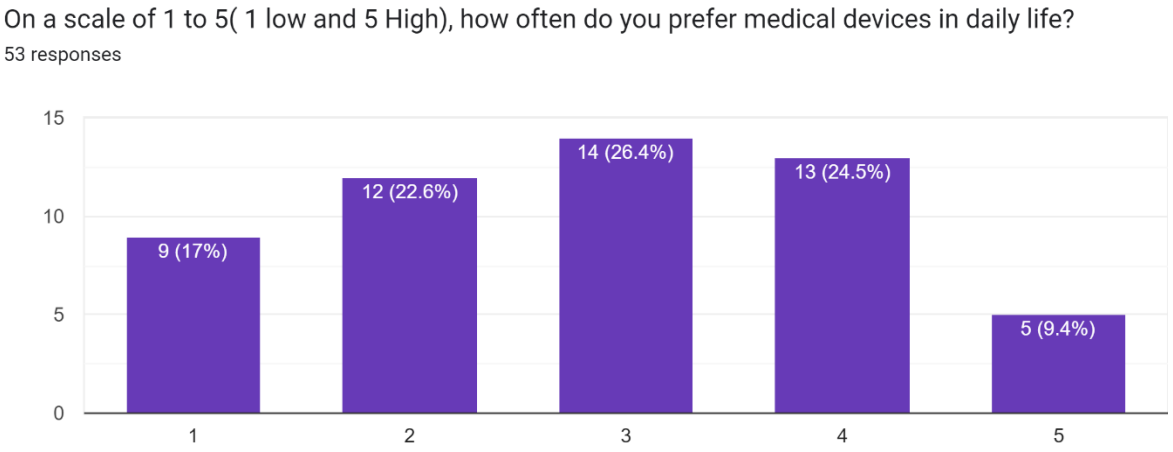
3.5 Data Analysis Plan: if necessary, analyze surveys and reports using MS Excel.

3.6 Ethical Considerations: The required research standards will be followed during the conduct of the research. To ensure the use of respondents' information, theirconsent will be requested, and appropriate authorization will also be carried out. The respondent's consent is required before their identity can be revealed.

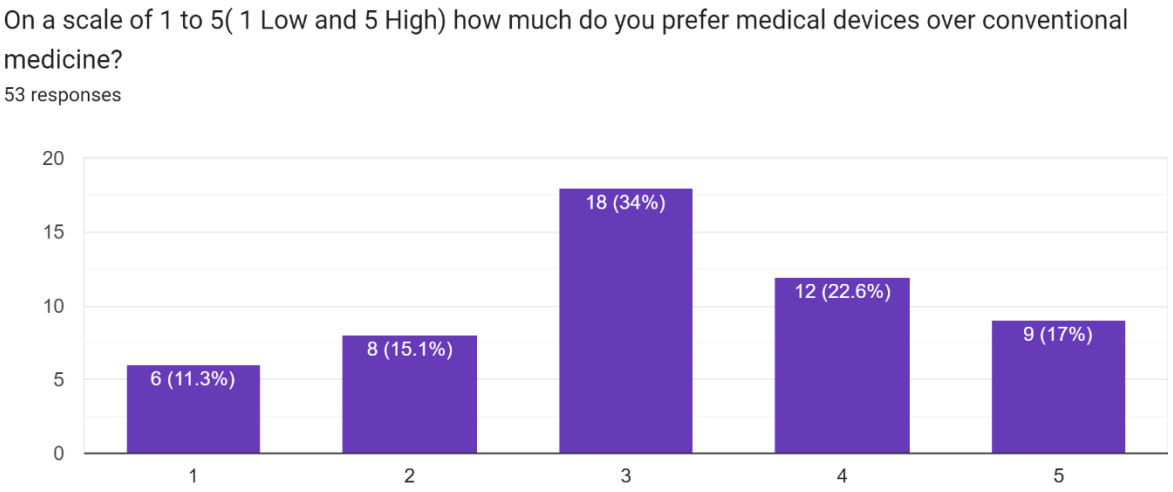
3.7 Operational Definition: "Medical device" refers to "any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes(s) of diagnosis, prevention, monitoring, treatment, or alleviation of disease or diagnosis, monitoring, alleviation of, or compensation for an injury."

- CDSCO: Central Drug Standards Control Organization.
- MHFW: Ministry of Health and Family Welfare.
- MDRA: the Indian Medical Device Regulatory Authority.

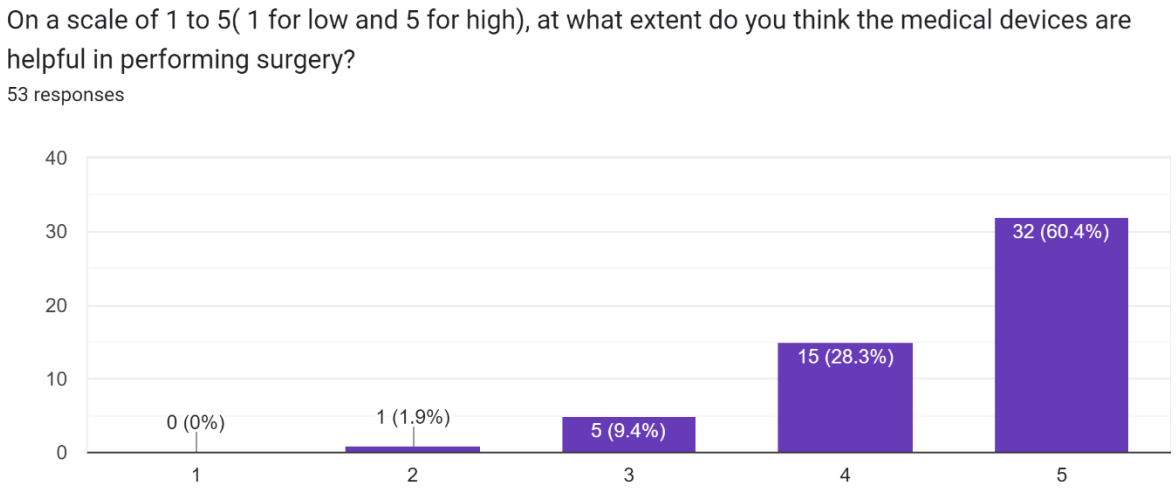
Result and Discussion



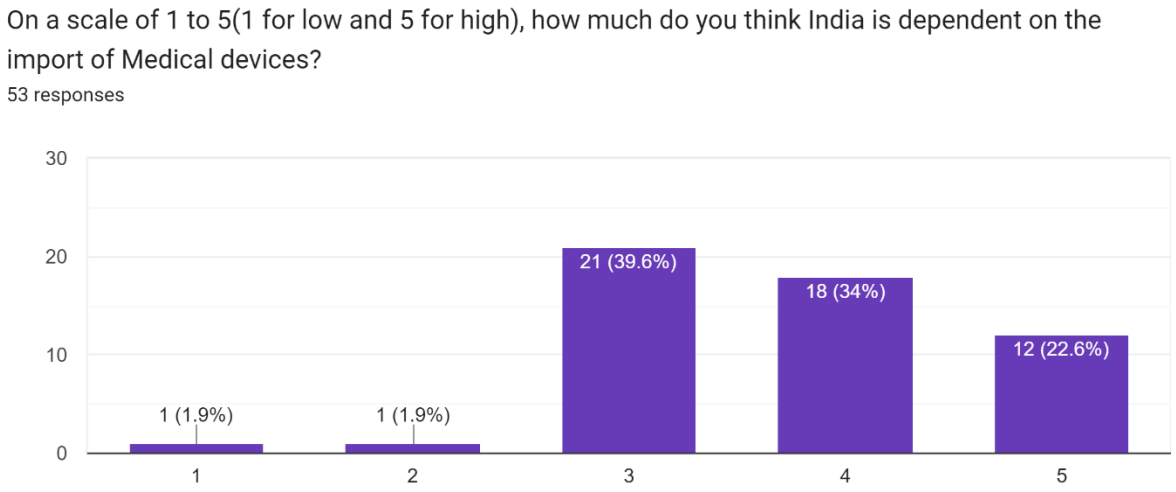
A total of 53 respondents were surveyed out of which 9 are not preferred medical devices in their daily life. The rest 44 were using it somehow in their daily life. There is huge potential in the Indian market, and it needs some awareness about the ease and use of medical devices.



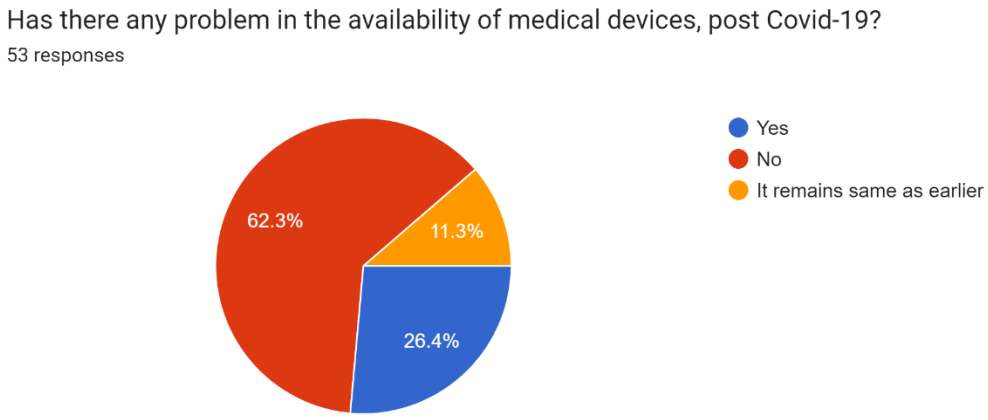
Out of 53, 14 are not preferred medical devices over conventional medicine. means there are some people in the Indian market who are relying on conventional medicine. by making them aware of medical devices we can make them to use or preferred to medical devices.



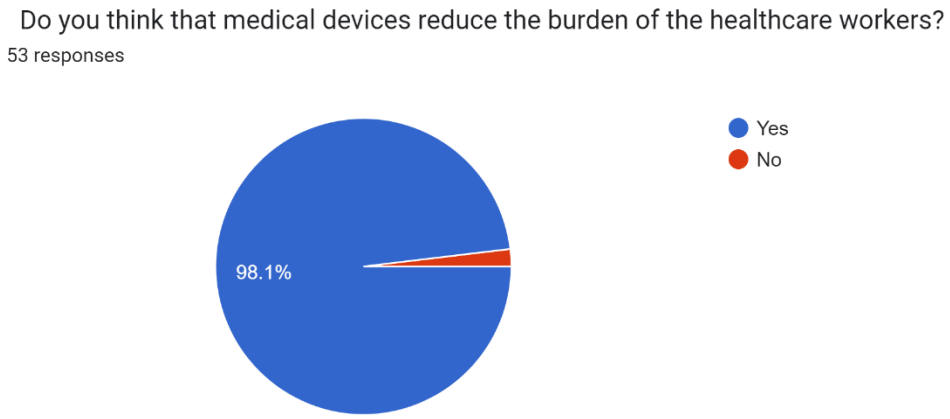
As per this Questionnaire, it is completely showing that people actually think that medical devices play an important role in performing surgery.



This is one of the important things to understand because we all know that India is to rely on overseas countries to import medical devices into India. High-end technology medical devices are imported from the countries like USA, Germany, and Japan.
India imports around 80% of its medical equipment, and it continues to be heavily reliant on foreign manufacturers, especially for more expensive products like cancer diagnostics, medical imaging, ultrasonic scanning, and polymerase chain reaction technology.[9]



As per this Questionnaire, 62.3% of people voted that there is no issue with the availability of medical devices, post covid-19.



Almost everyone is agreed with this thing that the use of medical devices actually reduces the burden on healthcare workers.

Conclusion:

Through the years, the diagnosis and treatment of patients have improved thanks to the use of technology in healthcare. The most major sector to have benefited from technology is unquestionably the healthcare sector. As a result, it steadily increased living standards and helped save many lives.

The disruptive power of technology cannot reasonably be excluded from the healthcare sector. This sector has a strong need for highly skilled individuals with vast academic backgrounds, but it also has substantial infrastructure and tool requirements. A extremely competitive market for healthcare innovation and technology is created by the world's ageing populations and expanding life expectancy. However, it seems that the industry has very significant innovation, which changes the environment yearly.

Also in the survey it is concluded that the medical device has a vital role in performing the surgery and making the surgery easy for doctors and in many other ways medical devices are helping in making the healthcare system.

Recommendations and Suggestions

- Lower and higher limits for safety and quality criteria are absent.
  It was discovered that the new document lacked upper limit and lower limit limitations as well as safety and quality criteria for medical devices.

- Describe the medical and paramedical staff's training.
  The government has to update the medical course curriculum and make accommodations since there is a shortage of training on new technologies and medical equipment.

- Permit the Medical Technology Advisory Board (MTAB) to identify the technique and priority medical device that are required due to the prevalence of illnesses.
  In terms of healthcare spending as a proportion of GDP, India behind other industrialized nations.

- The current policy is being followed in its enforcement is below satisfactory level so it should also be noted.

Limitations of Study

- There is a chance that the replies provided by the respondents may be biased.
- The analysis uses actual data, not projections.
- There was a limited amount of time which affected the accuracy.
- Only 20 doctors and 30 industry experts were involved in the study.
- The study was conducted in Jaipur only.

References:

1. Deloitte, N.A.T.H.E.A.L.T.H., 2016. Medical devices making in India- a leap for Indianhealthcare.

2. Pandey, A., & Aswani, H. (2021, December 21). India: Medical Devices: Compliances And Regulations In India.

3. Manu, M. and Anand, G., 2022. A review of medical device regulations in India, comparison with European Union and way-ahead. Perspectives in Clinical Research, 13(1),p.3.

4. Ortiz-Prado, -E.. Fernandez-Naranjo, R.. Torres-Berru, Y.. Lowe, R. and Torres, I., 2021. Exceptional prices of medical and other supplies during the COVID-19 pandemic inEcuador. The American journal of tropical medicine and hygiene, 105(1), p.81.

5. Saini, G., Budhwar, V. & Choudhary, M. Review on people's trust on home use medical devices during Covid-19 pandemic in India. Health Technol. 12, 527–546 (2022).

6. World Health Organization, 2020. Priority medical devices list for the COVID-19 responseand associated technical specifications: interim guidance, 19 November 2020 (No.
WHO/2019-nCoV/MedDev/TS/02T. V2). World Health Organization.

7. Nanda, S. and Som, B.K., Original Paper A Study of the Awareness of Wearable MedicalDevices in India: A Potential Market Perspective. Manas Mana, Gaurav Anand (2021). A review of medical device regulations in INia, comparison with European Unionand way-ahead. Volume 13, issue 1.

8 . Jarosławski, S., Saberwal, G. (2013) Case studies of innovative medical device companies from India: barriers and enablers to development. BMC Health Serv Res 13, 199.

9. https://www.trade.gov/country-commercial-guides/india-healthcare-and-medical-equipment#:~:text=Importing%20nearly%2080%20percent%20of,and%20polymerase%20chain%20reaction%20technologies.