



Importance of Quality Implementation in Healthcare in India

Jyoti Shah^{1*}, Abha Shukla², Sunidhi Badola², R K Kotnala¹

¹New Science Creators Institute, Naraina Phase II, Delhi-110028

²CSIR-National Physical Laboratory, New Delhi-110012

Received date: 09/03/2026, Acceptance date: 19/05/2026

DOI: <http://doi.org/10.63015/6hs-2497.3.2>

*Corresponding Author: shah.jyoti1@gmail.com

Abstract

Healthcare is universally recognized as a fundamental right; however, the assurance of quality remains indispensable. This review highlights the pressing need to strengthen healthcare standards in India. While numerous government schemes have been introduced to expand access and affordability, the delivery of medical care must adhere to standardized protocols to ensure reliability, safety, and equity. International frameworks, such as ISO standards, provide essential guidance for minimizing risks and enhancing patient outcomes. The COVID-19 pandemic has further underscored the urgency of reinforcing healthcare infrastructure and embedding quality assurance at every level of service delivery. Addressing these challenges is critical to achieving sustainable, resilient, and patient-centered healthcare for all. Moreover, as the world increasingly turns to India for affordable medical treatment, the implementation of international standards becomes vital to sustain trust, ensure patient safety, and position India as a global leader in healthcare excellence. Addressing these challenges is critical to achieving sustainable, resilient, and patient-centered healthcare for all.

Keywords: Healthcare, Quality system, ISO, ABHA, Ayushman Bharat

1. Introduction

The Covid-19 pandemic has created an unprecedented scenario which acted as an eyeopener towards the status of the healthcare system in the country. The lack of beds, intensive care units and oxygen cylinders all point towards a collapsed and failed healthcare system [1,2]. Healthcare system refers to a group of individuals, organizations and institutions that are involved in fulfilling the requirements of the community and providing resources to cater to the health needs of masses [3].

Healthcare in India is a very big domain which comprises of both the public and private healthcare sectors in rural as well as urban areas. There exists a huge gap in the quality of healthcare in these domains, in terms of infrastructure, the available facilities (medicines, instruments, trained staff) and the access of people to these facilities. The healthcare facilities are divided into the primary, secondary and tertiary level facilities [4].

In India, the responsibility and accountability in healthcare is shared by the central and state governments. The central government make policy, provides resources and technical assistance to the states. The Union Ministry of Health & Family Welfare (MoHFW) takes care of the implementation of various programs at the national level [5].

2. Understanding Quality in Healthcare

Quality is a term used to describe the inherent characteristics of any object, product or service, which makes it fit for its intended use. According to WHO, the Sustainable Development Goals (SDGs) point towards a global health coverage with access to quality healthcare services including essential medicines and vaccines at an affordable rate for all. It includes the quality of care in hospitals, public health

centres, emergency services etc. “Quality in Healthcare” is a multifaceted issue. The meaning of QUALITY in healthcare can be different for researchers, healthcare workers, doctors, patients and public. For example, for patients a good healthcare facility would be the one where they are listened to and treated politely, while for a doctor availability of specified drugs and working condition of the medical equipment is a matter of quality in healthcare [6].

To ensure quality in healthcare services, MoHFW launched the National Quality Assurance Standards (NQAS) in 2013. These standards are accredited by the International Society for Quality in Healthcare (ISQua) and are in line with the WHO global benchmarks. The aim of NQAS is to improve the quality of healthcare to make it more efficient and user friendly. According to a report by MoHFW, about 1600 public health facilities received National Quality Certification and 154 health facilities were NQAS certified till November 2020 [7].

3. Different Policies for Healthcare in India

• National Health Policy

The first National Health policy was initiated in 1983, followed by that in 2002 and the current National Health policy came into effect in 2017. The aim of the National Health Policy is to ensure that all people have access to the available healthcare facilities. This has to be done by improving the quality and minimizing the cost of the healthcare services. The gap between the public and private healthcare systems needs to be bridged by making the health-related services in private sector more affordable, efficient and aligned with the public demands. In India, the healthcare amounts to 1.8% of the GDP currently [8]. The National Health policy envisages to

increase the healthcare contribution to GDP to 2.5% by 2025 [9].

The major areas covered under the National health policy are:

- Swachh Bharat Mission, which focusses on cleanliness, hygiene, solid waste management, wastewater treatment and creating awareness among people regarding healthy sanitation practices.
- Providing a well-balanced, nutritional and healthy diet to all
- Addressing the issue of tobacco, alcohol and substance (drugs) abuse
- Improving the safety and addressing the issue of gender discrimination at workplaces
- Making health education an integral part of the school curriculum and promoting safe and hygienic health practices among students.
- Implementation of programs at national level for detection and elimination of communicable diseases like TB, HIV, leprosy, and non-communicable diseases like diabetes, hypertension, thalassemia etc. strengthen the healthcare system.

The National Health policy focusses on providing quality healthcare to all with major emphasis on poor, vulnerable and marginalised section of the society. The concept of preventive and promotive healthcare has been constantly stressed upon to ensure the highest level of well-being for masses.

- **Ayushman Bharat**

The Ayushman Bharat, launched in 2018, aims to achieve universal, accessible and affordable healthcare for all. One target of

this mission is to provide primary healthcare to the needy people by creation of 1.5 lakhs health and wellness centres throughout the country. The second part of the mission is to create the world's largest Public Healthcare Insurance Scheme which provides a health cover of Rs. 5 lakh per family in a year for the secondary and tertiary care hospitalization services, to around 10 crore poor and vulnerable families. The free drugs initiative plays an integral role in improving the quality of healthcare. Under this scheme, states have been given extra funds to provides essential drugs to people free of cost [10].

Some Important National health programs are:

- **RMNCH+A:** Reproductive, Maternal, Newborn, Child and Adolescent Healthcare: Under the RMNCH+A strategy of NHM, significant improvements have been achieved with regard to reduction of maternal mortality ratio, MMR and child mortality rates.

The MMR refers to the number of maternal deaths per 100000 births. MMR is an important factor as it signifies the quality of healthcare in a country. The Indian National Health Policy is dedicated to decrease the MMR in the country. Some of the initiatives taken by the government in this direction are: Janani Suraksha Yojana (JSY), Janani Shishu Suraksha Karyakaram (JSSK), Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA), LaQshya Programme. The main objective of all these programmes is to provide a safe motherhood by giving proper care, free of cost medicines, regular check-ups and no expense delivery to the pregnant woman in all the public health facilities. The LaQshya Programme ensures that the services related to maternity are assessed on the NQAS standards [11–13].

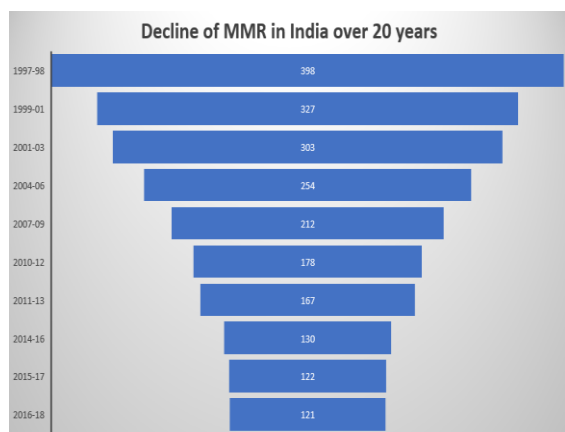


Figure 1: Mother mortality trend over the years

- **Universal Immunization Programme (UIP):**

This is world's largest public health programme, started in 1978, is one of the top programmes under the National Health Mission. Approximately 5.5 crore pregnant women and newborns are vaccinated annually under this mission, free of cost, for twelve preventable diseases.

Government launched Mission Indra Dhanush to aim towards full immunization coverage for children specially in hard-to-reach areas. Also, proper cold chain equipment for vaccine storage have been developed in various districts across the country. The Pulse polio programme is still going on a large scale to maintain the polio free status of the country. To keep the program going as desired, it is crucial that the production as well as distribution of the vaccines should be done through standard quality checks at each step [14,15].

- **National Vector Borne Disease Control Program (NVBDCP)**

For the prevention and control of vector borne diseases like Malaria, Japanese Encephalitis (JE), Dengue, Chikungunya, Kala-azar and Lymphatic Filariasis (LF), the National Vector Borne Disease Control Program (NVBDCP) was started. The spread of these diseases depends on many

factors like climate, cleanliness, types of vectors and their prevalence and may other ecological and social factors. The only way to prevent these diseases is to keep one's surroundings clean [16].

- **National Tuberculosis Elimination programme (NTEP)**

Government started the battle to fight tuberculosis (TB) in 1962. The programme was renamed as NTEP in 2020, which aims to make India TB free by 2025. Around 26.4 lakh people are suffering from TB in India alone which makes it 27% of the TB cases in the world. The main objective of NTEP is the timely detection and treatment of TB infected people for which the government has started 5 lakh DOT centres and around 21000 microscopy centres across the country. To further prevent the spread, section 269 and 270 of the Indian Penal Code have been applied. Even in the private sector, free diagnosis, treatment and drugs are given to all patients. The need is to spread awareness among people to report the disease and get treatment as soon as possible and stop it from further spreading [17].

- **Nations AIDS Control programme (NACP)**

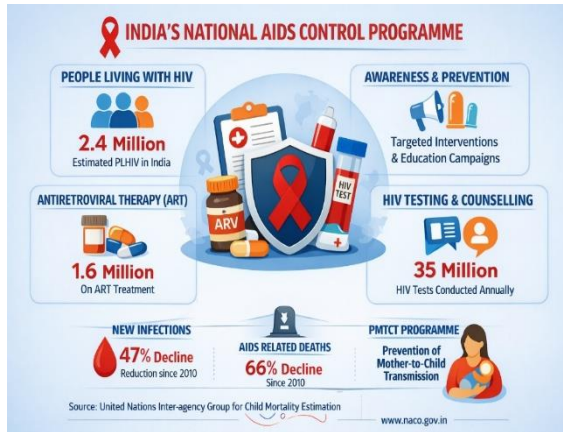


Figure 2: Source: www.naco.gov.in, image credit: AI copilot

A flagship programme of National AIDS Control Organization (NACO) which ensures safe blood transfusion practices and provides free of cost Anti-Retroviral Therapy (ART) to the infected people (Figure 2). Under its “Test and Treat” policy, free drugs and services for HIV and TB are available at all the ART centres. A network of laboratories is involved in quality testing in association with the non-government organizations (NGOs) and community-based organizations (CBOs). An HIV/AIDS prevention act is passed by the Indian Parliament in 2017 to prevent any kind of discrimination towards the HIV infected people. Literacy and open discussions are necessary to remove the taboo and make people understand the seriousness of the issue and come together to create a healthy environment so that more and more people can get diagnosed and treated [18].

A lot of other small and big programmes have been initiated by the government for improving the quality of healthcare. Some of them are:

- Rashtriya Bal Swasthya Karyakram
- National Leprosy Eradication Program
- National Mental Health Program
- Rashtriya Arogya Nidhi

- National Tobacco Control Program
- Integrated Child Development Service
- National Iodine Deficiency Disease Control Programme
- National Policy for Rare Diseases
- WASH programme: To improve water, sanitation and hygiene etc.

People will only benefit from these schemes if they are implemented properly keeping all the standards and quality checks in place.

4. Benefits of Quality in Healthcare

Quality in healthcare means the presence of a safe, efficient, and patient friendly system which not only avoids any kind of harm but also reduces wastage of resources [19]. There are a lot of benefits of quality in healthcare (figure 3). Many deaths occur due to human negligence and poorly maintained medical equipment. A study by Harvard University reveals that by improving the quality of treatment given to the critically injured patients, the deaths can be reduced to 50% [20]. Quality here means fast and reliable emergency services, accessibility of essential drugs at cost-effective price and the availability of well-trained doctors and medical workers. A patient-centric environment is the need of any healthcare facility.



Figure 3: Various benefits of quality in healthcare, image credit: AI copilot

Proper implementation of various government schemes also increases the quality of healthcare. Maintaining quality in these government schemes is a matter of serious concern. Since there are many stages from initiation to implementation, each stage should have separate quality checks to ensure that the purpose of the policy is fulfilled [21]. All the medical instruments should be well maintained and calibrated against the national standards. The storage of vaccines should be done at the desired temperature which again have to be maintained in good quality cold storage boxes. Maintaining uniform quality of healthcare in India is difficult due to its diversified cultural, social and economic variations. One way is to improve the quality of medical education, training the healthcare workers, developing their knowledge and skills, regular monitoring and evaluation and proper record keeping.

• Medical Tourism:

Due to the development of world-class healthcare facilities at an affordable rate, India has become the destination of choice for many people across the globe who are in dire need of medical treatment (figure 4) [22].

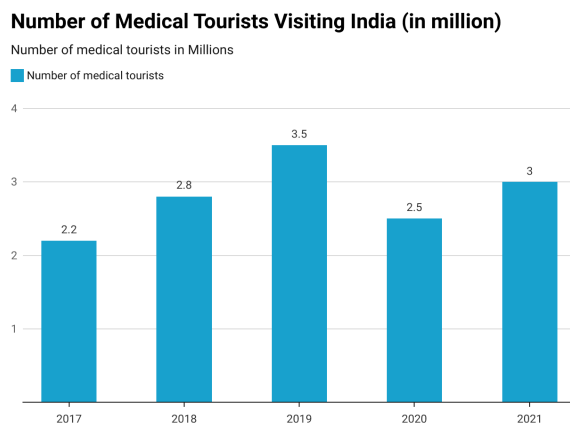


Figure 4: Number of tourist visiting India on medical visa

Less waiting time and state of the art healthcare facilities attract tourists towards

India. The Indian government has also started the facility of Medical Visa for such patients and their families. According to a report by the Ministry of Tourism, 1,82,945 foreign nationals came to India on medical visas in the year 2020 [23]. India receives majority of medical tourists from South Asian countries like Afghanistan, Bangladesh, Iraq, Bhutan, Sri Lanka, Maldives along with Canada, Australia etc. The traditional Indian medicinal system, AYUSH- Ayurveda, Yoga, Unani, Siddha, Homeopathy, combined with allopathy make an attractive offer for the tourists. The Indian pharmaceutical industry is a key player in exporting medicines throughout the world. Also, the market for medical devices in India is growing fast, becoming 4th largest in Asia. The ongoing Covid-19 pandemic has already created a disturbance in the lifestyle of public at a large scale and its after effects will put more burden on the healthcare sector. Looking at the other side, this might pave way for a big increase in the medical tourism and generation of high revenue.

5. Quality Implementation in Health Care: International Organization for Standardization (ISO)

The International Organization for Standardization (ISO) provides a platform for developing standards through common understanding and cooperation with all stakeholders. The implementation of standards is basically conformity assessment process of evaluating or measuring whether materials, products, processes, services, systems or persons meet requirements.

The conformity assessment for any standards implemented by any laboratories has been given by a third party known as accreditation body like for testing and calibration laboratories NABL in India accreditate that is recognized by an

independent body like International Accreditation Forum, IAF [24]. International Accreditation Forum operates a worldwide mutual recognition arrangement among Accreditation Bodies (ABs) in order that the results issued by Conformity Assessment Bodies (CABs) accredited by IAF members are accepted globally. The United Nations new road map is to improve health services and well-being of people's lives by 2030 is one of the UN Sustainable Development Goals [25]. To meet the ambitious Goal to improve people's health, implementation of Standardization in healthcare system is utmost important. ISO standards make it easier to compare health services, exchange information, aggregate data and safeguard the privacy of an individual's health. Implementation of ISO standards, organizations and companies make a proactive commitment to the principles of quality, transparency, accountability and safety. However, healthcare system is an increasingly complex and high-risk activity [26]. There are more than 1400 ISO health standards available Medical or Healthcare organizations. ISO 13485:2016 Medical Devices Certification, ISO 17025:2017 Laboratory Testing Standard, are the well known standards for the healthcare organizations.

In India the Association of Indian Medical Device Industry (AIMED) in collaboration with the Quality Council of India (QCI) and the National Accreditation Board for certification bodies (NABCB) has established a voluntary quality certification scheme for medical devices in India, ICMED 13485 to help ensure quality in manufacturing of medical devices [27]. ICMED 13485 - Based on the International Harmonized Standard (ISO 13485) "Quality Management Systems for Medical Devices" plus additional requirements specified under the scheme. National

Accreditation Board for Testing and Calibration Laboratories (NABL) provide third party laboratory accreditation services in performing tests and calibration in accordance with ISO/IEC 17025.

Healthcare services for the peoples increase the likelihood of desired health outcomes and are consistent with evidence-based professional knowledge decides the Quality of care. For achieving the quality in healthcare the following ISO Standards should be adopted by the health care organizations:

9001 Quality Management

ISO: 13485 Medical devices certification

ISO: 14001 Environmental Management Standard

ISO: 14064 Green House Gases

ISO: 15189 Medical Laboratories Quality Systems

ISO: 15700 Service Quality Management System

ISO: 16001 Social Accountability

ISO: 17021 Conformity Assessment

ISO: 17025 Testing and Calibration Laboratories

ISO: 18001 Occupational Health and Safety Management Series

ISO: 22000 Food Safety Management

ISO: 26000 Social Responsibility

ISO: 27001 Information Security Management Standard

ISO: 31000 Risk Management

ISO: 37001 Anti-bribery Management System

ISO: 45001 Occupational health and safety

ISO: 50001 Energy Management

ISO1789 Medical vehicle and their equipment. Road ambulance.

ISO standards make it easier to compare health services, exchange information, aggregate data and safeguard the privacy of an individual's health. By implementing ISO standards, organizations and companies make a proactive commitment to the principles of quality, transparency, accountability, and safety.

6. Importance of Standards for biomedical Devices in Healthcare system

Medical Devices: A medical device may be defined as a kit, apparatus, instrument, appliance, implant, or other article, intended to be used specially for human beings or animals for the specific purposes of:

- (i) Prevention, detection, diagnosis or monitoring of a disease or problem;
- (ii) Treatment or mitigation of any physiological condition or illness;
- (iii) Replacement or modification or support of the anatomy or inherited abnormality;
- (iv) Supporting or sustaining life;
- (v) Control of conception or
- (vi) Sanitization of medical devices [28].

According to Article 21 of Indian Constitution, Right to Health is one of the fundamental rights of every Indian citizen. The medical devices provide healthcare and help in improving the health of the individual of a nation. Therefore, quality control for biomedical devices is the foremost requirement for the running of a smooth and successful healthcare system. It acutely impacts the health of the nation's citizens along with the economy of the country and hence, the healthcare policies must focus on the "healthy equipments" in hospitals, pathology and imaging laboratories, pharmaceutical industries etc. Our government has already taken many initiatives in this direction. In spite of that, a large number of populations in India are

getting low quality healthcare facilities due to lack of well-equipped instruments, skilled staff, knowledge and last but not least a huge population. As per United Nation's child mortality estimates, around 7,21,000 infants deaths are reported in India in 2018 (Figure 5).

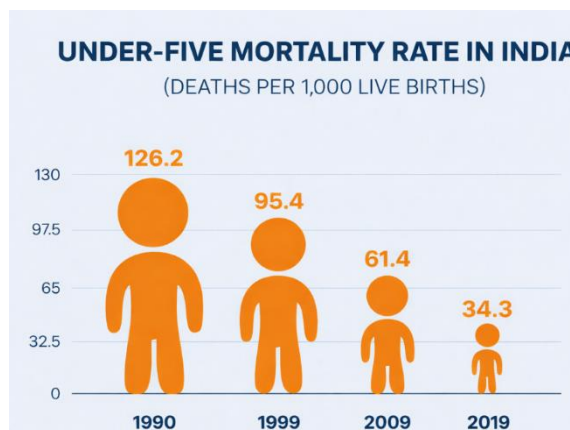


Figure 5: Source: United Nation's inter-agency group for child mortality estimation (UN IGME) 2020

According to UNICEF report 2020 Nigeria and India alone accounts for the one third of total under five deaths in children [29]. A study published in the Lancet, 2018, states that in spite of the different programs like Janani Suraksha Yojna which was launched in April 2005 have not improved the maternal and new born survival due to unskilled staff and low quality healthcare facilities. According to the report 15.6 million excess deaths were recorded in 2016 in 137 low and middle income countries including India out of which 8.6 million deaths were due to the poor quality of care or non- utilization of healthcare. The Report concludes that these deaths could be averted by investments into high quality health systems [30]. Being a low income country India lacks the quality healthcare infrastructure from beginning. A number of examples have been cited in literature in reputed journals regarding the poor, ignorant and corrupt healthcare structure. According to a world report, published in The Lancet in 2009, the trade of second hand/used equipments like

unsterilized used syringes were found responsible for causing the widespread Hepatitis B and consequent deaths in Gujarat, India [31]. Although after the incident, Indian government imposed the compulsory use of disposable syringes but we are not sure that how effectively the rules are being followed as the black marketing of medical waste still exists in the Indian healthcare system. The recent black marketing of used mask and gloves during Covid-19 second wave is the live example of playing with the life of citizens and failed medical waste disposal policies along with fractured healthcare system [32].

Even in super and multispecialty hospitals which are equipped with the modern high-tech facilities the inefficiency or ignorance (for example time to time calibration of the instrument) or the lack of standard or calibration facility may lead to the erroneous results or treatment which consequently may be fatal to the individual. Acquiring reliable high-quality data is also a huge constraint in improving the quality of healthcare system because most of the time the concerned staff is unaware of the errors in testing, treating or tracking biomedical devices. How dangerous this ignorance or unawareness or the flawed healthcare policies can be this can be understood from the following case studies. In a remarkable case a petition filed by a Delhi resident vs. Union health ministry in 2011, to Central information commission demanded that the hospital equipment procurement details and their maintenance schedule should be reflected on the website as many of the infants meet an untimely death due to the poor maintenance of the incubators or due to the equipment failure. Dr. Paul who was representing Director AIIMS stated that during the procurement of the medical equipment the quality of the equipment is compromised as during the bidding high quality equipment gets out of the league while competing with their cheaper counter parts and these cheap

equipments here for example incubators due to fault or design flaw end up with burning itself along with baby [33]. It is a horrible situation and these types of incidents are really very unfortunate. Here is a need to amend the government policies which emphasis more on quantity than quality. At least healthcare system should be exempted from these fixed criteria. A recent incident came across during the second Covid-19 wave in 2021 when Mumbai High Court admonished the Ministry of health and family Welfare, Govt. of India for indirectly defending the manufacturer of ventilators who delivered faulty ventilators to Maharashtra and might become the cause of casualties during the pandemic [34]. No doubt India has become more vigilant and concerned about its health facilities and infrastructure but more has to be done in this direction.

Not only in India, but worldwide these types of incidents have been reported where the malpractice in hospitals and path labs resulted into hospitalization and even deaths [35]. According to WHO millions of people die each year due to medical negligence and malpractices and its personal and socio-economic impact leads to the loss of around trillions of US dollars[36]. Globally many researchers have reported the losses and deaths due to the malpractices in healthcare sector since long back [37,38]. These instances triggered the need for regulations, standards and traceability in medical sector, concerning to the health and life of an individual. Out of which one of the most important is biomedical devices regulation, which has least developed among medicines and vaccines [39]. Although a lot of efforts in this direction have been made by national and international regulatory bodies in recent past years.

• **International Medical Device regulation**

According to WHO, the regulatory guidelines for the medical products whether

medical devices, equipment or medicines serve to limit the harmful impact of the product to the end user, non-compliance of the product with standards and or being ineffective. The government of a nation has a major role in the implementation of these regulatory guidelines as a law and its proper enforcement. All the major medical equipment and devices manufacturer countries have very important components in common. The first is the quality assurance system to ensure the compliance of device with the existing standards and norms and a system assuring clinical safety and performance of the device [40]. WHO defines standards as “documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, processes, and services are fit for their purpose” [41]. The widely accepted international standards in this field have been developed by organizations like international organization for standardization (ISO), International Electro technical Commission (IEC) and International Telecommunication Union (ITU). The global harmonization task force (GHTF) advises the nations to apply these standards according to their requirement and conditions in their countries so that a quality care can be provided to the end user/Patient.

7. India’s Movement on Quality Control of Biomedical Devices

It has been estimated that around 80% of the total required medical devices and equipments are being imported in India [42]. The fact is of great concern that we don’t stand with our own in the area of biomedical equipments and devices. Manufacturers are promoted for the production of the medical equipments but the major reason for their failure is the poor quality which does not meet the international standards. Therefore, with promotion of indigenous manufacturing quality control of the products is equally

important and the equipment traceability to international standards should be fixed. Although small and cheap medical devices with poor quality openly circulates in the country as we cannot afford the high-quality care for each and every individual of the nation. There is only one solution that we manufacture these devices independently but with regulation of strict quality guidelines. National Health Policy, 2017 promotes the domestic manufactures to produce indigenous medical devices to endorse the “Make in India” concept but with the condition the devices should comply with the quality standards. Harmonization of domestic medical standards with international standards, strengthening of medical devices regulation and the formation of a regulatory body on it, was recommended in the policy so that it will promote the manufacturing of indigenous medical devices with international standards [9]. The implementation of medical device rule, 2017 has effectively initiated the quality control of the equipments with international standards including Horizontal, semi horizontal and vertical standards, which state that “For all manufacturing sites, Quality Management System will need to be aligned with ISO 13485. Import of all medical devices will continue to be regulated by CDSCO. A network of NABL accredited laboratories will be set up both, by the Government and by other entities, for testing medical devices” [43]. It is of great importance to understand that a large number of health complications can be prevented by following the standards and norms related to the medical device and hence minimizing its error. The traceability of the measurement of the medical device should be fixed by authority to international organization to get the reliable data. Let us have a look at various medical segments and the quality required and maintained for medical devices in that sector in India.

- **Standards for Medical Equipments in Hospitals**

In Hospitals various types of medical equipments and devices are used for the diagnosis, testing and treatments. These instruments/devices fall in different categories according to their specialized functioning. There are certain standards and protocols not only for their operation but also for their storage, transportation, handling, maintenance etc. of the quality procedure ensures the safety of the patients and the paramedical staff.

Medical Radiation Equipment/treatment

Nuclear medicine imaging, sterilization of medical equipments using radiation, X-ray machines, Linac (linear accelerator), etc. falls in the category which uses high energy radiations or radioactive materials. For example, a medical equipment for treating a cancer patient may contain radioactive material. Radioactive materials are also used frequently in biomedical research. Basically, these materials are highly hazardous if used improperly, the exposure time and quantity is not properly controlled or is not disposed properly. Many such incidents have been reported in India. It may not only affect the operator of the machine but can be dangerous to patient and the persons in vicinity. Therefore, there are certain national/international guidelines by the respective agencies (Figure 6) regarding safety aspects, operation and disposal of the equipment/radioactive material which should be strictly followed to avoid the adverse effects during and after its use.

INTERNATIONAL	INDIA
International atomic energy (IAEA)	Atomic energy regulatory board (AERB)
International Commission on Radiological Protection (ICRP)	
National council on radiation protection and measurements	
U.S.FDA (Food and drug administration)	

Figure 6: International and national regulatory bodies for radiation

Atomic energy Acts 1962, along with the subsequent amendments Atomic Energy (Radiation Protection) Rules, 2004 (G.S.R. 303) provides the regulatory framework for the development control and use of radioactive material for the public welfare in India [44]. According to its section 21, it is the responsibility of the licensee to comply with the specified safety standards, time to time assessment of the exposure to the radiation for ensuring the safety of workers, patients or public. The licensee should ensure the preventive and remedial maintenance and satisfactory performance of the radiation protection and radiation monitoring equipments. Central government has designated Atomic Energy Regulatory Board (AERB) a competent authority which looks after all the radiation related affairs like licensing, approvals, renewals etc and enforcement of the regulatory framework for radioactive materials. As national accreditation board for calibration and testing laboratories (NABL) is the accreditation body for radiological calibration and testing under Quality Control of India (QCI), AERB recently on February 2021 signed an agreement with NABL that, as the radiation imaging it will accredit the quality assurance agencies in this area.

• Quality Control in Nanomedicine

Nanomaterials are defined as the materials having at least one dimension at nano scale specifically between 1-100 nm or upto 1000 nm in some cases. These nano materials have unique tunable physicochemical properties specific to their nano dimension which are absent in their bulk form [45]. Recently, nanotechnology has contributed to the noteworthy contribution to various drugs and medical products development. Nano medicine is a term frequently encountered in medical sector, which is defined as the use of nanomaterials for diagnosis, treatment, monitoring or control of disease or therapeutics. It has revolutionized the area of medical field but has several associated regulatory issues

also. Due to the alteration in the properties at nano scale nano medicine may stay for long and can easily penetrate the biological barriers in human body. Moreover, their pharmacokinetic parameters viz. metabolism, distribution and absorption in the body may vary drastically in comparison to their bulk counterparts (figure 7).

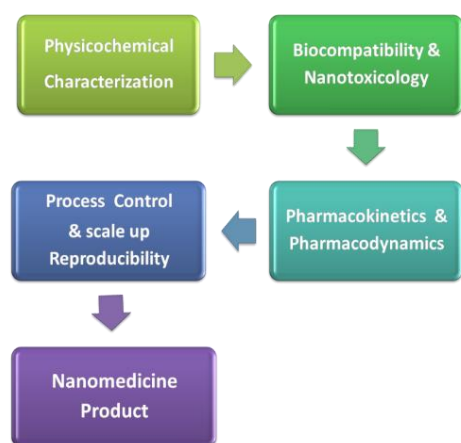


Figure 7: Challenges for the development of nano medicine [46].

Therefore, they can become detrimental to human health and their application in medical field requires strict quality control and regulatory guidelines. In other developed countries the nano pharmaceuticals guidelines are regulated by the drug related regulatory bodies like food and drug administration (FDA) in USA, medicines and healthcare products regulatory authority (MHRA) in UK, European medicine union (EMU) in Europe, Ministry of Health, Labour and Welfare (MHLW)/the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. Among all only European agencies have widely studied and published a broad range of guidelines related to nano materials and nano medicine. The other countries are still lacking the clear regulations regarding the implementation of nano medicine in the country [47]. In 2019, CDSCO, DBT, ICMR and MoHFW in coordination with

the stake holders in the area released some guidelines for the evaluation of nano pharmaceuticals. The guideline focuses on the development of new competitive and robust drugs with complete in-vitro and in-vivo study profiling according to the existing guidelines conforming to Drugs and Cosmetics Act, 1940 and New Drugs and Clinical Trials Rules, 2019. The guidelines are intended to develop the drugs with improved efficacy, safety and reduced toxicity, cost and dose.

8. Private Pathology Labs and Imaging Centres and Regulatory Standards

Pathology labs and imaging centres are the backbone of a healthcare system. The treatment of a disease/injury/illness very much depends on the diagnosis which is done by these laboratories. In nutshell half of the cure is done at the first stage i.e. the proper diagnosis and half depends upon its treatment.

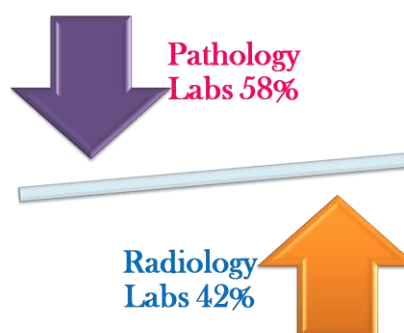


Figure 8: Diagnostic Industry Breakup

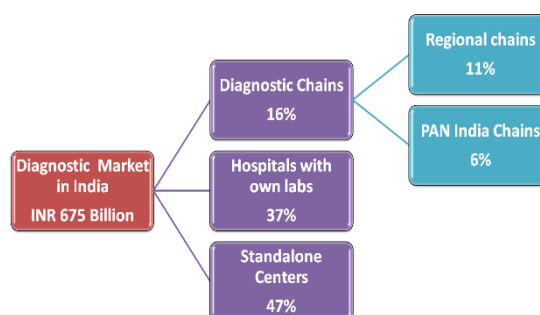


Figure 9: Market Structure of Indian Diagnostic Industry

Private pathology labs and imaging centers plays a very crucial role in Indian healthcare sector as these private labs dominated by their share in health sector and a major portion of Indian population has dependency on these labs for testing and diagnostics. 58% of the total labs are Pathology and 42% are doing radio imaging (figure 8).

Figure 9 reflects the breakup of the diagnostic market in India. These private pathology labs and diagnostic centers are governed by the legal framework of Clinical Establishment Act, 2010 with a motive to provide a minimum standard of healthcare service in India. According to our constitution healthcare is a state subject, therefore state has exclusive powers to select which union law to enforce and which to reject. As of now less than half of the total Indian states have enacted upon this act. In India there are framed guidelines, standards and SOPs which they have to follow to run their labs in standard manner. But it seems only in papers. It is so easy to get all the approvals to run pathology labs that they are growing as mushrooms in India. Anyway, the overall situation of the pathology labs and imaging centers is worst while considering the quality of service provided by these labs and they are far away from the standards [48]. Most of the time we come across the incidents where two or three pathology labs have different results. It is common practices of the pathology labs to provide erroneous diagnostic reports which is a threat to the public health, and the interesting fact is most of them are NABL accredited [49,50]. There are certain standards and guidelines for collecting test samples, their shelf life, transportation conditions etc., if these samples are tested beyond the prescribed shelf life, their reports are useless. All laboratory machines should be calibrated in prescribed time period and cross-checked for efficacy. In India laboratories do not even bother to train the staff properly. They are totally

unaware of the protocol and carry on to process the samples. Even in the laboratories where proper training to the staff is given, nobody bothers to keep an eye whether SOPs are properly being followed or not. This implies that labs are not bound to follow regulatory guidelines and performing unethical practices without any hesitation. Covid -19 pandemic is the recent example, where government authorized ICMR to regulate the guidelines for testing and treatment of the infection by SARS-CoV-2, where ICMR authorized only government labs to perform the testing, afterwards when load became higher other NABL accredited private labs also were given the responsibility of testing. Surprisingly, placing all the rules and guidelines on the haywire false/fake certificates were issued by these laboratories [51–54]. One can imagine how serious matter it was. While government was asking to break the contact chain of corona virus infection, thousands or lacs of fake reports were issued, which means that many infected persons were roaming in public infecting many more. No doubt inefficient testing and unethical practices of these labs was one of the contributory factors to the severity of disease in Second Covid wave. This should be treated as crime but with the down fall of the wave responsible agencies also went to hibernation or started the blame game to shrug off the responsibilities [55]. Nowadays these path labs and imaging centers have become a fancy business with a handsome earning, in spite of that its quality is being deteriorating. These are the loopholes in the system, need to be urgently reviewed and act upon. Otherwise, the system will never grow up to the international quality level and will be failure again and again while fighting against the unprecedented situations like Covid-19. Government has to take some initiatives in form of strict actions or penalties to limit these labs to perform within the standard protocol to maintain the quality of overall healthcare system

preventing deaths due to non-standardize equipments, malpractices and ignorance of the diagnostic labs.

The above discussed segments are interrelated and have interdependency on each other. Like a person cannot have a healthy life if any of the body organ is malfunctioning or not working. Similarly, for any system to work efficiently all of its components need to work together and honestly and on the predefined regulatory guidelines and standards to give a quality service to the public for their benefit. The second most important point is we will not be able to improve the healthcare quality unless we will be independent in this sector. Along with the policies, India needs to invest more and more on biomedical and devices research, developing standards. Several types of medical devices are being used in India as being a huge market for medical products; the development of our own indigenous system will help to boost the economy, as the huge amount which goes to foreign countries will remain in our countries along with opening a huge number of job opportunities for our young talent. Therefore, to achieve the goal of quality healthcare we must work on developing our own medical products, biomedical device and their standards with international traceability.

9. Challenges and Future Direction

India has a robust set of health programs and internationally benchmarked quality standards, but the real challenge lies in implementation—especially in rural areas, workforce training, and reducing out-of-pocket costs. Strengthening monitoring, expanding infrastructure, and improving awareness are critical steps. National Quality Assurance Standards (NQAS) is India's backbone for healthcare quality assurance, ensuring facilities meet international standards. However, The biggest challenge in quality implementation in the Indian healthcare system is the gap between policy design and ground-level

execution, particularly in primary healthcare delivery. Despite ambitious frameworks like the National Health Policy (2017) and Ayushman Bharat, fragmented infrastructure, workforce shortages, and weak accountability mechanisms hinder consistent, equitable, and patient-centered care [56,57]. Primary Health Centres (PHCs), which form the backbone of rural healthcare delivery, are often under-resourced, understaffed, and poorly equipped, leading to diminished community trust and reliance on informal or private providers. Studies highlight that vacancies among doctors, nurses, and laboratory staff remain widespread, with absenteeism further eroding confidence in public facilities. This imbalance is compounded by stark urban–rural disparities, where nearly two-thirds of India's population resides in rural areas but only one-third of health workers serve them. Even initiatives like Health and Wellness Centres under Ayushman Bharat, though promising, risk replicating existing inefficiencies unless systemic flaws in infrastructure, workforce motivation, and accountability are addressed. Quality assurance frameworks such as the National Quality Assurance Standards (NQAS) and Indian Public Health Standards (IPHS) exist, but adherence remains low, with only a fraction of PHCs meeting basic requirements [56]. Certification rates vary widely across states; some have strong uptake, while others lag due to weak governance. Strengthening training, monitoring, and funding mechanisms will be critical to sustaining its impact. A unified monitoring and evaluation framework is also critical. In essence, the challenge is not the absence of policy but the lack of effective implementation mechanisms that ensure reliable service delivery, equitable distribution of resources, and sustained community engagement. Without strengthening primary care infrastructure, institutionalizing a multidisciplinary public health cadre, and enforcing accountability

through robust monitoring, India's healthcare reforms risk remaining aspirational rather than transformative.

The future of healthcare policy implementation in India requires a more integrated and collaborative approach between the central and state governments. Strengthening federal–state coordination is essential to ensure that national health programs are uniformly applied while allowing flexibility for states to adapt them to local contexts. Establishing structured platforms for dialogue, such as joint task forces or intergovernmental councils, could help align priorities and reduce fragmentation in execution [58]. Leveraging digital health technologies, including telemedicine, electronic health records, and AI-driven analytics will further bridge gaps in monitoring and service delivery, particularly in rural and underserved regions. Programs like Ayushman Bharat- Pradhan Mantri Jan Arogya Yojana (PM-JAY) have demonstrated the potential of universal health coverage by providing financial protection to vulnerable families and combining insurance for secondary and tertiary care with strengthened primary healthcare infrastructure [59]. Capacity building at the state level remains a priority. Investments in workforce training, administrative efficiency, and infrastructure development will empower state health departments to implement central policies more effectively. Public–private partnerships (PPP) can complement these efforts by expanding reach, improving infrastructure, and fostering innovation in service delivery.

Future strategies must also emphasize equity and sustainability. The World Health Organization (WHO) underscores that quality of care is fundamental to achieving the Sustainable Development Goals, particularly in reducing maternal and child mortality. Aligning India's healthcare reforms with global frameworks such as Universal Health Coverage (UHC) will

ensure long-term resilience[19]. A comparative Table 1 highlights how different frameworks contribute to healthcare quality in India.

Finally, fixing the accountability for the implementation of quality standards in healthcare, prompt strict penalty and community engagement should be strengthened. Involving civil society, patient advocacy groups, and local communities in policy design and feedback processes will make healthcare more responsive, inclusive, and culturally appropriate. Together, these directions can transform India's healthcare system into one that is not only efficient and equitable but also sustainable and future-ready.

10 Conclusions: The Indian healthcare system stands at a critical juncture where the assurance of quality has become as important as access and affordability. Despite the introduction of ambitious national programs such as the National Health Policy (2017) and Ayushman Bharat, the persistent challenge lies in translating these frameworks into reliable, equitable, and patient-centered care across diverse regions. The COVID-19 pandemic exposed systemic weaknesses, shortages of beds, oxygen, and critical equipment, that underscored the fragility of infrastructure and the urgent need for robust quality assurance mechanisms. A major barrier to quality implementation is the uneven distribution of resources between urban and rural areas. Primary Health Centres, which should serve as the backbone of preventive and promotive care, often remain under-equipped and understaffed. This imbalance is compounded by the shortage of trained medical professionals, inadequate monitoring of standards, and weak accountability mechanisms. Even where policies exist, their execution falters due to fragmented governance and lack of uniform adherence to benchmarks such as the National Quality Assurance Standards (NQAS).

Another pressing issue is the quality of biomedical devices and medical equipment. Reports of faulty ventilators, poorly maintained incubators, and black-market circulation of medical waste highlight how lapses in regulation and enforcement compromise patient safety. The reliance on imported medical devices

In conclusion, India's healthcare system requires a paradigm shift from quantity-driven expansion to quality-centered delivery. Strengthening primary care infrastructure, institutionalizing a public health cadre, enforcing strict biomedical device regulations, and embedding ISO-based quality frameworks are critical steps

Table 1: Comparative Contributions to Healthcare Quality in India

Framework / Program	Scope & Focus	Key Contributions	Challenges / Gaps
WHO Quality Standards	Global benchmarks for patient safety, clinical effectiveness, and equity	Provides universal principles for quality of care; aligns with Sustainable Development Goals (SDGs)	Adaptation to local contexts; resource constraints in low- and middle-income countries
National Health Mission (NHM)	Strengthening primary healthcare and public health systems	Introduced State Health Systems Resource Centres (SHSRCs); improved maternal and child health indicators	Uneven implementation across states; limited monitoring capacity
National Quality Assurance Standards (NQAS)	Accreditation framework for public health facilities	Standardized domains: patient rights, clinical care, infection control, quality management; ISQua-accredited	Requires continuous training and audits; disparities in adoption
Ayushman Bharat – PM-JAY	Universal health coverage combining insurance and primary care	Financial protection for vulnerable families; Health and Wellness Centres for preventive care	Variability in state-level rollout; infrastructure gaps in rural areas
Public-Private Partnerships (PPP)	Collaborative models between government and private sector	Expanded reach, improved infrastructure, and innovation in service delivery	Risk of inequity if not regulated; accountability concerns

further complicates the situation, as indigenous manufacturing often struggles to meet international standards. Harmonization of domestic regulations with ISO frameworks, coupled with strict enforcement of medical device rules, is essential to ensure reliability and restore public trust. The broader implication of these challenges is that poor-quality care not only undermines health outcomes but also erodes confidence in public institutions. Studies have shown that millions of preventable deaths in India are linked not to lack of access but to inadequate quality of care. This reality emphasizes that quality implementation must be treated as a non-negotiable pillar of healthcare reform.

forward. Only by bridging the gap between policy and practice can India achieve sustainable, resilient, and patient-centered healthcare, positioning itself as a global leader in medical excellence.

Conflict of Interest: There is no conflict to declare.

References:

- [1] S. Nautiyal, Experts suggest measures to cater to challenge of shortage of ICU beds, ventilators for Covid-19 management, (n.d.). https://pharmabiz.com/NewsDetails.aspx?aid=138061&sid=1&utm_source=copilot.com.
- [2] B.K. Tirupakuzhi Vijayaraghavan, S. Nainan

- Myatra, M. Mathew, N. Lodh, J. Vasishta Divatia, N. Hammond, V. Jha, B. Venkatesh, Challenges in the delivery of critical care in India during the COVID-19 pandemic, J. Intensive Care Soc. 22 (2021) 342–348. <https://doi.org/10.1177/1751143720952590>.
- [3] What is a health system?, World Health Organisation (n.d.). https://files.who.int/a/fahobckpcontainer/production/files/05_What-is-a-Health-System_Factsheet.pdf?utm_source=copilot.com.
- [4] Health for All: The Evolving Role of India's Ministry of Health and Family Welfare in the 21st Century, Impact and Policy Research Institute (n.d.). https://www.impriindia.com/insights/ministry-health-family-affairs/?utm_source=copilot.com.
- [5] The Role of State and Central Government in Health Planning, (n.d.). https://bns.institute/behavioural-sciences/role-of-state-central-government-health-planning/?utm_source=copilot.com.
- [6] No Title, (n.d.). https://www.who.int/data/gho/data/themes/sustainable-development-goals?utm_source=copilot.com.
- [7] Update on National Quality Assurance Standards (NQAS), (n.d.). <https://www.pib.gov.in/Pressreleaseshare.aspx?PRID=2116213®=3&lang=2>.
- [8] What is healthcare budget?, (n.d.). <https://economictimes.indiatimes.com/news/budget-faqs/what-is-indias-healthcare-budget/articleshow/88250172.cms?from=mdr>.
- [9] G. Mitchell, R. Dole, J.R. Sasser, W.C. Ferguson, J.T. Lynn, M.D. Bromberg, A national health policy?, Rev. Fed. Am. Health Syst. 23 (1990) 22–35, 38, 42. https://doi.org/10.5005/jp/books/12912_41.
- [10] Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana, (n.d.). <https://www.myscheme.gov.in/schemes/ab-pmjay#details>.
- [11] Saving Mothers, Strengthening Futures: India's Success in Reducing Maternal Mortality, (n.d.). https://www.pib.gov.in/PressReleasePage.aspx?PRID=2113800&utm_source=copilot.com®=3&lang=2.
- [12] National Health Mission: Janani Suraksha Yojana, (n.d.). https://nhm.gov.in/index1.php?lang=1&level=3&sublinkid=841&lid=309&utm_source=copilot.com.
- [13] Steps taken by the Government for Maternal and Child health of Scheduled Castes (SC) and Scheduled Tribes (ST) population, (n.d.). <https://www.mohfw.gov.in/?q=en%2Fpressrelease->

- 149&utm_source=copilot.com .
- [14] Immunization, n.d. https://nhm.gov.in/index1.php?lang=1&level=2&sublinkid=824&lid=220&utm_source=copilot.com.
- [15] World Immunization Day 2024 India's Immunization Drive: A Commitment to Universal Vaccine Coverage and Health Equity, (n.d.). https://www.pib.gov.in/PressNoteDetails.aspx?NoteId=153405&ModuleId=3&utm_source=copilot.com®=3&lang=2.
- [16] Union Ministry of Health and Family Welfare; Government of India, (n.d.). <https://ncvbdc.mohfw.gov.in/index4.php?lang=1&level=0&linkid=405&lid=3681>.
- [17] National Tuberculosis Elimination Programme, (n.d.). <https://dghs.mohfw.gov.in/national-tuberculosis-elimination-programme.php>.
- [18] National AIDS Control Organisation, (n.d.). <http://naco.gov.in/>.
- [19] Delivering quality health services: a global imperative for universal health coverage, (n.d.). <https://www.who.int/publications/i/item/9789241513906>.
- [20] R.T. Petroze, J.C. Byiringiro, G. Ntakiyiruta, S.M. Briggs, D.L. Deckelbaum, T. Razek, R. Riviello, P. Kyamanywa, J. Reid, R.G. Sawyer, J.F. Calland, Can Focused Trauma Education Initiatives Reduce Mortality or Improve Resource Utilization in a Low-Resource Setting?, *World J. Surg.* 39 (2015) 926–933. <https://doi.org/10.1007/s00268-014-2899-y>.
- [21] Update on Maternal and Child Health Indicators under NHM, (n.d.). <https://www.mohfw.gov.in/?q=en/pressrelease/update-maternal-and-child-health-indicators-under-nhm>.
- [22] T. Statistics, Ministry of Tourism GOVERNMENT OF INDIA Ministry of Tourism GOVERNMENT OF INDIA INDIA TOURISM STATISTICS, (2021).
- [23] A. Jain, P. Singh, Laboratory Accreditation Framework in India (QCI / NABL), 20 (2024) 158–168.
- [24] Monitoring health for the SDGs, (n.d.). https://www.who.int/data/gho/data/themes/sustainable-development-goals?utm_source=copilot.com.
- [25] Healthcare services, (n.d.). https://www.iso.org/sectors/health/care-services?utm_source=copilot.com.
- [26] ICMED Certification, (n.d.). <https://ipc.gov.in/mandates/indian-pharmacopoeia/monographs/monographs-under-preparation/8-category-en/1146-icmed-certification.html>.
- [27] I. Council, O.F. Medical, Indian Council for Medical Research: National Ethical

- Guidelines for Biomedical and Health Research Involving Human Participants, 2017, 2018.
- [28] UNICEF, Responding to Covid-19 Annual Report, 2020.
- [29] M.E. Kruk, A.D. Gage, N.T. Joseph, G. Danaei, S. García-Saisó, J.A. Salomon, Mortality due to low-quality health systems in the universal health coverage era: a systematic analysis of amenable deaths in 137 countries, *The Lancet* 392 (2018) 2203–2212. [https://doi.org/10.1016/S0140-6736\(18\)31668-4](https://doi.org/10.1016/S0140-6736(18)31668-4).
- [30] K.E. Solberg, Trade in medical waste causes deaths in India., *Lancet* 373 (2009) 1067. [https://doi.org/10.1016/S0140-6736\(09\)60632-2](https://doi.org/10.1016/S0140-6736(09)60632-2).
- [31] India battles black market in used gloves and masks, (n.d.). <https://www.france24.com/en/20200828-india-battles-black-market-in-used-gloves-and-masks>.
- [32] Smt.Anushree Jain vs Ministry Of Health And Family Welfare on 11 November, 2011, n.d. <https://indiankanoon.org/doc/406094/>.
- [33] Bombay HC pulls up Centre for ‘virtually defending’ manufacturers of ‘defective’ Marathwada ventilators, (n.d.). <https://indianexpress.com/article/cities/mumbai/hc-pulls-up-centre-for-defending-manufacturers-of-defective-ventilators-supplied-to-marathwada-7334402/>.
- [34] A.K. Jha, I. Larizgoitia, C. Audera-Lopez, N. Prasopa-Plaizier, H. Waters, D.W. Bates, The global burden of unsafe medical care: analytic modelling of observational studies, *BMJ Qual. Saf.* (2013) bmjqs-2012-001748. <https://doi.org/10.1136/bmjqs-2012-001748>.
- [35] WHO calls for urgent action to reduce patient harm in healthcare, (n.d.).
- [36] T.A. Brennan, A.R. Localio, L.L. Leape, N.M. Laird, L. Peterson, H.H. Hiatt, B.A. Barnes, Identification of Adverse Events Occurring during Hospitalization, *Ann. Intern. Med.* 112 (1990) 221–226. <https://doi.org/10.7326/0003-4819-112-3-221>.
- [37] J.G. Anderson, K. Abrahamson, Your Health Care May Kill You: Medical Errors., *Stud. Health Technol. Inform.* 234 (2017) 13–17. <http://www.ncbi.nlm.nih.gov/pubmed/28186008>.
- [38] E.C. Monteiro, L.F. Leon, Metrological Reliability of Medical Devices, *J. Phys. Conf. Ser.* 588 (2015) 012032. <https://doi.org/10.1088/1742-6596/588/1/012032>.
- [39] Medical devices: managing the mismatch: an outcome of the priority medical devices project, (n.d.). <https://www.who.int/publications/i/item/9789241564045>.
- [40] Medical device regulations, (n.d.).

- <https://wkc.who.int/resources/publications/i/item/9241546182>.
- [41] India imports 80% of its requirement of medical devices: MoS Ashwini Choubey, (n.d.). <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/india-imports-80-of-its-requirement-of-medical-devices-mos-ashwini-choubey/articleshow/80885094.cms>.
- [42] Health Ministry Notifies Medical Devices Rules, 2017, n.d. <https://www.pib.gov.in/newsite/printrelease.aspx?relid=157955®=3&lang=2>.
- [43] GOVERNMENT OF INDIA DEPARTMENT OF ATOMIC ENERGY, n.d. <https://www.barc.gov.in/about/07.pdf>.
- [44] J. Jeevanandam, A. Barhoum, Y.S. Chan, A. Dufresne, M.K. Danquah, Review on nanoparticles and nanostructured materials: history, sources, toxicity and regulations, *Beilstein Journal of Nanotechnology* 9 (2018) 1050–1074. <https://doi.org/10.3762/bjnano.9.98>.
- [45] S. Soares, J. Sousa, A. Pais, C. Vitorino, Nanomedicine: Principles, Properties, and Regulatory Issues, *Front. Chem.* 6 (2018). <https://doi.org/10.3389/fchem.2018.00360>.
- [46] R. Foulkes, E. Man, J. Thind, S. Yeung, A. Joy, C. Hoskins, The regulation of nanomaterials and nanomedicines for clinical application: current and future perspectives, *Biomater. Sci.* 8 (2020) 4653–4664. <https://doi.org/10.1039/D0BM00558D>.
- [47] Competition Commission of India, Annual Report 2018-19, n.d. <https://doi.org/https://www.cci.gov.in/public/images/annualreport/en/3-annual-report-2018-191652253330.pdf>.
- [48] J. RP, FALSE DIAGNOSIS IS A THREAT - A CASE STUDY, *Asian Journal of Pharmaceutical and Clinical Research* (2019) 1–2. <https://doi.org/10.22159/ajpcr.2019.v12i2.27886>.
- [49] Bad blood: how India's uncontrolled pathology labs put you at risk, (n.d.). <https://economictimes.indiatimes.com/prime/pharma-and-healthcare/bad-blood-how-indias-uncontrolled-pathology-labs-put-you-at-risk/primearticleshow/68587067.cms?from=mdr>.
- [50] Plasma Diagnostic lab in Patna involved in selling fake RTPCR reports, (n.d.). https://www.business-standard.com/article/current-affairs/plasma-diagnostic-lab-in-patna-involved-in-selling-fake-rtpcr-reports-121093000317_1.html.
- [51] D raids 5 labs for allegedly issuing fake COVID tests during Kumbh Mela; seizes Rs 30 lakh, (n.d.). <https://www.republicworld.com/india/ed-raids-5-labs-for->

allegedly-issuing-fake-covid-tests-during-kumbh-mela-seizes-rs-30-lk.

- [52] Pune: Three nabbed for issuing fake RT-PCR test reports, (n.d.). <https://timesofindia.indiatimes.com/city/pune/3-nabbed-for-issuing-fake-rt-pcr-test-reports/articleshow/82360742.cms>.
- [53] Lab technician arrested in Hyderabad for issuing fake RT-PCR reports, (n.d.). <https://www.deccanchronicle.com/nation/in-other-news/280521/lab-technician-arrested-in-hyderabad-for-issuing-fake-rt-pcr-reports.html>.
- [54] NABL, a voluntary accreditation body, has no regulatory powers: N Venkateshwaran, CEO, (n.d.). <https://www.moneycontrol.com/news/business/companies/nabl-a-voluntary-accreditation-body-has-no-regulatory-powers-n-venkateswaran-ceo-7449571.html>.
- [55] V. Patel, R. Parikh, S. Nandraj, P. Balasubramaniam, K. Narayan, V.K. Paul, A.K.S. Kumar, M. Chatterjee, K.S. Reddy, Assuring health coverage for all in India, *The Lancet* 386 (2015) 2422–2435. [https://doi.org/10.1016/S0140-6736\(15\)00955-1](https://doi.org/10.1016/S0140-6736(15)00955-1).
- [56] Ministry of Health & Family Welfare Initiatives & Achievements-2023, n.d. <https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=1990674®=3&lang=2>.