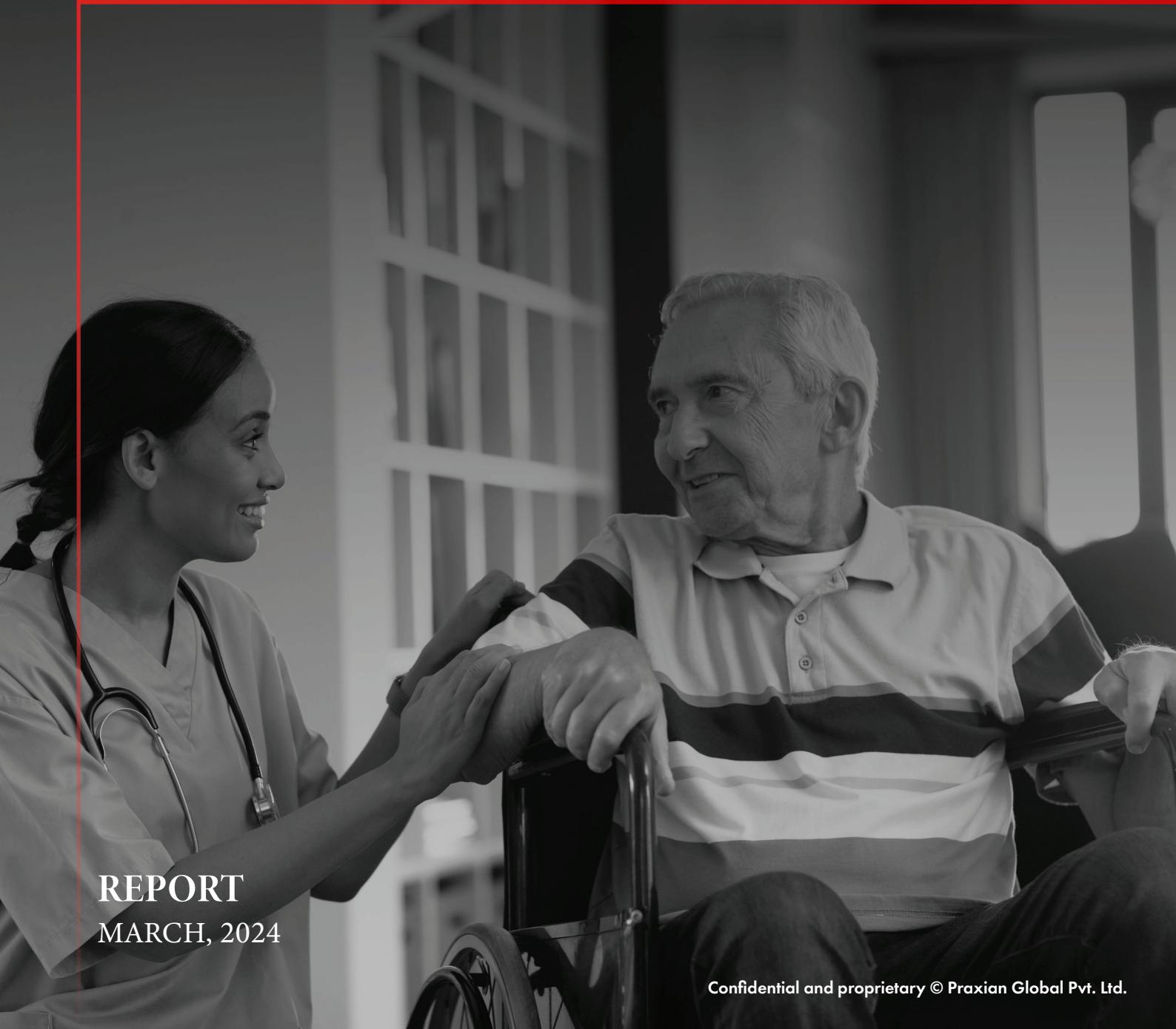


FORGING A SAFER FUTURE

India's blueprint for patient safety excellence



REPORT
MARCH, 2024

Foreword



Jaxay Shah

Chairperson

Quality Council of India (QCI)

In the healthcare system, quality healthcare, and patient safety stand as a cornerstone of progress and human well-being. In today's world, a quality healthcare ecosystem is of paramount importance. It encompasses not only the credibility and access of hospitals but also the safety of patients. Quality healthcare goes beyond the confines of medical interventions; it encompasses the entire patient experience; from the moment they seek care to their journey toward recovery and beyond. It is a commitment to excellence, driven by evidence-based practices, continuous improvement, and a deep sense of compassion and empathy for those entrusted to our care.

Patient safety is not a mere aspiration but an imperative, demanding a culture of transparency, accountability, and constant vigilance in identifying and addressing potential hazards. Health is Wealth, as rightly stated in our rich cultural ethos, resonates with our dedication to safeguarding the sanctity of human life through healthcare.

The pursuit of patient safety demands collective action. NATHEALTH, in collaboration with NABH and QCI, is ensuring that patient safety is preeminent in every healthcare center in India. It is crucial to ensure the well-being and safety of patients across the entire value chain of the healthcare ecosystem through rigorous accreditation processes, quality improvement initiatives, and greater accountability mechanisms.

I am hopeful that through the collaboration between NATHEALTH and NABH, significant strides will be made in ensuring patient safety in healthcare institutions. On the journey toward a patient-centric healthcare system, it is essential to leverage our collective expertise and drive transformative change. Mahatma Gandhi once said, "It is health that is real wealth and not pieces of gold and silver." Embracing this wisdom, our mission aligns with the grand vision of Viksit Bharat, wherein every individual's health is a priority in our nation's march towards Amrit Kaal.

Together, let us endeavor to create a healthcare environment where the safety and well-being of every patient are upheld as the highest priorities, ensuring a brighter and healthier future for all in achieving Viksit Bharat.

Jai Hind!

Foreword



Dr. Narottam Puri

Principal Advisor, Quality Council of India
Advisor (Medical), Fortis Healthcare Ltd.
Advisor (Health Services & MVT), FICCI

Safety is defined as not being in danger or as a state of being safe. Obviously, patient safety is of paramount importance not only to the receiver but also to the provider of care in a hospital setting. This is because hospitals are recognized as riskier than bungee jumping and mountain climbing.

While we recognize the gravity of the situation, the efforts to mitigate the risks suffer from inadequacies. Poor information regarding gravity is not only confined to the public but also to medical and nursing students, and often to practicing doctors. Part of this is due to scant data in our country, inadequate data analysis, and subsequent action based on the data.

Simple mitigating measures like compliance with proper hand hygiene, medication reconciliation and administration, correct patient and correct site identification can avoid a lot of unsavory episodes.

Huge patient inflows causing time constraints, complexities of management, staff training, and poor communication are some of the factors that result in harm.

WHO has identified Patient Safety Goals and it is important that these are implemented in letter and spirit.

I am delighted to be associated with NATHEALTH's commitment to being an active participant in ensuring the safety of our patients and medical community.

Wish NATHEALTH all the success it deserves.

Foreword



Dr. Ashutosh Raghuvanshi

President, NATHEALTH

MD & CEO, Fortis Healthcare Ltd.

As President of NATHEALTH and MD & CEO of Fortis Healthcare Limited, I am proud to introduce "**Forging a Safer Future: India's Blueprint for Patient Safety Excellence**," a collaborative effort with NABH, NATHEALTH, and Praxis Global Alliance. This white paper represents a crucial step towards enhancing patient safety in India, offering a detailed overview of the current landscape, challenges, and actionable recommendations for improvement.

With contributions from healthcare professionals nationwide, this document underscores the need for a collaborative approach to bolster patient safety, highlighting key areas such as data infrastructure, workforce development, patient empowerment, and technology use. It also stresses the importance of policy reforms and adequate resource allocation.

This initiative aligns with our commitment to high-quality, safe healthcare services and acts as a call to action for all stakeholders in the healthcare sector. It represents our collective determination to ensure healthcare safety for every patient in India.

I am confident that the insights and strategies outlined here will significantly advance our patient safety efforts. Together, we are on a journey towards a future where exceptional patient safety is a reality for all.

Foreword



Dr. Atul Mohan Kochhar

MD, DNB, MNAMS, FAAD
CEO, NABH

In today's rapidly evolving healthcare landscape, unintended harm is still a constant and leading cause of morbidity and mortality which reveals that ensuring patient safety is paramount. As the healthcare industry continues to advance, so must our commitment to providing the highest standards of care and protection for those we serve.

At the National Accreditation Board for Hospitals & Healthcare Providers (NABH), our mission is to promote and enhance the quality of healthcare delivery in India. We recognize that patient safety is not merely a goal, but a fundamental principle that must guide every aspect of our work. It is imperative that patients and their families feel confident in the care they receive, knowing that their well-being is our top priority.

As leaders in the healthcare industry, both NABH and NATHEALTH have long been champions of healthcare quality and patient safety, advocating for rigorous standards and continuous improvement in healthcare delivery. It is with great pleasure and pride that I extend my heartfelt congratulations to NATHEALTH on the release of this groundbreaking whitepaper on patient safety. This whitepaper represents a significant milestone in our collective efforts to advance the cause of patient safety and quality care across India's healthcare landscape.

This whitepaper serves as a comprehensive guide to understanding the intricacies of patient safety within the healthcare ecosystem. It explores the latest research, best practices, and innovative strategies aimed at mitigating risks and preventing harm to patients. By equipping healthcare professionals with the knowledge and tools necessary to optimize patient safety, we can foster a culture of continuous improvement and accountability across the industry. The insights and recommendations presented in this whitepaper are a testament to the dedication and expertise of the individuals and organizations involved. I am sure that this document serves as a valuable resource for healthcare providers, policymakers, and stakeholders alike.

As we navigate the challenges and opportunities of modern healthcare, collaboration and communication are essential. I commend the authors, researchers, and industry experts who have contributed their insights to this whitepaper. Together, we can uphold the highest standards of patient safety and ensure that every individual receives the quality care they deserve. Your dedication to improving patient safety is truly commendable, and I am confident that your insights will inspire positive action and innovation in the years to come.

I commend NATHEALTH for their unwavering commitment to advancing healthcare in India and for their partnership in this important endeavor. By joining forces, we can amplify our impact and drive meaningful change in patient safety practices nationwide.

I invite healthcare providers, policymakers, and stakeholders alike to join us in our ongoing efforts to prioritize patient safety. Together, we can make a meaningful difference in the lives of those we serve, advancing the collective goal of achieving excellence in healthcare delivery and taking the Quality, Safety and Wellness to the last man in the line.

Jai Hind.

Praxis Note



Aryaman Tandon

Managing Partner & Cofounder
Praxis Global Alliance

The pursuit of a safer healthcare environment for all patients in India has been a continuous journey. Our firm has embarked on a comprehensive nationwide assessment of patient safety practices, culminating in this white paper. Through a rigorous assessment involving 1,125 healthcare professionals across diverse roles and regions, coupled with in-depth interviews with industry leaders and experts, we have gained valuable insights into the current state of patient safety in India.

This white paper acknowledges the commendable strides India has taken with initiatives like NABH, NABL, and NQAS. However, significant challenges remain. Our analysis reveals a spectrum of issues, ranging from staffing limitations and communication gaps to a lack of robust safety culture, inadequate patient empowerment, and resource constraints, further amplified by the looming threat of antimicrobial resistance.

Recognizing the urgency for improvement, this white paper presents a comprehensive nine-lever strategic approach. This framework encompasses collaborative leadership, data infrastructure, workforce development, patient empowerment, communication, technology integration, policy reforms, public awareness, and resource allocation. Each lever is meticulously designed to address specific aspects of patient safety, fostering a holistic and sustainable transformation. The white paper goes beyond proposing a framework. It outlines a detailed implementation roadmap, defining achievable goals, timelines, and the critical roles of key stakeholders – including the QCI, NABH, NABL, and NATHEALTH among others. This roadmap serves as a blueprint for driving patient safety excellence, aligning with global standards and contributing to India's national healthcare goals.

As we navigate the complexities of the Indian healthcare landscape, a collective effort is imperative. We must embrace a culture of shared responsibility, continuous learning, and a relentless pursuit of excellence in patient safety. Only through a concerted effort involving healthcare professionals, regulatory bodies, industry associations, government agencies, and the broader community can we truly transform patient safety practices and ensure the well-being of every individual entrusted to our care.

We, at Praxis Global Alliance, extend our gratitude to the numerous stakeholders who contributed their invaluable insights and expertise to this endeavor. Together, we can pave the way for a safer, more equitable, and patient-centric healthcare system that upholds the highest standards of quality and safety.

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Name	Organization	
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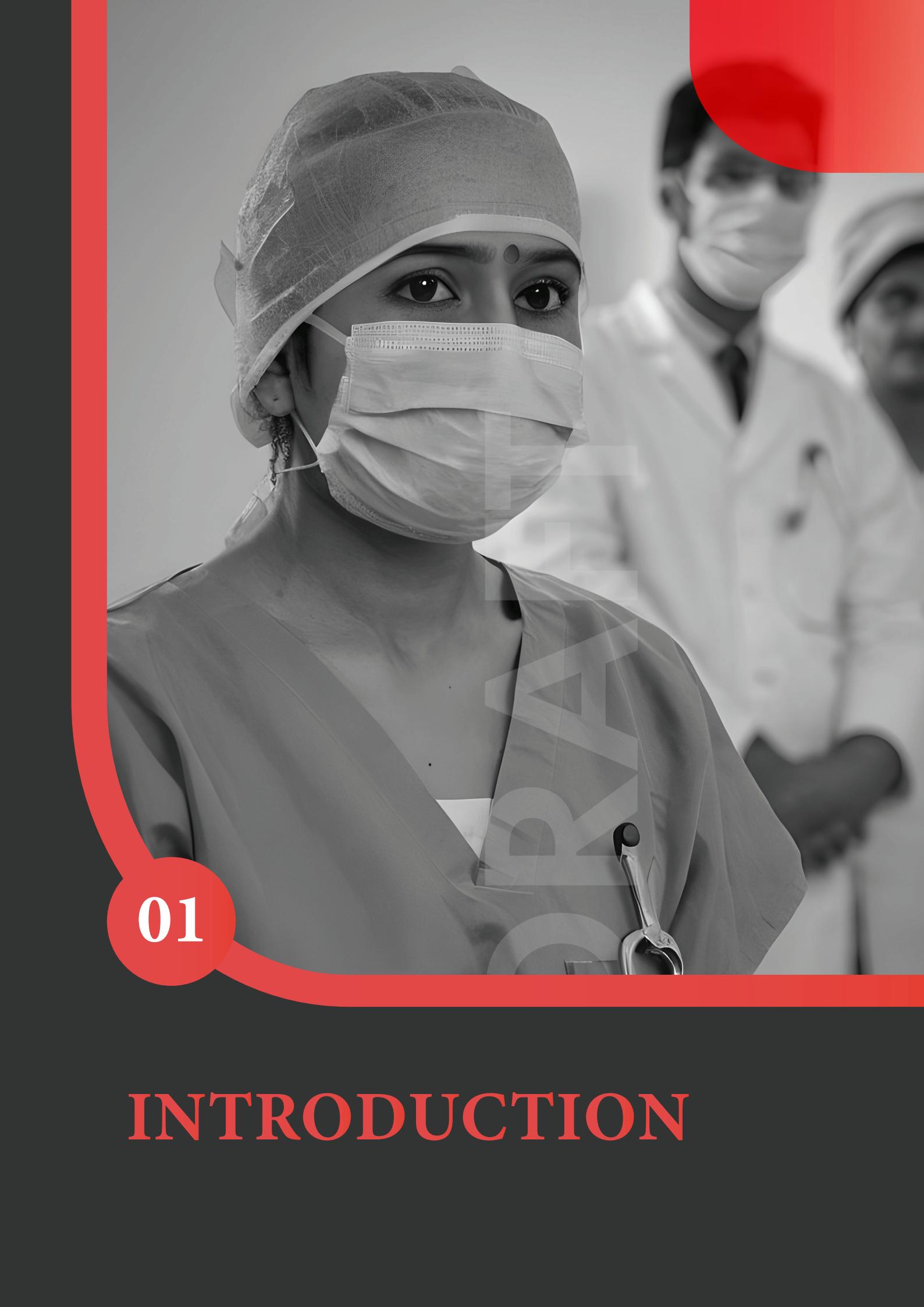
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Glossary of terms

Acronym	Description
AEMT	Adverse Effects of Medical Treatment
AMR	Antimicrobial Resistance
ASSOCHAM	The Associated Chambers of Commerce and Industry of India
BCMA	Bar Code Medication Administration
CDSCO	Central Drugs Standard Control Organisation
CHC	Community Health Center
CII	Confederation of Indian Industry
CHC	Community Health Centre
CMS	Centers for Medicare & Medicaid Services
CSO	Civil Society Organization
DALY	Disability-Adjusted Life Years
DHC	District Health Center
EPS	Electronic Prescribing Service
FICCI	Federation of Indian Chambers of Commerce & Industry
HCP	Healthcare Provider
ICD-10	International Classification of Diseases, 10 th Revision
IRDA	Insurance Regulatory and Development Authority
IPHS	Indian Public Health Standards
IPSG	International Patient Safety Goals
ISQua	International Society for Quality in Health Care
JCI	Joint Commission International
MOHFW	Ministry of Health and Family Welfare
MusQan	Mission Quality for the provision of quality child-friendly services
NABH	National Accreditation Board for Hospitals
NABL	National Accreditation Board for Testing and Calibration Laboratories
NAP-AMR	National Action Plan on Antimicrobial Resistance
NATHEALTH	Healthcare Federation of India
NHA	National Health Authority
NQF	National Quality Forum
NHM	National Health Mission

NHSRC	National Health Systems Resource Centre
NQAP	National Quality Assurance Program
NQAS	National Quality Assurance Standards
NPSC	National Patient Safety Council
NPSIF	National Patient Safety Implementation Framework
PAG	Patient Advisory Group
PFAC	Patient and Family Advisory Councils
PFPS	Patients for Patient Safety
PHC	Primary Health Center
PHF	Public Health Facility
PvPI	Pharmacovigilance Programme of India
QCI	Quality Council of India
QSEN	Quality and Safety Education for Nurses
RUP	Re-use Prevention
SaQushal	Safety and Quality, Self-Assessment Tool for Health Facilities
SDI	Socio-demographic Index
TEG	Technical Expert Group
UHC	Universal Health Coverage
UT	Union Territory
WHO	World Health Organization



01

INTRODUCTION

1.0 INTRODUCTION

Patient safety is a key dimension of healthcare quality, standing alongside accessibility, acceptability, effectiveness, affordability, efficiency, and people-centeredness. Ensuring patient safety is at the core of providing quality healthcare. It involves safeguarding patients from any avoidable harm or potential risks associated with medical treatment.

Exhibit 1

Key patient safety components

	Description
Physical safety	→ Involves designing, planning, and maintaining hospital infrastructure, addressing critical aspects such as the location of departments, safety of electrical installations, etc.
Safety of engineering and other services	→ Involves proper installation and maintenance of equipment , regular inspections, mandatory alternate electric supply, and emergency systems for critical areas like ICU
Fire safety and safe environment in hospital	→ Includes availability of fire extinguisher, fire exit plan, training, and mock drill of staff for using firefighting equipment and evacuation
Clinical care safety	→ Involves rigorous infection prevention practices , including proper handwashing, sterilization of instruments, and use of personal protective equipment

Location of vital departments, regular maintenance, and fire preparedness are crucial for physical safety. Ensuring **proper electrical wiring, water supply, and acoustics** falls under engineering and service safety. Also, having a fire safety plan is an important aspect of addressing the safety concerns inside a hospital. Clinical care safety prioritizes infection control and medication error reduction, which are significant concerns in India. Studies reveal high rates of medication errors and hospital-acquired infections, necessitating focused efforts to create a safer healthcare environment.

1.1 Understanding patient safety and its definition

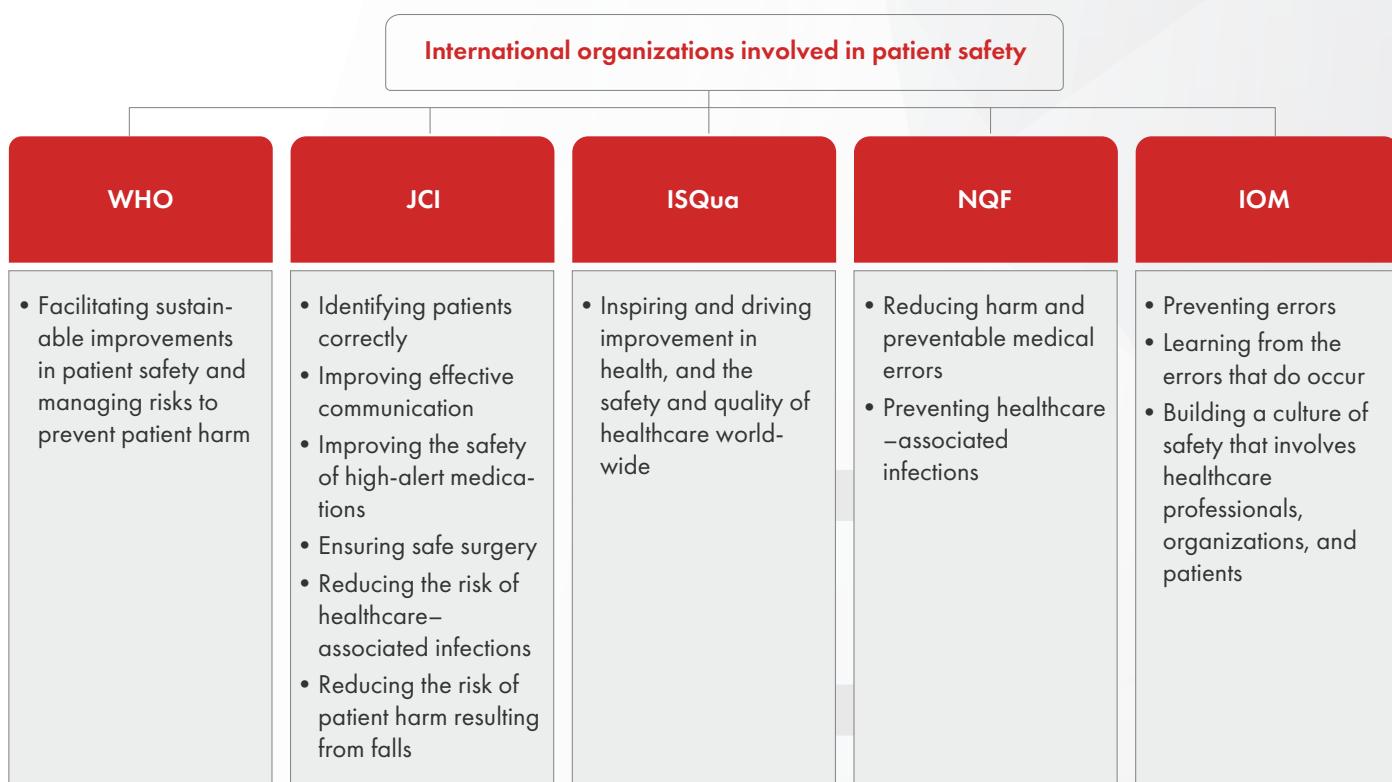
Several international organizations, such as the WHO, JCI, ISQua, National Quality Forum, and World Alliance for Patient Safety, are involved in promoting patient safety across the globe.

According to WHO, patient safety is defined as **“the absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with health care to an acceptable minimum.”**



Exhibit 2

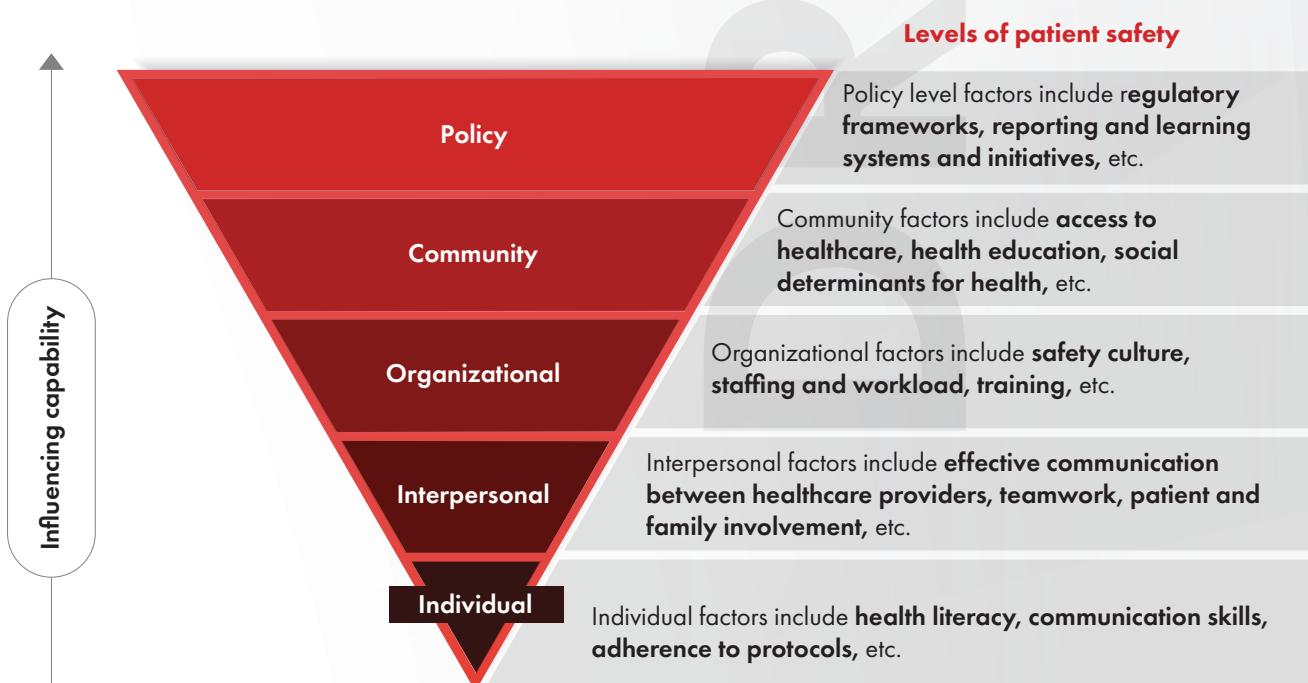
International organizations involved in patient safety and their key objectives



Patient safety is not only about the patient/individual but also about the entire system's involvement in patient safety. These include patient safety levels/factors – individual, interpersonal, organizational, community, and policy.

Exhibit 3

Levels of patient safety



The impact of safety lapses is particularly high in low and middle-income countries, including India. As per the WHO research, these lapses contribute to an alarming **134M** adverse events annually in low and middle-income countries, leading to **2.6M deaths**. In high-income countries, around **1 in every 10** patients is harmed in healthcare. **Above 50% of harm** (1 in every 20 patients) is preventable; half of this preventable harm is attributed to medications.

1.2 Patient safety aspects – Clinical and product safety

Exhibit 4

Patient safety aspects – Clinical and product safety

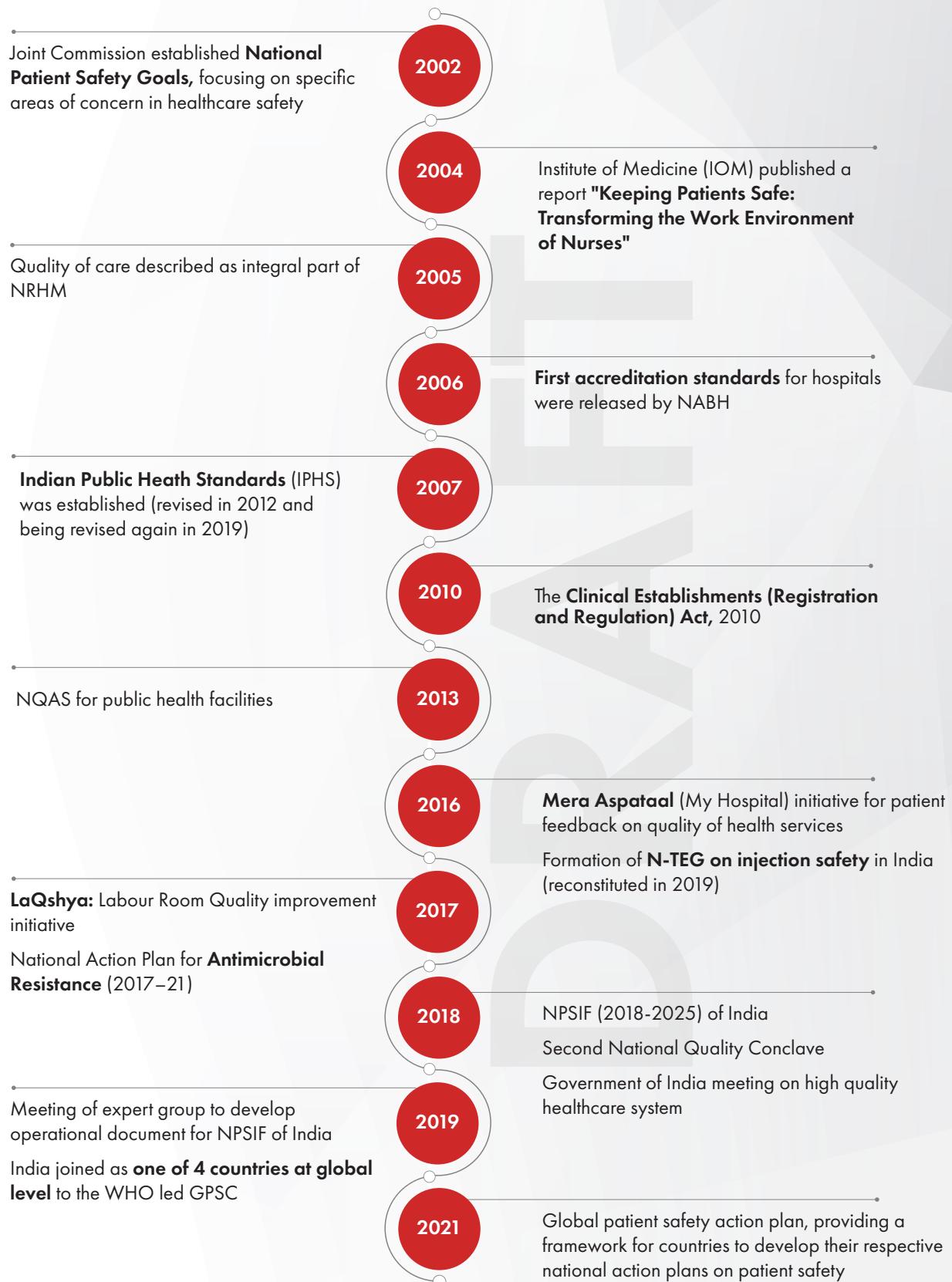


This concept encompasses clinical and product aspects of healthcare, such as safe surgical procedures, secure childbirth, injection safety, blood safety, medication safety, and the safety of medical devices. It also extends to ensuring the safety of organ, tissue, and cell transportation and donation, as well as the proper management of biomedical waste. Addressing patient safety involves preventing healthcare-associated infections and addressing issues related to unsafe clinical practices, inadequate processes, and inefficient systems. Patient safety data tracks incidents and perceptions to identify areas for improvement in preventing healthcare errors and harm to patients.

1.3 Evolution of patient safety

Exhibit 5

Evolution of patient safety



The Joint Commission established **National Patient Safety Goals** in **2002**, focusing on specific areas of concern in healthcare safety. The NQF endorsed a list of serious reportable events in 2002, leading to the identification of Never Events*, which became the basis for changes in reimbursement policies by CMS in 2008.

Other prominent initiatives include the **"Keeping Patients Safe: Transforming the Work Environment of Nurses" report published in 2004**, and the **QSEN project, initiated in 2006**. International organizations initiatives such as PFPS, established by WHO in 2005, engage patients and families globally to advocate for safer, people-centered healthcare. WHO's ongoing efforts include the Global Patient Safety Network and initiatives like the Medication Without Harm Challenge. JCI sets global patient safety standards with its IPSGs for 2023. The purpose of the six IPSGs is to promote specific improvements in patient safety.

Exhibit 6

JCI's six IPSGs

1	Identify patients correctly	This goal stresses the importance of using two identifiers for accurate patient identification , enhancing safety through standardized processes and staff training
2	Improve effective communication	This goal aims to reduce medical errors by establishing clear communication processes and fostering a culture of openness among healthcare staff
3	Improve the safety of high-alert medications	This goal minimizes risks by implementing stringent safety protocols , reducing medication errors , and enhancing patient safety
4	Ensure safe surgery	This goal focuses on checklists , patient consent , and teamwork to minimize surgical risks and enhance patient safety
5	Reduce the risk of healthcare-associated infections	This goal aims to prevent infections in healthcare settings through measures like hand hygiene , infection control rules , and surveillance
5	Reduce the risk of patient harm resulting from falls	This goal aims to prevent patient harm from falls by identifying risk factors and implementing individualized prevention plans in healthcare settings

Note(s): *Never Events or Serious Reportable Events is a compilation of serious, largely preventable, and harmful clinical events, designed to help the healthcare field assess, measure, and report performance in providing safe care



02



PATIENT SAFETY IN INDIA

2.0 PATIENT SAFETY IN INDIA

2.1 Current state of patient safety

Exhibit 7

Benchmarking India's patient safety indicators against key economies

Metrics	Units	Norway	Canada	UK	Australia	USA	India
Deaths due to AEMT, 2019	% of total deaths	0.07	0.14	0.20	0.22	0.17	0.35
DALYs due to AEMT, 2019	% of total DALYs	0.05	0.12	0.13	0.16	0.16	0.22
Maternal mortality rate, 2020	Per 100K live births	2.00	11.00	10.00	3.00	21.00	103.00
Neonatal mortality rate, 2021	Per 1K live births	1.29	3.41	2.80	2.37	3.27	19.12
Patients reporting medication-related mistake, 2020	% of total population	7.40	5.10	3.70	3.00	5.20	9.50
Treatable mortality rate, 2020	Per 100K population	51.00	58.00	71.00	47.00	98.00	180.00*

Low  High

Note(s): *data as of 2018

Source(s): GBD, OECD, WHO, Praxis analysis

The study on the effects of adverse events in medical treatment upon patient safety for the year 2019 reveals that India lags behind other countries both in comparison as well as in the global average for both deaths and DALYs due to AEMT. The deaths due to AEMT in India were estimated to be **0.35%** of the total deaths in 2019, whereas the global average stood at merely **0.21%**. Similar trends are seen in the DALYs due to AEMT, where India's DALYs were estimated at **0.22%** of total DALYs, significantly higher than the global average of DALYs as a percentage of total DALYs, which stood at **0.16%**. The maternal mortality rate in India was **103 per 100K live births**, substantially higher compared to developed countries, for which the rate was **less than 5 per 100K live births**. The neonatal mortality rate in India was reported to be 19.12, higher than in other developed countries. **9.5%** of the total population reported medication-related mistakes in India, while the treatable mortality rate stood at **180 per 100K population** in India, much higher than in developed countries, indicating the need for proper patient safety protocols.

2.2 Regulatory bodies and standards

Exhibit 8

Accreditation bodies and regulations

Accreditation bodies and regulations

Associated bodies	NABH	<ul style="list-style-type: none"> Formulates and implements accreditation initiatives for hospitals and healthcare organizations Defines benchmarks for the advancement of the health industry in terms of safety and quality of care Indicates quality indicators such as monitoring of medication error rate, % of adverse drug reactions, etc.
	NABL	<ul style="list-style-type: none"> Accredits medical laboratories in India, ensuring adherence to international standards for testing quality and reliability Enhances accuracy and reliability of diagnostic tests which contributes to accurate diagnoses, improved patient safety and quality of care
	NHSRC	<ul style="list-style-type: none"> National Health Mission initiatives like National Quality Assurance Standards, Kayakalp, and LaQshya focus on patient safety parameters: medication safety, surgical safety, infection prevention, etc.
	TEG	<ul style="list-style-type: none"> Focuses on injection safety, including healthcare waste management Aims to diminish the reuse of injection equipment by introducing safety-engineered devices
	CDSCO	<ul style="list-style-type: none"> Thorough review process which prevents harmful drugs, safeguarding patients, and ensuring effective treatments Monitors drug safety by analyzing adverse reactions reported by healthcare professionals and patients

Regulations	Clinical Establishments Act, 2010	<ul style="list-style-type: none"> Facilitates the registration and regulation of all clinical establishments nationwide Ensures that the security and safety of the patients, staff, visitors is mandated through the safety installations
	Pharmacy practice regulations, 2015	<ul style="list-style-type: none"> Involves the compounding and labeling of drugs and devices, excluding labeling by manufacturers, repackers, or distributors of non-prescription drugs and commercially packaged legend drugs and devices
	Drug & Cosmetics act 1940	<ul style="list-style-type: none"> Governs the import, manufacturing, and distribution of drugs in India
	PvPI	<ul style="list-style-type: none"> Collects, compiles, and analyzes adverse events related to drugs, providing recommendations to the CDSCO for necessary regulatory actions
	IPHS	<ul style="list-style-type: none"> Established in 2007 as a reference for planning and upgrading healthcare infrastructure, ensuring uniform standards across sub-centers, PHCs, CHCs, sub-district, and district hospitals
	SaQushal	<ul style="list-style-type: none"> Evaluates hospitals from a patient safety standpoint, enhancing staff proficiency in patient safety Provides support to patients and their families in decision-making processes Reinforces evidence-based practices crucial for advancing patient safety and healthcare quality
	AMR Plan	<ul style="list-style-type: none"> Outlines strategic priorities and interventions from 2017–21 to tackle the public health threat of AMR Covers all five major objectives and the additional priority of strengthening India's leadership on AMR
	NPSIF	<ul style="list-style-type: none"> Elevates patient safety standards across all tiers of healthcare Cultivates a proficient and capable healthcare workforce

2.2.1 NABH

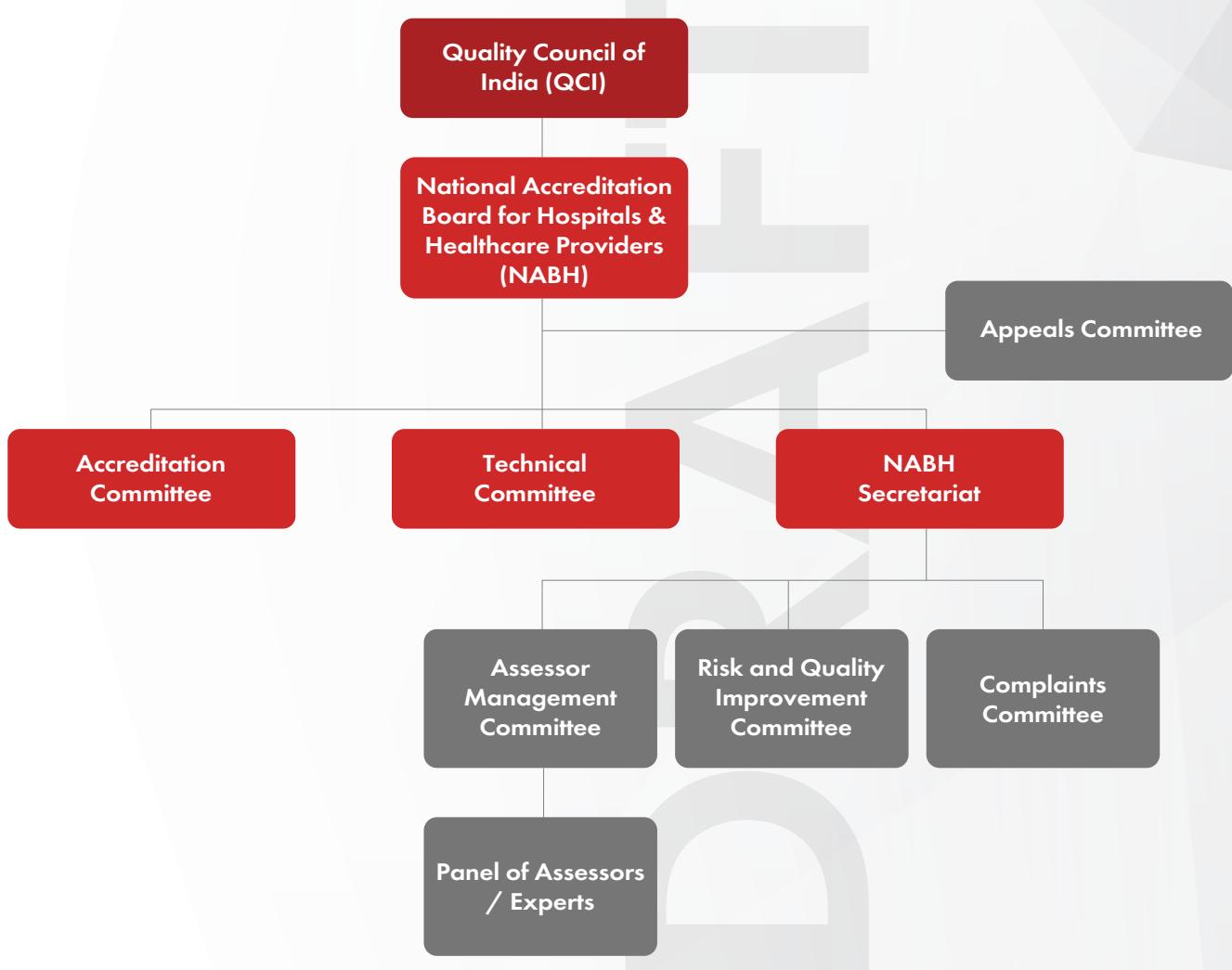
QCI is a non-profit and autonomous organization established in 1997 by the Indian government and industry associations such as **ASSOCHAM, CII, and FICCI**. QCI's main purpose is to drive quality movement across industries (including healthcare), provide accreditation, and establish credibility.

The NABH, an integral part of QCI, is tasked with **formulating and implementing accreditation initiatives** for hospitals and healthcare organizations, while also **defining benchmarks** for the advancement of the health industry in terms of safety and quality of care. Distinguished by its distinctive governing body, NABH includes representatives from various sectors, encompassing the Government of India, private hospitals, and key private associations such as CII, ASSOCHAM, and FICCI, among others.

NABH has indicated **quality indicators**, which a hospital preparing for accreditation must necessarily monitor. The total quality indicators listed as mandatory for the NABH accreditation are **32**.

Exhibit 9

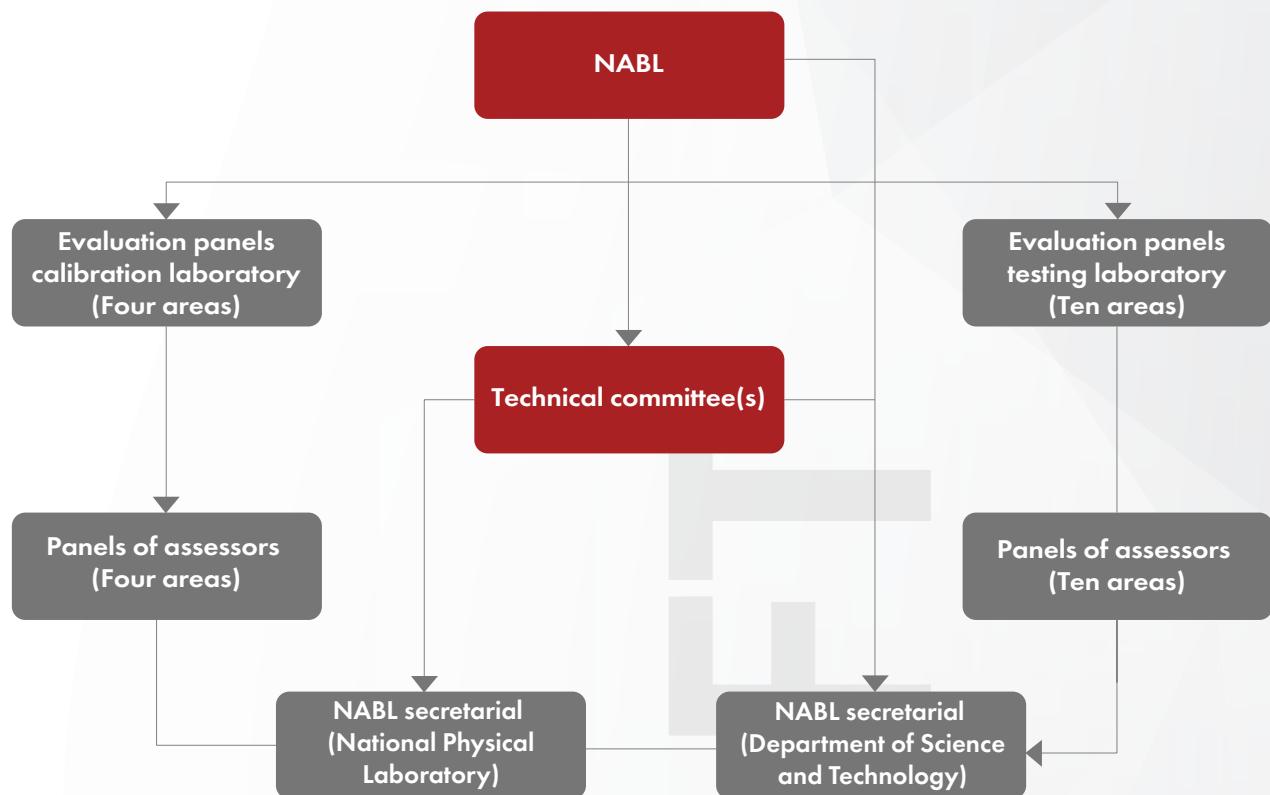
Hierarchical structure of NABH



2.2.2 NABL

NABL plays a significant role in ensuring patient safety in India by accrediting laboratories. NABL sets standards for the **competence**, **quality of testing**, and **calibration services** provided by laboratories across various sectors, including healthcare. By accrediting medical laboratories, NABL ensures that they adhere to international standards and best practices in testing methodologies, equipment calibration, and quality management systems. This accreditation process helps to enhance the reliability and accuracy of diagnostic tests conducted in medical laboratories, thereby contributing to improved patient safety and quality of care. Additionally, NABL accreditation provides assurance to patients, healthcare providers, and regulatory authorities regarding the reliability and competence of laboratory services, ultimately promoting confidence in the healthcare system.

Organization structure for policy implementation of NABL



2.2.3 NHSRC

Established in **2006**, the NHSRC's mandate is to assist in **policy and strategy development** in the provision and mobilization of technical assistance to the states.

Key values of NHSRC include:

- Promotes **health equity and well-being** for all people
- Promotes **engagement and partnership** across sectors to foster research by contributing to policies and strategies
- Ensures and improves **public health functions** through continuous monitoring, supportive supervision, and helping the states meet the standards
- **Strengthens, supports, and mobilizes** communities to improve health

2.2.4 TEG

The MOHFW established a TEG specifically focused on **injection safety**, including healthcare waste management in India. The **injection safety implementation project**, shared and discussed in the inaugural meeting of the **TEG on injection safety** in New Delhi on July 13, 2016, is a collaborative effort supported by the TEG and the Government of India. The project aims to **diminish the reuse of injection equipment** by introducing safety-engineered devices and addressing the issue of overused injections through a behavior change communication strategy. The Government of India has already advised the states to progressively shift the procurement in the government sector to **RUP syringes** in a phased manner, since 2018.

2.2.5 CDSCO

The CDSCO ensures patient safety in India through **rigorous processes**. It evaluates the **safety and efficacy of new drugs** before approval, **monitors adverse drug reactions** post-market, and **regulates pharmaceutical manufacturing standards** to prevent the distribution of substandard medications. CDSCO also **oversees clinical trials** to uphold ethical and safety standards and conducts public awareness campaigns to educate patients and healthcare professionals about medication safety. Through these efforts, CDSCO plays a pivotal role in safeguarding patient health and well-being in the country.

2.2.6 Clinical Establishments Act, 2010

The Parliament of India enacted the Clinical Establishments Act on August 17, 2010, to facilitate the **registration and regulation** of all clinical establishments nationwide. The overarching aim is to set forth **minimum standards** for the facilities and services offered by these establishments, aligning with the constitutional mandate outlined in Article 47. This constitutional directive emphasizes the imperative for enhancing public health, and the Clinical Establishments Act serves as a pivotal tool in realizing this goal by establishing comprehensive regulations for the healthcare sector. The Act applies to all kinds of clinical establishments in the public and private sectors, of all recognized systems of medicine including single-doctor clinics. The only exception is establishments run by the armed forces which are not regulated under this Act.

The Clinical Establishments Act also has regulations that ensure **the security and safety** of the patients, staff, visitors, and relatives as mandated through the safety installations and measures. The hospital is required to demonstrate preparedness for emergencies, both fire and non-fire, emphasizing safety for patients, attendants, staff, and visitors. Adherence to local fire safety laws is essential, covering prevention, detection, mitigation, evacuation, and containment. Staff training and documented mock drills are obligatory.

2.2.7 Pharmacy Practice Regulations, 2015

Pharmacy practice involves the **compounding and labeling** of drugs and devices, excluding labeling by manufacturers, repackers, or distributors of non-prescription drugs and commercially packaged legend drugs and devices. It also encompasses the **responsible and secure storage** of drugs and devices, along with the meticulous maintenance of accurate records.

The pharmacist's practitioners are currently licensed, registered, or otherwise authorized under the Act to counsel or otherwise administer drugs. They bear the responsibility of ensuring the safe, suitable, and cost-effective utilization of medications.

2.2.8 Drug & Cosmetics Act, 1940

The Drugs and Cosmetics Act of 1940, a legislation of the Indian Parliament, governs the **import, manufacturing, and distribution** of drugs in India. Its fundamental goal is to guarantee the safety, effectiveness, and adherence to state quality standards of drugs and cosmetics sold in the country. The regulation states that the surveillance of safety for Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homoeopathy drugs places legal responsibility on the drug manufacturer and marketer.

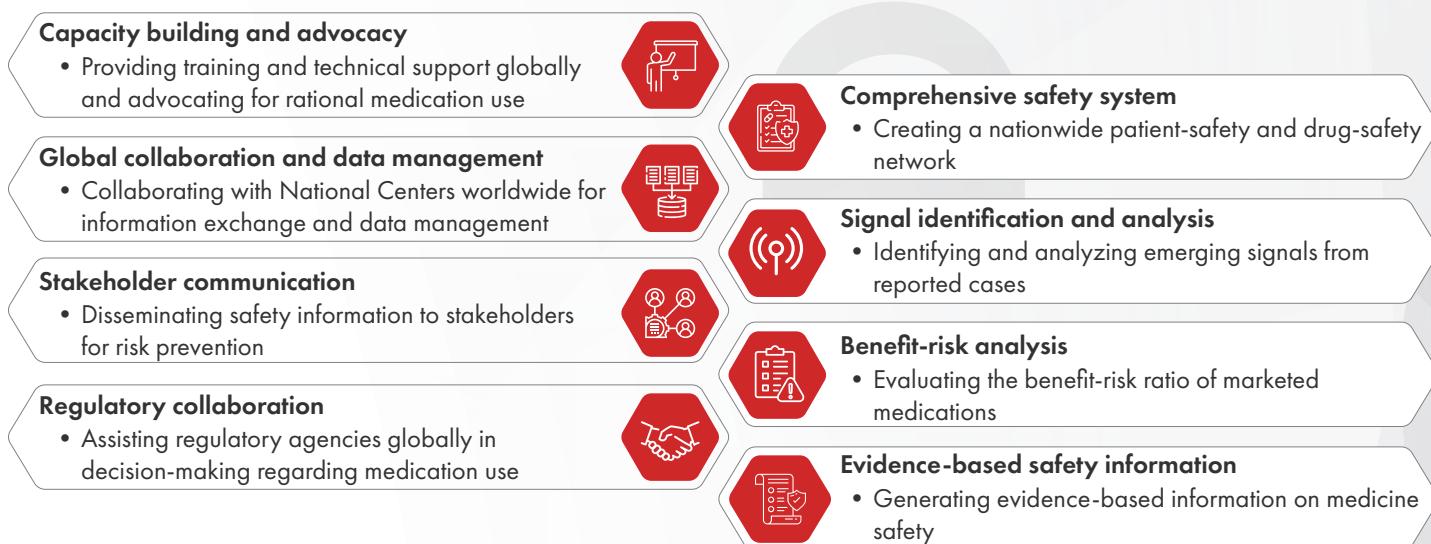
2.2.9 PvPI

The PvPI serves as the flagship **drug safety monitoring initiative** of the Government of India. It systematically **collects, compiles, and analyzes** adverse events related to drugs, providing recommendations to the CDSCO for necessary regulatory actions. The mission of this program is to safeguard the health of the Indian population by ensuring that the benefits of the medicine outweigh the risks associated with its use while the vision is to improve patient safety and the welfare of the Indian population by monitoring the safety of medicines, thereby reducing the risks associated with their use.

Exhibit 11

Key objectives of PvPI

PvPI objectives



2.2.10 IPHS

The IPHS were established in 2007 as a reference for **planning and upgrading healthcare infrastructure**, ensuring uniform standards across sub-centers, PHCs, CHCs, sub-district, and district hospitals. Revised IPHS guidelines, accommodating changing protocols and new programs, provide flexibility to meet diverse state needs, serving as a benchmark for continuous quality improvement. States and UTs are encouraged to adopt these guidelines to enhance public healthcare.

Exhibit 12

IPHS



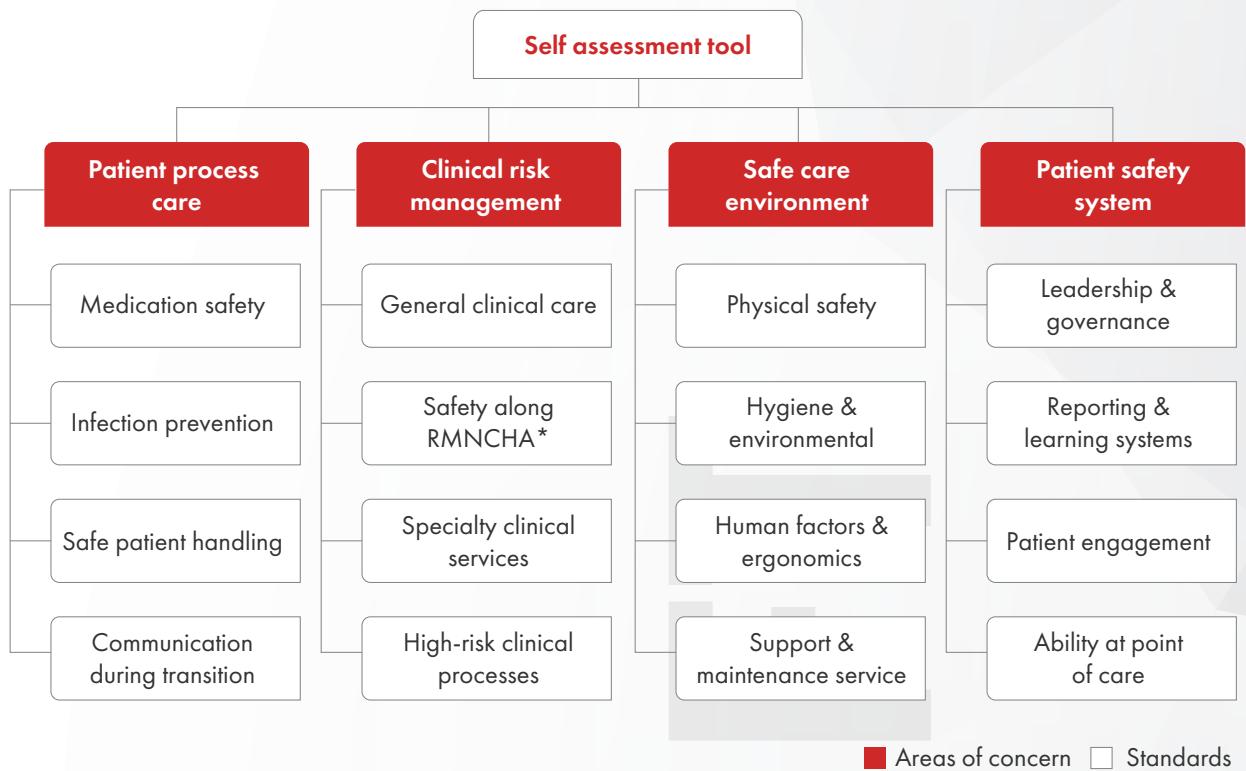
2.2.11 SaQushal

SaQushal is a self-assessment tool for hospitals and clinics to evaluate their performance on various safety and quality aspects. It helps to identify areas for improvement and implement corrective actions.

SaQushal encompasses four areas of concern: **safe patient care process, clinical risk management, safe care environment, and patient safety systems**. Each area of concern comprises four safety standards, delineating various parameters. In total, there are **sixteen standards**, providing a comprehensive overview.

Exhibit 13

SaQushal – Overview of areas of concern and standards of self-assessment tools



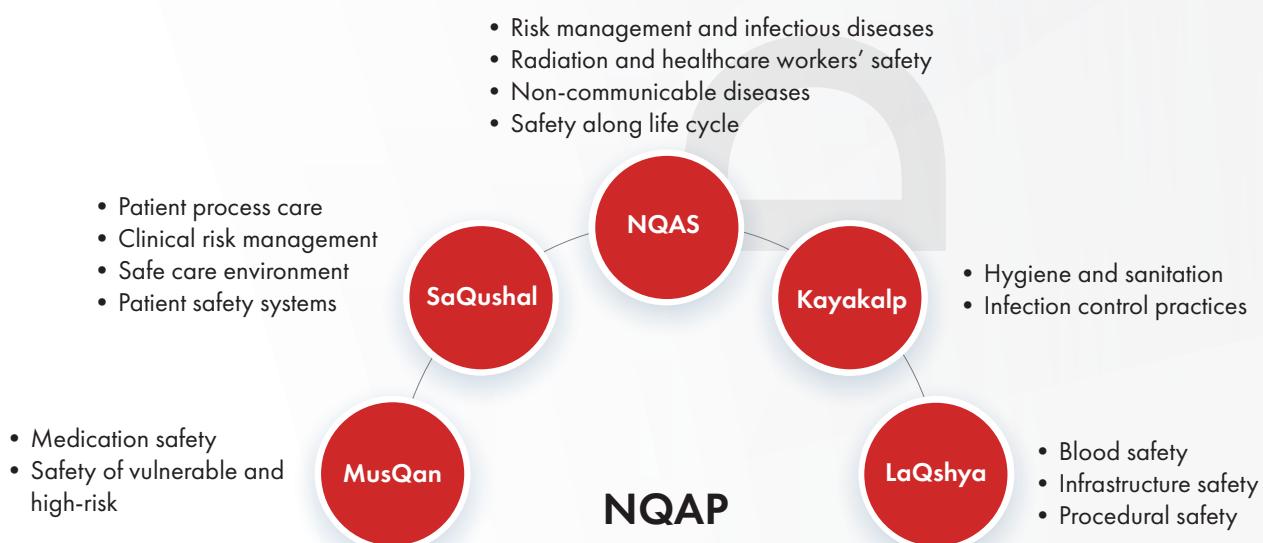
*RMNCHA - Reproductive, Maternal, Newborn, Child, Adolescent Health

The MOHFW, Government of India, introduced the **NQAS** to elevate service quality and healthcare outcomes across various facilities. NQAS is a national program that establishes benchmarks for quality and safety in healthcare facilities. Facilities performing well in **SaQushal** can progress toward **NQAS** certification, signifying a steadfast commitment to providing high-quality and safe care.

These benchmarks have gained national and international recognition from entities like the **NHA**, **IRDA**, and **ISQua**. The initiative is anchored on quality standards, encompassing fundamental principles of the Quality Management System. With **74 quality standards** and **362 measurable elements** at the district hospital level, the framework inherently addresses diverse aspects of patient safety, including clinical care safety, environmental considerations, medication safety, infection prevention, surgical safety, fire and electrical safety, and infectious waste management.

Exhibit 14

NQAP and its domains



Furthermore, NQAS incorporates global patient safety campaigns such as a **safe surgery checklist, safe childbirth practices, safe injections, medication review and optimization, and promotion of non-mercury devices**. The Kayakalp scheme incentivizes PHFs to uphold high levels of cleanliness, hygiene, and infection control. **LaQshya** focuses on **enhancing intra and immediate partum care and promoting respectful maternity** care in labor rooms and maternity operation theatres. Addressing broader social, nutritional, and quality service concerns, the **MusQan initiative** ensures the **provision of quality child-friendly services** in public health facilities.

The NQAS have been crafted considering the specific requirements of **public health facilities** and **incorporating global best practices**. These standards are currently applicable to **DHCs, CHCs, PHCs, and Urban PHCs**. The primary objective of NQAS is to enable HCPs to assess the quality of their services for continuous improvement, utilizing predefined standards to elevate their facilities to certification standards. Organized into 8 comprehensive "Areas of Concern," the **NQAS covers service provision, patient rights, inputs, support services, clinical care, infection control, quality management, and outcome**. This structured approach facilitates providers in systematically evaluating and enhancing various aspects of their healthcare delivery. Crucially, these standards are accredited by the ISQUA, attesting to their adherence to global benchmarks in terms of comprehensiveness, objectivity, evidence-based practices, and the rigorous development process. This accreditation reinforces the credibility and reliability of the NQAS in promoting **excellence** and **accountability** within healthcare facilities.

Exhibit 15

Measurement system for various levels of facilities

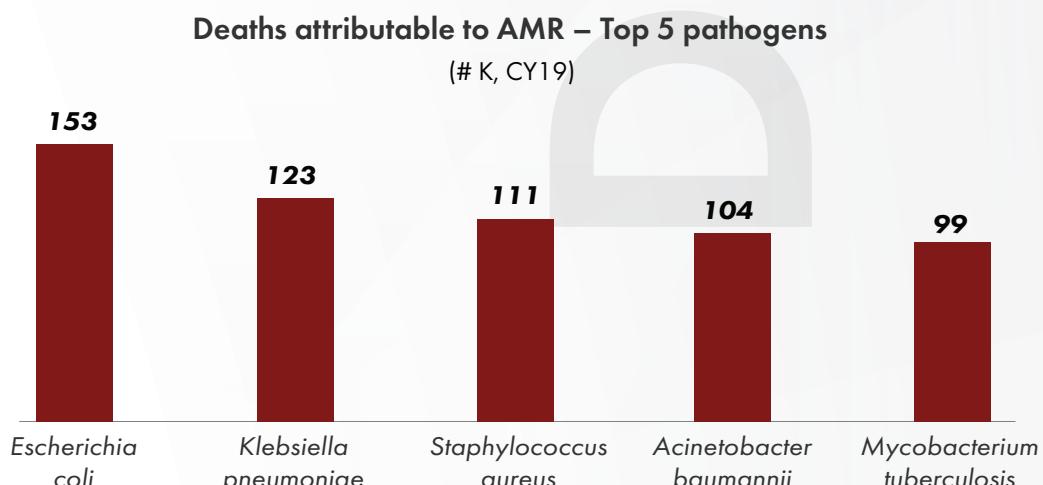
Parameter	District hospital	Community health center	Primary health center	Urban primary health center	Health and wellness center
Areas of concern	8	8	8	8	8
Standards	75	65	50	35	50
Measurable elements	380	297	250	200	129
Checklists	21	12	6	12	1

2.2.12 National AMR Plan

Globally, **4.9M+** people who died in 2019 suffered from drug-resistant infections, with AMR directly causing **~1.3M** of those deaths. In 2019, India witnessed **297K deaths attributable to AMR**, with an additional **~1M deaths** associated with AMR. Among 204 countries, India ranks **145th** in terms of age-standardized mortality rate per 100,000 population associated with AMR.

Exhibit 16

Deaths attributable to AMR



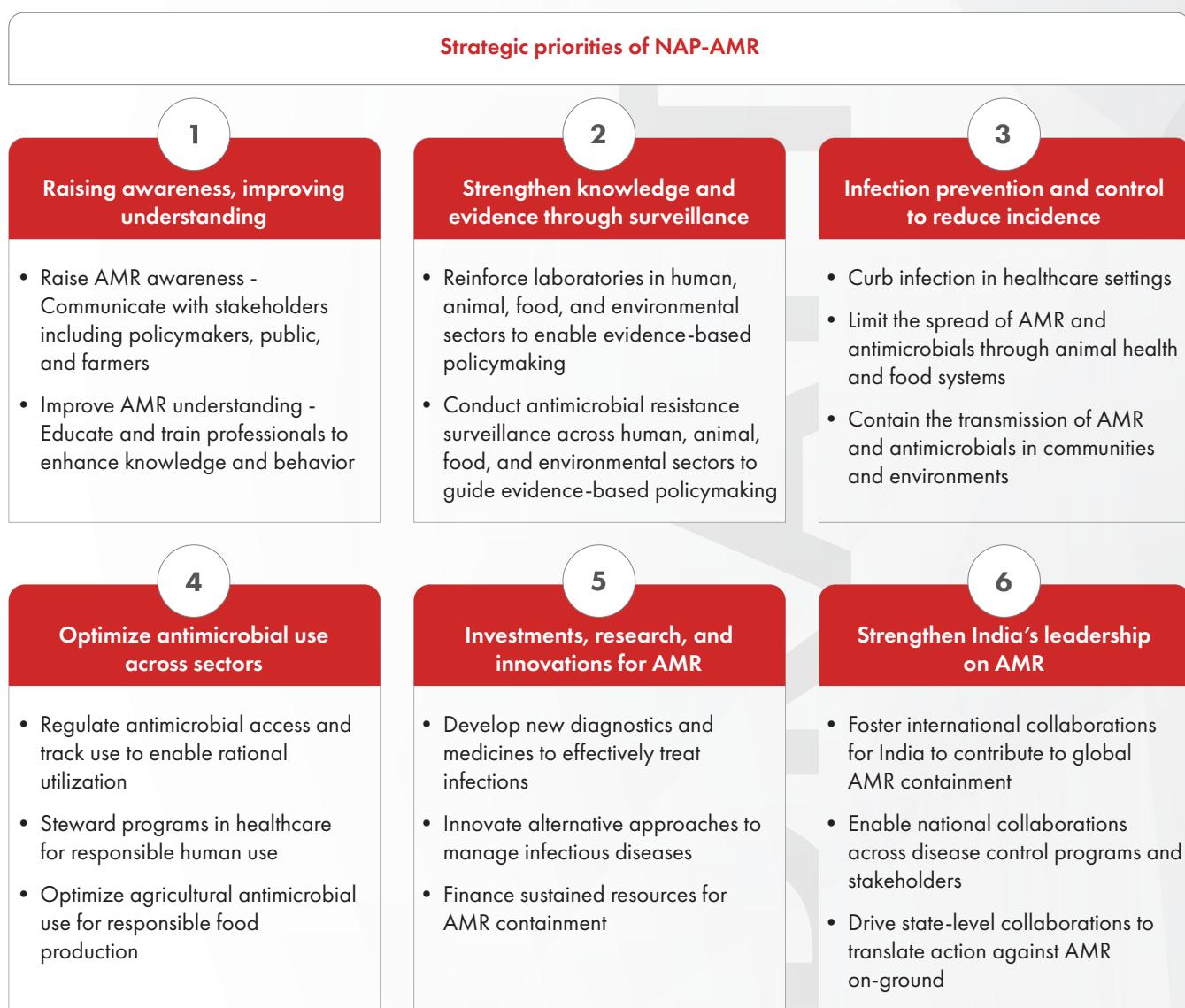
Source(s): IHME, Praxis analysis

AMR deaths in India exceed mortality from leading diseases like cancer, respiratory infections, diabetes, and maternal conditions. Five pathogens drive most AMR deaths: ***Escherichia coli* (~153K deaths)**, ***Klebsiella pneumonia* (~123K)**, ***Staphylococcus aureus* (~111K)**, ***Acinetobacter baumannii* (~104K)**, and ***Mycobacterium tuberculosis* (~99K)**. The next critical steps are **financing** and **monitoring this plan** using available data. Implementation and funding of India's national action plan based on current evidence can help address the major threat AMR poses to public health in the country.

India's **NAP-AMR** outlines strategic priorities and interventions from 2017-21 to tackle the public health threat of AMR. The primary objective of the NAP-AMR is to effectively combat AMR in India and make substantial contributions to global endeavors addressing this challenge. Adopting a **One Health approach**, which is an integrated, unifying approach to balance and optimize the health of people, animals, and the environment, targets key aspects of AMR across human, animal, agricultural, fisheries, and environmental sectors.

Exhibit 17

Strategic priorities of NAP-AMR

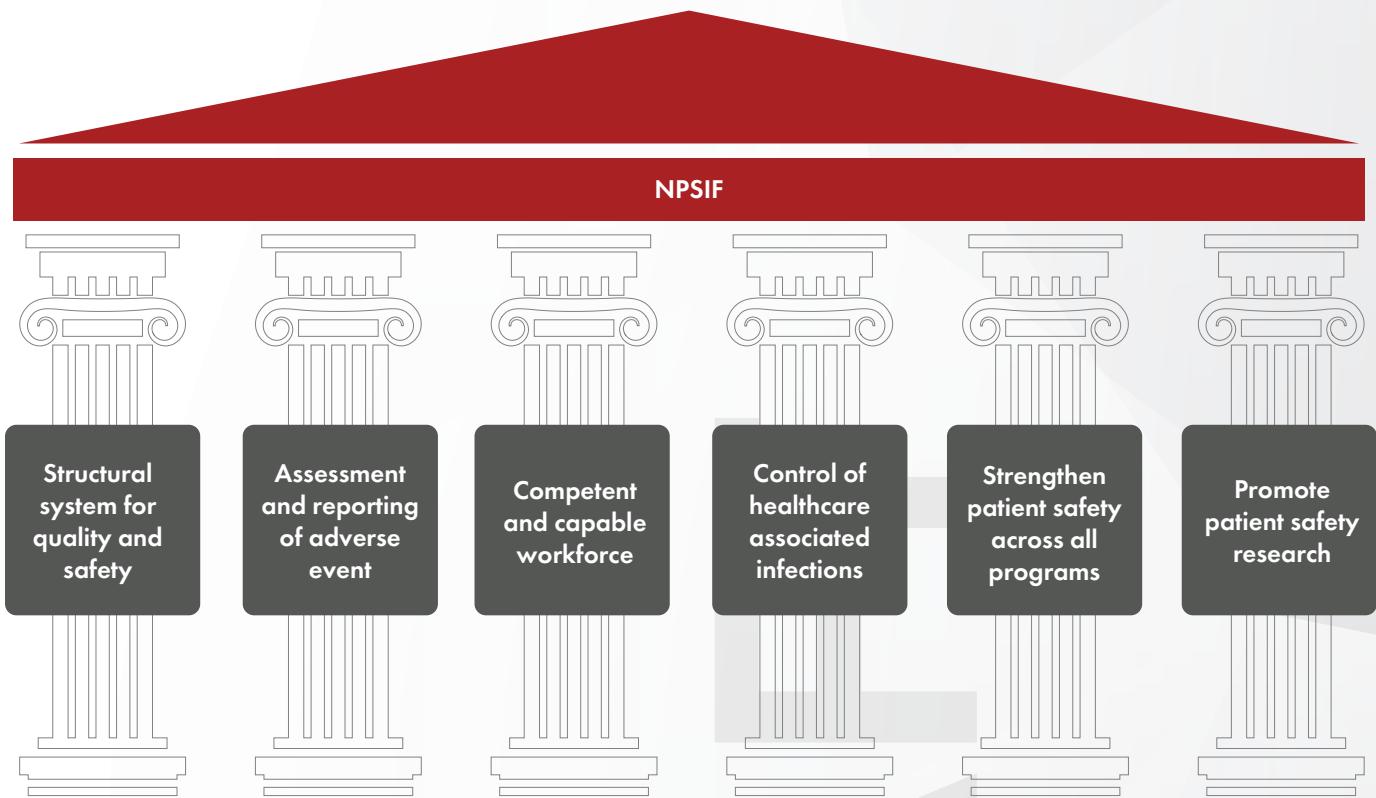


Strategic priorities focus on **raising awareness, optimizing antimicrobial use, promoting research and innovation, and facilitating collaborations** from the international to state levels to translate the plan into tangible action against AMR.

2.2.13 NPSIF (2018-25)

The overarching objective of the NPSIF is to elevate patient safety standards across all tiers of healthcare, encompassing diverse modalities of healthcare provision. This includes activities related to prevention, diagnosis, treatment, and follow-up, all within the broader context of enhancing the overall quality of care and advancing toward UHC over the next decade.

Overview of NPSIF



In pursuit of enhancing patient safety, a meticulous process involving stakeholder consultations and a comprehensive review of global and regional patient safety frameworks has identified **six strategic objectives**:

- **Elevate the structural systems** supporting healthcare to enhance both quality and efficiency, spanning national, subnational, and healthcare facility levels
- **Systematically evaluate the nature and magnitude** of adverse events, establishing a robust system for reporting and continuous learning to improve patient safety
- **Cultivate a proficient and capable healthcare workforce**, instilling awareness, and sensitivity towards patient safety as integral components
- Institute measures to **prevent and control healthcare-associated infections**, contributing to a safer healthcare environment
- **Execute global patient safety campaigns** and fortify patient safety integration across all healthcare programs, aligning with international efforts
- **Bolster capacity** for and advocate patient safety research, thereby contributing to the ongoing advancement and promotion of patient safety practices

The National Steering Committee, under the Ministry of Health & Family Welfare, Government of India, plays a pivotal role in orchestrating the nationwide implementation of the patient safety framework. Its mandate includes **technical advisory, supervisory, administrative, and regulatory responsibilities** delegated to existing authorities mandated by relevant healthcare legislation. The committee's composition is comprehensive, including officials from the Ministry of Health, representatives from technical support institutions, the NHM, NHSRC, state quality assurance committees, professional associations, WHO, private sector associations, medical colleges, accreditation agencies, consumer protection groups, and pharmacovigilance agencies. This diverse representation ensures a holistic and collaborative approach, integrating expertise from various domains to effectively steer patient safety efforts nationally.

03

DEEP DIVE INTO PATIENT SAFETY IN INDIA - PRIMARY ASSESSMENT WITH HCPs



3.0 DEEP DIVE INTO PATIENT SAFETY IN INDIA – PRIMARY ASSESSMENT WITH HCPs

3.1 Key objectives of the patient safety assessment

Exhibit 19

Key objectives of the assessment

Objectives	Patient safety culture	Mitigating constraints	Adverse event reporting enhancement	Operational workflow	Patient safety across work areas
	Assessing stakeholders	Assessing staffing levels	Evaluating reporting practices	Streamlining processes	Identifying high risk areas
	Identifying culture deficits	Resource allocation	Risk identification and mitigation	Balancing productivity with risk mitigation	Strategy identification
	Fostering safety first environment	Developing workforce strategies	Fostering a just culture	Strengthening risk management practices	Ensuring equitable safety standards

Data sources: Staff assessments, management team interactions, expert interviews, policy frameworks, stakeholder engagement forums

Tools: Questionnaires, interviews, data analysis, gap analysis, and patient safety resources

This enhanced framework for a **national-level patient safety assessment** in India is designed to understand the current levels of patient safety. This patient safety assessment was aimed at understanding the varying perspectives on patient safety held by different stakeholders, including healthcare professionals like doctors and nurses, as well as hospital leadership. Secondly, we investigated the **impact of staffing levels** on patient safety across various departments and regions. In addition, we aimed to improve **risk identification** by examining current practices for reporting adverse events and exploring opportunities for enhancement. Finally, the assessment sought to **optimize safety standards** by evaluating regional variations in patient safety challenges. This information will be used to develop targeted interventions that ensure consistent and high patient safety standards across the entire healthcare system.

Exhibit 20

Research methodology

Parameter	Survey	Interview
Goal definition	To understand current gaps in patient safety	To understand current gaps and best practices to mitigate them
Stakeholders	<ul style="list-style-type: none"> Hospital admins Doctors Nurses Management team Other medical staff 	<ul style="list-style-type: none"> Doctors Nurses Management team Patient safety experts Key policy makers
Design	Close-ended questionnaire	Open-ended questionnaire
Population	1,125	44
Format	Online surveys	Online meeting
Type of answers	Objective	Descriptive
Institutions involved	NABH and NATHEALTH	NABH, NATHEALTH, and AHPI
Data analysis	Quantitative (statistical)	Qualitative (transcription and narrative analysis)

The research methodology integrates both survey and interview methodologies, encompassing both qualitative and quantitative measures. The primary objective is to comprehensively comprehend the prevailing best practices and identify existing gaps within the patient safety system. The survey component involved the participation of **1,125 hospital staff members**, while **interviews were conducted with key stakeholders, including doctors, nurses, management teams, and patient safety experts**. The surveys were disseminated through reputable platforms such as the NABH and the NATHEALTH forums. Concurrently, the interviews were facilitated through an online meeting format, ensuring an efficient and structured engagement with the diverse set of stakeholders involved.

The **survey questionnaires** and the **interview discussion guides** were prepared based on the different measures of patient safety aspects – teamwork, staffing, work pace, organization learning, response to error, supervisor support for patient safety, communication, incident reporting, accreditation impact, event reporting frequency, information exchange, and overall perception along with the understanding of current best practices across the healthcare delivery system for patient safety.



3.3 Sources of input

Exhibit 21

Sources of input

Key approach elements	N	Details	Key areas to explore
Management interviews	10	<ul style="list-style-type: none"> • In-depth interviews of 30–45-minute conversations with hospital management team 	<ul style="list-style-type: none"> • Key government policies • Regulatory landscape with respect to patient safety
Government officials' interviews (key policy makers and industry)	2	<ul style="list-style-type: none"> • In-depth interviews of 30–45-minute conversations with government officials 	<ul style="list-style-type: none"> • Information accessibility • Patient safety culture • Patient centricity • Decision making on patient safety aspects
Doctor interviews	5	<ul style="list-style-type: none"> • In-depth interviews of 30–45-minute conversations with key doctors 	<ul style="list-style-type: none"> • Patient safety challenges to be addressed • Best practices and recommendations
Nursing staff interviews	10	<ul style="list-style-type: none"> • In-depth interviews of 30–45-minute conversations with nursing staff in hospital (chief of nursing staff) 	
Hospital admin interviews	10	<ul style="list-style-type: none"> • In-depth interviews of 30–45-minute conversations with hospital admin/supervisor 	
Patient safety expert calls	7	<ul style="list-style-type: none"> • In-depth interviews of 30–45-minute conversations with hospital admin/supervisor 	<ul style="list-style-type: none"> • Patient involvement and communication • Recent improvements in patient safety • Best practices
Doctor survey	~1,125		<ul style="list-style-type: none"> • Working area • Management's patient safety priority • Communication • Reporting patient safety incidence • Ratings • Hospital-level patient safety understanding • Patient safety challenges to be addressed
Nursing staff survey		<ul style="list-style-type: none"> • Survey forms were distributed to doctors, nursing staff, and hospital admins across the city tiers and regions (with the help of NABH) 	
Hospital admin survey			
Secondary research	-	<ul style="list-style-type: none"> • International Organization (WHO) reports • Press releases • Documentations 	<ul style="list-style-type: none"> • Patient safety practices • Regulatory compliance
Praxis knowledge base	-	<ul style="list-style-type: none"> • Relevant data points and insights from Praxis knowledge base 	<ul style="list-style-type: none"> • Patient safety practices • Regulatory compliance

04

ANALYSIS AND OBSERVATIONS



4.0 ANALYSIS AND OBSERVATIONS

4.1 Patient safety challenges – Hospitals

Exhibit 22

Key challenges in the patient safety system

Unsafe injection

- Unsafe injection practices, such as **reuse of needles and syringes**, can lead to the transmission of bloodborne infections such as **HIV and hepatitis**



High rates of healthcare associated infections

- High rates of healthcare-associated infections in India **increase morbidity and mortality**, strain healthcare resources, and escalate healthcare expenditure

Medication safety

- Medication errors are common in India due to factors such as **improper labeling, dosage miscalculations, and lack of patient education**



Anti-microbial resistance

- High rates of AMR can result in antibiotics becoming ineffective in treating common infections, **leading to increased morbidity and mortality**

Medical device safety

- Faulty medical devices pose risks of **malfunctions, injuries, and complications**, compromising patient safety and treatment outcomes significantly



Healthcare infrastructure

- Insufficient healthcare facilities** lead to overcrowding in hospitals, compromising patient safety
- Public institutions face challenges upgrading to **NABH standards**, hindering patient safety efforts and quality healthcare delivery

Unsafe practices like **improper injection techniques** and **inadequate medication management** put patients at risk. The **safety of medical devices** themselves is also a concern. Furthermore, **Healthcare-Associated Infections** (HAIs) pose a significant threat, often due to inadequate hygiene protocols. Finally, the **rise of antimicrobial resistance** and **limitations in healthcare infrastructure** add further layers of complexity to the patient safety landscape in India.

4.1 Patient safety challenges – Diagnostics

Exhibit 23

Key challenges in the patient safety system

Ionizing radiation exposure

- Overexposure to ionizing radiation** from diagnostic imaging procedures such as X-rays and CT scans can increase the risk of radiation-induced health effects



Low awareness among patients

- Patients have limited awareness** of the importance of quality diagnostics and may not be adequately informed about the risks

Training of healthcare workers

- **Inadequate training** leads to overlooking crucial details, misinterpreting test results, or jumping to the wrong conclusion, potentially causing delays in proper treatment and adverse patient outcomes



Inadequate regulatory oversight

- **Regulatory oversight** of diagnostic laboratories in India is insufficient, leading to less adherence to quality standards and potential risks to patient safety

Waste disposal

- **Improper handling and disposal of hazardous waste** poses risks to patient safety and environmental contamination and increases the risk of healthcare-associated infections among patients



Lack of digitalization

- Hinders ability to communicate effectively, **leverage decision support tools**, access timely and accurate information due to **manual data entry errors**, and ensure interoperability of patient data



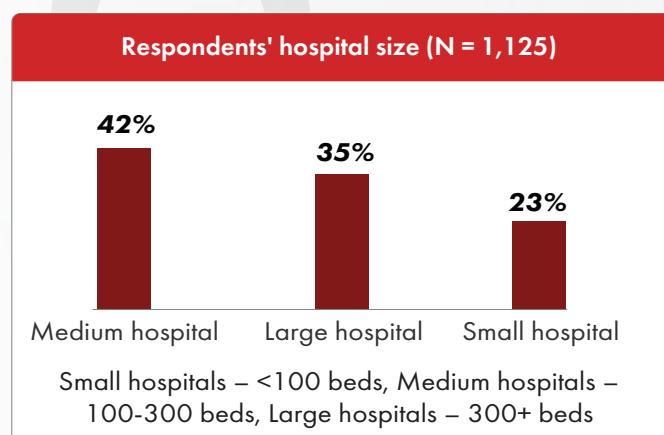
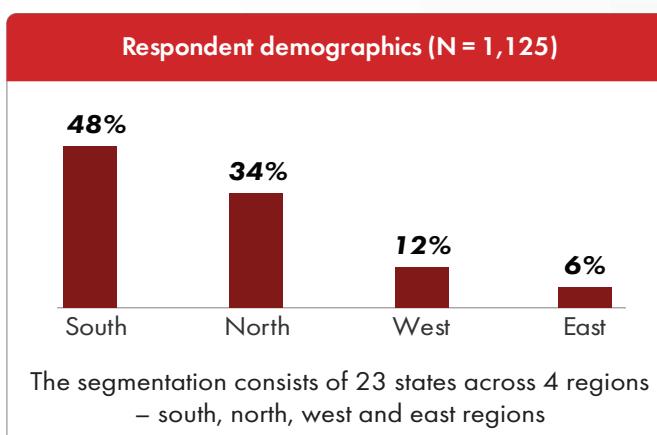
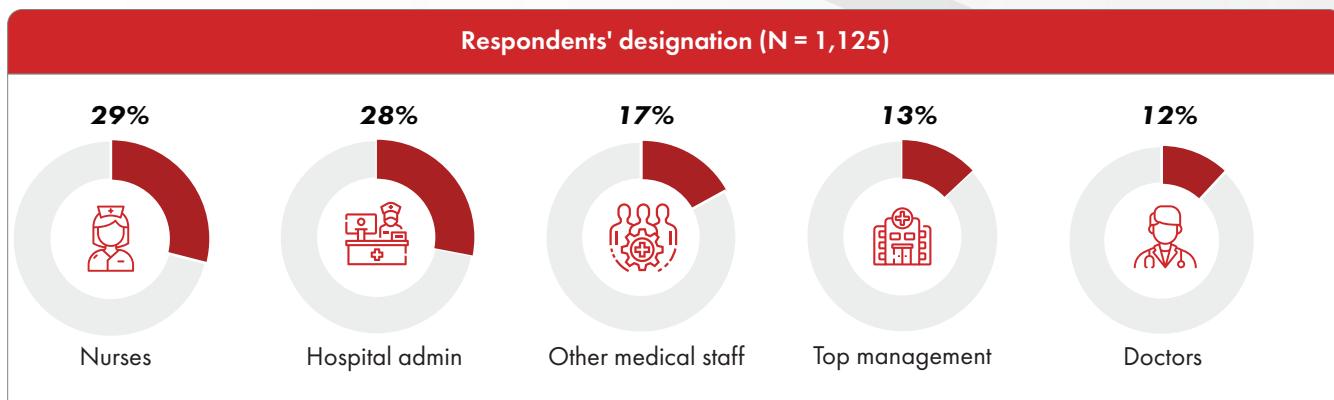
Inadequate training of healthcare workers contributes to errors in interpretation and treatment, while **low patient awareness** about the importance of quality diagnostics increases the problem. **Insufficient regulatory oversight** of diagnostic laboratories results in lesser adherence to quality standards, further compromising patient safety. Additionally, the **lack of digitalization** hinders effective communication, access to timely information, and the utilization of **decision support tools**, impeding efforts to ensure patient safety in diagnostics. **Waste disposal** is also a significant issue and poses significant risks, potentially leading to adverse health effects.

4.3 Observation & data analysis – Stakeholders' perspectives

Over 1,125 healthcare professionals participated in an assessment exploring patient safety challenges in Indian hospitals. The respondents came from various regions, with nearly half (48%) residing in the south. Nurses and hospital administrators formed the majority, accounting for 29% and 28% of participants, respectively. The assessment covered hospitals of different sizes, with **medium-sized facilities representing the largest portion** (42%), followed by large (35%) and small (23%) hospitals.

Exhibit 24

Assessment of the respondents' profile

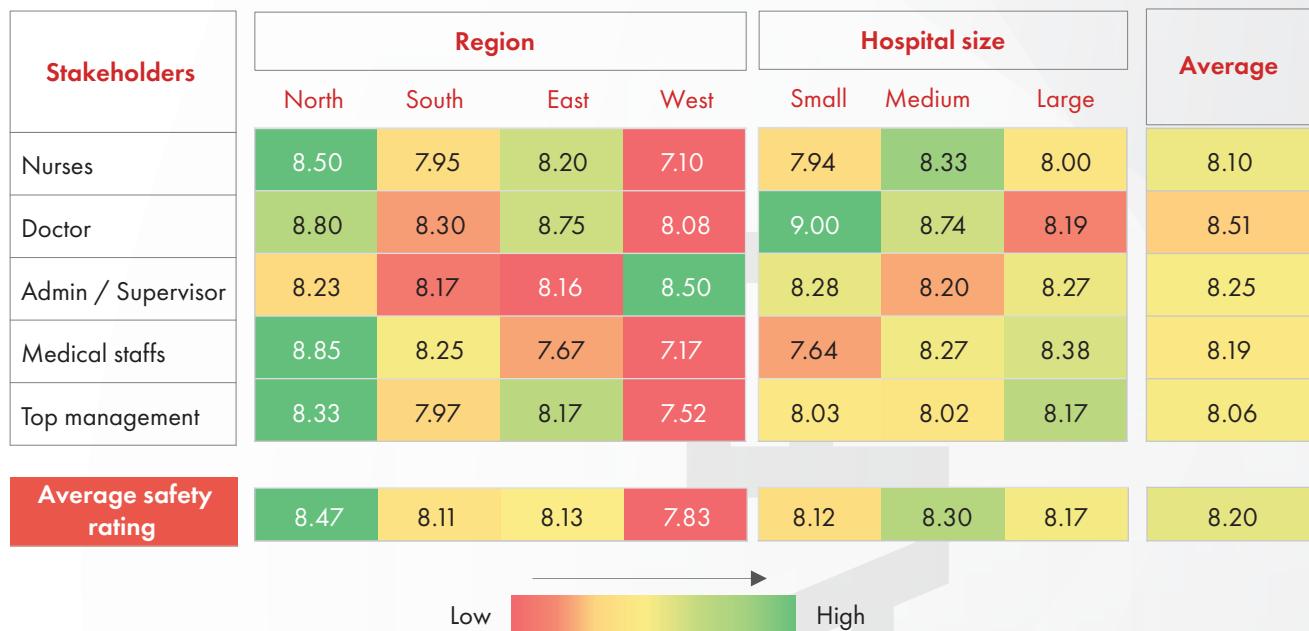


4.3.1 Patient safety rating and adverse event reporting

The average patient safety rating landed at **8.20**, with doctors expressing the most confidence in patient safety (**8.51**) compared to other participants. Top management, on the other hand, had the lowest perception with an average rating of **8.06**. Interestingly, the assessment also revealed regional variations. The northern region scored the highest (**8.47**) for patient safety, while medium-sized hospitals came out on top when comparing hospital sizes.

Exhibit 25

Patient safety rating perception of stakeholders



The average adverse event reporting (**last 12 months**) landed at **3.95**, with doctors expressing the least reporting in patient safety (**2.65**) compared to other participants. Top management, on the other hand, had the highest event reporting perception with an average rating of **4.80**. The northern region has the highest adverse event reporting (**4.70**), while medium-sized hospitals came out on top when comparing hospital sizes.

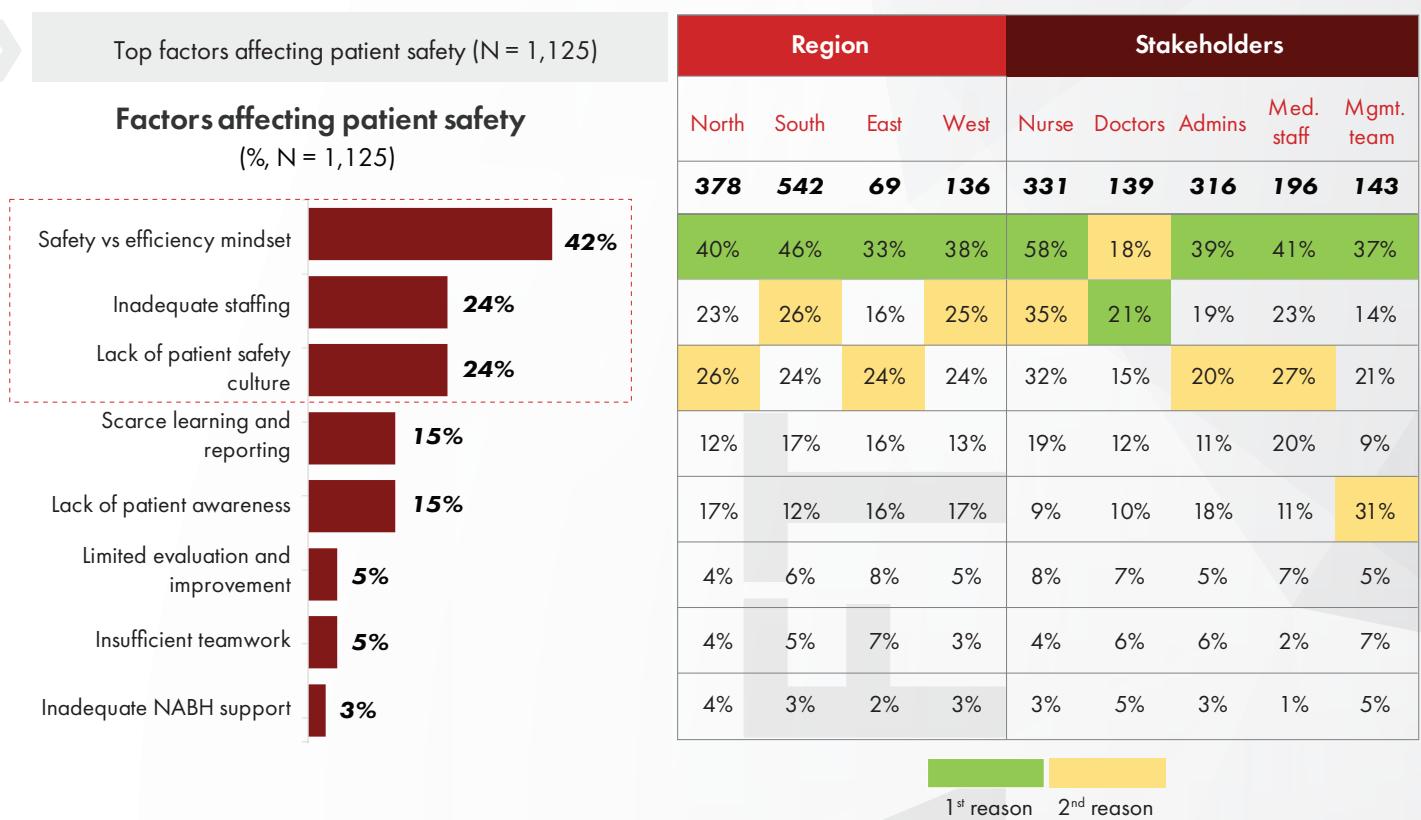
Exhibit 26

Analysis of adverse event reporting (**last 12 months**) by stakeholders



Exhibit 27

Factors affecting patient safety – Stakeholders' perspective



4.3.2 Stakeholder's perspective – Nurses

Exhibit 28

Factors impacting patient safety – Nurses' perspective

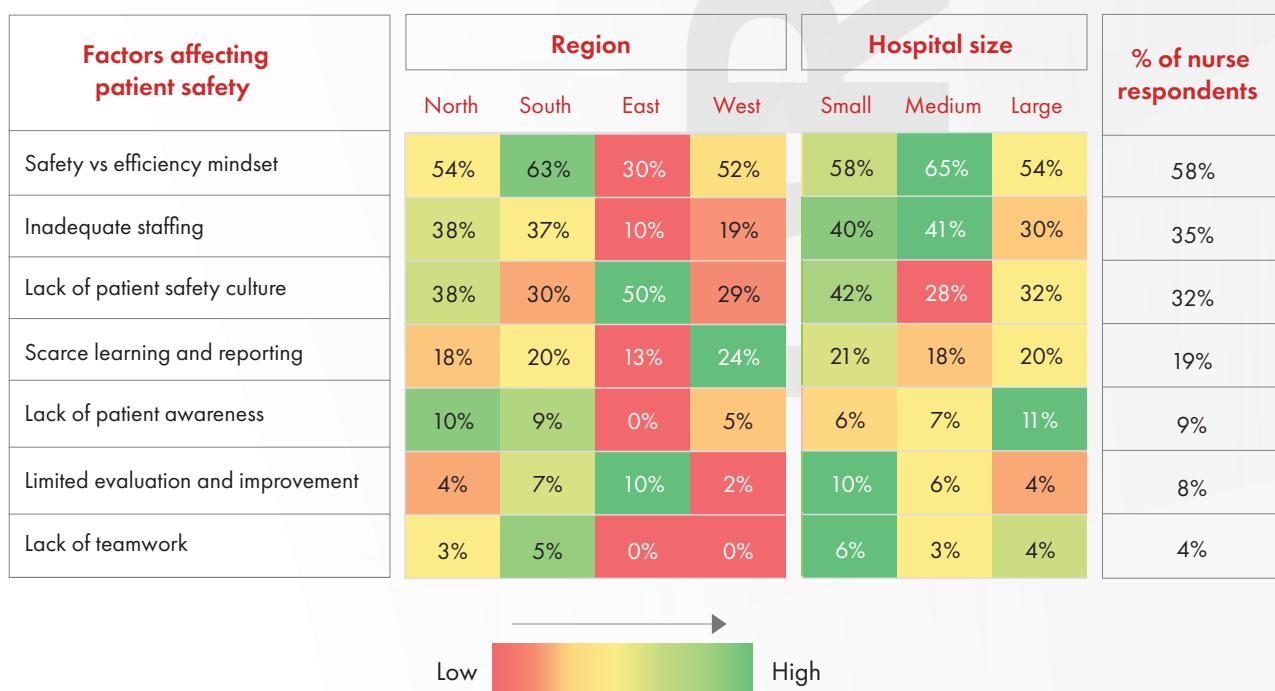


Exhibit 29

Factors affecting patient safety – Voice of nurses

Factors	Challenge description	Degree of importance	Voice of nurses
Safety vs efficiency mindset	<ul style="list-style-type: none"> Patient safety gap: There are clear areas in hospitals that require improvement to enhance patient safety, including patient identification, handovers and communication, managing high-risk medications, confirming surgical patients, and preventing hospital-acquired infections and falls 		<p>“Nurses frequently face dilemmas between following procedures and prioritizing patient safety. To bridge this gap, there's a crucial need for comprehensive improvements in nursing education,”</p> <p>- Nursing head, Large private hospital, Delhi</p>
Lack of patient safety culture	<ul style="list-style-type: none"> Siloed work culture: Departmental isolation and a lack of collaboration hinder effective communication and learning across disciplines 		<p>“Hospitals and colleges must collaborate more effectively. Current training falls short, leading nurses to spend valuable time training instead of providing patient care,”</p> <p>- Senior nurse, Small private hospital, Kolkata</p>
Inadequate staffing	<ul style="list-style-type: none"> Increased workload: Required to take on additional responsibilities and care for more patients than they can effectively manage Higher risk of errors: Fatigue and stress can impair judgment and decision-making 		<p>“The workload is overwhelming & it's affecting both patient outcomes & our own well-being. Urgent action is needed to address this staffing shortfall to ensure patient safety,”</p> <p>- Nursing staff, Medium private hospital, Mumbai</p>
Lack of patient awareness	<ul style="list-style-type: none"> Patient experience gap: Limited focus on understanding and addressing the patient's concerns and needs during clinical procedures 		<p>“Patients often lack awareness of existing safety guidelines when seeking treatment. Empowering patients can help them make informed decisions,”</p> <p>- Senior nurse, Large private hospital, Bangalore</p>
Scarce learning and reporting	<ul style="list-style-type: none"> Knowledge gaps & documentation errors: Inadequate training or unclear guidelines on specific protocols (e.g., IPSG, 6 mandates of medication administration) can lead to errors in documentation and communication 		<p>“Incident reporting is crucial for quality improvement. Errors must be escalated immediately to investigate their causes effectively,”</p> <p>- Nurse, Government hospital, Delhi</p>

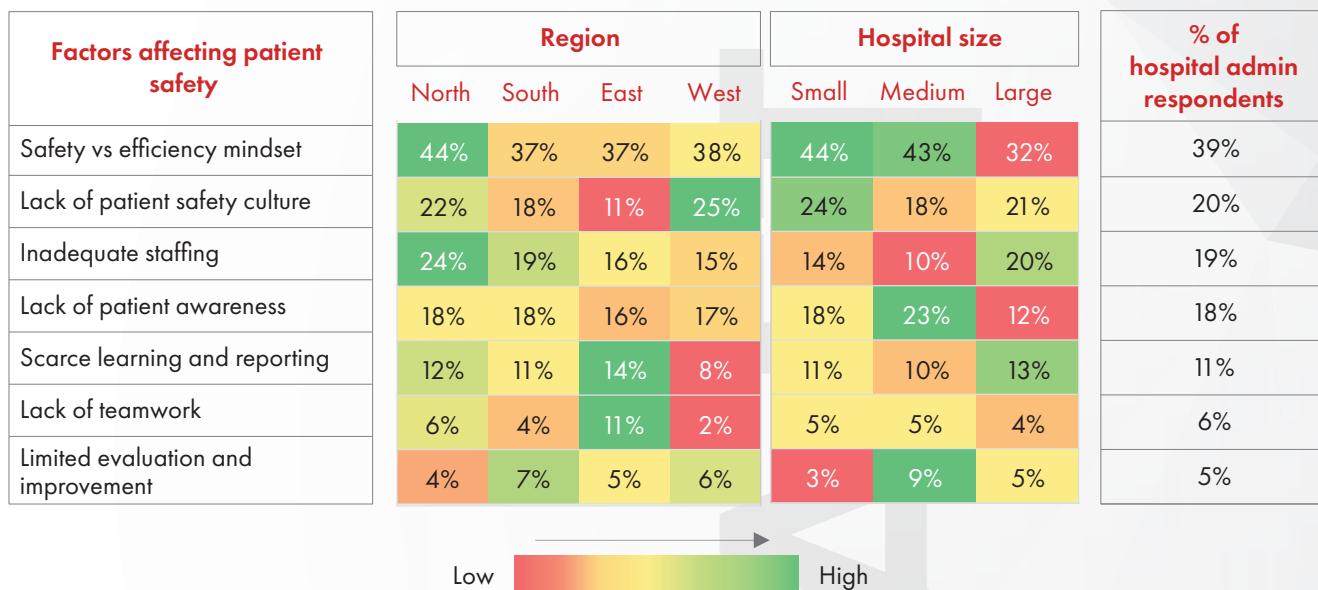


Staffing issues were paramount, with **58%** of nurses identifying the **pressure to balance safety concerns and efficiency** as a major challenge. **Inadequate staffing (35%)** issues were also significant, suggesting issues with understaffing, burnout, and potentially unsafe nurse-to-patient ratios. These factors directly impact the foundational issue of patient safety culture (32%), wherein nurses may feel less empowered or supported to prioritize safety protocols. Limited resources for learning and timely reporting of safety events (19%) impact the ability to identify and address potential risks. While less prominent, addressing issues surrounding patients' rights (9%), overall evaluation and improvement mechanisms (8%), and fostering stronger teamwork (4%) can bolster patient safety through holistic support across the healthcare delivery system.

4.3.3 Stakeholder's perspective – Hospital admins

Exhibit 30

Factors impacting patient safety – Admins' perspective



Foremost, the pressure to balance **safety with efficiency (39%)** emerges as the biggest challenge, suggesting potential conflicts between necessary safety measures and operational demands. A substantial 20% of administrators highlighted a lack of a robust safety culture, indicating a need for greater emphasis on safety protocols and accountability throughout the hospital system. Inadequate staffing (19%) also proves significant, potentially implying issues with understaffing and overworked personnel, which can indirectly compromise patient care.

4.3.4 Stakeholder's perspective – Hospital doctors

Exhibit 31

Factors impacting patient safety – Hospital doctors' perspective

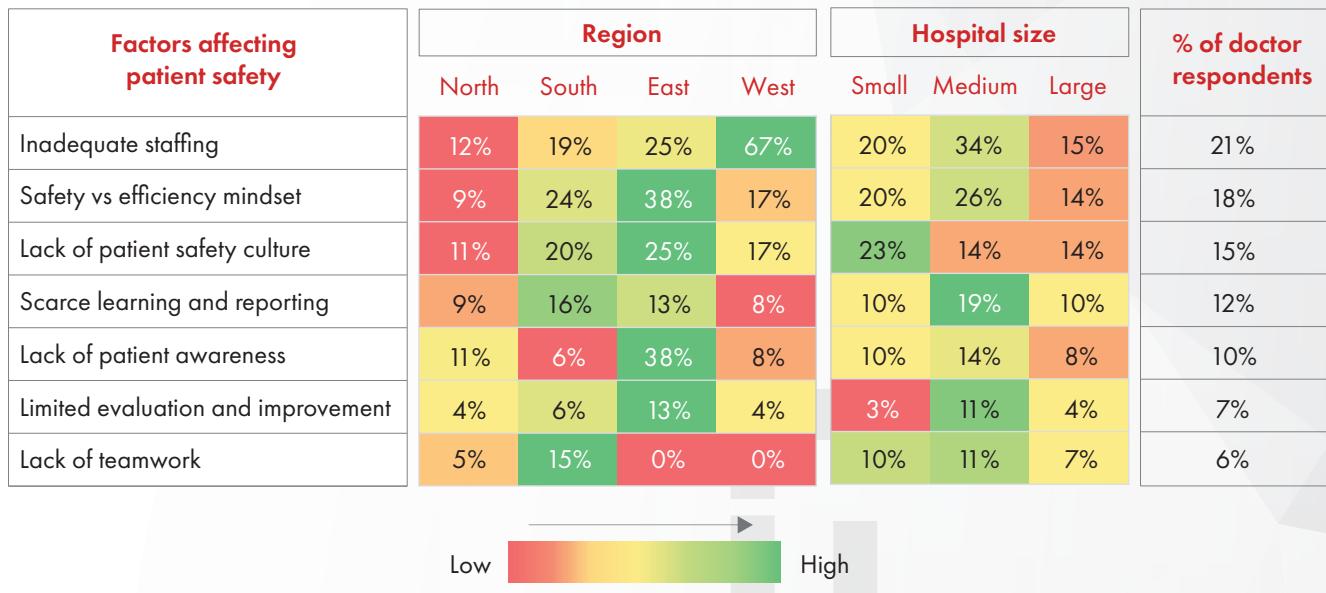


Exhibit 32

Factors affecting patient safety – Voice of doctors

Factors	Challenge description	Degree of importance	Voice of doctors
Lack of patient safety culture	<ul style="list-style-type: none"> Lack of robust framework: Lack of safety protocols and reporting systems hinder doctors, risking errors, adverse events, and compromised patient outcomes, impacting care quality 		<p>“Lack of standardized safety protocols results in inconsistent care practices, heightened risk of errors, and compromised patient safety outcomes,”</p> <p>- Senior doctor, Large private hospital, Delhi</p>
Inadequate staffing	<ul style="list-style-type: none"> Increased workload: Required to take on additional responsibilities and care for more patients than they can effectively manage Higher Risk of Errors: Fatigue and stress can impair judgment and decision-making 		<p>“Increased workload from understaffing jeopardizes patient care. Immediate action is needed to ensure quality and patient safety,”</p> <p>- Senior doctor, Small private hospital, Kolkata</p>

Scarce learning and reporting	<ul style="list-style-type: none"> Lack of learning: Increases the risk of errors and hindering collaboration. It leads to outdated practices, stagnant skills, and dissatisfaction, compromising patient care and overall effectiveness in the healthcare system 		<p>“I advocate for comprehensive training modules to bridge the gaps in medical education. Lack of these resources compromises patient care and hinders professional development”</p> <p>- Senior doctor, Medium private hospital, Mumbai</p>
Limited evaluation and improvement	<ul style="list-style-type: none"> Less tracking and less improvement: Less tracking hinders doctors' skill development, risking medical errors and reducing patient care quality 		<p>“With less data at hand, we need to go forward with existing practices giving us no scope of improvement in our own methods. A continuous tracking is essential”</p> <p>- Senior doctor, Government hospital, Delhi</p>
Lack of patient awareness	<ul style="list-style-type: none"> Patient education gap: There's a need for increased patient education on safety protocols, healthcare processes, and standard operating procedures (SOPs) 		<p>“I am concerned about the consequences of patient unawareness. Limited understanding leads to delayed care”</p> <p>- Senior doctor, Government hospital, Delhi</p>



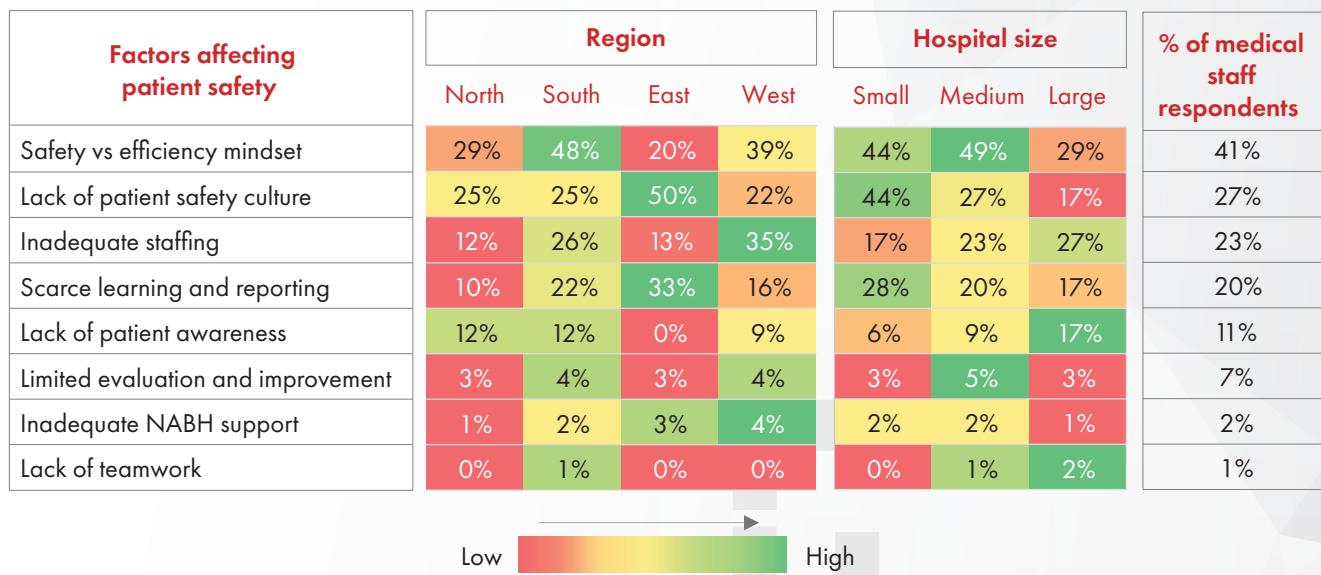
An assessment of **139** hospital doctors from across India highlights several factors that compromise their ability to ensure optimal patient safety. **Inadequate staffing was a major concern**, with **21%** of doctors citing it as a significant challenge. This indicates potential issues with understaffing and overburdened healthcare professionals. The pressure to balance safety concerns with efficiency (18%) was another key factor, suggesting a tension between upholding strict safety protocols and maintaining a fast-paced workflow. A lack of well-defined patient safety culture (15%) underscores the need for a stronger emphasis on safety practices and accountability. Additionally, challenges related to learning and reporting systems (12%) point to a need for improved knowledge sharing and systems to promptly address potential safety hazards.



4.3.5 Stakeholder's perspective – Other medical staff

Exhibit 33

Factors impacting patient safety – Other medical staff's perspective



The most significant issue is the **conflict between safety and efficiency (41%)**, which reveals the pressure healthcare professionals feel to potentially sacrifice safety in favor of speed. A deficient patient safety culture (27%) underscores the need for stronger systems promoting safety-focused practices. 23% of respondents mentioned inadequate staffing cultures that might result in burnout and overwork, underscoring yet again how understaffing directly affects patient care. Limited resources for learning and timely reporting of safety events (20%) suggest a need for enhanced training and systems that facilitate quick identification and mitigation of risks.

4.3.6 Stakeholder's perspective – Hospital management team

Exhibit 34

Factors impacting patient safety – Hospital management team's perspective

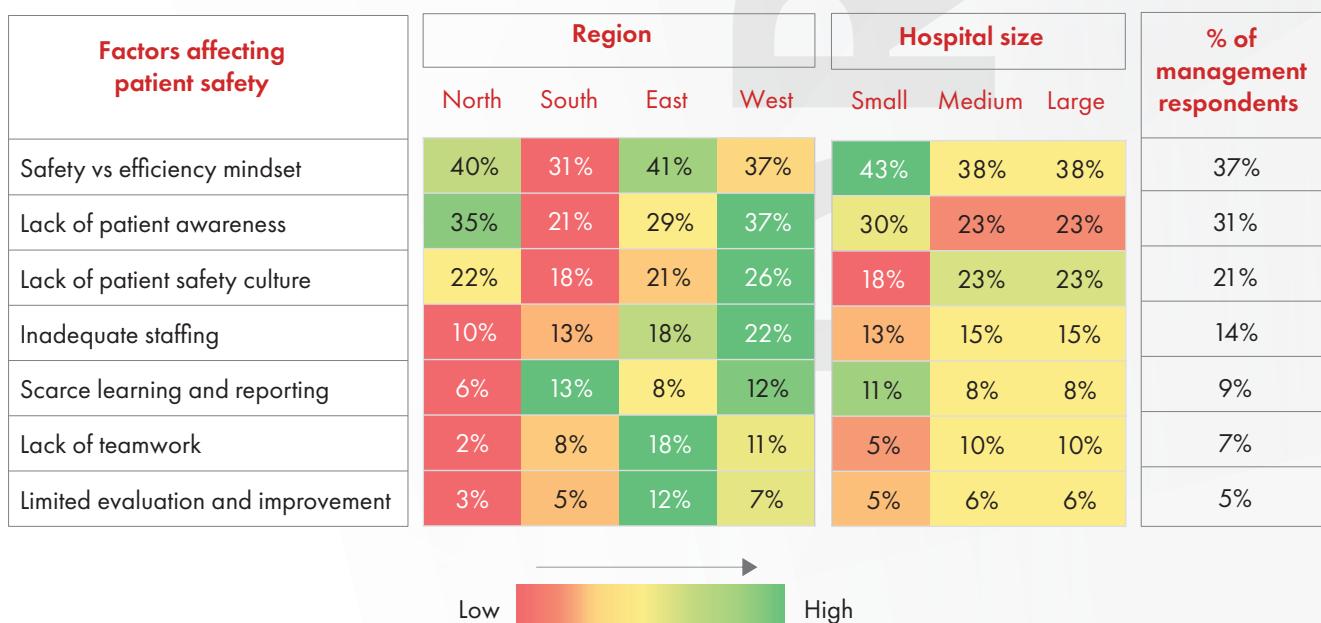


Exhibit 35

Factors affecting patient safety – Voice of management team

Factors	Challenge description	Degree of importance	Voice of management team
Lack of patient safety culture	<ul style="list-style-type: none"> Uneven standards: Inconsistent application of patient safety standards and awareness across hospitals has created a significant disparity in the quality of care 		<p>“I am worried about the big difference in the quality of care across the levels of healthcare system”</p> <p>- Chief of staff, Large private hospital, Delhi</p>
Inadequate staffing	<ul style="list-style-type: none"> Resource constraints: Limited resources in mid-tier hospitals hinder implementation of basic safety protocols, jeopardizing patient safety 		<p>“Critical patient safety is compromised by staff shortages, outdated equipment, and limited training. Immediate investments are needed to be addressed for optimal care”</p> <p>- Senior nurse, Small private hospital, Kolkata</p>
Safety vs efficiency mindset	<ul style="list-style-type: none"> Affordability barrier: Providing safe care can be too costly for some patients, leading to accessibility issues. Companies focus on improving efficiency to enhance their profit margins 		<p>“The main problem is the pricing structure of high-quality care”</p> <p>- Chief medical officer, Small private hospital, Mumbai</p>
Scarce learning and reporting	<ul style="list-style-type: none"> Data collection issues: Despite existing standards (QCI/NABH), data collection challenges persist, likely due to resource limitations or lack of awareness 		<p>“At the top tier, about half of the NABH hospitals will likely have this data. The other 50% are more on the entry level side. At the national level, it's probably just a tiny fraction”</p> <p>- Admin team, Government hospital, Delhi</p>
Lack of patient awareness	<ul style="list-style-type: none"> Implementation gap: Knowledge of safety protocols is not the primary obstacle; cultural resistance and pricing limitations hinder effective implementation 		<p>“It's the consumer who's not ready to pay for the high-quality service due to lack of awareness”</p> <p>- Chief executive officer, Large private hospital, Bangalore</p>



The most pressing is the conflict between **safety concerns and efficiency (37%)**, indicating a struggle to balance thoroughness with operational demands. A **limited focus on patient rights (31%)** suggests a potential need to improve patient-centered communication and uphold patient autonomy in the healthcare process. Additionally, a **weak patient safety culture (21%)** highlights the importance of building a robust framework where safety is ingrained at all levels of the organization. Concerns over **inadequate staffing (14%)** point to the need for addressing potential understaffing and ensuring appropriate workload distribution to prevent staff burnout that can impact patient care.

4.3.7 Hospital work area assessment

Exhibit 36

Factors affecting patient safety across various work regions

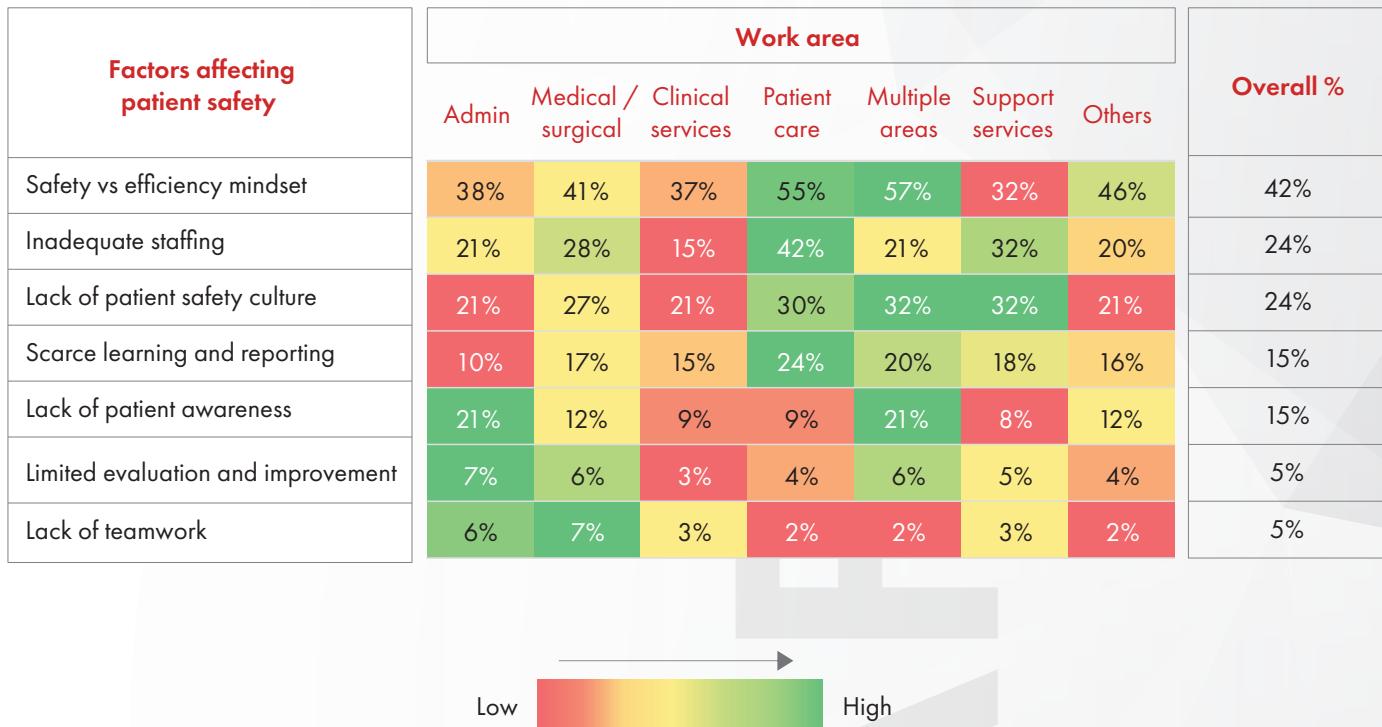


Exhibit 37

Factors affecting patient safety – Voice of diagnostics experts

Factors	Challenge description	Degree of importance	Voice of diagnostics experts
Safety vs efficiency mindset	<ul style="list-style-type: none"> Cutting corners on protocols: Non-adherence of safety measures in diagnostic procedures like lack of proper cleaning before blood draws and the reuse of needles for multiple patients can increase the infection risk 		<p>“The practice of skipping proper cleaning procedures before drawing blood to save time can be harmful. It's a shortcut that compromises safety standards and risks patient health”</p> <p>- HOD Pathology, National lab chain, Delhi</p>
Scarce learning and reporting	<ul style="list-style-type: none"> Inadequate training and learning systems: Lack of proper training and skill development for staff handling diagnostic procedures, coupled with limited mechanisms for reporting 		<p>“Inadequate training and learning systems for skill development pose significant challenges leading to errors in diagnosis and inefficiencies in the healthcare system”</p> <p>- Pathologist, Standalone lab, Bangalore</p>

Lack of patient awareness	<ul style="list-style-type: none"> Patient disengagement in safety: Lack of patient awareness and knowledge about proper safety practices in diagnostic procedures, leaves patient disengaged 		<p>“Lack of patient awareness leads to delayed healthcare-seeking behavior, uninformed decision-making, and poor adherence to follow-up care,”</p> <p>- HOD, Regional lab chain, Mumbai</p>
Lack of patient safety culture	<ul style="list-style-type: none"> Oversight and negligence: Negligence in adhering to the proper order of draw for blood samples and inadequate endorsement of safety practices 		<p>“Negligence in proper blood sample collection and safety practices compromises sample integrity, patient safety, diagnostic quality, and regulatory compliance,”</p> <p>- Senior doctor, Government hospital, Delhi</p>
Limited evaluation and improvement processes	<ul style="list-style-type: none"> Deficient safety evaluation processes: Lack of continuous monitoring of safety protocols highlighted limited evaluation and improvement processes to assess and strengthen patient safety measures 		<p>“I believe there's a need to closely adhere to guidelines in monitoring and evaluating special needle injuries for enhanced safety,”</p> <p>- Pathologist, Regional lab chain, Mumbai</p>



From diagnostics standpoint, **inadequately trained staff**, coupled with a lack of **proper reporting mechanisms for errors**, can lead to missed diagnoses or even **infections due to improper sterilization** procedures. Furthermore, limited patient understanding of safety protocols hinders their ability to participate actively in their care. Additionally, inconsistent adherence to established protocols, such as the **correct order for blood draws**, and a **lack of robust evaluation processes for safety measures**, create an environment where gaps remain unaddressed.



4.4 Recommendations

With the identification of areas of improvement for patient safety in India – collaborative environment, leadership, data infrastructure improvement, public awareness, patient awareness, technology advancement, communication, and policy changes – we are structuring our recommendations through these **9 levers** to address the challenges to improve the patient safety and experience in Indian healthcare delivery system.

Exhibit 38

Recommendations – 9 levers to improve patient safety in India

Recommendation	Description	Current level of implementation
Collaborative leadership	<ul style="list-style-type: none"> Involves shared decision-making, teamwork, and cooperation, promoting collective problem-solving, continuous improvement, and institutionalizing patient safety 	
Data infrastructure	<ul style="list-style-type: none"> Encompasses foundational systems enabling collection, storage, analysis, and secure healthcare data management to enhance patient outcomes 	
Workforce development	<ul style="list-style-type: none"> Involves training healthcare professionals, integrating patient safety modules into educational programs, and promoting continuous learning 	
Patient empowerment	<ul style="list-style-type: none"> Involves enabling control over healthcare decisions, treatments, well-being, through education, involvement, and integrating patient feedback mechanisms 	
Information sharing and communication	<ul style="list-style-type: none"> Involves exchanging data, ideas, and insights to ensure optimal healthcare outcomes and risk mitigation 	
Technology integration	<ul style="list-style-type: none"> Involves incorporating tools into practices to enhance efficiency, productivity, using EHRs, BCMA, and advanced tech for risk identification 	
Policy reforms	<ul style="list-style-type: none"> Involves changing policies, structures for efficiency, transparency, accountability, emphasizing patient safety frameworks, reporting systems, and regulation enforcement 	
Public awareness	<ul style="list-style-type: none"> Entails understanding issues, events, achieved through education, outreach, diverse communication channels, collaboration with NGOs, and integrating patient safety into education 	
Resource allocation	<ul style="list-style-type: none"> Involves distributing time, money, personnel, materials among tasks, emphasizing safety alerts sharing, performance incentives, and data consistency 	

Level of implementation

→
Low  High

4.4.1 Desired state

Exhibit 39

India's current and desired level of patient safety indicators

	Current state	Desired state
Patient harm is minimized and ideally eliminated	<ul style="list-style-type: none">Deaths due to AEMT per 100,000 population – 2.33DALY due to AEMT per 100,000 person-years – 73.38Treatable mortality rate – 180	<ul style="list-style-type: none">Deaths due to AEMT per 100,000 population – downward trendDALY due to AEMT per 100,000 person-years – downward trendTreatable mortality rate – downward trend
Safety is a top priority at all levels	<ul style="list-style-type: none">Maternal rate per 100,000 live births – 103Neonatal mortality rate per 100,000 live births – 1,912	<ul style="list-style-type: none">Maternal rate per 100,000 live births – <70Neonatal mortality rate per 100,000 live births – 0
Effective systems and processes are in place	<ul style="list-style-type: none">OverburdenedLacks standardization	<ul style="list-style-type: none">Establishment of an effective healthcare system and process
Everyone feels empowered to contribute to safety	<ul style="list-style-type: none">Hierarchical barriersLack of empowerment	<ul style="list-style-type: none">Inclusive healthcare environmentOpen communication and shared responsibility
Continuous learning and improvement are the norm	<ul style="list-style-type: none">Inconsistent training and learning	<ul style="list-style-type: none">Integrate robust training modulesFocus on the quality and consistency of patient safety protocols
Accessibility and equity are ensured	<ul style="list-style-type: none">Disparities in healthcare facilities and resources	<ul style="list-style-type: none">Fostering accessibility and equity

4.4.2 Collaborative leadership

In patient safety, collaborative leadership promotes shared responsibility, effective problem-solving, and a collective commitment to continuous improvement, fostering safer care delivery and better outcomes for patients.

Exhibit 40

Best practices across the globe – Collaborative leadership

United States



Problem: Ineffective implementation of known safety solutions across healthcare systems in the US

Solution: National Steering Committee for Patient Safety (NSC) was established with leaders from 27 org, to encourage greater coordination of collective patient safety efforts

United Kingdom



Problem: Health inequalities, unwarranted variations in care, high rate of anti-microbial infections

Solution: Integrated Care Board, comprising of 42 org, aimed to increase early diagnosis rates for cancer, reduce antimicrobial resistant infections, address health inequality gap

Australia



Problem: Inefficiencies in care delivery, limited patient engagement, medical errors and inconsistencies in quality of care

Solution: Australian Commission on Safety and Quality in Health Care, comprises of multiple govt. and private healthcare bodies, aimed to ensure better health outcomes and experiences for all patients

India



Solution for India

Implore healthcare leaders to foster collective action plan and to devise a self assessment tool to uphold patient safety

Potential challenges

Limited resources, complex healthcare landscape and cultural barriers

How to overcome

Collaboration with diverse stakeholders, addressing resource gaps, and promoting open communication about patient safety

Investing in developing a healthcare workforce, working closely with local people and communities, using resources wisely

Partnering with healthcare providers, devising framework for the commission, developing national safety and quality standards

Resource limitations (funding, infrastructure, staff), scalability (reaching masses)

Variability in patient safety and healthcare quality

PPP (to leverage resources and expertise), community – based engagement and pilot projects

Develop benchmarking programs through allocation of sufficient resources

Following is a roadmap outlining achievable goals, key stakeholders, and the role of QCI / NABH / NABL and NATHEALTH:

Recommendations – Collaborative leadership

Short term (1-2 years)

Shared and collective leadership:

- Establish a **National Patient Safety Council** with representatives from NABH, NABL, NATHEALTH, healthcare providers, patient advocacy groups, and government bodies

National action plan:

- Assess patient safety issues, engage stakeholders, and map resources** such as online toolkits to create a baseline report and action plan for low-cost, high-impact interventions

Mid term (2-5 years)

Community engagement:

- Partner with local communities and NGOs** to address cultural barriers, raise awareness, and encourage patient participation in safety initiatives

Resource mobilization:

- Secure public-private partnerships** to leverage resources, expertise, and infrastructure for broader program implementation

Long term (5+ years)

National safety and quality standards:

- Develop and implement **evidence-based national standards**, considering India's context and adapting them over time based on data and feedback

Continuous monitoring and evaluation:

- Regularly monitor progress, analyze data** from self-assessment tools, and adapt the plan based on evidence and best practices

Recognition and incentives:

- Recognize facilities** achieving sustained excellence in patient safety for 5 consecutive years

Relevant stakeholders

QCI / NABH / NABL:

Collaborate on quality standards and accreditation processes

NATHEALTH:

Represent private healthcare providers and facilitate participation

Government bodies:

Provide funding, policy support, and regulatory oversight

Healthcare providers:

Implement the plan at the facility level

Patient advocacy groups:

Ensure patient voices are heard and advocate for their safety needs

Local communities:

Provide valuable insights and collaborate on culturally sensitive solutions

4.4.3 Data infrastructure

Implementing data infrastructure for patient safety enables systematic collection, analysis, and utilization of healthcare data. It facilitates evidence-based decision-making, and early detection of trends or issues, and enables continuous monitoring to identify areas for improvement, ultimately enhancing patient safety and quality of care.

Exhibit 42

Best practices across the globe – Data infrastructure

United States	Canada	United States	Canada
Problem: Lack of standardized terminology across different EHR formats created a barrier to consistent data use, even though national coding standards were in place	Problem: Standardized data methods were essential to reduce outcome and satisfaction disparities in thoracic surgery	Problem: Efforts to reduce high rates of Central Line-Associated Blood Stream Infections (CLABSI) have highlighted the importance of systematic data collection and sharing to improve patient outcomes	Solution: Standardized hospital practices reduced CLABSI by 28% over 24 months , improving care quality
Solution: Improved EHR integration and data sharing have led to better analysis and healthcare outcomes across organizations	Solution: Seminars that combined standardized data with physician feedback analyzed over 30,000 patient records and generated more than 200 recommendations for improving quality		
Solution for India Assessing EHRs for coding standards, collaborate with vendors, and conduct regular compliance checks	India Unifying data framework with standardized coding and centralized tracking improves patient outcome analysis	Healthcare collaboration creates harm prevention bundles , with regular monitoring to improve patient outcomes	
Potential challenges T2+ cities face limited resources, data infrastructure, awareness, and system compatibility challenges	Data consistency across healthcare facilities is hindered by technology adoption resistance	Limited funding restricts the implementation of evidence-based practices and training	
How to overcome Allocating adequate funding and resources for training and infrastructure	Standardizing data protocols , train staff, and demonstrate benefits to promote quality data	Training healthcare staff, implement data validation protocols, and for data quality conduct regular audits	

Following is a roadmap outlining achievable goals, key stakeholders, and the role of QCI / NABH / NABL and NATHEALTH:

Recommendations – Data infrastructure

Short term (1-2 years)

Evaluate existing EHR systems:

- NATHEALTH can collaborate with QCI / NABH / NABL to develop a **national framework** for assessing EHR system compatibility with coding standards

Pilot program in T2+ cities:

- The government can partner with healthcare providers in tier 2+ cities to **implement a unified data collection framework** aligned with national standards. This pilot can inform larger-scale rollouts

Mid term (2-5 years)

Standardization and interoperability:

- Collaborate with healthcare IT vendors to establish **standardized data exchange formats and ensure seamless integration** with existing systems

Centralized data repository:

- **Develop a secure, centralized system** for collecting and analyzing patient safety data across participating institutions. This could be facilitated by NATHEALTH in collaboration with government agencies

Long term (5+ years)

National safety and quality standards:

- Develop and implement **evidence-based national standards**, considering India's context and adapting them over time based on data and feedback

Continuous monitoring and evaluation:

- **Regularly monitor progress, analyze data** from self-assessment tools, and adapt the plan based on evidence and best practices

Recognition and incentives:

- **Recognize facilities** achieving sustained excellence in patient safety for 5 consecutive years

Relevant stakeholders

Government: Partner for pilot, secure funding, develop data repository, support capacity building

QCI / NABH / NABL:
Regulatory oversight, framework development and evaluation of pilot data collection programs

NATHEALTH: Develop assessment framework along with QCI / NABH / NABL, pilot program liaison, industry advocate for funding, collaborate with government agencies for data repository creation

Healthcare professionals: Actively participate in data collection, utilize data collection tools, report incidents, and implement harm prevention strategies

IT vendors: Develop and maintain interoperable EHR systems meeting national standards

4.4.4 Workforce development

Workforce development in patient safety ensures healthcare professionals have the necessary skills, knowledge, and resources to deliver high-quality care. It enhances competency, promotes adherence to best practices, and empowers staff to identify and mitigate risks, ultimately improving patient outcomes and reducing adverse events.

Exhibit 44

Best practices across the globe – Workforce development

United States 	Australia 	United Kingdom 
Problem: Poor communication and teamwork within healthcare settings led to errors and patient harm Outcome: Effective communication streamlines care delivery, improved patient outcomes , and reduced errors	Problem: Better communication and addressing disclosure hesitancy after errors were lagging Outcome: Transparent disclosure practices protected patient rights , promoted trust, and decreased liability concerns	Problem: Healthcare suffered from poor communication across departments and limited opportunities for frontline staff input Outcome: Empowering frontline staff to voice concerns has fostered collaborative teamwork and has enhanced overall safety
India 		
Solution for India Identify team challenges , customize training, provide convenient video simulations for professionals to meet organizational needs	 Customize training materials with diverse teaching methods like lectures, role-playing, simulations, and case discussions	 Engage senior management and frontline staff , identify risks, conduct site visits, develop action plans with feedback
Potential challenges Tailoring training to overcome cultural/linguistic barriers and addressing skepticism about relevance	 Addressing cultural resistance to disclosure and overcome resource limitations (funding, infrastructure, staff)	 Limited resources hinder regular safety walkrounds and obtaining active frontline staff participation
How to overcome Promoting cultural sensitivity through training and seek funding for digital infrastructure development	 Offering confidential reporting , address reputation concerns, and upgrade technology for better accessibility	 Securing leadership support , gain staff buy-in, and create an open culture for addressing concerns

Following is a roadmap outlining achievable goals, key stakeholders, and the role of QCI / NABH / NABL and NATHEALTH:

Recommendations – Workforce development



4.4.5 Patient empowerment

Patient empowerment in patient safety fosters active involvement, communication, and shared decision-making between patients and HCPs. It enhances patient understanding, encourages reporting of concerns, and promotes adherence to treatment plans, leading to safer care practices and improved health outcomes.

Exhibit 46

Best practices across the globe – Patient empowerment



Following is a roadmap outlining achievable goals, key stakeholders, and the role of QCI / NABH / NABL and NATHEALTH:

Recommendations – Patient empowerment

Short term (1-2 years)

Strengthen existing PFACs:

- Strengthening the foundation of established PFACs by developing a **flexible framework**

Onboarding and orientation:

- Implement targeted outreach strategies to **onboard diverse new members** into existing PFAC
- Conduct **orientation sessions** to familiarize new members with PFAC roles, responsibilities, and communication channels

Facilitation and communication:

- Appoint a **facilitator** to ensure smooth PFAC operation and establish **regular communication channels**

Education for patients:

- Educate the patients on proper hygiene practices during **sample collection and waste disposal**

Mid term (2-5 years)

Enhance PFAC operations:

- Provide **comprehensive training** for council members on patient safety principles, communications
- Implement hotline **infrastructure with trained staff** to address patient concerns and inquiries

Standardize feedback mechanisms:

- Develop **standardized formats** for collecting and submitting patient **survey data** to relevant authorities
- Analyze results to identify areas for improvement and create **targeted plans** based on patient feedback

Long term (5+ years)

Technology integration:

- Invest in **IT infrastructure** to seamlessly integrate PFAC activities with existing hospital systems, enabling **efficient response and follow-up** to patient feedback

Communication channels:

- Explore **communication channels** besides online surveys, considering varied digital literacy levels, and prioritizing **data security and privacy** protocols to build trust and encourage participation

Relevant stakeholders

Government agencies: Fund, guide framework development, collaborate on training, invest in IT infrastructure and research for patient safety

Healthcare Providers (HCP): Strengthen PFACs, dedicate resources, and advocate for technology integration to improve patient safety

Patient Advocacy Groups (PAG): Develop outreach strategies, train patient representatives, and partner on public awareness campaigns

NGOs & Civil Society Organizations (CSOs): Assist in reaching underserved populations, offer specialized training, and collaborate on research

QCI / NABH and NATHEALTH: Collaborate on developing standards and conducting assessments for PFAC effectiveness to ensure patient safety

QCI / NABL and NATHEALTH: Promote education on proper hygiene practices and advocate for continuous improvement through training programs

4.4.6 Information sharing and communication

Effective information sharing and communication are essential for patient safety to ensure the accurate transfer of vital data between healthcare professionals, reduce errors, prevent misunderstandings, and promote coordinated care, ultimately enhancing patient outcomes.

Exhibit 48

Best practices across the globe – Information sharing and communication



Following is a roadmap outlining achievable goals, key stakeholders, and the role of QCI / NABH / NABL and NATHEALTH:

Recommendations – Information sharing and communication

Short term (1-2 years)

Training:

- Implement training programs in **Integrated Care Assessment and Planning** for healthcare professionals, using **culture-adapted learning guides**
- Training focused on staff proficiency in handling procedures and protocols to minimize errors, particularly during the **pre-analytical phase of diagnostics**

Standardized data:

- Develop and **pilot standardized data sets** with decision-making tools and care planning strategies for clinical assessments, focusing on **high-priority patient safety areas**

Governing body:

- Establish a **focused patient safety governing body** to define the data collection and analysis framework

Stakeholder engagement:

- Regularly conduct **meetings and workshops** with key stakeholders to address concerns, fostering **transparency and collaboration**

Mid term (2-5 years)

Technology adoption:

- Choose a **secure and user-friendly platform** and train healthcare staff on data input and system utilization

Data extraction tool:

- Develop and deploy a **standardized data extraction tool** for seamless data sharing, considering local infrastructure limitations

Addressing concerns:

- Collaborate with **QCI/NABH and NATHEALTH** to develop educational materials addressing data privacy concerns and promoting standardized reporting protocols for hospitals

Long term (5+ years)

Interoperability

- Work towards **interoperability** between healthcare information systems, facilitating information exchange across diverse settings

Scaling up:

- Based on successful pilots, **scale up standardized data collection and analysis** across the country, continuously evaluating and refining the system

Relevant stakeholders

Government: Establish policies supporting integrated care assessment and planning training

QCI / NABH and NATHEALTH: Provide expertise in crafting culture-adapted learning guides, contribute to developing standardized data sets, and develop and integrate communication standards into accreditation criteria to incentivize hospitals for improvement

Healthcare Professionals: Engage inter-department professionals in regular meetings to discuss concerns regarding patient safety for transparency and better planning

QCI / NABL and NATHEALTH: Targeted training programs for diagnostic staff to enhance proficiency in procedure handling, setting up plan for showcasing disposable syringes, and explaining waste disposal procedures to patients

4.4.7 Technology integration

Technology integration in patient safety is crucial to streamline processes, enhance efficiency, reduce errors, and improve communication among HCPs. It enables real-time access to patient data, decision support systems, and monitoring tools, ultimately contributing to better clinical outcomes and overall quality of care.

Exhibit 50

Best practices across the globe – Technology integration

United Kingdom 	United States 	United Kingdom 
Problem: Medication errors and risk of fraud due to paper prescriptions and lack of communication between healthcare providers and pharmacies	Problem: Human errors due to manual processes, missed or duplicated doses, and time consumption in verification and checks	Problem: Fragmented reporting and underused safety data hinder understanding and collaboration on patient safety in the NHS
Solution: Reduced medication errors, adverse drug events, enhanced prescription security, and improved coordination via integration with EHRs	Solution: Reduced human errors by scanning barcodes for medication and patient identification, prevention of missed and duplicate doses, and created a clear audit trail	Solution: Centralized system reduced adverse events, enabled quick best practice sharing, and informed decisions with data insights
Solution for India Providing stakeholder training on EPS software, integrating with existing EHR systems and gradual implementation	Evaluating BCMA software compatibility, training the staff on barcode scanning protocols and piloting BCMA	Implementing standardized reporting and professional training and analyzing data to target interventions for high-risk safety areas
Potential challenges Limited access to EHR systems, compatibility issues and resistance from healthcare providers and pharmacies for transitioning	Limited financial resources, uneven IT infrastructure in hospitals, and lack of standardized medication barcode systems	Integrating diverse health systems requires extensive effort, terminology unification, and comprehensive staff training
How to overcome Implementing strict confidentiality and regular audits, and conducting thorough testing, and ongoing technical support	Conducting thorough user training and phased implementation along with quality control checks with error reporting mechanism	Developing integration plan with interoperability standards, and working with facilities for standard terminologies

Following is a roadmap outlining achievable goals, key stakeholders, and the role of QCI / NABH / NABL and NATHEALTH:

Recommendations – Technology integration

Short term (1-2 years)

Comprehensive training:

- Implement **comprehensive training programs** on **EPS** and associated workflows for all stakeholders, addressing **compatibility issues** and ensuring a smooth transition

Pilot testing and gradual implementation:

- Conduct **pilot testing** of **EPS** and **BCMA software** in select facilities, gradually scaling up implementation across hospitals and pharmacies

Mid term (2-5 years)

Standardization and integration:

- Foster **standardization** of medication **barcodes** and drug packaging, along with **terminologies and reporting protocols** across public and private facilities

BCMA implementation and monitoring:

- Deploy **BCMA** across the healthcare ecosystem, monitoring usage and performance to identify areas for improvement

Data-driven safety interventions:

- Analyze data from healthcare institutions to identify **recurring safety patterns** and **high-risk areas**, developing **targeted safety interventions** based on these insights

Long term (5+ years)

Advanced integration:

- Explore and integrate advanced technologies like **artificial intelligence and machine learning** for real-time risk identification and prediction

Relevant stakeholders

Government agencies: Fund, standardize, and facilitate collaboration for training, pilot testing, and implementation

Healthcare Providers (HCP): Participate in training, pilot programs, and implementation, ensuring smooth integration and data collection for patient safety initiatives

Patient Advocacy Groups (PAG): Advocate for patient safety, educate patients, and monitor the effectiveness of implemented safety measures

NGOs & Civil Society Organizations (CSOs): Support vulnerable populations, raise public awareness, and contribute to research in this tech-based patient safety area

QCI / NABH / NABL and NATHEALTH: Collaborate on developing standards, conducting assessments, and evaluating the effectiveness of implemented safety measures

4.4.8 Policy reforms

Implementing policy reforms in patient safety enhances regulatory standards, healthcare policies, and oversight mechanisms. It strengthens accountability, promotes transparency, and ensures alignment with evidence-based practices, ultimately safeguarding patient rights and improving overall healthcare quality and safety.

Exhibit 52

Best practices across the globe – Policy reforms

United Kingdom



Problem: Lack of standardized protocols impedes the timely identification of patients at risk of falling, posing significant challenges to patient safety

Solution: Improved patient outcomes, increased staff awareness, and fostered a safer environment for patient care

United Kingdom



Problem: Prevalence of medical errors & incorrect diagnoses is exacerbated by patient misidentification and the risk of compromising patients' data confidentiality

Solution: Common framework for accurately identifying patients to minimize miscommunication & errors, fostering trust and confidence in the healthcare system

United States



Problem: Extended healthcare stays and diversion of resources to treat preventable pressure ulcers occur due to lapses in patient care

Solution: Timely interventions and treatment for patients at risk of pressure ulcers improves the overall patient experience

India



Solution for India

Monitoring & reviewing audit results, analyzing trends in fall incidents, and disseminating learning to enhance patient safety

Potential challenges

Resource constraints, financial limitations, and insufficient staffing

How to overcome

Encouraging open dialogue & collaboration among healthcare professionals while providing training on accurate data recording

Streamlining a protocol to identify patients & record accurate information & incorporating patient identification policies into training

Developing a **comprehensive plan of care, maintenance, & identification** of risk factors compromising skin integrity

Complexities in implementing a uniform patient policy and limitations in technological infrastructure

Variations in the level of education among healthcare staff and **insufficient funding, staffing, and resource allocation**

Seeking partnerships to secure funding, while gradually introducing & **scaling up technology solutions** based on existing infrastructure

Utilizing in-person & digital training methods to cater to a diverse workforce, & **collaborating with organizations** to pool resources

Following is a roadmap outlining achievable goals, key stakeholders, and the role of QCI / NABH / NABL and NATHEALTH:

Recommendations – Policy reforms

Short term (1-2 years)

Develop and implement a national framework:

- This framework should establish **common goals, standards, and expectations** for patient safety across all healthcare settings

Establish a national patient safety reporting system:

- This would allow healthcare providers to **report patient safety incidents and near misses**, which would help to identify trends and areas for improvement

Launch public awareness campaigns:

- These would help **educate** patients and their families about their rights and responsibilities

Mid term (2-5 years)

Integrate patient safety into the curricula of healthcare professionals:

- This would ensure that all healthcare providers have the knowledge and skills they need to provide safe care

Develop and implement evidence-based patient safety practices:

- These practices would be based on the **best available research** on how to prevent patient harm

Strengthen enforcement of patient safety regulations:

- This would help to ensure that healthcare providers are complying with the national framework for patient safety

Accreditation through tiered system:

- Accreditation for all labs, potentially through a **tiered system (local, state, national)** and training the other bodies for accreditation

Long term (5+ years)

Research on patient safety at the national level:

- It would help to identify new ways to **prevent patient harm and improve** the quality of care

Develop and implement new technologies:

- These technologies could include EHR, which can help **improve medication safety** and communication among healthcare providers

Create a culture of patient safety in healthcare organizations:

- This culture would emphasize the **importance of patient safety and encourage** all staff members to report safety concerns

Relevant stakeholders

Government agencies: Develop a national framework, establish a reporting system, fund research, launch public awareness campaigns, and strengthen enforcement through policies and regulations

Healthcare Providers (HCP):

Participate in framework development, implement safety, report incidents, and integrate patient safety into training curricula

Patient Advocacy Groups (PAG):

Advocate for a patient-centered framework, educate patients on safety rights, monitor implementation, and collaborate on research and public awareness campaigns

QCI / NABH and NATHEALTH:

Collaborate on developing safety standards, conduct assessments of healthcare facilities, evaluate the effectiveness of implemented safety measures, and promote best practices

QCI / NABL and NATHEALTH:

Push for accreditation for all diagnostic labs, possibly through creation of a tiered system and ensuring standards through training of other accreditation bodies

4.4.9 Public awareness

Implementing public awareness of patient safety educates individuals about healthcare risks, rights, and resources. It encourages informed decision-making, promotes patient advocacy, and fosters community engagement in healthcare quality improvement efforts, ultimately leading to safer care delivery and better patient outcomes.

Exhibit 54

Best practices across the globe – Public awareness

United States



Problem: Inadequate communication channels and a lack of emphasis on shared decision-making between healthcare providers & patients

Solution: Patients asking pertinent questions & educating themselves about their medical conditions, treatment options, & potential risks

United Kingdom



Problem: Inconsistent integration of patient safety modules into healthcare training programs & **inadequate dissemination** of information to patients

Solution: Important discussions & inspired action by individuals on how to actively contribute to their own safety during medical interventions

United States



Problem: Widespread prevalence of adverse events stemming from unsafe care, compounded by the **lack of awareness among patients regarding their rights**

Solution: Patients **educated about their rights** and encouraged to take a more proactive role in their care through safety display and posters

India



Solution for India

Engaging underrepresented patient partners to collaboratively create patient story galleries, highlighting their healthcare journeys

Potential challenges

Limited financial resources and high patient volumes & workload

How to overcome

Establishing public-private collaborations to pool resources, while encouraging senior staff to actively involve junior staff

Conducting themed awareness days showcasing organizational efforts to ensure patient safety

Planning a safety display featuring patient incident posters & providing a **suggestion box** for improving hospital safety

Limited technology infrastructure and historical reliance on healthcare providers for decision-making

Campaigns not prioritized amidst other pressing healthcare challenges, & limited incorporation of patient safety modules

Innovative & cost-effective technology solutions to overcome infrastructure issues and **advocating for policy changes**

Following is a roadmap outlining achievable goals, key stakeholders, and the role of QCI / NABH / NABL and NATHEALTH:

Recommendations – Public awareness

Short term (1-2 years)

Focus on local, low-cost initiatives:

- Utilize existing infra., like waiting areas for patient story galleries and safety displays
- Partner with medical colleges for themed awareness days, leveraging their resources and student reach
- Public awareness campaigns, utilizing circulars and advertisements, to educate a broader audience, especially in smaller communities

Engage diverse patient populations:

- Collaborate with NGOs serving underrepresented communities to include their perspectives and experiences in awareness campaigns

Leverage technology strategically

- Utilize cost-effective solutions like social media and SMS campaigns to overcome limited internet reach in rural areas

Mid term (2-5 years)

Develop national patient safety campaigns:

- NATHEALTH can partner with QCI / NABH / NABL and other stakeholders to create large-scale campaigns

Advocate for integration of patient safety modules:

- Collaborate with medical education bodies to incorporate patient safety into curriculums, fostering a future generation of safety-conscious healthcare providers

Pilot innovative solutions:

- Explore tech-enabled platforms to educate patients and families about their rights and roles in ensuring safety

Long term (5+ years)

Establish a national patient safety resource center:

- This center could act as a repository of best practices, research findings, and educational materials for patients, providers, and policymakers

Promote cultural shift towards shared decision-making:

- Collaborate with community leaders and healthcare professionals to address cultural factors and empower patients to participate actively in their healthcare decisions

Relevant stakeholders

Government agencies:
Provide financial and policy support to bolster patient safety initiatives

PAGs and NGOs: Offer community outreach and patient perspectives to inform patient safety practices

Healthcare professional associations and medical colleges: Integrate patient safety into education and training to cultivate a safety-focused workforce

Accreditation bodies (QCI / NABH / NABL):
Set patient safety standards and provide accreditation pathways to drive safety improvements and launching public awareness campaigns

NATHEALTH: Facilitate collaboration among healthcare institutions and leverage industry expertise to accelerate patient safety advancements

4.4.10 Resource allocation

Limited resources can compromise patient care. Resource allocation ensures fair distribution and prioritizes critical needs, minimizing risks and harm.

Exhibit 56

Best practices across the globe – Resource allocation

United Kingdom



Problem: Fragmented safety alerts & protocols in healthcare leads to **inconsistent awareness & implementation** of safety measures across different settings

Solution: Improved patient safety through **timely dissemination of safety alerts** to healthcare providers, **enhancing awareness & adoption** of safety measures

United States



Problem: Need to **incentivizing quality care** and **reducing healthcare costs** by transitioning from a fee-for-service to a value and quality-based model

Solution: 420+ Accountable Care Organizations (ACOs) served nearly 11 million Medicare beneficiaries, **saving Medicare** approximately US\$1.8B in 2022

Australia



Problem: Limited transparency & accessibility of hospital performance data pose challenges for patients & policymakers in making informed healthcare decisions

Solution: MyHospitals platform offers **detailed hospital performance data**, **improving accountability** & assisting patients in making informed choices

India



Solution for India

Developing a **centralized digital platform** for **issuing & tracking** safety alerts & conducting regular training sessions

Establishing a **collaborative healthcare provider network** and implement performance-based incentives

Developing an **interactive online platform** with updated data for patients to **compare hospital performance metrics**

Potential challenges

Fragmented healthcare system with limited mechanisms for monitoring and reporting adverse events and safety issues

Lack of integrated patient care models while ensuring accountability & quality standards in a diverse healthcare landscape

Inconsistent data standards among hospitals and limited digital infrastructure in some regions

How to overcome

Strengthening regulatory oversight and accountability mechanisms for patient safety

Developing pilot programs to assess feasibility & impact of ACO-like models in India, ensuring accountability in healthcare delivery

Standardizing data collection & reporting protocols for hospitals while investing in digital infrastructure

Following is a roadmap outlining achievable goals, key stakeholders, and the role of QCI / NABH / NABL and NATHEALTH:

Recommendations – Resource allocation

Short term (1-2 years)

Centralized platform:

- Develop a **centralized digital platform** for issuing and tracking safety alerts, ensuring **accessibility** for diverse healthcare providers across the country

Training and collaboration:

- Conduct **regular training sessions** on alert response and establish a **collaborative network** for sharing best practices and resources, leveraging existing **professional associations and networks**

Mid term (2-5 years)

Performance-based incentives:

- Implement **performance-based incentives to encourage quality and cost-efficiency**, aligned with established patient safety metrics

Transparency and accountability:

- Create an **interactive online platform** for patients to view and compare hospital performance metrics, promoting **transparency and accountability**

Long term (5+ years)

Data integration and infrastructure:

- Address **data collection and reporting inconsistencies** through standardized protocols and collaborate with **government agencies and private stakeholders** to improve **digital infrastructure** in underserved regions

Relevant stakeholders

Government agencies: Fund development, collaborate on data sharing, and provide resources for infrastructure improvement for a central patient safety platform

HCP: Participate in the development of training sessions and collaborative networks and utilize the platform for issuing and responding to patient safety alerts

PAG: Advocate for patient-centered platform design, educate patients on access and utilization, and monitor platform effectiveness

QCI / NABH / NABL and NATHEALTH: Collaborate on developing central digitized platform standards, conduct platform-related assessments, and promote best practices in alert response and utilization

Summary of the recommendations

Exhibit 58

Recommendations – Summary

Short term (1-2 years)

Collaborative leadership:

- Establish a National Patient Safety Council with members from different stakeholders
- National Action Plan by assessing patient safety issues and engaging stakeholders

Data infrastructure:

- Evaluate existing EHR systems
- Pilot programs in T2+ cities for unified data collection framework

Workforce development:

- Leverage existing resources to gather insights
- Targeted campaigns based on specific theme like patient fall

Patient empowerment:

- Strengthen existing PFACs
- Training patients on essential skills like medication management, self monitoring
- Education for patients on hygiene practices

Information sharing and communication:

- Develop and pilot standardized datasets
- Focused patient safety governing body for creating data analysis framework
- Training for staff for procedure handling and integrated care

Technology integration:

- Comprehensive training on Electronic Prescribing Software (EPS)
- Pilot testing and gradual implementation of EPS and BCMA

Policy reform:

- Implementation of framework for patient safety
- Establish a patient safety reporting system

Public awareness:

- Focus on local, low-cost initiatives for awareness
- Engage diverse patient populations through NGOs

Resource allocation:

- Centralized platform for tracking safety alerts, training, and collaboration network development for sharing best practices

Mid term (2-5 years)

Collaborative leadership:

- Community engagement to address cultural barriers and raise awareness
- Resource mobilization through public-private partnerships to leverage resource and expertise

Data infrastructure:

- Standardization and interoperability
- Develop a centralized data repository

Workforce development:

- Develop mobile apps to provide patient safety information and resources
- Multi-stakeholder engagement through committee establishment

Patient empowerment:

- Enhance PFAC operations through training and increased resource allocation
- Standardize feedback mechanisms for patient survey data

Information sharing and communication:

- Platform creation to train staff on data handling
- Create data extraction tool for data sharing

Technology integration:

- Standardization and integration
- BCMA implementation and monitoring

Policy reform:

- Develop & implement evidence-based practices in curricula
- Strengthen enforcement of patient safety regulations
- Accreditation through tiered system

Public awareness:

- Develop national patient safety campaigns
- Advocate for integration of patient safety modules in curriculum

Resource allocation:

- Performance-based incentives for hospitals
- Transparency and accountability for hospital-level patient safety metrics

Long term (5+ years)

Collaborative leadership:

- National safety and quality standards
- Continuous monitoring and evaluation
- Recognition and incentives for facilities that demonstrate good patient safety systems

Data infrastructure:

- Nationwide implementation of unified data collection framework
- Advanced analytics techniques for predicting and reducing medication error

Workforce development:

- Advocate for systemic changes in training
- Promote cultural shift in decision making in healthcare through collaboration

Patient empowerment:

- Invest in IT infrastructure to seamlessly integrate PFAC activities
- Alternative channels for communicating patient safety rights, best practices

Information sharing and communication:

- Interoperability across information systems
- Scaling up standardized data collection and analysis across country

Technology integration:

- Advanced integration of technologies such as AI in the software

Policy reform:

- Conduct research on patient safety at national level
- Develop and implement new technologies like Electronic Health Record

Public awareness:

- Establish a national patient safety resource center
- Promote cultural shift towards shared decision-making

Resource allocation:

- Data integration and infrastructure through standardized protocols



5

CONCLUSION

CONCLUSION

While India saw a negligible decrease in patient safety incidents from 2010 to 2019, the rate remains higher than in comparable countries, highlighting the need for improved reporting, safety measures, and focus on the most vulnerable populations. While India has made strides through initiatives like NABH, NABL, and NQAS, challenges remain. Some of these include:

- **Staffing issues:** Pressure to balance safety and efficiency, inadequate staffing cultures, and limited resources
- **Communication gaps:** Between HCPs and patients, hindering information sharing and error prevention
- **Weak safety culture:** Lack of emphasis on safety protocols and accountability across all levels
- **Lack of patient empowerment:** Lack of essential knowledge about their rights, medication safety, and infection control practices
- **Resource constraints:** Inadequate financial resources and a shortage of qualified healthcare professionals make it difficult to improve patient safety levels in India

To address these, a **nine-pronged** approach is proposed:

- **Collaborative leadership:** Promotes collective problem-solving and continuous improvement while institutionalizing patient safety
- **Data infrastructure:** Focuses on establishing a national framework for data collection and analysis, using standardized formats, and ensuring secure data storage
- **Workforce development:** Involves training healthcare professionals, integrating patient safety modules into educational programs, and promoting continuous learning
- **Information sharing and communication:** Emphasizes implementing standardized data collection and reporting protocols, using secure platforms, and fostering collaboration among stakeholders
- **Technology integration:** Highlights the importance of using electronic health records, BCMA, and exploring advanced technologies for risk identification
- **Patient empowerment:** Involves strengthening patient advisory councils, providing training on patient safety principles, and integrating patient feedback mechanisms
- **Public awareness:** Focuses on using diverse communication channels for patient education, collaborating with NGOs for community outreach, and integrating patient safety into medical education
- **Policy reforms:** Emphasizes developing a national framework for patient safety, establishing a national reporting system, and strengthening enforcement of regulations
- **Resource allocation:** Highlights creating a centralized platform for sharing safety alerts, promoting performance-based incentives, and improving data collection and reporting consistency

With the recommendations mentioned above, India stands poised to make significant strides towards achieving the **desired state for patient safety**, i.e. minimize and ideally eliminate patient harm, with safety as a top priority at all levels. This desired state also includes significantly reducing AEMT rates, treatable deaths, and DALY, striving for WHO targets in maternal and neonatal mortality, implementing effective healthcare systems and processes, fostering an inclusive healthcare environment with shared responsibility, promoting continuous learning and improvement, and ensuring accessibility and equity in patient safety practices across the nation.

Core Activities of NABH

Accredits and certifies hospitals, healthcare providers, blood banks, & allied institutions, and, educates and trains for quality and patient safety in provision of healthcare.

Accreditation

- Hospitals, AYUSH hospitals, dental
- Small healthcare organizations (SHCOs), clinics, centers
- Medical Imaging Services
- Eye Care Organizations
- PHC
- Blood banks
- Panchkarma clinics
- Clinical trials accreditation program (Ethics Committee)
- NABH - International

Certification

- Entry level standards (Hospitals, SHCOs, AYUSH hospitals & centers)
- Medical laboratory
- Emergency department
- Nursing excellence

Empanelment

- CGHS Empanelment
- ECHS Empanelment
- MVTB Empanelment

New Programmes

- Digital health
- Care homes
- Stroke care centers
- Dental clinics

Projects

- Certification of AHWCs and integrated hospitals under NAM
- Inspection of homeopathy colleges
- Smile train centers
- Third party assessments of FOGSI partner hospitals

....and much more

16,300+
Accreditations & Certifications



4300+
Empanelment

WAY FORWARD

Scaling up quality in 1,00,000+ healthcare organizations and other medical establishments.

NABH programs data as on 15th March, 2024

ACCREDITATION

S. No.	Accreditation Program name	Total no. of accreditations
1	Hospitals	1327
2	Small Healthcare Organizations (SHCO)	943
3	Blood bank	154
4	Medical Imaging Services (MIS)	234
5	Dental healthcare service providers	372
6	Allopathic clinics	84
7	AYUSH	230
8	Panchakarma	90
9	Clinical trials (Ethics Committee)	191
10	Eye Care Organizations (ECO)	477
11	NABH – International	13



4,115
Accreditations

12,217
Certifications

4,322
Empanelment

CERTIFICATION

S. No.	Certification Program name	Total no. of certifications
1	Entry level hospitals	2484
2	Entry level SHCO	9130
3	Nursing excellence	230
4	Entry level SHCO	9130
5	Medical laboratory program	236
6	Emergency department	58
7	Entry level AYUSH (hospital & center)	79

EMPANELMENT

S. No.	Empanelment Program name	Total no. of recommended
1	ECHS Empanelment	2091
2	CGHS Empanelment	2194
3	MVTB Empanelment	37

20,654
Total Organizations

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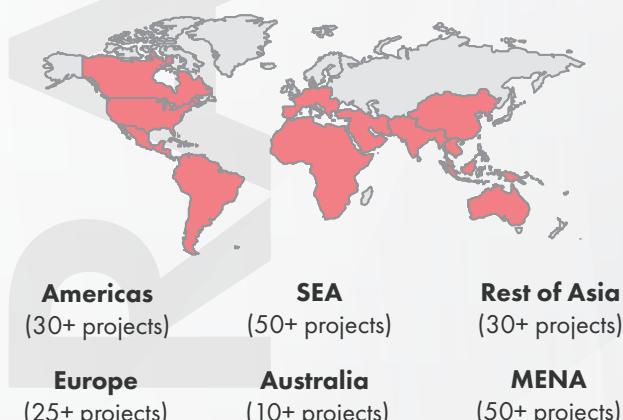
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THANK YOU

