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REVIEW PAPER

Review on people's trust on home use medical devices during Covid-19 pandemic in India

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Abstract
With the rapid development of the medical device against COVID-19 is an excellent achievement. There are numerous obstacles effectively facing the worldwide population, from manufacture to distribution, deployment and, acceptance. Many manufacturers have entered the market rivalry as people's knowledge and demand for home-use medical equipment has increased. India represents a compelling market opportunity for global medical device manufacturers. Substantial growth for the Indian medical device industry is expected to be driven by the current low per-person spending rate for medical devices. The growth of the medical devices industry in India raises competition law issues (anti-trust) and therefore maintaining public trust in home-use medical devices during COVID-19 will be as essential. The review article aims to create awareness among people about commonly used medical devices during the COVID-19 pandemic and to survey people's trust in home usable medical devices in India. In a worldwide pandemic, manufacturers of medical devices face insufficient storage and the impossibility of meeting the requirements of the health centre. The sale of some of the most significant medical devices has increased, making it more difficult for the medical device industry to satisfy demand with high-quality goods since the quality of COVID-19 items plays a vital part in the present scenario. Despite the difficulty in providing enough medical equipment during a pandemic, they are striving to adapt to the circumstance. After recognizing the need to promote awareness and grasp the selling, and production, handling of medical instruments during COVID-19 at home was conducted. In addition, medical equipment manufacturers and distributors look at this scenario as an opportunity to profit more. This review article would enable researchers during COVID-19 to build more knowledge and widespread trust in medical technologies respectively.

Keywords Medical devices · COVID-19 · Awareness · Trust · Quality equipment's · Regulations · Household devices

1 Introduction to medical devices

Medical devices employed in the healthcare business are becoming an increasingly essential aspect for the treatment and diagnosis of various medical problems, according to Samed (2014).

The growing demand for medical devices used to monitor the health parameters has shown an upliftment in their market, which has simultaneously increased the risk of hazards related to those devices [1]. Due to the negligence of the Indian government on medical device regulations, many new manufacturers have entered the market to gain profit by producing substandard products. Nowadays, blood pressure monitors (sphygmomanometers), pulse oximeters, nebulizers, glucometers, etc. are being made more and more user-friendly enabling people to manage their health independently and conveniently at an inexpensive cost. Sometimes, complex medical devices are used at home like dialysis machines, ventilators, infusion pumps, etc. they are used outside hospitals with limited use and guidance [2]. Consequently, the researchers are working on designing such devices to make them more user-friendly accordingly that the patients could use them without the help of medical professionals.

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According to McFadden et al. [3], healthcare is a significant service sector because of the importance of quality and safety in delivering patient care along with the high cost. The World Health Organization will define the medical device as any instrument, appliance, machine, equipment, apparatus, implant or other similar in-vitro reagent designed to be used singly or in combination for as a minimum of the manufacturer's medicinal purposes [3].

- Diagnosis, surveillance, prevention, therapy or illness alleviation;
- Treatment, alleviation, diagnosis, tracking, or injury indemnification
- Modification, replacement, investigation, or anatomy support or physiological process support
- Support or sustain life
- Design monitoring
- Medical equipment disinfection
- Information is provided by in vitro investigation of human body specimens
- The principal intended action, on a human body, must not be realized by pharmacology, immune or metabolism, but can be helped by such methods in its intended operation. (WHO; Medical equipment)

Samed states that there are approximately 300,000 medical devices in use, which range from a basic needle to a life support machine and are divided into numerous categories. Medical equipment is not only used to screen, diagnose and treat patients but also to restore the normal lifestyles of patients and monitor health indicators frequently to avoid illness. The function of medical devices increasingly expands with technology developments improving care quality throughout the whole medical continuum [4].

Screening and diagnosis: Screening and diagnosis are becoming increasingly accurate and complicated. Point of care / mobile diagnostic devices provide home care, which improves patient satisfaction and increases access to care inside and outside of pervasive and distant areas while facilitating external treatment.

Treatment/care: In addition to allowing physicians to manage very important and difficult patients, advanced surgical technology significantly reduces hospital duration. It makes it possible progressively to choose options but difficult operations such as knee replacement, bariatrics, pain management, etc.

Restoration: Hospitals and physiotherapy-rehabilitation facilities today allow patients to regain their health more quickly and return to their regular life by using modern aids and rehabilitation gadgets.

Monitoring: Health tests enable individuals to control their health at home and check health indicators regularly. In addition, equipment is utilized for remote patient monitoring to minimize hospitalizations and to reduce the load on the overburdened medical resources of the country. The cost of providing healthcare is significantly driven by medical technology. The expenditures of building a tertiary care hospital are estimated at 30 to 40% due to medical technology. Furthermore, medical equipment costs and diagnostics, depending on the kind of institution, contribute about 20%-25% of healthcare costs.

1.1 Classification of medical devices

Based on its risk and regulatory checks required for adequate security and efficacy, the FDA classifies medical devices into one of the three classes—Class I, II or III. The most risk to patients and/or users is that of Class I devices and the greatest danger to Class III devices.

Table 1 demonstrates the medical device categorization. The sort of premarketing submission/application required by the FDA is determined among other things by the class your device is allocated to. For marketing, a 510 k is necessary when your product is categorized under Class I or II and is not exempt. The limits on exemptions apply to all devices labelled as exempt. The device exemption limits are subject to 21 CFR xxx.9 where the xxx parts 862–892 are referred to. The application for a PMA is necessary for Class III devices unless your device is a pre-modifier device (subject to the market changes to or substantially equal to that device before the medical devices' transition in 1976) and PMA device is not sought. A 510 k is a road to the market in this scenario.

1.2 Public commonly used medical equipment's [6]

Medical Electrical Equipment is active medical equipment, the function of which relies on the energy supply or any power source other than that which the human body or gravitation directly generates and that works via the conversion of such energy.

1.2.1 Blood glucose monitors

Individuals diagnosed with type 2 diabetes or symptoms with prediabetes are needed to test their blood sugar levels frequently. It may be done at home using a gadget called a monitor for blood glucose. In this way, those who are suffering from diabetes can notify their doctor and quickly

Table 1 Classification of Medical Devices [5]

Risk level	Classification(s)	Examples
Low	Class I	Surgical retractors Tongue depressors
Low to Medium	Class I—supplied sterile Class I—with a measuring function Class IIa	Sterile surgical gloves Medicine cup with specific units of measurement Dental drills; ultrasound machines; digital or infrared thermometers
Medium to High	Class IIb	Surgical lasers Diagnostic X-ray
High	Class III	Prosthetic heart valves Absorbable surgical sutures Hip prostheses (for example, replacement of hip joint)
High	Active implantable medical devices (AIMD)	Pacemakers Artificial heart

provide remedial therapy for severe variations in the amount of glucose in their circulation.

1.2.2 Pulse oximeters

This device measures the concentration of oxygen in the blood, as enough oxygen is sent to all organs of the body through the blood cells to operate normally. When inadequate oxygen is present in the blood, hypoxemia may result in insufficient essential organs such as cardiovascular and brain function. In such cases, the pulse oximeter is beneficial for guaranteeing the affected individual timely medical attention.

1.2.3 Blood pressure monitors

For those with high BP (hypertension) or low BP(hypotension), this device is highly significant since it is recommended that you examine your blood pressure regularly and report it to your physicians. The direct effect of prescription medications is also measured to standardize an individual's blood pressure. Usually, about 110/70 to 120/80 is a person's normal blood pressure.

1.2.4 Pedometers and weighing scales

A pedometer is a basic gadget that indicates how many steps you took and how many calories were burnt. A weighing scale is highly useful and measures your body weight, as rapid mass changes might warn severe background disorders such as hormone imbalance or abnormal lipid metabolism. A BMI (Body Mass Index) between 18.5 to 24.9 indicates a healthy corporeal weight.

1.2.5 Thermometers

In every home, especially in the mountains and in winter, this fundamental equipment is important when an outbreak involves fever, cold and influenza. This thermometer can show if the body temperature is greater or lower than usual consequently that the proper course of prescription drugs is decided and rapid recovery is ensured. It is between 97° and 99 °F or 36 °C to 37.5 °C for the typical human body temperature.

2 Role of medical devices in COVID-19 pandemic

In the COVID-19 global health crisis, medical device industries are facing increased demand for certain medical devices. Medical device professionals are playing a crucial role to meet the demand for good quality products. Whereas due to the increased demand for medical devices worldwide many countries have restricted the export facilities. This has made the situation more challenging for countries dependent on imports to meet their requirements and has disruption sabotaged the supply chain. Throughout the COVID-19 pandemic, India has also faced a severe shortage of medical equipment's. To meet the demand, the Indian government decided to become "atam-nirbhar" or self-sustained. Medical device industries along with government support initiated the production of required products on a large scale. Same as pharmaceutical products, medical devices also have to pass clinical trials for market approval. Due to increased demand and the target to supply sufficient quantities of medical equipment's with justified quality standards and affordable prices, it's becoming challenging for industries to justify their production [6–12]. Table 2 illustrates the commonly used medical devices during COVID-19.

Table 2 List of Medical Devices Commonly Used During COVID-19 [8]

Type of equipment's	Medical Device name
Personal protective equipment's	Respirators
	Surgical Masks(2-ply;3-ply; N-95 masks etc.)
	Face shield
	Gloves
	Protective goggles
	Surgical gowns
Medical Equipment's	Infrared thermometer
	Pulse oximeter
	Digital sphygmomanometer

The pandemic of COVID-19 has a considerable influence on worldwide health care and is also noticed in related sectors. There is a need for efficient telehealth management and remote healthcare surveillance technologies. When implemented, Medical 4.0, can manage the current medical condition properly, as it will give sophisticated technology solutions to address the problems associated with the COVID-19 epidemic. In the framework of COVID-19, Haleem and Javaid [13] are investigating Medical 4.0, specifically. The research gives a short overview of the major medical revolution that has taken place to date, identifying important Medical 4.0 support technologies. This displays that, as with smart electrical devices and applications, the current research and manufacturing of intelligent medical equipment did not emerge in the same way. Engineers will play a significant part in addressing the health issues that the ordinary man might face. The principal rationing criteria presented in the literature are described by Pinho [14] and are explored as the current application for absolute resource scarcity. Finally, the author explains the current COVID-19 epidemic in Portugal and suggests certain recommendations to guarantee that resources are used equitably.

The COVID-19 pandemic produced significant medical supply scarcity necessary for treating the virus as a sickness around the world during the first half of 2020, leading to a large increase in consumption. Low-cost production centres such as China and Malaysia were the major makers in items such as facial masks, surgical gloves and medical gowns that were less technologically advanced Personal Protective Equipment (PPE). As many afflicted nations implemented export bans and explored measures to enhance domestic manufacturing, global shortages of PPE goods arose after the onset of COVID-19. The case study of the facial mask value chain in the United States suggests that Gereffi [15] showed misalignments between the goals of US authorities and the tactics of top multinational US facial mask manufacturers, resulting in extremely expensive delays in health results. Overall, the US N95 breathing shortage during the COVID-19 pandemic is a political failure rather than a commercial failure. The global framework for the value chain offers strategic alternatives that can result in more robust supply networks and diverse supply patterns.

2.1 Wearable devices for the detection of Covid-19

Wearable or Remote patient monitoring instruments (1) non-invasive remote surveillance devices or sensitive common physiological parameters and (2) wirelessly transfer patient information to your health care provider or any other surveillance entity. To enhance patient monitoring and treatment availability and assist reduce healthcare professional exposure to SARS-CoV-2 during the COVID-19-section, the FDA has approved EUAs for various remote and wearable patient monitoring devices [16].

Wearable gadgets can give unique insights into our health and welfare, such as activity trackers and smartwatches which was depicted in Fig. 1. Unlike conventional tests that may take place a few times a year in a clinical environment, wearables give constant access to physiological data in real-time. This allows for the detection of aberrations from the 'normal' basic principles of a person: an approach to treatment that differs fundamentally from existing practice, comparing mainly physiological measures with population statistics. Moreover, the potential of wearable health gadgets has grown more and more evident during the Coronavirus Disease 2019 (COVID-19) pandemic.

However, these investigations are limited. They cannot distinguish COVID-19 from other viral illnesses and are predestined to sample preference because senior individuals and those with a low income generally don't possess wearable devices or have access to them. The techniques of detection also demand huge datasets to train the utilized algorithms, and hence the (long) research, delaying deployment, must be performed for every new disease that produces distinct physiological and activity characteristics [17]. In addition, the absence of other data on physiology (works exclusively depending on heart rate) decreases diagnostic performance. One of the most promising approaches to the identification of infected people is the use of face masks with integrated sensors. The present epidemic has led to ubiquitous face masks that may thus make use of the platform to check health continuously. Including breath patterns and ratings, inflammatory biomarkers, and the possible detection of airborne disease, low-cost facial machines with integrated sensors may directly access many essential characteristics through expanded breath.

Tan et al. [18] suggested a cardiovascular 5G-enabled real-time surveillance system for COVID-19 deep learning patients. First, utilized 5G to deliver and receive wearable healthcare data. Secondly, the data processing architecture for Flink streaming is used for ECG data access. Use

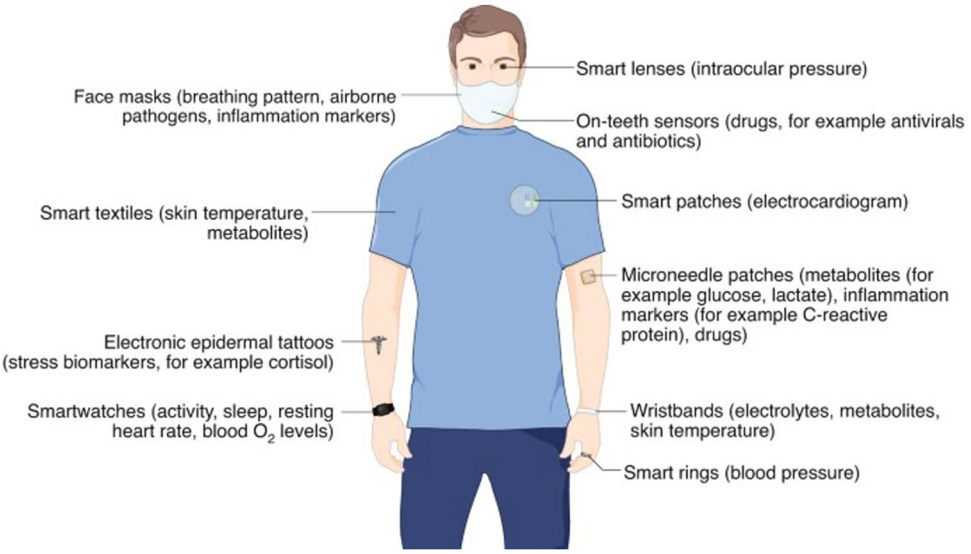

Fig. 1 Wearable Medical Devices During Covid-19

convolutionary neural networks and long-term model memory networks to automatically predict cardiovascular health for the patient with COVID-19. Theoretical analysis and practical findings suggest that our approach can handle these problems successfully and enhance cardiovascular diseases' predictability to 99.29%. Islam et al. [19] discussed the many wearable monitoring systems utilized in most cases for the support of afflicted persons (including heart and respiratory rate, oxygen, temperature saturation) and respiratory supportive systems (oxygen treatment, ventilate and CPAP devices). The gadgets are detailed based on the services they give, their functioning processes as well as the comparative study of their benefits and demerits with cost. It is envisioned that wearable technology is only capable of delivering initial therapy that can decrease the spread of this pandemic.

There is a wearable system/appliance that can track major symptoms of COVID-19. Hardware off-the-shelf and software elements such as simple sensors, microcontrollers, and devices are used to monitor body temperature and cardiac rate, respiratory rhythms and others of importance in alerting patients and remote medical staff about unusual symptoms related to COVID-19 or other similar diseases. Off-the-shelf components are also employed. Stojanović et al. [20], together with the early test results, provided the fundamental idea for the measurement principle, systems integration, DSP and networking. The rule is not only simple and low-cost, depending on our everyday use of components but also incredibly soundproof.

2.2 Remote monitoring (rm) of medical devices during COVID-19

The standards for RM procedure have so far been published in Italy, however, some recent national surveys showed that RM is not still extensively used in the clinical practice of Italian centres and its underutilization may be due to the lack of a specific reimbursement system by the National Public Health Service; however, this obstacle could be easily overcome either by reimbursement for each RM visit, or by a monthly service fee for continuous patients' remote monitoring. Moreover, training programs and competence courses dedicated to physicians and allied professionals on RM management of recipients are an unmet need to standardize the hospital organizational models and to realize an effective hospital-territory integration. Actually, during the COVID-19 outbreak, a great number of patients without RM probably will not receive the scheduled follow-up visit in a short time; thereby, it will create an unequal treatment between the recipients with and without RM in the same welfare state. The COVID-19 outbreak offers us the opportunity to reflect how it would have been useful a national program of telemedicine to ensure continuous care for all patients during a long period of social distancing and isolation, as that we are living.

Sun et al. [21] explore the toolbox for fast testing of the effect and reaction to NPIs intended to restrict COVID-19 spread of the newly built open-source mobile health platform Remote Assessment of Disease and Relapse (RADAR). Participant heart rates were low for Italy and Spain, further for Denmark the value is to $P = 0.02$, later ($P < 0.001$ for Italy, Spain, Great Britain and the Netherlands), and later ($P < 0.001$ for Italy, Spain, and the UK). We also observed that young persons had longer lockdowns and fewer daily rooms than older people.

Health monitoring system IoT-based with wireless corporate sensor network and gateway for the gathering and transfer of data was created by Kadarina and Priambodo [22] The system also used a data storage, analysis and visualization

application server. The prototype was utilized to measure SpO_2 and heart rate at home and an Android application which works as an IoT portal to gather sensor data and add position information before transferring the data to the servers. The prototype used the monitoring system. Thus they may monitor the state of patients and attempt to recover at any moment in self-isolation and take preventative measures if required.

3 Indian government towards the medical devices regulations

Due to the COVID-19 epidemic and then increasing demands for test kits, ventilators and other medical devices the Indian medical industry has been focused. The Regulations on Medical Devices 2017 (Rules of Procedure) of the Indian Medical Devices Industry under the Drugs and Cosmetics Act 1940 (the Act). The Rules entered into force on 1 January 2018.

The Rules are applicable in respect of:

- Substances employed in vitro and operatory dressings, chirurgical staples, blood, ligatures, operative sutures, blood component bags, and bandages covered by Sect. 3(b) of the Act, with or without anticoagulants covered under subclause I.
- Mechanical contraceptives including disinfectants (condoms, tubal rings and intrauterine devices), disinfectants and insecticides notified under (ii) of Sect. 3(b) of the Act
- Devices are notified sometimes under Sect. 3(b) of Subclause (iv) of the Act.

Following sub-clause (iv), Sect. 3(b) of the Act, the government notified 37 types of devices of a tighter restriction according to the Rules. Devices that were not previously notified needed a 'no objection certificate' from the Indian Drug Controller General (DCGI). A notice released on 11 February 2020 which came into force on 1 April 2020 made it obligatory for all devices to be registered and introduced a new process for all devices. At the same time, a further notification was issued by the Government amending the definition of medical instruments, also effective on 1 April 2020 [23].

3.1 Medical devices classification of the ministry of health

There are two classes: medical equipment that saves life and medical equipment that save a life. If a medical gadget is classified as a medical device for lifesaving use, the duty will be lowered. Drugs are defined as sterile devices. The Global Medical Device Nomenclature (GMDN) scheme was accepted by India as a member of the Asian Harmonization Working Group. In the Central Drug Standard Control Organization (CDSCO), each device that falls within the remit of this definition is further classed as being of risk; based on the usage intended and purpose [24]:

Figure 2 states the medical equipment classification based on classes. Class A belongs to low-risk medical devices such as absorbent surgical dressings, alcohol swabs, cotton wools etc. Further for class B, is low moderate-risk devices such as blood pressure monitoring devices, disinfectants, thermometers etc. Class C contains moderate high-risk devices such as haemodialysis catheters, implants etc. and class D, belongs to high-risk devices such as heart valves, angiographic guidewire, etc. The manufacturing of Class A & B devices is regulated by the State Licensing Authority, the State Drug Controller, as well as Class C & D via the Central Licensing Authority, which is the DCGI. These laws for medical devices in India are regulated by a part of the Ministry of Health and Family Welfare, i.e., CDSCO under the control of the Drug Controller General of India (DCGI).

3.2 Medical product registration

Medical equipment designated as medicinal products must be registered with the health ministry and is licensed to be marketed in India for import. This is not currently the case for other gadgets but is covered under the new law. The present legislation on Drugs and Cosmetics Act and the guidelines for manufacture and import of medical devices are in force in medical devices designated as medicinal products. Quality systems do not exist for medical equipment, however, the quality and performance of items recognized by CE or by FDA authorized are desired. Good Manufacturing Practices (GMP) and appropriate testing to demonstrate product quality must be used by medical device

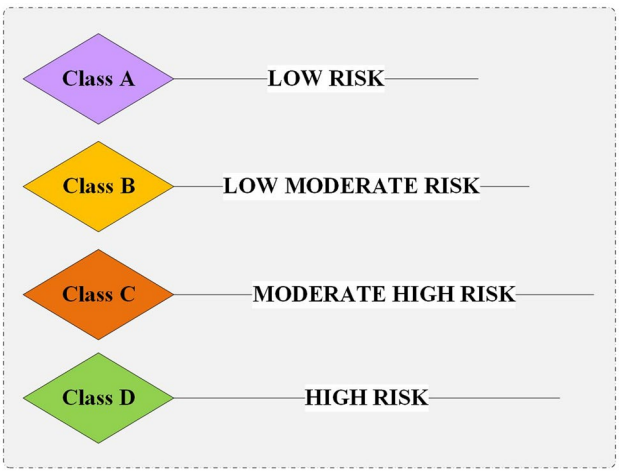

Fig. 2 Classification of Medical Devices

manufacturers designated as medicine [25]. The design, development and production of quality systems should be the responsibility. Risk management in ISO 14971 is also necessary for this type of equipment. According to Rule 24A of the Cosmetic Drugs Act, the registration will be completed and Form 40. The applicant in India may be the agency, manufacturer, or importer.

Applicant data such as address and name are requested by the General Controller of drugs India (DCG (I)). The Department also requires the name and location of the manufacturer, the factory, the importer, the local official and the local producer if one is available. The application is accompanied by a copy of the Plant Master File. In the Clarification of Guidelines for Manufacture and Import of Medical Devices, the information necessary in the Plant Master File is described [26]. List of countries in which the good is revoked from the market. A GMP and a master file are required for product information. The master file shall contain the components and materials used and production process information including flow diagrams, quality assurance process and procedures monitoring, risk management under ISO 14971 and test protocols, and stability, biocompatibility, toxicology and sterilization validation/verification reporting where applicable. The GHTF recommendations or ISO standards labelling of devices are accepted. Medical device manufacturers must have documented distribution record processes, complaint management, incident reporting and product recall. Product recall procedures are required. A medical device registration designated as medicine is five years valid.

4 Awareness of the medical devices in India

A study performed by AdvaMed, a medical device manufacturing organization which is spearheading the world's efforts to deliver medical technology to 1300 Indians from 17 countries finds that despite an overwhelming 72% are using medical devices, 89% are unfamiliar with this equipment. "This poll shows individuals in India don't know about medical equipment sufficiently, nonetheless they want to know more. Sanjay Banerjee, CEO of Zimmer India and Chairman of the AdvaMed India Working Group, stated that it is quite surprising that 60% of respondents believe medical devices to be equal to drugs." While India is a price-conscious market, the survey revealed quality is a critical component in the country's growing middle class. It indicated that 75% believes medical device quality is crucial since the patient's safety is of the utmost importance.

The high-grade gadget would assist 72% of respondents to avoid the expenditures of recurring hospitalization. AdvaMed Vice president, Abby Pratt, USA, replied: "In contrast to many others in India, where the lowest alternative is unmistakably chosen, our study shows that quality is crucial in sophisticated medical equipment since it has a connection with safety [27]. Notable is the relation between quality and brand name that 80% of respondents observe. Indian consumer health has grown increasingly conscious of their health requirements. This awareness is attributable to an increase in education and the simple access through digital means to reliable medical material. Consumers have been equipped with this information to play an active part with their physicians in their medical decisions [28]. In addition, by obtaining health and lifestyle guidance, people focus more and more on preventative health. India does not currently have legislative measures to compensate people with an implant or defective medical devices for concerns of health.

Under the law, corporations can only be responsible in a clinical study for compensation if anything goes wrong. The defective case of hip implant Johnson & Johnson is typical of the failure to provide regulatory control mechanisms for corporate forgeries, lack of administration, violation of business/medical pharmaceutical ethics, and lack of knowledge of the consumer. An uncertain, incomplete and inaccurate regulatory environment is a source of fear for investors. Domestic manufacture is unable to test uncontrolled equipment from start-up onto a patient since the surgeon is unable to meet standards. As a vital human-life sector, the medical equipment sector must get adequate attention as a matter of urgency to make the sector functional and transparent to make health equipment inexpensive and mass accessible.

A Medical Wearable Device is a vital sign surveillance device that includes the surveillance of one or more physiological vital elements that are applied for medical diagnosis and fitness monitoring; blood glucose level; blood pressure; pulse rate; ECG mode; reparability rate; (e.g., blood oxygen saturation). Many of these gadgets are now available on the market. They are not particularly popular in India despite their utility. It might be because of a low consciousness level. Shweta Nanda et al. [29] focused on the level of knowledge and sensitivity for appropriate population data in the Delhi-NCR medical devices. In addition, the main parameters for the training, qualification and purchasing power parity for use in this device are identified in this research. The insights from the wide literature on health assist to build the conceptual behavioural framework that serves as the basis for data collection. A better understanding of certification marking is essential with mobile medical devices and mobile apps becoming increasingly popular.

5 Effects of medical device industry

In delivering various health services, medical devices play an essential role. Medical devices are widely defined, and are neither absorbed nor metabolized by the body, since they are employed in the "diagnosis, treatment, mitigation, therapy

or prevention of illness." From simple medical supplies such as syringes and latex gloves to sophisticated imaging and implanted devices such as cardiovascular defibrillation, this phrase applies to everything. Through the development of new medical technologies that increase their treatment and diagnosis of disease, the medical equipment sector is a significant part of a broader healthcare system [30]. In the delivery of health services, most medical equipment's are used as inputs and typically they are not regarded to be services alone.

Medical devices utilized as durable medical devices, prostheses or orthicons are the biggest exceptions. As a consequence, Medicare has decided to pay indirectly for numerous medical equipment with a medical device fee in its service payment rates. For example, the artificial lens cost includes the payment to Medicare at a hospital or ambulatory cataract surgery clinic. The Commission has typically not investigated the details of medical devices in its Medicare Payment Policy assessment since Medicare does not pay for medical devices directly. By examining its general size and composition, developing new medical devices, the function of the FDA, and some essential aspects of the market for medical instruments. It also looks at how Medicare spends more in detail on medical equipment.

5.1 Key features of the medical device market

Subsequently, the FDA has granted authorization to market its goods, the manufacturers of medical devices are mostly involved in the sale of medical devices to providers, such as hospitals, medical doctors and nursing homes, instead of individual customers. The dynamics in the market for medical devices vary greatly, however devices may be broken down into two groups at a general level: traditional devices and high-tech equipment (Reivich et al. [31]). Products such as surgical clothing, routine injury dressings and operational trays are conventional equipment [31]. These devices may be rather easily manufactured with relatively low entry hurdles for new firms and a relatively small differential in products (i.e., customers, like hospitals, can move with minimum difficulties from one manufacturer to another). Thus these devices are considered much like commodities and the prices of their makers are mutually competitive. Relatively low-profit margins and typically producers require huge sales volumes to make a profit. In consequence, it is highly crucial to be able to win long term supply contracts with major institutional customers, such as hospital chains.

There are very different dynamics of the market in high-tech equipment, such as IMD, advanced diagnostics and certain types of instruments. Producers usually face larger entry obstacles such as considerable R&D expenditures, patent attendance and more FDA regulatory scrutiny. This reduces competition within this market and can provide better revenues for such gadgets than traditional ones. Due to their wide diversity, big medical device firms market a combination of conventional and high-tech equipment. There are a lot of advantages to this diversification. Firms can leverage their high-tech flagship items to increase their sales of other more traditional medical equipment. At the same time, the earnings from the sale of traditional devices contribute to the cash flow required by firms for their high-tech goods to study and develop [7].

5.2 Impact of COVID-19 on medical devices industry and their supply

The COVID-19 outbreak has brought the world to a halt. The global pandemic had a dramatic influence on companies and sectors worldwide. There is a lack of beds, masks, fins and testing equipment at hospitals. Because of a rapid demand rise for particular medical equipment, the medical equipment industry is disrupted to fulfil public demand. The demand for PPE kits, fans and test kits etc. is becoming increasingly challenging for medical device manufacturers [32–34].

Many key exports in this epidemic have limited supplies and have affected import-dependent countries. In India, several medical items are imported from various nations such as orthopaedic implants, syringes, gloves, bandages, magnetic resonance imaging equipment and computed tomography. The Indian government chose to create the medical equipment it needed itself in other nations to decrease its reliance on other countries. The Indian government believed that its flagship project "Make in India" will assist satisfy the growing need for vital medical equipment. The Indian government has assisted the medical device sector in a national emergency in conjunction with the Association of Indian Medical Devices Industry(AIMED), led by Rajiv Gauba, Cabinet Secretary and DOP Secretary Dr P.D. Vaghela [35, 36].

Figure 3 indicated the factors of demand and supply chain in the medical devices industry. As the demand rises and per capita consumption of medical devices improves, the potential of this market is projected to be opened. India is poised as an attractive place to build manufacturing facilities, particularly for multinational businesses seeking to align their worldwide production footprint on changing consumer trends, with the potential for strong local demand and other supporting factors. In the next decade, it will be anticipated that the Indian medical equipment industry would rapidly expand by 15%. Government plans will lead to universal insurance coverage, efforts like Make in India and private healthcare companies will expand. Despite the double-digit increase in the market for medical equipment in the last 10%, Indian medical device per capita consumption remains substantially low at ~ USD 3.0. Singapore and Puerto Rico are good examples of export centre markets (where exports are significantly higher than domestic sales).

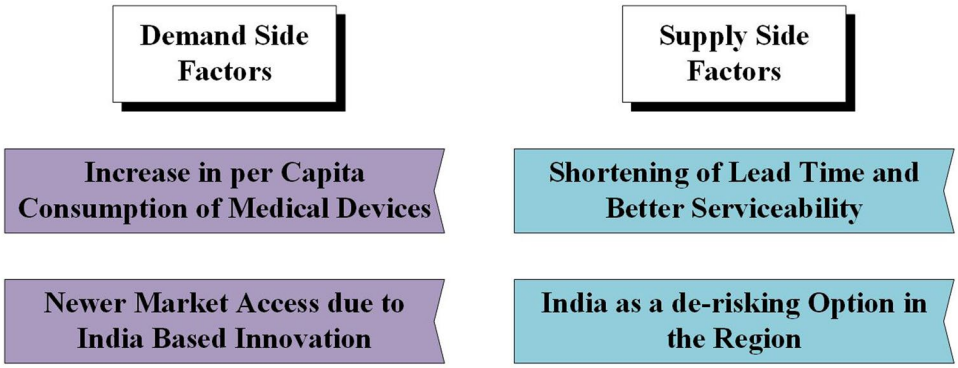

Fig. 3 Demand and Supply Side Factors

6 Medical device industry in India states

The Indian medical business enjoys double-digit growth and developed markedly in the past decade. However, it is important to solve some obstacles in offering access to quality, affordable healthcare throughout the country. Total expenditure on healthcare in India stood at only 3.9% of GDP, compared with 8.9% in Brazil, 6.2% in Russia and 5.2% in China. Out-of-pocket expenses amount to 61%, with just 25% of the population insured [37]. While medical device firms focus mainly on increasing life expectancy and enhancing the quality of treatment, affordability for a wide range of impacts needs to be increased. Therefore, the challenge for firms in India is to make cost-effective medical equipment that would enhance penetration and usage efficiently. The Make in India program will be important to the medical equipment industry in this regard.

The medical devices sector in India is tiny, with disproportionate import dependence and a complicated regulatory framework. The global market in medical devices and technology is anticipated to rise to 520 billion dollars by 2020, from an estimated 3.7 billion dollars in 2014. The Indian market is fourth in Asia behind China, Japan and South Korea and ranks among the world's top twenty. But per person in India, USD 3 is the lowest per capita medical equipment spending in the BRIC countries (USD 7 in China, USD 21 in Brazil and USD 42 in Russia) [38]. It lies behind sophisticated economies like the United States (USD 340). This existing medical device penetration in India provides a significant growth opportunity. The industry consists of four major sectors with a double-digit development potential that shows various features and is connected subsections. In addition to the four industrial categories, which are illustrated in Fig. 4, the Indian medical appliance industry includes consumables and implants, diagnostic imaging and instruments and patient assistance.

As the "Make in India" Medical Devices Initiative gets pace, dependency on imports will diminish. This allows you to cut the import bill that can become considerable if it is uncontrolled by 2025. The import bill would be considerable for both growth paths—organic and inorganic development for the medical devices industry in India, where 70 per cent of the demand for medical equipment is fulfilled by imports. In addition to cutting the import bill, 'Make in India' has the potential to attract investment, create foreign-exchange income, enhance exports and generate direct and indirect jobs.

6.1 Healthcare in Indian industry during COVID-19 pandemic

The pandemic crisis of COVID-19 is a recall of the necessity for any government of investing in the health system. There is a strong focus, therefore, on health care in India in the coming several years, most industry analysts predict. India already invests just 1.2% of its GDP in healthcare but the Government of India (GOI) plans to raise its public health expenditure to 2.5% of its GDP, with particular attention given to the disadvantaged by 2025 [39]. A comparable increase will take place in the medical equipment industry as expenditure in the Indian healthcare sector increases. India imports over 80% of its medical equipment and entry barriers are smaller than other sectors. In India, imports continue to be significantly dependent, especially for higher-end items such as cancer diagnostic, medical imaging, ultrasound and PCR technologies, for various medical equipment and gadgets. Imports are increasing fast as world-class hospital organizations such as Max, Hinduja Group, Fortis, and Apollo are building up high-end infrastructure and opening up the Indian healthcare sector with $2 billion.

The GOI started cardiac pricing inspections in July 2017, which reduced the selling price to 70% below the prevailing market rates. Similar price caps were seen later in the year for knee implants. After they were included in the national list of essential medicines, the prices were reduced (NLEM). At now, 37 medical devices, which are controlled under the Drugs and Cosmetics Act, have been notified as "Drugs." Of these, NLEM contains cardiac stents, drug-eluting stents, knee implants, condoms and intrauterine devices and is subject to price caps announced. There is no price control of the other

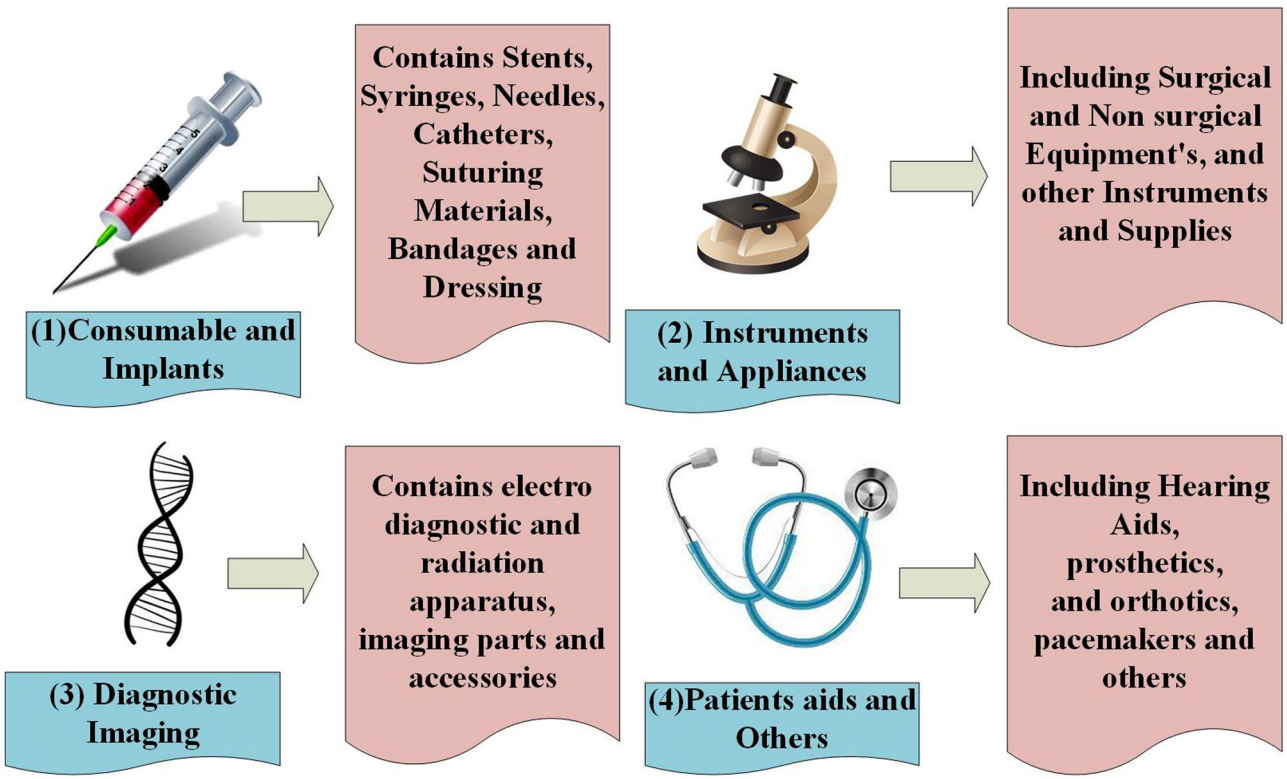

Fig. 4 Medical Devices Industry Segments [38]

medical devices. The prices for medical equipment on the market are exposed in below Table 3 for the years 2018–2020.

During the current COVID-19 pandemic, the supply chains were significantly affected for the Personal Protective Equipment (PPE) and some items have been deficient, especially N95 Face Breath Filters (FFRs; "masks"). Deborah Plana did a mask survey to ascertain origin and maker in the inventory of major academic medical schools in Boston, MA [41]. In addition, the accompanying website demonstrates how to make and operate this test device was assembled to produce a basic device (not sufficient) for evaluating the filtering performance and testing of masks in the inventory. Chao, Cheng-Min et al. utilized the theory of transaction costs and social interaction to build trust and trust in the supply chain.

Data were obtained from acquisition staff in 128 Taiwanese hospitals who are responsible for selecting suppliers of medical devices. The results revealed that elements of management decision, such as accuracy, communication and perceived advantages, had a favourable influence on trust. However, behavioural ambiguity had a substantial detrimental impact on trust. Inspect the satisfaction with recovery and relation between retrieval satisfaction and three output variables, which were: the truth, commitment and loyalty. He studied the related effects of procedural justice (PJ), distributive justice (DJ) and interactional Justice (IJ). Munjae Lee et al. [42] intended to set priorities on improving the distribution structure of medical devices and to provide an innovative distribution structure improvement plan with a focus on stakeholders in the medical appliances sector using the analytical hierarchy (AHP) technique. The AHP study revealed that supply reliability, transparency, efficiency, smart supply and cost reduction were the most significant factors.

Table 3 Medical Equipment's Market Price [40]

Medical Devices & Equipment	2018	2019	2020 (est)
Total Market Size	8,500	8,974	11,280
Total Local Production	4,700	5,100	5,300
Total Exports	1,100	1,480	1,520
Total Imports	4,900	5,354	7,500
Imports from the U.S	1,225	1,338	1,875

7 Quality management system of medical devices

The Indian market for medical devices with 700 manufacturers is now the fourth largest in Asia and one of the 20 world's top producers. The sector is over $7 billion in the country and provides both multi-national and indigenous companies with interesting business landscapes and possibilities. The

recent decision of the Government of India to permit 100% FDI in the medical device sector has been the fillip which may further enhance production and provide a better environment to foster innovation and sustain domestic growth [43]. To provide good healthcare, in October 2005, GOI expanded to regulate various classes of implantable devices in the list of medical devices covered by the Drugs and Cosmetics Act of 1940. In October 2018 this list was further amended to regulate numerous other kinds of implanted devices.

The Federal lawmaker requested a development method that is usability-oriented to decrease the likelihood of application errors, proposed by Norman Geissler et al. [44]. (DIN EN 62,366). The investigation question thus concerns how medical equipment makers apply this standard. Nearly all organizations have assessed usability as being significant to product development, but it is still possible to enhance knowledge of usability in companies and increase the number of qualified usability specialists in the process. In the maintenance process for medical equipment, Manar Al-Jazzazi et al. [45] offer a technique of determining user demand. Methods of data collection, phases of the research model and descriptive analyses are provided. In the maintenance process of Medical Devices maintenance, the regulations on technology and verification can be implemented.

Water employed for industrial operations can be derived from many sources and should therefore be treated to meet quality standards in the areas of purity, salinity and chemical, physical and microbiological characteristics before entering the water supply network. In an effort to develop recommendations to assure the microbiological safety of industrial water for MD production, D'Ugo et al. [46] analyze the microbiological quality of the water used in the manufacture of the MD in Italy. Yee et al. [47] offer as a predictor of the performance of R&D project medical devices a framework that combines organizational elements such as top management support, incentive system, infrastructure, training and cooperation. Efficient project R&D management may minimize project lead times by reducing the critical path of the whole development of the product and thereby boosting the success rate of the research and development project. In addition to identifying important organizational variables, organizational culture is recognized as the potential moderator for the success of the R&D project.

7.1 Pricing strategies of medical devices during pandemic

To control the price of medical devices and supply the public with equipment during the pandemic at a reasonable price. Importers and producers were requested by NPPA to supply verification data relating to prices. In the current scenario, the medical devices industry and importers are asked by the general public to reduce the retail costs for medical devices.) India's National Pharmaceutical Pricing Authority (NPPA) gives producers and importers of 24 medical device categories three weeks to provide all of these items with price data [48]. In a directive on 16 February, NPPA indicates that it is mandated to monitor the maximum retail price (MRP) for medical equipment notified by the government as pharmaceutical, and, where necessary, to regulate it in the public interest. At present, 28 medical device types are under the remit of the authority for compulsory regulation. The Authority is now looking for pricing control in all 24 medical device categories.

The types of products NPPA requested information for include nebulization, in-vitro diagnostic equipment, an HBA and HCV, unpeaceable hypodermal syringes etc. NPPA has also sought information for this type of product. Rajiv Nath, Coordinator of the Indian Medical Device Industry Association (AiMeD), commented on the directive that while the NPPA was looking to monitor the maximum retail price of products covered by its competence, the catch of the imported landed price on which GST was first paid (first point of sale) with MRP might be more cautious, in order possibly to monitor irrationally high trading costs. By the way, the Drugs Law regulates all medical equipment, although thus far only 37 have been notified of their adherence. Gousgounis and Neubert [49] explore the methodology of several case studies based on 11 SME interviews, how and why price-setting methods for home health and direct-to-consumer medical devices have been developed. The results of the study show that pricing decisions in novel HHDTC medical equipment are based largely on market pricing strategies and competitive pricing practices and, to a lesser degree, on value-based price-setting procedures.

8 Home use medical devices environment

Healthcare is progressively moving from a clinic to home, which uses smartwatches, apps and other technology that may be connected to the wireless network and may apply an algorithm to the information collected to monitor people's signs and symptoms through television. The unprofessional and professionals are relying on home healthcare equipment's for self-monitoring of their health and using a wide variety of technologies as it has become part of their lifestyle. Home health care equipment's is accompanied by digital displays easier for people to understand without knowledge. These devices have been made consumer-friendly at affordable prices. For example, the elderly in a susceptible group is rising and the demand for innovative

digital health solutions is growing with this expansion, which will allow individuals to live independently and be treated for as long as feasible. Table 4 explores the types of home health care devices.

8.1 Historical use of medical devices in the home

The most popular forms of medical equipment used for medicine or first aid are present in almost every home. Common medication management equipment includes cups to measure medicines in liquid forms, such as cough medicines, and divisions to reduce pill size and dose [51]. First aid equipment's include thermometers, bandages, ace bandage, heating pads, and snakebite kits, including oral, rectal, in-ear, and forehead. Additionally, assistive technology and sustainable healthcare equipment are employed in the house in general. Mobility devices (such as wheelchairs, walkers, docks, crutches) or sensory aids are most commonly assistive technology (e.g., glasses, hearing aids) [52]. Other frequent aid technologies include prosthetic instruments or orthotic devices (e.g. artificial legs or arms, shoe inserts, leg braces). Sustainable medical equipment comprises environmental equipment, such as customized beds, lift equipment and toileting aids.

Some medical gadgets were recently made into consumer items to make it easier and more autonomous for people to handle their health care (and inexpensively). A broad array of blood and urine test kits for different substances and disorders are available (e.g., illegal drugs, cholesterol, pregnancy). Different monitors and meters, such as blood pressure and glucose blood, are available to measure the health status indicators (for people with diabetes). New consumer devices include measuring blood coagulation for those using blood-thinning medicines, blood oxygen levels (pulse oximetry and international normalization, PT/INR) and sleep apnea.

8.2 Household medical devices during Covid-19

The present COVID-19 pandemic has also increased the rate at which the integration of artificial intelligence and technology into healthcare reduce healthcare workers' exposures. The number of persons with COVID-19 in need of acute medical resources was decreased through social separation and quarantine measures. Technology-assisted evaluations of vital signs, such as pulse rates, body temperature, blood pressure and respiration rate, can be used to evaluate those who are homeless and quarantined, offer basic care for others and identify periods at which home care is no longer suited [53]. Mobile apps hopefully support measures for the general health of persons who test positively for SARS-CoV-2 such as contact tracking and enforced insulation.

In this pandemic, the development of domestic surveillance technology is accelerated to meet demand. In particular, contact tracking and warning applications in several countries such as Austria, Singapore, and Australia are utilized to better manage COVID-19 distribution, and many other nations are developing these applications. Apple and Google have also introduced their exposure notification system to identify possible COVID-19 exposures and inform affected users to further instructions using the Bluetooth technology. Contact tracking applications quickly alert users of a person who is diagnosed with COVID-19 after being exposed closely. This will encourage users to isolate themselves or to get tests for SARS-CoV-2 in other situations. While in many cases the phrase "digital contact tracing" is used, we think the term "exposure notice" is more precise. The usage of exposure notification applications is strongly encouraged to reduce part of the human work needed to trace contracts effectively [54].

This delineates a home monitoring device as a product used by health care professionals to monitor, for example in the home of a patient, without (direct) monitoring, and which gathers personal health data. For instance, a home monitoring application monitors the user's heart rate. We recognize that "home surveillance" is an umbrella word for "remote patient surveillance." For example, it satisfies our definition by a technology that remotely monitors a patient in a hospital without direct supervision by a healthcare provider. In contrast, telemedical visits are not considered a home-monitoring device, as patient-healthcare professionals engage directly. 'Health-related data' as we define the term might comprise health information like the rhythm of the user's heart and/or information that supports health inferences such as information acquired through exposure-notification applications from the global positioning systems [55]. Healthcare practitioners who thereafter communicate with their patient's important results may get the data generated by domestic monitoring devices. However, users and/or patients of the home surveillance systems gather the data and may choose or may not share it with third parties or healthcare professionals. Some home surveillance systems are classified as medical equipment legally, while others are not. The US Food and Drug Administration (FDA) has been employing different means to combat the COVID-19 epidemic and to make it possible for medical devices to be introduced faster. However, there have been other dangers in the fast development of new gadgets and other home surveillance goods during this epidemic.

8.3 Medical equipment preserved at home

The easiest way to find if you have caught the disease is a COVID-19 detection test. You can call your doctor immediately if the test findings are positive. Most individuals in close contact with COVID-19 are only minor infected and can heal at home. Home symptom alleviation therapy comprises relaxation, strong

Table 4 Types of Home Health Care Devices [50]

Category	Devices
Medication Administration Equipment	Dosing equipment (e.g., cups, eyedroppers, blunt syringes) Nasal sprays, inhalers Medication patches Syringes/sharps
Test Kits	Pregnancy test Male/female/stress hormone test Cholesterol test Allergy test Bladder infection test HIV test Hepatitis C test Drug, alcohol, nicotine test
First Aid Equipment	Bandages Ace bandage, compression stocking Snakebite kit Heating pad Traction Ostomy care Tracheotomy care Defibrillator
Assistive Technology	Eyeglasses Hearing aid Dentures (full or partial) Prosthetic device Orthotic device, including braces Cane or crutches Walker Wheelchair Scooter
Durable Medical Equipment	Hospital bed Specialized mattress Chair (e.g., Geri-chair or lift chair) Lift equipment Commode, urinal, bedpan
Meters/Monitors	Thermometer Stethoscope Blood glucose meter Blood coagulation (PT/INR) meter Pulse oximeter Weight scale Blood pressure monitor Apnea monitor Electrocardiogram monitor Fetal monitor
Treatment Equipment	IV equipment Infusion pumps Dialysis machines Transcutaneous electrical nerve stimulation systems
Respiratory Equipment	bi-level positive airway pressure, demand positive airway pressure equipment, Ventilator, and continuous positive airway pressure, and Oxygen cylinder Oxygen concentrator Nebulizer Masks and cannulas Respiratory supplies Cough assist machine Suction machine Manual resuscitation bags

Table 4 (continued)

Category	Devices
Feeding Equipment	Feeding tubes (nasogastric, gastrostomy, jejunostomy) Enteral pump
Voiding Equipment	Catheter Colostomy bags
Infant Care	Incubator Radiant warmer Bilirubin lights Phototherapy Apnea monitor
Telehealth Equipment	Cameras Sensors Data collection and communication equipment (e.g., computer) Telephone or internet connections

consumption of liquids, respiratory exercises and medicines on-the-counter. The medicinal items which are highly sought after and can help combat coronavirus at home are given below [56].

8.3.1 Pulse oximeter

An oximetry measuring device detects the quantity and speed of oxygen in the blood. They are especially helpful to COVID-19 patients who have breathing problems due to low levels of oxygen. Make sure you're at room temperature using this device. Rub together your hands to warm them up if they are not. Sit down and rest before inserting your finger in the oximeter. You must place the pulse oximeter on your finger index. You can observe the beat waves on your finger's oximeter as the pulse oximeter is being read. The usual pulse oximeter measurement range is between 95 and 100%. Values below 90% are regarded as low and imply that extra oxygen is necessary.

8.3.2 Incentive spirometer

When utilizing an incentive spirometer, you breathe air via a tube linked to a broad air column that contains a piston or a ball. As you breathe in, the ball or piston in the column expands. The piston height shows how much air you inhale. You may feel dizzy if you take a big breath to do this work out. Stop practising and relax when you're dizzy or want to go out. At initially, just a few inches up the piston could be lifted. You should be able to inhale more air if you continue to use the spirometer, and normal respiration can rebound.

8.3.3 Oxygen cylinder

Containers that store oxygen and clinical gases under high gas pressure in a non-liquid condition are recalculated oxygen and clinical air chambers. They have an oxygen level controller and valve, like a simple button that correspondingly increases or reduces oxygen flow. These cylinders are available as required from smaller mobile devices to larger 10L containers. The cylinders are of standard sizes and feature controls and accessories according to worldwide standards.

8.3.4 Patient monitor multi-parametric

These are medical instruments that constantly measure, calculate and display physiological data to monitor their patients. It might be basic, measure only one to two vital signs, measure many parameters and be used for critical patients in intensive care units and specialist operations. There are portable electrically powered and battery-operated versions at bedtime. The device has patient cables, monitors and adapters that are designed to warn physicians of changes in a patient, depending on the parameters to be controlled (e.g. ECG, blood pressure, heart rate, temperature, respiration rate and respiratory gas concentration).

The pandemic has not escaped from the effect of medical device manufacturers. Similar to pharmaceutical firms, healthcare facilities are frequently used by the manufacturers for the collecting of clinical trial data. Before manufacturers can be awarded market approval certificates, most medical device items must complete pre-and post-market clinical trials. In the continuing development of the COVID-19 pandemic, medical devices businesses have difficulty in making informed judgments in the context of uncertainties over their products, supply networks and regulatory requirements. Professionals using medical devices have to ask for a stop in the middle of fear. Whether it's terrible or how severe, the reality is: thoughtless behaviour will worsen it. Although adrenaline tells us to create as rapidly as possible, now is the time for quality.

8.4 Risk factors of household medical devices

Year	Author	Proposed Objective	Other Techniques	Important Features	Limitations and Future Work
2020	P.S. Stewart et al. [57]	Risk factors for device-related chronic infections	Biofilm-related device infection	Implanted biomaterial substantially reduces the local injected microorganism's infectious dose	Inborn immunity deficiency The morbidities that affect biofilm infection are required to be better understood
2019	Wenyan Song et al. [58]	FMEA and gray related analyses to enhance the safe usage of medical devices	Swiss cheese model and SHEL model	Improving the medical device's clinical use quality	In the enhanced FMEA technique, failure modes can be considered
2020	Ivan E. Ivanov et al. [59]	New medical devices are obtained through a collection of policies, methods and processes	Risk-based testing is based on risk analysis	Create a more robust design before implementing an actual system	It is essential to ensure that the gadgets are functional, reliable and secure
2020	Dean S. Picone et al. [60]	Assess the quantity, kind, validated percentage and cost of online domestic BP devices	Established protocols	Improve BP device validated availability	Worldwide improvements to BP device precision criteria require regulatory proceedings urgently
2019	Fabrizio Clemente et al. [61]	60 homebound ventilator-dependent patients FMECA analysis home ventilation service	Threshold and variables that contribute	Additional examination of the reasons for failures is enriched with the identification of significant errors	Extended FMECA approach has been beneficial in enhancing risk analysis depth
2021	Joseph Peter Salisbury et al. [62]	Risk of a general immersive VR system remote patient surveillance	Surveillance with predicate analysis	Immersive VRaMD can fulfil regulatory standards effectively	Fewer on the design of a certain system

9 Technical hitches in medical device

Some medical equipment may not be safe for all users or usage settings, however, makers of medical devices are accountable for the maximum feasible detection and mitigation of the risks. In the FDA guideline paper, Kaye and Crowley [63], p. 7) explain that the use-related risks emerge for one or more of these reasons: Usage safety: Integration into risk management of human aspects [63].

- Devices will be utilized in unforeseen ways.
- Devices are utilized in an anticipated but insufficiently regulated manner.
- Device use needs to exceed the user's physical, perceptive or cognitive capacity.
- The usage of devices does not meet user expectations or intuition about the operation of devices.
- The device operation utilization environment [references], not the user's understanding of this effect.
- When the gadget is used in a certain setting, the user's physical, perceptive or cognitive abilities are surpassed.

Three of the most common intravenous pump errors are miscalculation of the dose, transcription data error input, and titration of incorrect medicine. When a professional install a pump when it is initially entered the home, the first two faults (both of which lead to the misdoes) are less frequent for domestic use. The third fault (faulty medication) is likely, particularly when more than one type of medicine is used by the caregiver. The pump operator may, in any circumstance, modify the rate of supply accidentally and erroneously. All such errors might jeopardize the lives of people.

Inappropriately, the objective of certain firms is to gather apathy to patients and/or users in the context of this public health catastrophe. The FDA has already cautioned customers against bogus goods, such as unlicensed vaccinations or home test kits, which promise treatment, prevention or cure of COVID-19. In addition, the United States Federal Trade Commission warns customers to prevent frauds of coronaviruses, such as disregarding online test kits and vaccine promises. Consumers need to be effectively safeguarded against counterfeit home surveillance equipment. The General Public Prosecutor should actively watch this sector and initiate claims for consumer protection if necessary. Clinicians can also assist educate patients and alert them of certain items in the field that are fake [64].

9.1 Public trust on medical devices

Trust in technology is believing that a tool, machine or device will not fail. The relationship between patients and physicians is based on trust. Profound personal information is often disclosed and trust that is kept secret. The clinic's trust patients, including those under invasive surgery and indefinite use of chronic drugs, to accept their diagnosis and prescribed therapies [65]. To build this trust level, physicians and health care institutions must, first and foremost, convince individuals that the best interest of patients lies above

their own financial or non-financial interests. However, in the past half-century, healthcare trust has plummeted [66]. 73% stated they had great trust in the leaders of the medical profession in a 1966 study of people in the USA, but in a 2012 poll, just 34% answered this. The decreased trust in medical clinicians and organized medicine is supposed to contribute to many factors, including increased controlled care and the related financial incentives, highly publicized conflicts of interest between clinicians and the pharmaceutical and device manufacturers, limited communication time, fragmentation of clinical-patient relations as well as consumerism. Trust in health care among Black people and individuals from other groups with challenges to accessing health care, healthcare inequalities, and open racism within the health care system is much lower.

The focus of confidential literature on health care systems is on patient, physician and patient's trust in health systems. interpersonal trust [67]. The Trust supports effective medical systems and Artificial Intelligence (AI) both has enormous promise and hazards for medicine. Medical AI failures may decrease public trust in medical treatment. Trust plays a key role in health connections according to Emily LaRosa et al. [68], introducing AI can have substantial implications on these trust ties. We argue that medical AI systems should be considered as supporting technologies that go beyond normal medical device functionalities. Three separate principles may be universalized across federal regulatory bodies to ensure that the deployment and widespread use of AI healthcare technology does not impact patient-doctor trust in any way. Furthermore, Simone Borsci et al. [69] indicates that trust is a collection of convictions that an individual has before using or experiencing a technology or system; (ii) it has been established during the user-system relationships and (iii) depending on cumulative system experience. This study analyzes current trust studies and their relevance to the user experience notion.

In recent decades the Internet of Things (IoT) had arisen in various areas and IoT may greatly help healthcare. To manage the IoMT devices and medical files by building a distributed custody and health data privacy chain, Fotopoulos et al. [70] proposed a blockchain-enabled authorisation system. The key idea is to establish the trust domains of the various players and IoMT devices in such a way that fine-grain access is possible through a) taking into account the different roles and capabilities of the IoMT devices and b) their interactions with users/stakeholders. Their critical characteristics are the main ones. The variables impacting patients' use of the eHealth IoT have been examined by Arfi et al. [71]. To accomplish this aim, a framework for the study that applies the UTAUT model and adds the risk–trust connection to the prediction of IoT utilization in a medical setting was created. To that end, the research framework that applies to the contributions of this study can enhance the design of connected devices, increase patient communication, and help developers, medical experts, and marketers to more correctly target prospective users accordingly.

9.2 Pandemic period trust on medical devices

New trust concerns are produced by the coronavirus illness (COVID-19). This might have been unavoidable in the face of a new disease pathogen that failed to meet pre-conceived assumptions (for example, transmission through asymptomatic carriers), which led to rapid progress in scientific understanding of the illness. However contradictory signals, dubious treatments in research papers, political involvement with advice on health and choices on therapy effectiveness, pseudo-science and conspiracy theories except for the prevailing lack of trust in science [72]. Moreover, insufficient testing, expensive hurdles for treatment, and excessively high levels of cases and fatalities of COVID-19 were facing Black and Latino communities and further threatened their trust in the physicians, the health care system, public health and sciences.

Science isn't express us always what we want to hear. Science can lead to company closures, unemployment, no family or friends, or the cancellation of vacation plans during a pandemic. But without political leaders supporting good research, we will not exit this epidemic. The public must be able to obtain and trust information from scientific bodies such as the CDC and the FDA without questioning their reasons. Science provides mankind with an opportunity to combat Mother Nature [73]. We need to be intelligent and thorough with our hands. Six research works explore challenges to trust and strategies of alleviating them in this edition of JAMA. Arora addressed medical misinformation problems and provide clinical and societal counter-strength methods from the use of social media to the dissemination of vaccine messages, to community-level health systems, to mammography misconceptions. In the course of the COVID-19 pandemic, the cohesive response of public health has been complicated by disagreements and inconsistencies, both real scientific disputes and medical misinformation. These have also created clinicians with problems. Laura Lalieve et al. [74] presented the design and manufacture of a heart surgery suture guide as a case studio for 3D printing medical equipment produced during the pandemic COVID-19. 3D emergency medical device printing emerged as a viable option in the COVID-19 pandemic to address deficiencies. The production of medical equipment in small numbers in hospitals is an attractive opportunity for crisis management. Healthcare professionals and the production of additives are ready, but regulatory adjustments are necessary.

10 Problem statement and motivation

Home use medical devices have become part of our daily lifestyle. People have started using healthcare equipment's at home to keep track of their health, which made it essential for manufacturers to provide easy to use devices and with time introduction of a tracking system have made it easier for them to track products throughout the product cycle and recall products with defects. Medical device tracking has made it easier to check product authenticity by scanning barcodes, QC codes, and chips present on the products [75].

In this global pandemic situation, medical device manufacturers are also dealing with inadequate stockpiling and the inability to meet the healthcare centre requirement. The sale of some of the essential medical equipment's has ramped up making it difficult for medical device companies to meet the required demand with high-quality products as during this unfolding situation of COVID-19 quality of products plays an important role. They are trying to adapt to the situation despite challenges to supply sufficient protective equipment's and medical devices essential during this pandemic situation. Medical devices belonging to class II and class III have been introduced to the market with insufficient safety data with a hike in the price of some medical devices and protective equipment's [76].

11 Objective of the research work

The survey on medical equipment used at home was conducted after recognizing the need to make people better aware and understand medical devices sale, production during COVID-19, and their tacking. With the assistance/guidance of my research guide, questionaries' for surveys were designed. The survey was kept short and concise to make participants friendly. This survey was conducted in the region of northern India covering Haryana, Delhi, Uttar Pradesh, Uttarakhand, Punjab states, irrespective of caste and religion, and participants were randomly selected and were asked to submit their responses and share the survey form with others to make people more aware of medical equipment's. People from working or non-working sectors irrespective of their gender and age were asked to submit their responses. It consists of 14 questions and the same was distributed to random participants via email and text messages.

12 Conclusion and future scope

The ongoing spread of the COVID-19 pandemic has impacted medical equipment manufacturers. More people are choosing home healthcare, increasing in demand for medical devices that can be used at home. By 2025, it is predicted that India's medical equipment industry would have surpassed $50 billion. Device manufacturers all over the world are watching this rapidly emerging demand, and focusing on catering to it more effectively. In domestic health care, medical devices used during COVID-19 should be suitable for the users and the surroundings in which they are utilized. Trust in the medical device is vital, and is critically dependent on the ability of governments to communicate the benefits of medical devices, and to deliver the devices safely and effectively. The extent of adherence to such norms is debatable, and there is a general lack of trust in the products manufactured in India. Thus the review article explores people trust among medical devices during COVID-19. Several platforms such as wearable medical devices and medical remote controls influence COVID-19 are studied. People with non-communicable illnesses can better self-monitor their vitals at home by using medical equipment and wearables.

The proliferation of home medical equipment is helping people reduce their dependence on clinical support and pathological and diagnostic facilities for every single need. Since most of the healthcare expenditure in India is still borne out of pocket by the patients and their families. Medical gadgets provide significant cost savings to those who are economically disadvantaged. India is a price-competitive market that predominantly manufactures low- to mid-tech products. This concluded that Indians are becoming more concerned about their self-health monitoring and more inclined towards home useable medical equipment's. Researchers might also focus on the invention of advanced novel ways to improve medical equipment' resilience and safety in the home environment. Novel gadgets such as better cochlear implants and pacemaker's medication systems will provide more technical developments in future. Miniaturization of several components, including microprocessor and nanotechnology, will allow a range of medical devices for both formal and outside health care applications for the benefit of improvements. The potential scale of demand for such devices in India is massive enough to justify the reduction in costs without hurting the sustainability factor for device makers. All these custom factors must be taken into account consequently that medical devices for people who have trust in-home health care are safe and efficient. This research stresses the utmost importance of public trust for the functioning of the healthcare system and society.

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