सत्यमेव जयते

National
PATIENT SAFETY IMPLEMENTATION

Framework (2018-2025)

INDIA

MINISTRY OF HEALTH & FAMILY WELFARE
Government of India

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जगत प्रकाश नड्डा
Jagat Prakash Nadda

स्वास्थ्य एवं परिवार कल्याण मंत्री
भारत सरकार
Minister of Health & Family Welfare
Government of India

MESSAGE

Patient safety is being increasingly recognized as an issue of global importance in health care which is a function of Universal Health Coverage (UHC). In India a multitude of initiatives are underway in the health sector which address different patient safety aspects independently. Swachha Bharat Abhiyan, Kayakalp Hospital Awards, health systems strengthening through National Health Mission, National Quality Assurance Standards for public health facilities, National Action Plan on Antimicrobial Resistance are some of these initiatives.

It was realized that much is being done for patient safety in India but in a fragmented manner. The strategies and interventions should not be regarded as stand-alone initiatives that are working in silos but as part of a whole exercise and it is vital to bring them together under one umbrella. Therefore, the development of National Patient Safety Implementation Framework to synergize multitude of initiatives for additive and summative effects on the overall patient safety scenario has become imperative for our nation.

I envisage that all stakeholders in health care have an important role to play in the successful implementation of this National Patient Safety Implementation Framework and I urge them to come forward to ensure quality assured patient centric care that gives paramount importance to patient safety outcomes in service delivery. I wish that the National Patient Safety Implementation Framework (NPSIF) will help attain patient safety goals in a coordinated manner and contribute to overall agenda of improvement of quality of care within the context of Universal Health Care in India.

(Jagat Prakash Nadda)

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Government of India
Department of Health and Family Welfare
Ministry of Health & Family Welfare
Dated : 14th April, 2018

Message

Patient safety is a fundamental element of health care. It represents one dimension of quality of care alongside accessibility, acceptability, effectiveness, efficiency and people-centeredness. It encompasses both medical and non medical domains and patient safety problems due to communication errors, patient management errors and Clinical performance errors.

Patient safety errors can be avoided by adopting quality assurance practices applied in other industries, adopting new technology, health care staffs' continuing education and error reporting systems. It requires a multi-pronged approach directed towards laying SOPs for patient handling, diagnosis, treatment etc, adoption of hand hygiene and other universal precautions, availability of checklists, rational use of medicine, training of health care professionals, strengthening health care infrastructure, a hospital accreditation programme, awareness generation among patients. All these concepts should be an integral part of all national programmes and health care initiatives.

National Patient Safety Framework is a unifying framework that brings together the diverse programmes being implemented, to give better expression to patient safety elements. This framework document is intended for adoption by both public and private sector. I hope that with further technical guidelines on the subject safety of patients will be ingrained in health care delivery across public and private sectors.

(Preeti Sudan)
14.4.18

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Dated the 16th April, 2018

MESSAGE

In health care settings harm can be caused by a range of errors or adverse events. Over the past ten years patient safety has emerged as an important discipline which entails coordinated efforts to prevent harm caused by the process of health care itself. The concept of "Quality" that originated in industry and manufacturing slowly percolated into health care and now patient safety and quality of care are seen as closely intertwined.

Even though many data management systems exist there is little documentation on errors, negligence, HCAI, adverse events etc., newer challenges are also emerging in the health sector space such as online pharmacies and the need for their regulation. In response of these challenges a wide range of initiatives on patient safety are being implemented at different levels of health care by central and state governments and in both public and private sectors to address the diverse issues of patient safety and there is a multiplicity of national and international stakeholders working in this area.

Taking cognizance of the patient safety challenges and to harmonise the many initiatives, Ministry of Health & Family Welfare has developed an overarching framework on Patient Safety in India with the aim to improve patient safety at all levels of health care across all modalities of health care provision, including prevention, diagnosis, treatment and follow up within overall context of improving quality of care and progressing towards Universal Health Care in coming decade. I call upon the states, the private sector and other stakeholders to adopt the framework with zeal and enthusiasm.

(Sanjeeva Kumar)

Dr. Promila Gupta
Director General of Health Services

सत्यमेव जयते

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GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF HEALTH SERVICES
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MESSAGE

दिनांक/Dated.....13.4.18.

The first idea of patient safety is enshrined in the Hippocratic Oath itself, which emphasises upon the concept of 'do no harm'. Though the concept of 'do no harm' is old but it is as relevant today with the advent of modern medicine and ever more complicated procedures. Estimates show that in developed countries 1 in 10 patients are harmed while receiving hospital care and out of 100 patients, 7 in developed and 10 in developing countries will acquire health care-associated infections (HAIs). However, availability of concrete data has been a limitation in India.

The different aspects of patient safety include error in diagnosis, adverse events following drugs & devices, surgical errors & hospital acquired infections, unsafe injections & blood products and bio-medical waste management. Simple things like - hand hygiene, personal protection, hospital environment, bio-medical waste disposal, serviced patient care equipment, proper disposal of waste, patient etiquettes are low cost interventions that help reduce additional health care cost. Universal Precautions help reducing the risk of hospital acquired infections.

Many of the above aspects are addressed in different strategies and programmes of Ministry of Health & Family Welfare. To name a few the National Health Mission builds on the health systems in the country, Clinical Establishment Act (2010) emphasises upon rights of the patients, Mother & Child Tracking System, Adverse Event Following Immunization, pharmacovigilance programme are adverse event surveillance systems. Then there are many nascent programmes such as surveillance of antimicrobial resistance and health care associated infections which need to be scaled up. In order to bring all the patient safety initiatives under one umbrella, the National Patient Safety Framework has been developed for India which lays down six pillars for patient safety in India and aspires quality assured safe care to patients across the health sector in the country.

Gupta 13/4/18

(Dr. Promila Gupta)

Preface

Patient safety is the reduction of unnecessary harm associated with health care to an acceptable minimum. It is a fundamental element of health care and is intended for freedom for a patient from unnecessary harm or potential harm associated with provision of health care. Over past ten years patient safety has been recognized as an issue of global importance, but much work remains to be done.

The estimated burden of unsafe care is 1 in 10 patients receiving health care. It is estimated that globally of the 421 million patients hospitalized annually, 42.7 million patients suffer from adverse events. Major areas of concern are hospital associated infections (HAI), unsafe surgeries, unsafe injections, safe births, medication safety, blood safety and faulty medical devices. In 2013, the unsafe care is third in rank of causes of death globally after heart disease and cancer. Considering the magnitude of the problem, unsafe care is one of the major public health problems.

Managing medical errors is more complex, it has been based on the "personal approach", the individual involved in the care at the time of incident are held responsible, which is referred to as blaming. Systematic improvements cannot be made as long as we focus on blaming individuals. At hospital setting patient safety consists of four domains, i.e. (i) health care providers, (ii) recipients of health care, (iii) health care infrastructure and (iv) reporting and feedback on performance. If these issues are addressed appropriately, there appears to have a wide scope for improvement.

The process of development of nation patient safety implementation framework consisted of approval of ministry to develop framework, constitution of an expert group, convening of group consultations, developing draft framework, seeking comments of the partners and designing final draft. The framework covers legal & regulatory aspects, external quality assessment, nature and scale of adverse events, competent & capable workforce, prevention & control of hospital associated infections, building patient safety campaign and building capacity in patient safety research. The plan is to implement the programme over 2018-2025.

Directorate General of Health Services, MOH&FW, Government of India acknowledges the support provided by the WHO Country Office India, experts from different fields and NHSRC, who made the final draft and incorporated all the comments received from public domain.

Dr. Inder Parkash
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Abbreviations

AD	Auto Disable (syringe)
AEFI	Adverse Events Following Immunisation
AIIMS	All India Institute of Medical Sciences, New Delhi, India
AMR	Anti-Microbial Resistance
ASQua	Asian Society for Quality in Healthcare
BMW	Biomedical Waste
CEA	Clinical Establishment Act
CEO	Chief Executive Officer
CHC	Community Health Centre
CSR	Corporate Social Responsibility
DGHS	Directorate General of Health Services
FEMA	Failure Effect Mode Analysis
FRU	First Referral Unit
GMP	Good Manufacturing Practices
GoI	Government of India
HAI	Healthcare Associated Infections
HCF	Healthcare Facilities
HIC	Hospital Infection Control
HRH	Human Resources for Health
IAPO	International Alliance of Patients' Organizations
ICMR	Indian Council of Medical Research
IDSP	Integrated Disease Surveillance Program
IEC	Information, Education and Communication
IHR	International Health Regulations
IPC	Infection Prevention and Control
IPHS	Indian Public Health Standards
IPD	In-patient Department
ISQua	International Society for Quality in Healthcare

MCI	Medical Council of India
NABH	National Accreditation Board for Hospitals & Healthcare Providers
NACA	National Authority for Containment of Antibiotic resistance
NABL	National Accreditation Board for Testing and Calibration Laboratories
NCI	Nursing Council of India
NHSRC	National Health System Resource Centre
NHP	National Health Policy
NHM	National Health Mission
NOTP	National Organ Transplant Program
NOTTO	National Organ and Tissue Transplant Organization
NPSIF	National Patient Safety Implementation Framework
NQAS	National Quality Assurance Standards
MoHFW	Ministry of Health and Family Welfare
MS	Member States
PHC	Primary Health Centre
PEP	Post-Exposure Prophylaxis
QCI	Quality Council of India
OPD	Out-Patient Department
PHC	Primary Healthcare Centre
PIP	Program Implementation Plan
PVPI	Pharmacovigilance Program for India
RMNCH	Reproductive, Maternal, Neonatal and Child Health
RUP	Reuse Prevention (syringe)
SEAR	South-East Asia Region
SEARO	South-East Asia Regional Office
SIP	Sharps Injury Prevention (syringe)
SOP	Standard Operational Procedure
THOA	Transplant of Human Organs Act
UHC	Universal Health Coverage
UT	Union Territory
WHA	World Health Assembly
WHO	World Health Organization

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Structure and Purpose of the Document

This document is an endeavor integrate the discrete patient safety concepts and activities into a single national level policy framework, so that patient safety issues can be addressed in holistic way with commitment and contribution from all stakeholders – central and state governments, patient rights groups, professional associations, medical education institutions, agencies for quality and accreditation and of course healthcare providers at millions public and private healthcare facilities of all sizes and functions. This document provides a formal institutional framework for patient safety in the country as well as mandates for establishing the process for adverse event reporting system, capacity building, infection control and patient safety research.

This document is structured in three broad sections:

Section one provides Introduction to the subject, rationale and current situation of patient safety in India.

Section Two is the main body of the document which states the goal and guiding principles for National Patient Safety Implementation Framework and six strategic objectives to achieve the stated goal. Each strategic objective has been further elaborated into key priorities and specific actions.

Section there gives a strategic action plan on defined priorities and activities along with responsible institutions and timelines.

Though this framework is policy level document, it is relevant for all stakeholders.

Health Ministries and Directorates at state level should incorporate the key strategies from this document into their state specific policies to provide enabling institutional structure and processes for patient safety.

Program managers for various programs should understand the planned activities in this framework, so that specific activities can be integrated and their no duplication or redundancy in execution.

Managers at health care facilities should undertake the preparatory at their hospital / department level to ensure assessment, reporting and mitigation of patient safety risks.

This document is also useful for patient and consumer rights groups, patients, their relatives and community at large so they should understand their right and responsibilities for enabling safe care.

'Patient Safety is Everyone's Responsibility'

SECTION 1

Introduction, Rationale and Current Scenario

1. Introduction

Patient safety is a fundamental element of health care and is defined as a freedom for a patient from unnecessary harm or potential harm associated with provision of health care. Patient safety represents one of quality of care dimensions alongside accessibility, acceptability, effectiveness, efficiency and people-centeredness. It encompasses different aspects that are crucial to delivering quality health services. It is about safe surgical care and safe childbirth, it is about injection safety, blood safety, medication safety, medical device safety, safe organ, tissue and cell transportation and donation. It is also about bio-medical waste management, prevention of healthcare associated infections and much more. Failure to deliver safe care is attributed to unsafe clinical practices, unsafe processes and poor systems and processes.

Estimates show that in developed countries as many as 1 in 10 patients is harmed while receiving hospital care. The harm can be caused by a range of errors or adverse events. Of every 100 hospitalized patients at any given time, 7 in developed and 10 in developing countries will acquire Health Care-Associated Infections (HAIs). Hundreds of millions of patients are affected worldwide each year. Simple and low-cost infection prevention and control measures, such as appropriate hand hygiene, can reduce the frequency of HAIs by more than 50%. There are an estimated 1.5 million different medical devices and over 10,000 types of devices available worldwide. The majority of the world's population is denied adequate access to safe and appropriate medical devices within their health systems. More than half of low- and lower middle-income countries do not have a national health technology policy which could ensure the effective use of resources through proper planning, assessment, acquisition and management of medical devices. Key injection safety indicators measured in 2010 show that important progress has been made in the reuse rate of injection devices (5.5% in 2010), while modest gains were made through the reduction of the number of injections per person per year (2.88 in 2010). An estimated 234 million surgical operations are performed globally every year. Surgical care is associated with a considerable risk of complications. Surgical care errors contribute to a significant burden of disease even though 50% of complications associated with surgical care are avoidable. Safety studies show that additional hospitalization, litigation costs, infections acquired in hospitals, disability, lost productivity and medical expenses cost some countries as much as US$ 19 billion annually. The economic benefits of improving patient safety are therefore compelling. Industries with a perceived higher risk such as the aviation and nuclear industries have a much better safety record than health care. There is a 1 in 1,000,000 chance of a traveler being harmed while in an aircraft. In comparison, there is a 1 in 300 chance of a patient being harmed during health care.

Patient safety has been increasingly recognized as an issue of global importance and in 2002, WHO Member States agreed on a World Health Assembly resolution on patient safety. In recent years, there is growing recognition that patient safety and quality of care are critical dimensions of Universal Health Coverage (UHC).

That is why Patient Safety strategies and interventions cannot be regarded as stand-alone initiatives, they cannot be in silos. They must be aligned with the overall health goals and embedded into broader strategies and incorporated into the existing programs.

2. Background and Rationale

In recent years there has been an increasing attention on improving quality of healthcare in India within broader Universal Health Coverage (UHC) context. Patient safety has been recognised as one of the key important components of quality of care and many initiatives have been taking place at central and state levels to address diverse issues of patient safety. Challenges in patient safety in India are various, ranging from unsafe injections and biological waste management to medication and medical device safety, high rates of health care associated infections, anti-microbial resistance etc. There is a wide range of initiatives in patient safety being implemented in India at different levels of care in both public and private sectors, and there is a multiplicity of national and international stakeholders working in this area.

In 2015 during the 68th WHO Regional Committee for South-East Asia all Member States of the Region, including India, endorsed the "Regional Strategy for Patient Safety in the WHO South-East Asia Region (2016-2025)" aiming to support the development of national quality of care and patient safety strategies, policies and plans and committed to translate six objectives of the Regional Strategy into actionable strategies at country level. In this context, Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) constituted a multi-stakeholder Patient Safety Expert Group in August 2016. The Group was given a task to operationalize patient safety agenda at country level and develop a National Patient Safety Implementation Framework (NPSIF).

Development of a NPSIF is imperative for India because even though a range of initiatives for patient safety are implemented in the country, they are implemented in a fragmented manner by multiple stakeholders and sometimes overlap. It is vital to bring everything together under one umbrella. The NPSIF will ensure implementation of patient safety activities in a coordinated manner and contribute to overall agenda of improvement of quality of care within UHC context in India.

3. Current Situation of Patient Safety in India

3.1 National policies and strategies, institutional mechanisms, legal and regulatory framework, stakeholders' involvement

- Laws, regulations, policies and strategies on the quality of care do exist in the country, however they are largely fragmented.
- Consumer protection act deals with medical negligence and deficiency of services but has failed to define the rights of the patients. Legal rights of the patients are set out in the Clinical Establishment Act (CEA), but the CEA is not being implemented across India.
- National Pharmaceutical Pricing Authority (NPPA) and Drugs Controller General of India (DCGI) have mechanisms to see that patients' rights in terms of medication and device are protected and they are not overcharged.
- National Health System Resource Centre (NHSRC) has been designated as nodal agency at national level for implementing Quality Assurance program in public health facilities. National Quality Assurance Standards have been developed by NHSRC for specific quality and patient safety needs of public health institutions. These standards specifically cover requirements of RMNCHA and Disease control programs.

- The Ministry of Health and Family Welfare (MoHFW) publishes a regular national report on the performance of the health care system; however, it is limited to indicators for quality of care that in turn are designed around Reproductive, Maternal, Neonatal and Child Health (RMNCH).
- Under the Right to Information Act, all public facilities must report all information available at institutional level. In doing so, it is assumed that the quality of care is perceived as inadequate in quality, the facility might face the risk of media scrutiny and trials in case of honest reporting.
- Selected Private sector chain hospitals and individual institutions have implemented substantial measures to implement patient safety. As these hospitals constitute very small proportion of overall care providers these measures remain isolated and has limited in effect.
- Public reporting on quality of care to some extent exists in the country, but needs adjustment and improvement. Demand from population side is not adequate enough to influence policy directions.
- Accreditation mechanisms for healthcare facilities (including accreditation of laboratories and diagnostic facilities) are in place. Existing Accreditation system of hospitals; the National Accreditation Board for Hospitals and Healthcare Providers (NABH) is pertinent and provides enough flexibility. Insurance Regulatory Development Authority (IRDA) has issued a notification for the health entities to consider NABH Entry level accreditation for availing reimbursement benefits from the insurance providers.
- The public institutions are not currently actively involved in NABH Accreditation. Many of the public institutions which have enrolled into NABH/NABH Safe I/NABH Entry level have challenges to upgrade themselves to the desired standards. Public Hospitals are undertaking accreditation against National Quality Assurance Standards (NQAS) developed by MoHFW. Both NABH and NQAS standards are accredited by ISQUA.
- MoHFW, The Central Pollution Control Board (CPCB), Atomic Energy Regulatory Board (AERB), Professional Councils, regulatory bodies, NHSRC, NABH, ESI, Public Sector Units (PSUs) providing health care in other relevant ministries/departments like Defence, Railways, Environment, etc. are the key government departments and bodies responsible for execution.

3.2 Nature and scale of adverse events and surveillance systems

- Mechanisms of assessing the overall burden of unsafe care in the country exist for some programmes, such as Adverse Events Following Immunization (AEFI), Pharmacovigilance Program of India (PVPI), etc. but not for all.
- A patient safety incident surveillance and a system of reporting and learning from all adverse events and "near misses" at national and sub-national levels exist for certain events like needle-stick injuries, AEFI, Pharmacovigilance, Haemovigilance, Death audits etc. but not for all. Root cause analysis done for Maternal deaths, neonatal deaths, AEFI, etc. but not for all diseases/ conditions. But not all Institutes follow the same standards all the time as no regulatory mechanisms exist.

3.3 Health workforce: education, training and performance

- Registration and re-registration, certification, and re-certification as well as continuous professional education of health care professionals are available for three different categories of health care workers.
- It is difficult to estimate the adequate number of appropriately trained and skilled staff in patient safety currently in position. Multiple trainings take place within the frames of different programs and projects, at different levels of governance (central and state) and health care (from primary through tertiary) and in many cases they are not well documented.

- Periodic assessments of awareness and understanding of basic patient safety principles and practices among different categories of healthcare workers is not done in public sector hospitals. Information about the same from the private sector is also not available.
- Whereas patient safety as a separate topic may not be available in different curricula, overall concept as well as many elements of patient safety are reflected across different syllabuses, including undergraduate, postgraduate and continuous medical education.
- STGs and protocols are available within the most important vertical national programs (TB, Vector Borne Diseases (VBD), HIV/AIDS, Maternal and Child Health (MCH), etc.). Under CEA, the STGs for 215 medical conditions under 21 specialties have been prescribed (reference http://clinicalestablishments.nic.in/).
- Under IPHS, there are elements of patient safety in general and infection control in particular. Even though it is not mandatory, there are some budgetary provisions to adopt and implement these standards. The standards run from sub-centre to district levels.
- Important elements, such as fire safety, seismic safety, device safety, the physical safety of health care facilities are also important in the Indian context though usually not included in patient safety paradigm most of the time.

3.4 Prevention and control of HAI

- Institute based systems for infection controls have been developed, but there is lack of integrated national level program, policy or guidelines which cover health care institution at all levels.
- There is no system of reporting HAI at any level and there is no authority in place to collect, analyse and report HAI at country level.
- Biomedical Waste Management Rules were first notified in 1998. These rules have been revised comprehensively recently in 2016 & 2018 (Amendment). These rules have helped in regulating management of biomedical waste by health care institutions.
- National Guidelines on Clean Hospitals (Swacchta Guidelines) were released in 2014. Government of India (GoI) has launched Kayakalp programme to improve general cleanliness and hygiene, infection control and waste management practices in public hospitals.
- NCDC and ICMR have created a network of laboratories for Antimicrobial Resistance surveillance in the country. Many private sector chain hospitals and autonomous institutes also have their own Infection control systems. 10 Network laboratories have been identified in the first phase to initiate antimicrobial resistance surveillance of four common bacterial pathogens of public health importance to determine the magnitude and trends of AMR in different geographical regions of the country.
- A concise interim guideline on infection control has been uploaded on NCDC website as a ready reference for the hospitals to start implementing infection control practices in their setting. National infection control programme has been drafted and is in the process of finalization. ICMR has also issued Infection Control Guidelines. There are other guidelines available, developed by institutions/ under various programs, e.g. RMNCH, Hospital Manual by DGHS, NACO manual.
- NABH has a system of surveillance for HAI but limited to NABH accredited hospitals only. There is also software to track hospital associated infection reports by the All India Institute of Medical Sciences (AIIMS) Trauma Centre.
- An expert group by the PMO office had given national recommendations which have been discussed at a high level in the Ministry of Health with all the central government hospitals for the implementation of sterilization practices.

- In the RMNCH programme, infection management and environmental plan was introduced in 2007 and implemented countrywide. Similarly, in the event of outbreaks, the respective guidelines for infection prevention and control are being issued. At the DGHS level, a hospital manual with elements of infection control has been implemented in the central public hospitals. NACO manual for infection control developed in 2006 is available in the public domain.
- It was observed that sporadic institute based system does exist in the country, but not at the national level, and a lot of activities are happening that have not been institutionalized.
- Hospital Infection Control Committee are mandatory in accreditation programme/s. The key stakeholders involved in the Committee could be the head of facility (administrator/manager), representative of a nursing staff, key clinicians, lab specialist/microbiologist, biomedical engineer with clear roles and responsibilities (e.g., biomedical engineer is responsible for building construction and maintenance, which is also key element in infection prevention and control).
- Currently only 192 combined Biomedical Waste Treatment Facilities (CBMWTF) exist in the country against 500 to 600 needed.

3.5 Patient safety in different programs

- A national policy and plan for surgical services at various levels of care have not been thought of until now. Surgical checklist is not uniformly implemented.
- 24x7 Basic Emergency Obstetric and Newborn Care (BEmONC) and Comprehensive Emergency Obstetric and Newborn Care (CEmONC) services up to Community Health Centre (CHC) level are available in most of the states.
- Multiple guidelines for even up to Primary Health Centre (PHC) level are available; Janani Suraksha Yojana, Janani Shishu Suraksha Karyakaram, Integrated Management Neonatal Childhood Illnesses, Sick Newborn Care Units, Indian Public Health Standards, BEmONC, CEmONC, SBA. However in private sector provision of desired services is not standardized.
- Safe Injection Guidelines by Indian Academy of Paediatrics and National Centre for Disease Control were released and are available online. The new Policy Guidance by WHO, issued in 2015, on Safe Injections is also available.
- An excellent surveillance of Needle Stick Injuries (NSIs) in all accredited hospitals is being conducted. Enhanced compliance with Biomedical Waste Management (BWM) rules in both public and private institutions are envisaged. But the data is more internal and larger picture of the issue of NSIs is not available. This is a major occupational hazard and many of the episodes are not getting reported.
- Variable implementation of the guidelines on infection prevention and controls are available especially in private sector, is important to address.
- Ensuring all health care providers are vaccinated against Hepatitis B (National Health Policy Recommendation) and waste handlers against tetanus is crucial to ensure safety from occupational hazards of health care providers. Availability of Post-Exposure Prophylaxis (PEP) for needle stick injuries at all causalities or emergency rooms/Operation Theatres (OTs) and other intervention sites are a big missing area.
- Since frontline health workers such as ASHAs and other village level volunteers are actively involved diagnostic practices such as conducting rapid diagnostic tests (e.g. for malaria) through finger pricking etc. therefore, BMW practices should reach the frontline health workers to ensure their safety as well as patient safety.
- Essential Drug List is available and is being used by the government institutions. High-Quality control by DCGI at manufacturing level is available.

- National STGs for common health conditions are available (issues discussed earlier).
- Medical colleges collect data related to adverse drug reactions. National Portal to register instances of spurious drugs is available.
- In the decentralized mechanism of drug storage, at the sub-district level, safety norms are not adequately followed.
- Blood is defined as a "drug" under the Drugs and Cosmetics Act and Rules thereof, and therefore blood banks are considered manufacturing units and can only function under a license issued by the State Food and Drug Administration (FDA) with approval of DCGI.
- All units of blood collected in the licensed Blood Banks undergo mandatory screening for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), Malaria and Syphilis before being issued for transfusion.
- National Blood Transfusion Council provides policy directions to all the licensed Blood Banks through respective State Blood Transfusion Councils.
- All blood banks report to NACO/National Blood Transfusion Council (NBTC) through a Strategic Information Management System (SIMS) Also, a web- cum-mobile application had been created on the National Health Portal, which helps to locate the nearby blood banks, available blood groups, and units of blood available.
- NACO/ NBTC has recently published a baseline Assessment Report of 2626 Blood Banks of India and gaps in quality of Blood Transfusion Services have been identified.
- DGCI has a few national medical device regulatory and monitoring programmes, but to a very limited extent.
- Medical devices are well covered under Clinical Trials Services Unit (CTSU). A draft bill is in the public domain. A separate legislation is in the offering. Also, product liability is coming up strongly as part of the new consumer protection act which is supposed to go to the parliament end of 2016-beginning of 2017.
- Though much has not been done on medical device safety in India, a Health Technology Assessment Division exists in NHSRC and was recently designated as a WHO Collaborating Centre.
- Safer medical devices as per Good Manufacturing Practices (GMP) and WHO standards for infection control and patient safety exist.
- The deceased organ donor programme is quite robust; developing regional centres, state centres even individual numbers are being given to the hospitals that are doing transplantation. But it is also true that states do not wish to respond accordingly. Legal conditions regarding foreign trafficking have also been covered.
- Comprehensive legislation in the form of the Transplant of Human Organs Act (THOA), National Organ Transplant Program (NOTP), National Organ and Tissue Transplant Organization (NOTTO), different SOPs, including for selection and safety of donors; allocation policies, IEC, national registries are available.

3.6 Patient Safety Research

- There are research activities going on in this area, but they are very fragmented and not widely shared and utilized for decision making purposes.
- There is Minimal funding on patient safety research.
- Research institutions have limited capacity and academic foundation for patient safety research.
- Facilities both private and public hesitate to publish research on patient safety as this may tarnish the image of the hospital.
- The global burden disease study collect data on adverse effect of medical treatment.

SECTION 2

Goal, Guiding Principles and Strategic Objectives

1. Goal and Overall Scope

The goal of the NPSIF is to improve patient safety at all levels of health care across all modalities of health care provision, including prevention, diagnosis, treatment and follow up within overall context of improving quality of care and progressing towards UHC in coming decade.

NPSIF applies to national and sub-national levels as well as to public and private sectors. Being a cross-cutting concept by nature, the scope of patient safety applies to all national programmes and envisages collaboration of wide range of national international stakeholders both within and outside health sector.

2. Guiding Principles

- **Articulating health system approach:** Invest more in strengthening health system across its core elements:
  - Ensure ***health services*** which deliver effective, safe, quality personal and non-personal health interventions to those that need them, when and where needed, with minimum waste of resources.
  - Invest in well-performing ***health workforce*** that works in ways that are responsive, fair and efficient to achieve the best health outcomes possible, given available resources and circumstances (i.e. there are sufficient staff, fairly distributed; they are competent, responsive and productive).
  - "Establish and maintain well-functioning health information system that ensures the production, analysis, dissemination and use of reliable and timely information on health determinants, health system performance including those related to medication errors, hospital acquired infections and other patient safety related aspects.
  - Ensure ***equitable access to essential medical products, vaccines and technologies*** of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use.
  - Design effective and efficient ***health financing system*** that raises adequate funds for health, in ways that ensure people can use needed services, and are protected from financial catastrophe or impoverishment associated with having to pay for them.
  - Strengthen ***leadership and governance*** to ensure strategic policy frameworks exist and are combined with effective oversight, coalition building, regulation, attention to system-design and accountability.

- **Defining evidence-based interventions:** Prioritize and implement those interventions that proved to be effective and efficient in improving patient safety at global, regional and country levels. Continuously invest in evidence generation to ensure the required adjustments throughout implementation.
- **Targeting all levels of care:** Bring patient safety to the core of healthcare provision given its cross-cutting nature and applicability to all modalities of healthcare provision, including prevention, diagnosis, treatment and follow up.
- **Adopting patient-centred approach:** Put the patients in the centre and involve and empower them to become equal partners in ensuring provision of healthcare that is respectful of, and responsive to, individual preferences, needs and values, and ensures that patient values guide all clinical decisions.
- **Promoting collaborative action**: Engage all stakeholders to improve patient safety - not only within, but also outside the health sector. There should be not only healthcare workers, health managers and decision-makers but also patients and their families, professional organizations, civil society and media. Everybody has different, but crucial role to play in patient safety. While it is important to recognize these differences in roles and responsibilities, it is equally important to recognize the connections between them.
- **Ensuring sustainability and monitoring progress:** Make interventions sustainable through addressing patient safety as policy objective with strong political commitment and respective institutionalization efforts and monitor implementation of interventions at different levels: national, sub-national and institutional levels with collectively agreed key performance indicators.

3. Strategic Objectives

Implementing patient safety framework would require a holistic and pragmatic approach. Patient safety concepts should be interlaced with building blocks of health system so safety culture becomes integral part of healthcare delivery. Six strategic objectives have been identified for this purpose after due consultation with stakeholders and reviewing global and regional frameworks for patients safety. Each strategic objective has been further explained in terms of key priorities and specific interventions. Following are the strategic objectives :

Strategic Objective 1: To improve structural systems to support quality and efficiency of healthcare and place patient safety at the core at national, subnational and healthcare facility levels.

Strategic Objective 2: To assess the nature and scale of adverse events in healthcare and establish a system of reporting and learning.

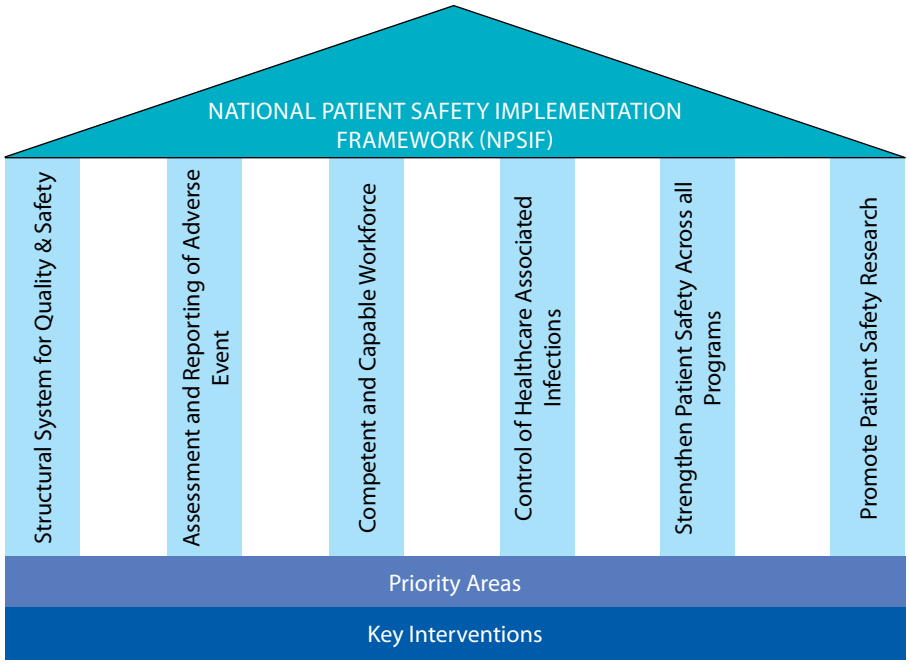
Strategic Objective 3: To ensure a competent and capable workforce that is aware and sensitive to patient safety.

Strategic Objective 4: To prevent and control health-care associated infections.

Strategic Objective 5: To implement global patient safety campaigns and strengthening Patient Safety across all programmes.

Strategic Objective 6: To strengthen capacity for and promote patient safety research.

Figure1. Building Blocks of National Patient Safety Implementation Framework



Strategic Objective 1: To improve structural systems to support quality and efficiency of healthcare and place patient safety at the core at national, subnational and healthcare facility levels.

Developing quality and safety culture is a long term endeavor and requires enabling environment at policy, administrative and service provision level. This requires investments for creating structures for quality and safety and having credible quality accreditation system and regulatory mechanism to ensure compliance to minimum safety standards. India has a vibrant and growing health sector with mix of public and private providers. Further health is a state subject and each state government sets its own legislative, administrative, financing and healthcare delivery models as per priorities and context. This makes developing a pan-India institutional structure a challenging task. A rational approach would be to have an overarching national framework under which states are given flexibility to design their own institutional mechanism and modalities for quality & safety in public and private sector.

Framework should provide options of quality assurance and accreditation system that private and public healthcare providers can adapt as per requirements and preference. The institutional framework should be more a facilitator than regulator so as to let flourish a self-sustainable quality and safety culture. There is also need for developing culture for safe healthcare communication and involving patients in their treatment and welfare. Following are key priority areas improving structural systems for quality and safety.

Key Priority 1.1: Institutionalize patient safety and strengthen legislative and regulatory framework

Patient's safety should become integral part of healthcare delivery system through institutionalisation within the existing policy, regulatory and program management framework. Following is the proposed institutional framework for patient safety India.

i. National Level: National Patient Safety Steering Committee will be constituted under aegis of Ministry of Health & Family Welfare. This committee will have representation from all relevant governmental and non-governmental stakeholders. Quality Assurance mechanism under National Health Mission

(NHM) will also be utilized. This committee will work to implement a robust patient safety framework in country and coordinate with different stakeholders. Committee will be supported by a dedicated patient safety secretariat in Directorate General of Health Services, MoHFW. This secretariat will provide technical support for implementing patient safety including drafting technical guidelines & developing training material. The detailed TORs for National Patient Safety steering committee are given in Annexure.

ii. State Level: at the state level there will be a designated nodal officer for implementing patient safety framework. State quality assurance committees have been constituted in all the states chaired by Principal Secretary (Health). As quality and patient safety are related concepts, it is therefore natural to use existing quality assurance committees for monitoring and implementation of patient safety framework too. A sub-committee on patient safety will be constituted under the state quality assurance committee. If required large states may engage a dedicated technical staff to support patient safety activities though National Health Mission. Though designated state nodal officers for quality assurance should be over all responsible for patient Safety activities also. TORs and functions of quality assurance committees and officers can be revised to include the patient safety components explicitly. Similarly, district quality assurance committees will be responsible for implementing the patient safety framework at district level through their existing mechanism.

iii. Integration of patient safety Programs & Schemes: Patients safety concepts should also be strengthened in all vertical disease control program considering safety of both provider and patients/ beneficiary. Some important aspects are injection safety and reporting of AEFI in immunization programs, infection control in DMCs under RNTCP program, Blood Safety under National AIDS control program etc.

iv. Clinical Establishment Act includes patient safety requirements for registration of clinical establishment. Patient safety concept should also be incorporated in draft Public Health Act or any such legislation which will contribute regulatory framework in health sector.

v. Publicly funded health insurance schemes should incorporate provision for payment based on patient safety performance/ safety indicators such as hospital acquired infection rates, medication errors and use of safe surgery checklist.

Key Priority 1.2: Strengthen quality assurance mechanisms, including accreditation system

Quality assurance and accreditation mechanism for public and private healthcare facilities needs to strengthen so patient safety can be assured at point of delivery. While efforts will be made to increase the coverage of quality certification/ accreditation , there also need to strengthen the existing quality standards by incorporating the patient safety requirements more adequately in their assessment criteria. Following are the measures proposed:

i. At national level a set of minimum patient safety indicator will be defined by Ministry of Health and Family Welfare. These indictors will be reported by all healthcare facilities both in public and private sector. Framework recommends leveraging the reporting mechanism instituted under existing quality assurance programs and accreditation systems.

ii. Ministry of Health & Family Welfare will also define minimum patient safety standards to be incorporated by accreditation agencies in their respective assessment criteria for quality accreditation.

iii. National Quality Assurance Program for public health facilities has defined a set Key performance indicators for each level of facilities to be reported on monthly basis. These KPIs will be revised to include minimum patient safety indicators defined at national level.

iv. For private sector NABH will be required to include the minimum patient safety indicators in their accreditation programs including entry level certification. Selected indicators applicable to clinical laboratories will also be included in NABL accreditation program.

v. A ranking/grading system for healthcare facilities based on patient safety indicators will be introduced.

vi. Provision for "Patient Safe Healthcare Institutions" certification will be instituted. The criteria will be based on existing quality standards such as NQAS and NABH. Ministry of Health & Family Welfare may institute a special body for issuing patient safety certification.

vii. Healthcare facilities will be encouraged to achieve quality accreditation through existing quality certification/ accreditation systems available for public and private healthcare facilities. Provision for financial incentives in reimbursement from insurance providers will be made for certified/ accredited hospitals.

viii. To ensure that quality standards measure patient safety issues adequately, patient safety concerns such as fire safety, seismic safety, medical device safety and structural safety will be included in existing quality standards and norms.

Key Priority 1.3: Establishing a culture of safety and improving communication, patient identification, handing over transfer protocols in healthcare facilities

Patient safety concepts need to be incorporated in the work culture of healthcare providers and the way they communicate to each other while delivering the care. Apart from service providers, patients and community at large also need to be sensitized on patient safety related issues. For this purpose, following activities are suggested:

i. A comprehensive communication strategy for patient safety will be developed involving all stakeholders. The communication strategy will be developed targeting both patient/ community as well as care providers.

ii. For ensuring safe communication amongst care providers for delivery of healthcare services, standard operating procedures and checklist will be developed for error prone processes such as handover, verbal orders and transfer of patients.

Key Priority 1.4: Establishing patient-centered care and involving patients as partners in their own care

The objective of patient safety framework cannot be achieved without considering perspective of patients. In-fact patient is the most important stakeholder and should be at centre of healthcare design and delivery process. Following activities are suggested for achieving patient involvement for safe care:

i. Developing educational and information material on patient safety such as audio-visual material, Posters, Brochures and IT based aids. Information on patient safety will be disseminated to both patient as well as care providers using communication channels such Mass Media, Print Media and Social Media.

ii. Integrate web based grievance redressal system and toll-free helplines on patient safety within the existing ICT system of MoHFW (including toll free number and IT based solutions). This system will also enable anonymous reporting of incidents and practices compromising the safety of patients. The incidents reported will be examined by an independent agency.

iii. Promoting establishment of patient right groups and facilitating their involvement in policy discourse and monitoring of patient safety outcome.

Strategic Objectives 2: To assess the nature and scale of adverse events in health care and establish a system of reporting and learning

A universal error and adverse events reporting system is crucial to know the extent of harm caused by unsafe care. Although just having reporting system does not mitigate the risk of getting harm, it does serve as the catalyst for improvement, regardless of the level of care. Following actions are proposed for establishing a credible system for reporting of adverse events:

Key Priority 2.1: Generating evidence for policy making

Since limited information is available about overall burden of unsafe care in India, it would be prudent to estimate the baseline quantum of unsafe care in Indian health care system. For this purpose following activities are proposed:

i. Scope of errors and adverse events will be defined for Indian context based on internationally agreed benchmarks and best practices.

ii. A baseline assessment of public and private healthcare facilities will be conducted for estimating the extent of errors and adverse events for defined scope. The survey can be conducted by a designated autonomous national level institution.

Key 2.2: Establishing robust surveillance systems for monitoring patient safety

A universal reporting and feedback system for reporting of errors and adverse events needs to established for the country. This system should be non-punitive, confidential, independent, timely, system oriented and responsive in nature. Following are the specific activities:

i. Developing system of reporting of errors, near miss and adverse events from facilities to state and national level. This will include standardization of adverse event definitions, reporting formats and establishing a web- based reporting system across public and private healthcare facilities.

ii. Public Health programs such as Immunization and NACP already have some system of reporting of adverse event specific to their activities. Accreditation programs such as NQAS & NABH also mandate for reporting adverse events. There are national programs for pharmacovigilance and materiovigilance. All these reporting systems will be streamlined and integrated to establish a comprehensive patient safety surveillance system.

iii. Guidelines for errors and adverse events reporting will be developed by Ministry of Health & Family welfare. This will include definitions, categorization and directory for errors, near miss and adverse events as well as process, codes and protocols to be followed by public and private healthcare institutions for patient safety reporting.

iv. Annual reports on quality of care and patient safety will be released by Ministry of Health & Family Welfare based on the data available from patient safety surveillance system and quality assurance program/ accreditation system. A national level Resource Centre/Technical Institute will be designated to analyse patient safety data and prepare report on behalf of MoHFW.

v. Patient safety risk assessment checklists will be developed for primary, secondary and tertiary care facilities for identifying and mitigating risks through internal assessment and quality improvement approach.

vi. Health Workers' safety is as important as patient safety. Minimum healthcare workers' safety requirements will be issued by MoHFW, which needs to be incorporated in all licensing and accreditation programs.

Key Priority 2.3: Ensuring supportive legislative mechanisms for effective functioning of patient safety surveillance systems

Adequate legal and policy level provisions will be required to create an enabling environment for non-punitive and system oriented surveillance system:

i. A system for analyzing the patient safety reports and feedback mechanism for taking corrective actions will be established with support of NHSRC & Patient Safety Secretariat.

ii. The proposed Public Health Act will make provision for mandatory reporting of adverse events by healthcare facilities.

iii. Adequate legal provisions will be made to keep sensitive patient safety reporting confidential and exempted from public access and litigation.

Strategic Objective 3: To ensure a competent and capable workforce that is aware and sensitive to patient safety

To sustain patient safety efforts it would need to be made part of the work culture at healthcare facilities. This would require a workforce that is sensitive, well trained and competent on patient safety issues. Though adverse events can be mainly attributed to failure of the system rather an individual, however, trained and sensitised care providers can prevent the harm and help in building an error free work environment. The Patient safety framework emphasises upon a "catch them young" approach, whereby patient safety principles are incorporated in medical and nursing education, and then sustain the accumulated skills through continual medical/ nursing education and on the job trainings. Following are the priorities:

Key Priority 3.1: Strengthening education, training and professional performance inclusive of skills, competence, and ethics of health-care personnel

To ensure health workers competence on patient safety multipronged approach is recommended which include making it part of professional licensing requirements as well creating institutional capacity for trainings. Following are the specific actions:

i. Knowledge of basic patient safety concepts will be incorporated as part of evaluation criteria for medical, nursing and paramedical licensing exams. Certain credit hours of attending the online-courses/CMEs on patient safety will be made mandatory as criteria for renewal of professional licenses.

ii. Academic and technical support intuitions at national and state level will be identified to develop training courses and deliver onsite/online trainings on patient safety.

iii. An institutional framework will be prepared for developing and updating evidence based standard treatment guidelines in Indian context.

iv. National Standard Treatment Guidelines for all disease conditions will be developed in phased manner and will be made available for healthcare providers though user-friendly applications and implementation tools.

Key Priority 3.2: Improving the understanding and application of patient safety and risk management in health care

The understanding of patient safety should start from the medical and nursing education and should be extended to healthcare facilities through safe work culture and positive learning environment that enables care providers to apply their learning and strengthen their skills. Following specific actions are planned to achieve this objective:

i. Medical, Nursing and paramedical educational curricula will be mapped for existing components of patient safety. The syllabus for undergraduate and postgraduate level courses will be revised to incorporate adequate learning objectives for patient safety based on WHO patient safety curriculum guide.

ii. Patient safety principles will also be incorporated into in-service education programs and on job trainings organised by employers in public and private health sectors.

iii. Practical guidelines for implanting patient safety at health care facilities will be developed. These guidelines will guide hospital administrators and care providers for implementing patient safety program at facility level.

iv. Patients Safety components will also be incorporated in job description of different cadres of workforces and their performance appraisal criteria. Financial and non-financial incentives such as awards can enhance adherence to safe care practices.

v. A National Patient Safety day/ week will be observed across the country. Notification on desirable activities for this occasion will be issued by MoHFW.

vi. Further to facilitate learning on patient safety, a web based/ Mobile based learning platform will developed.

Strategic Objective 4: To prevent and control health-care associated infections

Healthcare Associated Infections are a major challenge in ensuring patient safety. This situation is further aggravated in public hospitals due patient overload and inadequate workforce. There is no credible data on burden of Health Care Associated Infection in India (HCAI). HCAI is a multidisciplinary challenge and requires multipronged approach to contain it. Following are key priorities –

Key Priority 4.1: Strengthening infection prevention and control structure and programmes across all healthcare services and all levels of care

The risk of health care associated infections can be mitigated through establishing a sustainable infection control program at health care facilities. A systems improvisation to this practice would be to connect these facility level programmes & committees with policy level objectives and interventions. Following key actions are proposed:

i. A national level strategic plan for infection prevention and control will be prepared by Ministry of Health & Family Welfare. This will have close linkage with related programs such as Antimicrobial Resistance Program and National Action Plan on Viral Hepatitis.

ii. Institutions which have successfully implemented infection prevention and control programs, will be identified and their best practices will be disseminated for evidence based learning and scaling up.

iii. Functioning of infection control committees at facility level be strengthened and development of standard operating procedures to be undertaken along with regular reporting of indicators.

iv. Infection Control activities in various national health programs will be integrated.

v. A system for surveillance of Healthcare Associated Infections will be established in phased manner. Data of HCAI will be collected and analysed by the agencies responsible for patient safety reporting.

Key Priority 4.2: Providing appropriately cleaned, disinfected or sterilized equipment for patient care as required

Adequate financial resources will be made available to ensure availability of equipment and consumables for disinfection and sterilization of equipment. This will be taken under the overall umbrella of NHM for public health systems and through specific hospital levels budgets for other hospitals.

Key Priority 4.3: Providing a safe and clean environment by improving the general hygiene sanitation and management of healthcare waste in healthcare facilities

Hygiene, Sanitation and waste management are closely linked with infection control outcomes. Swacha Bharat Abhiyan has given an impetus for improving cleanliness in hospitals and surroundings. Following actions are suggested to further promote sanitation and hygiene in healthcare facilities:

i. Hand Hygiene program will be further reinforced in medical and nursing curriculum and in service training at health care facilities.

ii. Implementation of Kayakalp – clean hospital scheme will be further reinforced by disseminating good practices and replicating role models across countries.

Strategic Objective 5: To implement global patient safety campaigns and strengthening Patient Safety across all programs

Key Priority 5.1: Safe surgical care

i. Safe surgery checklist will be adopted for secondary and tertiary care level hospitals to make sure that all elective and emergency surgeries are performed using safe surgery checklist.

ii. WHO 24X7 Emergency and essential surgical norms will be adopted in all healthcare facilities providing surgical care.

iii. Appropriate sterilization practices will be adopted within National Trauma Care and National Burns program.

iv. Guidelines for surveillance and prevention on venous thromboembolism will be developed and implemented.

Key Priority 5.2: Safe childbirth

i. Quality Assurance standards for maternal health care and assessment tools for labor rooms and maternity operation theater will be reviewed and updated based on latest evidences including respectful maternal care and natural birthing process

ii. Quality standards for labour room and OT will be expanded and reinforced at private health care facilities to ensure quality of intrapartum and post-partum care

Key Priority 5.3: Safe injections

i. Vaccination of all healthcare providers against Hepatitis B in addition to waste handlers against tetanus to ensure occupational safety concerns among healthcare providers

ii. Strengthen the post-exposure prophylaxis (PEP) for needle stick injuries at all causalities/OTs and other intervention sites

Key Priority 5.4: Medication Safety

i. Standard operating procedures for disposal of discarded/ expired drugs as per BMW rules 2016 will be developed.

ii. Adverse drug reaction surveillance will be strengthened and implemented across all public and private health care facilities with close coordination between state health departments, pharmacovigilance agencies, professional associations drug manufacturers and national vertical programs.

Key Priority 5.5: Blood Safety

i. Voluntary Non Remunerated Blood Donation will be promoted though improved donor selection, recruitment, retention and referral through an effective communication strategy and capacity building.

ii. Adverse donor and transfusion reactions surveillance will be implemented at all levels of care.

iii. Hospital transfusion committee will be constituted with standard composition and terms of reference and rational use of blood and blood products will be promoted.

Key Priority 5.6: Medical device safety

i. Usage of non- mercury devices and equipment will be promoted.

ii. Availability of biomedical engineers will be ensured at health care facilities.

iii. SOPs for utility; breakdown; monitoring of medical devices, restricting reuse of single-use purpose devices, clear policy on condemnation of equipment and SOPs of calibration for electronically operated medical devices will be developed and made available to health care facilities.

Key Priority 5.7: Safe organ, tissue and cell transplantation and donation

i. Deceased donor programme will be reinforced and modified as necessary.

ii. Scale-up IEC for organ donation, training of personnel in addition to registration of organ retrieval centers.

iii. Dissemination of relevant information and ensure uniform implementation across region/state/institutions/hospital/tissue banks on legislation (THOA), National Organ Transplant Programme (NOTP), National Organ and Tissue Transplant Organization (NOTTO), different SOPs, including for selection and safety of donors; allocation policies, and national registries.

Strategic Objective 6: To strengthen capacity for and improve patient safety research

Key Priority 6.1: Consolidation of patient safety research and utilization for decision-making

A repository of good quality research on patient safety and allied themes will be created at national level. This will be pursued through Indian Council of Medical research (ICMR) which is the nodal medical agency for research in the country.

Key Priority 6.2: Reinforcing research for patient safety

i. Studies will be conducted for estimation of the overall burden of unsafe care including point prevalent survey of hospital acquired infections.

ii. Research on different aspects of patient safety at country and state level will be prioritized.

SECTION 3

Action Plan & Monitoring Framework

1. Action Plan

Key: S= Short Term (Six Month) ; M= Mid Term (six months to one year) L= Long Term (More than one year)

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short- term M/Medium-term L/Long-term	Expected Output
Strategic Objective 1: **To improve structural systems to support quality and efficiency of healthcare and place patient safety at the core at national, subnational and healthcare facility levels**					
1.1 Institutionalize patient safety and strengthen legislative and regulatory framework	1.1.1 Constitute national level steering committee as a central coordinating mechanism for Patient Safety (on the basis of Patient Safety Expert Group)	MoHFW /DGHS/ DDG /NODAL OFFICER/ TAG TAG= Regional state person, NHP, Research based organization, pharmacovigilance, patient organization, private bodies (CII, FICCI, AHPI)	March 2018	S	Steering Committee is established at central level and functional
	1.1.2 Designate Patient Safety focal points at State level (on the basis of Quality Assurance Committees)	State Governments/ State Director General Health services/ Medical Services & State QA Officer	July 2018	M	Focal points for patient safety are designated in all states
	1.1.3 Establish nodal division/ sub committee for patient safety/quality of care at central and state levels	MOHFW/ SQAC	July 2018	M	Patient Safety Department is established and functional
	1.1.4 Incorporate Patient Safety principles and concepts in vertical programs	MoHFW/DGHS/ ALL PROGRAMME OFFICERS	October 2018	L	Vertical disease programmes address Patient Safety
	1.1.5 Incorporate Patient Safety principles and concepts in Public Health Act	MoHFW/NHSRC	July 2018	M	Public Health Act includes the clause on Patient Safety
	1.1.6 Streamline patient safety in different insurance schemes and link patient safety with pay for performance	MoHFW & IRDA	December 2018	L	Insurance schemes at central and state levels consider payment for better performance based on Patient Safety indicators

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short- term M/Medium-term L/Long-term	Expected Output
1.2 Strengthen quality assurance mechanisms, including accreditation system	1.2.1 Development and commissioning of minimum patient safety standards and Indicators	MoHFW/ National Patient Safety Secretariat	July 2018	M	
	1.2.2 Incorporate selected Patient Safety indicators as key performance indicators within the Quality Assurance Program	NHSRC	July 2018	M	Patient Safety indicators incorporated in key performance indicators within the Quality Assurance Programme
	1.2.3 Incorporate selected Patient Safety indicators within the accreditation system for hospitals and laboratories, including entry level accreditation	NHSRC NABH/ NABL	July 2018	M	Selected Patient Safety indicators incorporated into accreditation system for hospitals and laboratories, including entry level accreditation
	1.2.4 Introduce hospital performance monitoring/ ranking system based on number of indicators, including patient safety indicators	HMIS & NHSRC	December 2018	L	Hospital performance monitoring/ ranking system is introduced and incorporates Patient Safety indicators
	1.2.5 Establish Special Commission to declare "Patient Safe Healthcare Institution" based on adherence to defined standards (Quality Assurance, NABH, etc.)	MOHFW/DGHS	March 2019	L	Special Commission is established by order and functional
	1.2.6 Streamline accreditation programs for availing incentives in reimbursement benefits the insurance providers	NABH/NQAS/STATE STANDARD/ BIS/ IRDA/ RSBY	July 2018	M	Provision of incentives for Accreditation from any organization like NABH/NQAS/ISO/state govt. accreditation
	1.2.7 Incorporate fire safety, seismic safety, device safety, structural safety of healthcare facilities into the existing Quality Assurance and Accreditation standards	NABH/NQAS/NATIONAL BUILDING CODE/state govt.	July 2018	M	Quality Assurance and accreditation Standards incorporate fire safety, seismic safety, device safety, structural safety of healthcare facilities
1.3 Establishing a culture of safety and improving communication, patient identification, handing over transfer protocols in healthcare facilities	1.3.1 Develop comprehensive communication strategy for Patient Safety, targeting different stakeholders	MOHFW/DGHS	July 2018	M	Communication strategy is in place
	1.3.2 Streamline standardization of Patient Safety initiatives at different levels of care through SOPs, algorithms, checklists, etc. (link to Strategic Objective 5)	MOHFW/DGHS /NHSRC	December 2018	L	Number of SOPs, algorithms, checklists are developed and introduced into the system (link strategic objective 5)

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short- term M/Medium-term L/Long-term	Expected Output
1.4 Establishing patient-centred care and involving patients as partners in their own care	1.4.1 Ensure Patient Safety processes are clearly communicated to patients and caregivers prior, during and after intervention (using different communication means: videos, mobile apps, leaflets, brochures, etc.) through existing Quality Assurance and accreditation programmes	National Patient Safety Secretariat	March 2019	L	Patient Safety processes are clearly communicated to patients through different communication means
	1.4.2 Integrate web-based grievance system and toll-free helpline for Patient Safety within the existing ICT system of MoHFW	MOHFW/DGHS/NHM	2018-2019	M	Web-based grievance system and toll-free helpline for Patient Safety in all healthcare facilities established
	1.4.3 Introduce anonymous reporting system in healthcare facilities to be used by healthcare facility staff, students, residents, patents and families. Ensure analysis of the inputs to the system is done by third independent party	National Patient Safety Secretariat/ Nodal officers state level	December 2019	L	Anonymous reporting system established in healthcare facilities and is analyzed by third party
	1.4.4 Promote establishment of patient groups	MoHFW/ State Health Departments/ Rogi Kalyan Samities / NGOs/ Consumer Right Groups	March 2019	L	Patient groups registered and functional
	1.4.5 Facilitate involvement of patient groups in policy development and implementation processes	MoHFW/ State Health Departments/ Rogi Kalyan Samities / NGOs/ Consumer Right Groups	Ongoing	M	Patient groups involved in the development of … policies, strategies and plans
Strategic Objective 2: **To assess the nature and scale of adverse events in healthcare and establish a system of reporting and learning**					
2.1 Generating evidence for policy making	2.1.1 Conduct baseline assessment of the overall burden of unsafe care in the country, including public and private sector	Any institution as designated by Dte.GHS	December 2018	L	Baseline assessment of the overall burden of unsafe care conducted
2.2 Establishing robust surveillance systems for monitoring patient safety	2.2.1 Develop Patient Safety incident surveillance system and system of reporting and learning from all adverse events and near-misses at national, subnational and healthcare facility levels (web-based). Surveillance system to consider environmental safety elements.	MOHFW/National Patient Safety Secretariat	December 2018	L	Web-based Patient Safety incident surveillance system and system of reporting and learning from all adverse events and near-misses is established at national, subnational and healthcare facility levels
	2.2.2 Streamline reporting on Patient Safety initiatives within the existing programmes and reporting mechanisms and introduce new ones as per need	MoHFW/ National Programmes/ NHM	March 2019	L	Periodic reports on patient safety initiatives are available on annual basis

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short- term M/Medium-term L/Long-term	Expected Output
	2.3.3 Develop and reinforce error reporting guidelines and codes in public and private institutions	MoHFW/ National Patient Safety Secretariat NHM	July 2018	S	Error reporting guidelines are developed and reinforced in public and private facilities
	2.2.4 Strengthen public reporting on quality of care	NHM/ NHSRC	March 2019	L	Annual reports on quality of care are publicly available
	2.2.5 Develop checklist for patient safety risk assessment at healthcare facility level along with provision for voluntary disclosure of information	National Patient Safety Secretariat	6 months	M	Checklist for patient safety risk assessment at healthcare facility level is developed
	2.2.6 Develop a system for ensuring healthcare workers safety and link it to existing Quality Assurance and accreditation programmes	MoHFW	2018	S-M	System for healthcare workers safety established
2.3 Ensuring supportive legislative mechanisms for effective functioning of patient safety surveillance systems	2.3.1 Establish a system of analysis all reported incidents to guide appropriate interventions at national, state and institutional levels	National/State Level Patient Sefety Officer/Qa Officer of NHSRC	2018	M	System of analysis of all reported incidents established
	2.3.2 Incorporate the special clause in existing legal documents on mandatory reporting of adverse events and near-misses	PUBLIC HEALTH ACT	2019	M	Special clause on mandatory reporting of adverse events and near-misses is incorporated in …
	2.3.3 Enact special Law or Act for making sensitive healthcare data exempt from public domain	MoHFW/State Government	2020	L	Special Law or Act for making sensitive healthcare data exempt from public domain is enacted
***Strategic Objective 3*: To ensure a competent and capable workforce that is aware and sensitive to patient safety**					
3.1 Strengthening education, training and professional performance inclusive of skills, competence, and ethics of health-care personnel	3.1.1 Revise licensing/certification and re-certification standards of all categories of health workforce, ensuring the requirement for a specific number of credit hours on Patient Safety	Professional Councils/ MoHFW	2019	S	licensing/certification and re-certification standards of all categories of health workforce revised
	3.1.2 Identify institutions by central/state govt. and develop a sustainable framework for ongoing education and capacity building of Health care workers both in public and private sectors	central/state govt. Professional councils and bodies, medical and nursing colleges, district hospitals & training institutions like SIHFW	Ongoing process	S	Frame work developed and institutions identified
	3.1.3 Establishing national institutional framework and methodology for collating, developing and commissioning evidence based STG's in Indian context.	Professional bodies MoHFW/DGHS NHSRC	2018	S	Guide on STG development is endorsed
	3.1.4 Developing and implementing unified national STGs for each disease/condition (through collation/revision of existing and development of new ones)	MoHFW/DGHS (vertical programmes) Professional bodies NHSRC	Ongoing process	M-L	Unified national STGs are available for all diseases/conditions

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short- term M/Medium-term L/Long-term	Expected Output
3.2 Improving the understanding and application of patient safety and risk management in health care	3.2.1 Develop/adjust the Patient Safety pre-service educational curricula/training modules through mapping and converging the available materials with their further institutionalization at undergraduate and postgraduate level (reference to WHO Patient Safety Curriculum Guide)	Leading agency: Professional councils Contributing agency: Academic institutions NIHFW	2018	S	Patient Safety pre-service educational curricula/training modules developed/adjusted
	3.2.2 Incorporate patient safety basic principles and practice in all in-service education/on job training for all categories of health workforce	Lead agency: Employer Contributing agency: NIHFW DGHS/vertical programmes Accreditation agencies	Ongoing process	S	Patient safety basic principles and practice are incorporated in all in-service education/on job training for all categories of health workforce
	3.2.3 Developing the practice guidelines on Patient Safety targeting healthcare providers	MoHFW/ Patient Safety Secretariat	December 2018	L	Practical Implementation guidelines on patient safety are developed and issued.
	3.2.3 Introduce elements of Patient Safety in job descriptions of different categories of health workforce and ensure their usage for monitoring performance at different levels, and linking that to promotion and financial incentives	Health Directorates Employer	2019-20	M	Elements of Patient Safety incorporated in job descriptions of different categories of health workforce
	3.2.4 Organize Patient Safety weeks/days across the country to promote different components of patient safety.	MoHFW/DGHS	July 2018	S	Patient Safety weeks/days organized
	3.2.5 Develop a IT based learning solutions for disseminating information on patient safety	MoHFW NHSRC	March 2019	M	IT based learning solutions developed for patient safety
Strategic Objective 4: **To prevent and control health-care associated infections**					
4.1 Strengthening infection prevention and control structure and programmes across all healthcare services and all levels of care	4.1.1 Develop national level IPC strategy/plan/ programme (link to National Action Plan on AMR NAP-AMR)	MOHFW (NACA/ National Patient Safety Secritriat)	2018	S	National IPC strategy/plan/ programme available
	4.1.2 Review existing frameworks, programmes and best practices, identify existing key hospitals which have successful IPC programmes and replicate and scale up their experience	National Conference for good practice conducted by NHM in collaboration with NHSRC/ NABH	2018-19	S	Existing IPC frameworks, programmes and best practices in selected hospitals reviewed and scaled up (through the national IPC programme)

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short- term M/Medium-term L/Long-term	Expected Output
	4.1.3 Establish special Committees for the IPC programme at institutional levels, that must have Standard Operating Procedures (SOP) and indicators for monitoring implementation of IPC programmes in healthcare facilities	Central government, Quality assurance cell/Infection control committee at district and state level and Individual hospitals	2019-20	M	Special Committees for the IPC programme at institutional levels established, operate and monitored based on SOPs (through the national IPC programme)
	4.1.4 Improve effectiveness of the Hospital Infection Control Committees that is presently mandatory in accreditation programme/s	MoHFW in collaboration with NABH/ NHSRC	2018	S-M	Standardized forms
	4.1.5 Explore the regulatory framework for integration of IPC within the national health programmes and in the overall national health system	MoHFW & CEA	2018-20	M	Amendment of act
	4.1.6 Raise awareness about IPC having much broader scope than what is currently practiced and propagated	NACA/ Patient Safety Unit	2020	S-M	Awareness raising activities implemented
	4.1.7 Promote the concept of hospital safety with proper incorporation of IPC elements in it	NACA/ Patient Safety Unit	2019-20	S-M	Hospital safety programme available national, or through quality assurance or accreditation programmes)
	4.1.8 Establish a system for HAI surveillance and consider its phased introduction and implementation	ICMR	2022	Long Term	Surveillance system of HAI established and implemented
	4.1.9 Designate authority to collect, analyze and report HAI at national level	NCU/NACA	2017-18	S	Authority to collect, analyze and report HAI at national level is designated
4.2 Providing appropriately cleaned, disinfected or sterilized equipment for patient care as required	4.2.1 Ensure incorporation of budget for implementation of IPC programmes in all relevant national programmes and institutional budgets with the comprehensive and precise elements, including consumables	MoHFW & State Government	March 2018	S	Proposals can be incorporated in PIPs of NHM.

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short- term M/Medium-term L/Long-term	Expected Output
4.3 Providing a safe and clean environment by improving the general hygiene sanitation and management of healthcare waste in healthcare facilities	4.3.1 Reinforce the hand hygiene programme in medical and nursing curriculum and in service training at all levels of health care with strong awareness raising and training component	MCI, NCI, HISI	2019-20	M	Hand-Hygiene programme scaled up at all levels of care (through IPC national programme or separately)
	4.3.2 Put in place mechanisms to ensure uniform adherence to and compliance with the available guidelines and standards, including BWM rules, in both public and private health care facilities across the country	Ministry of Health and Ministry of Environment & CC (CPCB)	2022	L	Mechanisms for uniform adherence to and compliance with the available injection safety guidelines and standards, including BWM rules, in place
	4.3.3 Reinforce implementation of Kayakalp by getting good practices, replicating and scaling-up across the country	NHSRC	Ongoing	S	Best practices of Kayakalp implementation documented and scaled up
Strategic Objective 5: To implement global patient safety campaigns and strengthening Patient Safety across all programmes					
5.1 Safe surgical care	5.1.1 Uniformly adopt surgical safety checklist that cover elective and emergency surgeries	DGHS/State dte. Of Health services/ SQACs	2020	L	Surgical checklist adopted uniformly across the country
	5.1.2 Uniformly adopt WHO 24X7 Emergency and Essential surgical norms in all institute which provide surgical care	DGHS/State Dte. Of Health services	2020	L	Essential and emergency surgical norms
	5.1.3 Adopt the appropriate anesthetic and sterilization practices within National Trauma Care and National Burns Programme				
	5.1.4 Improve public awareness across diverse groups on what constitutes safe surgery	Directorate Central /state/SQAC	2022	L	Awareness raising activities implemented
	5.1.5 Carry out regular monitoring and surveillance of SSI	MoHFW/ NHM/ SQAC	2020	M	Surveillance system of SSI in place
	5.1.6 Carry out regular monitoring and surveillance of Venous Thromboembolism (VTE). Develop and introduce guidelines on prevention of VTE.	DGHS	2020	S-M	Guidelines on prevention of Venous Thromboembolism (VTE) in place
5.2 Safe childbirth	5.2.1 Review and update available standards regularly for greater efficiency	DGHS/ Programme Divisions	July 2018		Revised QA standards and assessment tools for Maternity Care
	5.2.2 Expand and reinforce the available standards to private sector as well as to all levels of care	DGHS & State Governments	March 2020	L	At least 80% of the MNH care providers are included under the scope
5.3 Safe injections	5.3.1 Ensure all healthcare providers are vaccinated against Hepatitis B in addition waste handlers against tetanus to ensure occupational safety concerns among healthcare providers	MoHFW (& State Governments	December 2018	M	Mechanisms established for mandatory vaccination of health care providers
	5.3.2 Mandate post-exposure prophylaxis (PEP) for needle stick injuries at all causalities/OTs and other intervention sites	NACO/ MoHFW/ Hospitals	July 2018	M	Mechanisms established for post-exposure prophylaxis for needle stick injuries
	5.3.3 Facilitate inclusion of the injection safety module in the MBBS course.	MCI	2022	L	MBBS course contains injection safety module

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short- term M/Medium-term L/Long-term	Expected Output
5.4 Medication Safety	5.4.1 Develop SOPs for disposal of discarded/expired drugs as per standard guidelines.	Hospital management & State Government	2020	S-M	SOPs for disposal of discarded/ expired drugs developed
	5.4.2 Ensure implementation of surveillance of adverse drug reactions universally	Pharmacology Departments, CMSS, State Health Departments, National Pharmacovigilance Cell, Patient Groups, Private Hospital Chains IMA Drug Controllers Drug Manufacturers Development Partners	2019		Surveillance system of adverse drug reactions in place and operational
	5.4.3 Incorporate pharmacovigilance within all national vertical programme	National Pharmacovigilance Programme/ National Programmes	2019	S-M	All national vertical programmes include pharmacovigilance component
5.5 Blood Safety	5.5.1 Promote Voluntary Non Remunerated Blood Donation with improved donor selection, recruitment, retention and referral through an effective communication strategy and capacity building	MoHFW/ NACO/NBTC/CDSCO	2019	S/M	90% voluntary blood donation
	5.5.2 Ensure implementation of surveillance of adverse donor and transfusion reactions universally	MoHFW/ NIB/ HvPI/ CDSCO	2019	S/M	All licensed blood banks and blood donors report adverse reactions
	5.5.3 Develop/revise SOPs for ensuring healthcare workers' safety and disposal of discarded blood in accordance with BMW Rules	MoHFW/ NACO/ NBTC/ NHSRC	2022	S/M	SOPs for ensuring healthcare workers' safety and disposal of discarded blood and consumables developed/revised
	5.5.4 Constitution of Hospital Transfusion Committees as per standard composition and terms of reference in every hospital transfusing blood/ blood components	MoHFW/ NACO/ NBTC/ State Government	2022	S/M	Standard norms prepared and disseminated Hospital Transfusion Committees created
	5.5.5 Promote appropriate clinical use of blood and blood products and ensure adherence to safe transfusion practices	MoHFW/ NBTC/ HvPI/ CDSCO	2022	S/M	
5.6 Medical Device safety	5.6.1 Bring medical devices other than syringes and plastic waste under the BMW rules	Dte.GHS (Env Cell), CDSCO, MoEF&CC	2022	S/M	BMW rules include diverse medical devices (beyond plastic waste)
	5.6.2 Promote usage of Non-Mercury devices and equipment	Dte.GHS (Env Cell), CDSCO, MoEF&CC	2018	M-L	Non-Mercury devices and equipment are in use across India

Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short- term M/Medium-term L/Long-term	Expected Output
	5.6.3 Ensure services of the biomedical engineering in all healthcare facilities for continued maintenance of medical equipment from installation till the equipment is used. NS HICC should monitor the same wherever relevant	Dte. GHS (Env Cell)/ DSHS guidelines	2020	S/M	Position of biomedical engineer is established at …HICC and filled
	5.6.4 Make available updated SOPs for utility; breakdown; monitoring of medical devices, restricting access of single-use devices for reuse purposes, clear policy on condemnation of equipment and SOPs of calibration for electronically operated medical devices	Hospitals as per DGHS/ DSHS guidelines	2020	S/M	Updated SOPs for utility; breakdown; monitoring of medical devices, restricting access of single-use devices for reuse purposes available SOPs of calibration for electronically operated medical devices available Policy on condemnation of equipment in place
5.7 Safe organ, tissue and cell transplantation and donation	5.7.1 Reinforce the deceased donor programme and modify as necessary	MoHFW/DGHS/NOTP	2022	S/M	Deceased donor programme modified and reinforced
	5.7.2 Scale-up IEC for organ donation, training of personnel in addition to registration of organ retrieval centers	MoHFW/DGHS/NOTTO	2022	S/M	IEC for organ donation, training of personnel in addition to registration of organ retrieval centres scaled up
	5.7.3 Disseminate relevant information and ensure uniform implementation across region/state/ institutions/hospital/tissue banks on legislation (THOA), National Organ Transplant Programme (NOTP), National Organ and Tissue Transplant Organization (NOTTO), different SOPs, including for selection and safety of donors; allocation policies, and national registries	MoHFW/DGHS/NOTP	2022	S/M	
Strategic Objective 6: To strengthen capacity for and promote patient safety research					
6.1 Consolidation of patient safety research and utilization for decision-making	6.1.1 Establish a repository of all good quality research on patient safety and allied themes.	Lead agencies: ICMR, NML, Department of Health Research, National Patient Safety Secretariat	December 2018	M	Repository on good quality research on patient safety and allied themes established
6.2 Reinforcing research for patient safety	6.2.1 Initiate research on estimation of the overall burden of unsafe care including point prevalent survey of hospital acquired infections.	Academic Institutions ICMR NIHFW NHSRC	2017- 19	L	Study/ies on burden of unsafe care available
	6.2.2 Prioritize research on different aspects of patient safety at country and state level	Academic Institutions ICMR NIHFW NHSRC	2017-22	M-L	Study/ies on different aspect of patient safety at country and state level available

2. Human Resources

Implementation of the patient safety framework will require additional dedicated resources. Most of the interventions will be implemented within the existing programmes and by well-established organizations and institutions. Existing Institutional support structures for Hospital Administration & Quality Assurance will be utilized for implementation for patient safety initiatives. Additional trainings as per thematic areas will be undertaken for the health workforce for taking forward patient safety initiatives. Health Care Associated Infection prevention and control would be an area needing major strengthening through funds, availability of Hospital Infection Control Nurses and establishment of surveillance systems. Beside , technical support from international partners can also be envisaged as per mutual agreement and based on organizational mandates and priorities.

3. Budget and Potential Source of Funding

It will be important to ensure the specific budget lines for patient safety in general or for different elements of the same (capacity building, surveillance systems, infectional prevention and control, hand-hygiene, etc.) are included in all vertical national programmes. In case of the establishment of national programmes on IPC, for example, the central and state budget has to consider the same. In addition to that, technical support from international partners can also be envisaged as per the mutual agreement and based on organizational mandates and priorities. Budget can be earmarked under institutional budgets of hospitals.

4. Monitoring and Evaluation

Strategic Objective	Intervention	Indicator	Target
Strategic Objective 1			
Priority area 1	Establishment of patient safety cell/ divisions at central and state level	Operationalization of Patient Safety Secretariat/ Cells at national and state level	National Patient Safety Secretariat Operationalized 80% of states have instituted patient safety sub committee under state quality assurance committee .
Priority area 2	Patient Safety Certification	Proportion of facility achieved patient safety certification	80% Public Hospitals 80% Private Hospitals
Priority area 3	Patient Safety SOPs and Checklist safe communication	Proportion of healthcare facilities using SOPs and Checklist	80%
Priority area 4	Grievance redressal system	Proportion of states established grievance redressal system for patient safety	80%
Strategic Objective 2			
Priority area 1	Base line assessment of estimating burden of unsafe care	Proportion of states where baseline assessment conducted	100%
Priority area 2	Patient Safety Surveillance System	Proportion of healthcare facilities participating in surveillance system	60%
Priority area 3	Legal provision for safe guarding surveillance information	Incorporation of mandatory reporting in Legal Framework/ instrument	Provision incorporated
Strategic Objective 3			
Priority area 1	Training of healthcare workers on patient safety	Proportion of states with state level trainers on patient safety	80%

Strategic Objective	Intervention	Indicator	Target
Priority area 2	Practice guidelines and Training Manual on Patient Safety	Proportion of facilities where practice guideline/ SOPs are available	80%
Strategic Objective 4			
Priority area 1	Surveillance of HCAI	Proportion of facilities reporting HCAI monthly	80%
Priority area 2	Budgetary Provision sterilized equipment	Proportion of district hospitals are having dedicated CSSD	60%
Priority area 3	Adherence to BMW rules	Proportion of facilities linked with common treatment facilities.	90%
Strategic Objective 5			
Priority area 1	Adoption of Surgical Safety Checklist	Proportion of health care facilities implementing safe surgical checklist	80%
Priority area 2	Safe Child Birth facilities	Proportion of Labour Rooms quality certified	70%
Priority area 3	Vaccination of Healthcare providers	Proportion of vaccinated staff for Hepatitis B	80%
Priority area 4	Adverse Drug Reaction Reporting	Proportion of facilities reporting adverse drug reactions	90%
Priority area 5	Establishing hospital transfusion committee	Proportion of secondary and tertiary care hospitals established transfusion committee	90%
Priority area 6	Availability of Bio Medical Engineers	Proportion of secondary and tertiary care facilities appointed a dedicated biomedical engineer	60%
Priority area 7	IEC for organ donation	Percentage increase in persons registered for organ donation	50%
Strategic Objective 6			
Priority area 1	Repository for good quality research on patient safety	Number of research papers collated for Indian context	100%
Priority area 2	Funding for patient safety research	Percentage increase in funding for patient safety research	100%

5. Communication Strategy

Communication strategy for patient safety will consider the following aspects:

i. ***Overall purpose and key issue:*** Patient safety related issues have to be linked to the behavior change that needs to occur to improve patient safety in the country.

ii. ***Context***: Strengths, Weaknesses, Opportunities, and Threats (SWOT) that affect the situation have to be analyzed in details.

iii. ***Gaps in information*** available to the program planners and to the audience that limit the program's ability to develop sound strategy. These gaps will be addressed through research in preparation for executing the strategy.

iv. ***Audiences*** (Primary, secondary and/or influencing audiences): Communication strategy for patient safety will clearly define target audience that will include policy makers at national and state levels; health managers and public health professionals at national state, district and institutional levels; general population, including patients, caregivers and families; different categories of healthcare workers and support staff employed by healthcare organizations; volunteers, involved in provision of healthcare to the population; media and international organizations and stakeholders. It is critical to define the groups of primary, secondary and influencing audiences).

v. ***Objectives and positioning*** in the broader health system context: Communication strategy for patient safety will consider availability of similar strategies (or communication elements) on either covering broader health system issues or specific thematic issues.

vi. ***Key Message Points***: Development of key messages for IEC materials will be based on the materials already available within different vertical programmes across the country. Materials periodically released by WHO willbe utilized as a basis for further development/adjustment/revision of the local materials. IEC materials will be translated into local languages and pre-tested before finalization with all defined target groups. Prioritization of key messages.

vii. ***Channels and Tools:*** The communication tools and channels will be defined for each target audience accordingly. It is important to ensure that the following key principles are at the core of all communication activities and are reflected in the full range of IEC materials: accessibility, feasibility, credibility and trust, relevance, timeliness, clarity and comprehensiveness.

viii. ***Management Considerations and Partner Roles and Responsibilities:*** Successful management requires leadership, clearly defined roles and responsibilities, close coordination and teamwork between all the participants, and adherence to a timeline and budget. It is important to distinguish the lead organization from collaborating partners, by identifying the key functional areas and skills that need to be in place to carry out the strategy. Typically, these roles include management coordination, policy, research, advertising, media planning and placement, PR, community-based activities, training, monitoring and evaluation.

ix. ***Timeline for Strategy Implementation:*** If the communication strategy will be implemented in phases, it will be important to establish a timeline that shows when the major activities of each phase will take place and where the key decision points are. Since communication efforts are usually tied to service delivery, training, and other areas, it is important to create a timetable with appropriate linkages to all these respective interventions.

x. ***Budget:*** Developing a detailed budget will ensure that financial resources will be available to carry out communication strategy in all its parts. The budget for communication strategy on patient safety will be either linked to the overall budget for patient safety framework and be reflected in PIPs or separate budget will have to be established for communication strategy.

ANNEXURE

National Patient Safety Steering Committee

This committee will have the overall responsibility for implementing patient safety framework in the country under the aegis of Ministry of Health & Family Welfare, Government of India. This committee will have a technical advisory and supervisory role. Administrative and regulatory functions will be vested with existing authorities under Clinical Establishment Act, professional councils, consumer protection acts, pollution control board. The committee will comprise Ministry of Health officials as well as representation from technical support institutions, NHM, NHSRC, Programme Division state quality assurance committees, Directorate of Health, professional associations, WHO, private sector associations, Medical Colleges, accreditation agencies, consumer protection groups, pharmacovigilance agencies. For the first tenure, the members of committee can be pooled from the expert group constituted for developing National Patient Safety Implementation Framework. Later additional members can be co-opted as per requirement. The committee will be chaired by Director General of Health Services (DGHS) and Deputy Director General (DDG) Public Health will be the member secretary of this steering committee. Steering committee will meet once in a quarter.

The steering committee will be supported by a National Patient Safety Secretariat staffed with fulltime technical and support staff. Secretariat can be located at Ministry of Health of Welfare or one of its technical support institutions. This secretariat will report Member Secretary (DDG Public Health) of National Patient Safety Steering Committee. The secretariat will work in close coordination with existing quality assurance institutional framework at national and state level.

Following are the functions of National Patient Safety Steering Committee:

1. Preparing the detailed action plan for implementation of national patient safety framework.
2. Operationalize the patient safety framework in the state health departments.
3. Defining the minimum set of reportable patient safety indictors for different level of hospitals.
4. Establishing reporting mechanism for reporting of patient safety indicators and adverse events from public and private sector hospitals.
5. Establishing system for grievance redressal on patient safety issues.
6. Periodic monitoring and feedback on reported patient safety indictors and grievance received.
7. Publishing periodic reports on status of patient safety practices and outcomes.
8. Promote research on patient safety related themes.
9. Develop the technical guidelines and implementation aids patient safety related topic.
10. Evolve and implement the communication strategy for patient safety including communication material for public and patients.
11. Design and disseminate the training packages for different healthcare cadres.

12. Facilitate / Provide master trainings on patient safety related themes.
13. Facilitating the participation and regular reporting from private sector.
14. Coordination and sharing of information with regulatory bodies, quality assurance committees and accreditation and certification agencies.
15. Channelizing technical assistance for the states & Health Facilities.

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MINISTRY OF HEALTH AND FAMILY WELFARE
Government of India
Nirman Bhavan, New Delhi