Ministry of Health & Family Welfare Directorate General of Health Services (Environment & Climate Change)

Date : 25/09/2017

# **Subject: Comments invited on Draft Patient Safety Implementation Framework-reg.**

Draft Patient Safety Implementation Framework has been developed by Dte.GHS, MoHFW. Comments/ suggestions are invited on the framework from public/ experts.

Suggestions/comments if any, may kindly be forwarded to Dr. Chhavi Pant JoshiDeputyAssistantDirectorGeneral,23061936,Email:patientsafety17@gmail.com Room No.-451'A-Wing',4th Floor,Nirman Bhawan, New Delhi-110108.



# **National Patient Safety Implementation Framework**

# INDIA

**Ministry of Health & Family Welfare** 

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Content

TBA

## 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
- BWM Biomedical Waste Management
- 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 Module Analysis
- FRU First Referral Unit
- GMP Good Manufacturing Practices
- Gol Government of India
- HAI Healthcare Associated Infections
- HCF Healthcare Facilities
- HIC Hospital Infection Control

**3** | Page

- HRH Human Resources for Health
- IAPO International Alliance of Patients' Organizations
- IDSP Integrated Disease Surveillance Programme
- 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 Health Care
- MCI Medical Council of India
- NABH National Accreditation Board for Hospitals
- NCI Nursing Council of India
- NHSRC National Health System Resource Centre
- NHP National Health Policy
- NHM National Health Mission
- NOTP National Organ Transplant Programme
- NOTTO National Organ and Tissue Transplant Organization
- NPSIF National Patient Safety Implementation Framework
- MoHFW Ministry of Health and Family Welfare

4 | Page

- MS Member States
- PHC Primary Health Centre
- PEP Post-Exposure Prophylaxis
- QCI Quality Council of India
- OPD Out-Patient Department
- PHC Primary Healthcare Centre
- PVPI Pharmacovigilance Programme 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

# Executive summary

TBA after finalization of the document

## 1. Structure and Purpose of the document

TBA after finalization of this document

#### 2. 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 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 can't be regarded as stand-alone initiatives, they can't be in silos. They have to be aligned with the overall health goals and embedded into broader strategies and incorporated into the existing programmes.

## 3. 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) has 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.

## 4. Current situation of patient safety in India

#### 4.1 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; there is a need to improve and consolidate these policies.
- 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 a designated quality assurance unit at national level, state and district levels. Information about quality standards is available at NHSRC. 50 national programmes are covered in the standards.
- 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 20 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 have to report all information available at institutional level. In doing so, it's assumed that the quality of care will be perceived as inadequate quality and the facility might face the disadvantage of media scrutiny and trails in case honest reporting.
- Select private sector chain hospitals and individual institutions have encompassed most components of the stated objective. However, the number is very low given the scale of health care services in India.
- 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. There is already a plan under NHM to undertake accreditation of all health facilities as per National QA Standards developed by NHSRC which are accredited by ISQUA.
- MoHFW, NABH, The Central Pollution Control Board (CPCB), Atomic Energy Regulatory Board (AERB), Professional Councils, regulatory bodies, other relevant ministries/departments like Defence, Railways, Environment, etc. are the key government departments and bodies responsible for execution of all the policies; thus their roles and responsibilities have to be clearly defined in the NPSIF.

#### 4.2 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.

#### 4.3 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. Further exploration and detailing is needed and can be done in collaboration with National and State respective councils, Professional Associations, State Health Directorates, etc.
- It is difficult to estimate the adequate number of appropriately trained and skilled in patient safety staff 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 are not mandated in public sector. Information about the same from the private sector needs to be explored further.

- 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.
- Separate patient safety chapter should be included in the Bachelor of Medicine & Bachelor of Surgery (MBBS) curriculum, and cover not only the well-known basic concepts but also aspects such as communication, facility management, etc.
- STGs and protocols are available within the most important vertical national programs (TB, Neglected tropical diseases (NTD), 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/). However, different STGs and SOPs may be available for the same disease/condition/procedure, especially if compared to public and private sectors.
- 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 and should also be part of the standards.
- Accreditation activity on going on in the country by NABH and by some private hospitals is for hospitals only and hardly touches the issues related to HRH education/training. Moreover, it is voluntary and is being implemented sporadically at different levels.

#### 4.4 Prevention and control of HAI

- National Centre for Disease Control (NCDC) is acting as the focal point for implementation of Anti-Microbial Resistance (AMR) programme.
   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 national by DGHS, NACO manual. National Infection Control policy is reported to be in final stage.
- 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.
- 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. NCDC and ICMR have created a network of laboratories for Antimicrobial Resistance surveillance in the country.
- Biomedical Waste Management Rules were first notified in 1998. These rules have been revised comprehensively recently. These rules have helped in regulating management of biomedical waste by health care institutions. National Guidelines on Clean Hospitals were

released about 3 year back. Government of India (GoI) has launched Kayakalp programme to improve general cleanliness and hygiene of the hospitals.

- NABH has a system of surveillance 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. Enforcement of biomedical waste management should be on a priority basis.

#### 4.5 Patient safety in different programmes

- 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. Hence, 24x7 Essential Surgical care norms for multiple trauma, abdominal emergencies e.g. perforations, obstructions etc. at First Referral Units (FRUs) are required.
- 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, private sector standardization of the provision of desired services is much wanted.
- Safe Injection Guidelines by Indian Academy of Paediatrics, National Centre for Disease Control and new Policy Guidance by WHO are 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, especially in private sector, is important to address. Direction by National and state level for implementation and monitoring, adoption of WHO guidelines all across India is required.
- 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/ Operation Theatres (OTs) and other intervention sites are a big missing area.
- As recommended in an expert group's meeting on injection safety in 2016, a module on injection safety should be made a part of MBBS curriculum. MCI and NCI should adopt modules based on this recent recommendation by the expert group.
- 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.
- Adherence to safe injections beyond immunization universally should be focused on as well.
- 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 to be implemented 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.
- Biomedical Engineers should be a full-time employee as most of the deaths in coronary care unit (CCU) occur due to machine failure which could be averted if the machines could be checked immediately.
- BMW rules 2016 cover infectious plastic, chemical/ cytotoxic and glass waste. It does not cover medical devices other than syringes and plastic waste.
- 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.

#### 4.6 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.
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#### **5** Implementation framework

#### 5.1 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.

#### 5.2 Guiding principles

- Articulating health system approach: Invest more in strengthening health system as a whole across its all 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 and health status
  - 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.

#### 5.3 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

# 6 Strategic objectives, priority areas and interventions

Key: S= Three Months; M= more than three to six months; L= More than six months

	tional, subnational and health-care facility le					-
Priority areas	Interventions	Responsible organizations/ Institutions	Timelines 2017-2022	Priority S/Short - term M/Med ium- term L/Long- term	Expected Output	Potential Source of funding
1.1 Institutionali ze 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)	JULY 2017	S (Three Months )	Steering Committee is established at central level and functional	MoHFW/ Partner Agencies Later on decided by MoHFW
	1.1.2 Designate Patient Safety focal points at State level (on the basis of Quality Assurance programme)	State Governments/ State Nodal Officers	AUG 2017	S	Focal points for patient safety are designated in all states	
	1.1.3 Establish nodal division/department	Nodal Officer	MORE	L	Patient Safety	

	for patient safety/quality of care at central	Patient Safety	THAN	6		Department is
	and state levels (TSU comprising training,		MONTHS			established and
	finance, monitoring and IEC experts)					functional
	TRAINING and Regional Coordonators)					
	1.1.4 Incorporate Patient Safety principles	MoHFW/DGHS/	MORE		L	Vertical disease
	and concepts in vertical programmes	ALL PROGRAMME	THAN	6		programmes
		OFFICERS	MONTH			address Patient
						Safety
	1.1.5 Incorporate Patient Safety principles	MoHFW/NHSRC	2017		S	Public Health Act
	and concepts in Public Health Act					includes the clause
						on Patient Safety
	1.1.6 Streamline patient safety in different	NHSRC/NABH	2018		L	Insurance schemes
	insurance schemes and link patient safety					at central and state
	with pay for performance (link to 1.2.5)					levels consider
						payment for better
						performance based
						on Patient Safety
						indicators
1.2	1.2.1 Incorporate selected Patient Safety	NHSRC	2018		М	Patient Safety
Strengthen	indicators as key performance indicators					indicators
quality	within the Quality Assurance Porgramme					incorporated in key
assurance						performance
mechanisms,						indicators within the
including						Quality Assurance
accreditation						Porgramme
system	1.2.2 Incorporate selected Patient Safety	NABH	2018		М	Selected Patient
	indicators within the accreditation system	NABL				Safety indicators
	for hospitals and laboratories, including					incorporated into

	entry level accreditation				accreditation system	
					for hospitals and	
					laboratories,	
					including entry level	
					accreditation	
	1.2.3 Introduce hospital performance	NHSRC	2018	М	Hospital	
	monitoring/ranking system based on				performance	
	number of indicators, including patient				monitoring/ranking	
	safety indicators				system is introduced	
					and incorporates	
					Patient Safety	
					indicators	
	1.2.4 Establish Special Commission to	MOHFW/DGHS	2018	М	Special Commission	
	declare "Patient Safe Healthcare				is established by	
	Institution" based on adherence to				order and functional	
	defined standards (Quality Assurance,					
	NABH, etc.)					
·	1.2.5 Streamline NABH accreditation for	NABH/STATE	2018	Μ	Accreditation from	
	availing reimbursement benefits from the	STANDARD/			any organization like	
	insurance providers (link to 1.1.6)	NQAS/BIS/ISO			NABH/NQAS/ISO/sta	
					te govt.	
					accreditation may	
					be taken availing	
					reimbursement	
					benefits from	
					insurance providers	
	1.2.6 Incorporate fire safety, seismic	NABH/NATIONAL	6 months	Μ	Quality Assurance	
	safety, device safety, structural safety of	•			and accreditation	

	healthcare facilities into the existing Quality Assurance and Accreditation standards	ISO/state govt.			Standards incorporate fire safety, seismic safety, device safety, structural safety of healthcare facilities	
1.3 Establishing a	1.3.1 Develop comprehensive communication strategy for Patient	MOHFW/DGHS	6 months	М	Communication strategy is in place	AGENCY
culture of	Safety, targeting different stakeholders (as				0, 1	
safety and	defined in section 2.6)					
improving	1.3.2 Streamline standardization of	MOHFW/DGHS	2019	М	Number of SOPs,	
communicati	Patient Safety initiatives at different levels	The SOP and			algorithms,	
on, patient	of care through SOPs, algorithms,	checklist will be			checklists are	
identification	checklists, etc. (link to Strategic Objective	developed by			developed and	
, handing	5)	NABH/NHSRC			introduced into the	
over transfer					system (link	
protocols in					strategic objective 5)	
healthcare						
facilities						
1.4	1.4.1 Ensure Patient Safety processes are	IEC CONSULTANT	2020	L	Patient Safety	
Establishing	clearly communicated to patients and				processes are clearly	
patient-	caregivers prior, during and after				communicated to	
centred care	intervention (using different				patients through	
and involving	communication means: videos, mobile				different	
patients as	apps, leaflets, brochures, etc.) through				communication	
partners in	existing Quality Assurance and				means	
their own	accreditation programmes					
care	1.4.2 Establish web-based grievance	CENTRALIZED	2018-2019	М	Web-based	

	system and toll-free helplines for Patient	PORTAL			grievance system
		TOLL FREE LINE			<b>o</b> ,
	Safety in all healthcare facilities	_			
		MOHFW/DGHS			helplines for Patient
					Safety in all
					healthcare facilities
					established
	1.4.3 Introduce anonymous reporting	REPORTING	2018	М	Anonymous
	system in healthcare facilities to be used	SYSTEM TO BE			reporting system
	by healthcare facility staff, students,	DEVLOPED BY			established in
	residents, patents and families. Ensure	MOHFW			healthcare facilities
	analysis of the inputs to the system is				and is analyzed by
	done by third independent party				third party
	1.4.3 Promote establishment of patient	STATE LEVEL	2018-2019	М	# of patient groups
	groups	INSTITUITION			registered and
		LEVEL			functional
	1.4.4 Facilitate involvement of patient	DGHS	ongoing	М	Patient groups
	groups in policy development and				involved in the
	implementation processes				development of
					policies, strategies
					and plans
			in health a		
	BJECTIVE 2: To assess the nature and scale	or adverse events	in nealth care	e and esta	iblish a system of reporting and
learning			2010 2010		
2.1	2.1.1 Conduct baseline assessment of the	NHSRC/ CROSS	2018-2019	М	Baseline assessment

Generating	overall burden of unsafe care in the	SECTION SURVEY			of the overall
evidence for	country, including public and private				burden of unsafe
policy	sector				care conducted
making					
2.2	2.2.1 Develop Patient Safety incident	FORMATS TO BE	2018	М	Web-based Patient
Establishing	surveillance system and system of	DEVLOPED BY			Safety incident
robust	reporting and learning from all adverse	MOHFW			surveillance system
surveillance	events and near-misses at national,				and system of
systems for	subnational and healthcare facility levels				reporting and
monitoring	(web-based). Surveillance system to				learning from all
patient	consider environmental safety elements.				adverse events and
safety					near-misses is
					established at
					national,
					subnational and
					healthcare facility
					levels
	1.3.3 Streamline reporting on Patient	MoHFW/	2019	М	Periodic reports on
	Safety initiatives within the existing	National			patient safety
	programmes and reporting mechanisms	Programmes/			initiatives are
	and introduce new ones as per need	NHM			available on annual
					basis
	1.3.4 Develop and reinforce error	MoHFW/ NHM	2019	М	Error reporting
	reporting guidelines and codes in public				guidelines are
	and private institutions				developed and
					reinforced in public
					and private facilities
	1.3.5 Strengthen public reporting on	NHM/ NHSRC	2019	М	Annual reports on

23 | Page

	quality of care				quality of care are publicly available
	2.2.2 Develop checklist for patient safety	EXPERTS FROM	6 months	Μ	Checklist for patient
	risk assessment at healthcare facility level	TAG			safety risk
	along with provision for voluntary				assessment at
	disclosure of information				healthcare facility
					level is developed
	2.2.3 Develop a system for ensuring	MOHFW	2018	S-M	System for
	healthcare workers safety and link it to				healthcare workers
	existing Quality Assurance and				safety established
	accreditation programmes				
2.3 Ensuring	2.3.1 Establish a system of analysis all	NATIONAL /	2018	Μ	System of analysis of
supportive	reported incidents to guide appropriate	STATE LEVEL			all reported
legislative	interventions at national, state and	PATIENT SEFETY			incidents established
mechanisms	institutional levels	OFFICER/QA			
for effective		OFFICER OF			
functioning		NHSRC			
of patient	2.3.2 Incorporate the special clause in	PUBLIC HEALTH	2019	Μ	Special clause on
safety	existing legal documents on mandatory	ACT			mandatory reporting
surveillance	reporting of adverse events and near-				of adverse events
systems	misses				and near-misses is
					incorporated in
	2.3.3 Enact special Law or Act for making			L	Special Law or Act
	sensitive healthcare data exempt from				for making sensitive
	<mark>public domain</mark>				healthcare data
					exempt from public
					domain is enacted

STRATEGIC OB	JECTIVE 3: To ensure a competent and capal	ole workforce that is	aware and se	nsitive to i	patient safety	
3.1 Strengthenin g 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	<ol> <li>Leading agencies: Professional Councils</li> <li>Contributing agencies: MoHFW</li> </ol>	2019	S	licensing/certificatio n and re-certification standards of all categories of health workforce revised	Not required
	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	Lead agency: central/state govt. Contributing agency: Professional councils and bodies, medical and nursing colleges, district hospitals & training institutions like	Ongoing process	S	Frame work developed and institutions identified	Central/S tate health departm ent

		SIHFW				
	3.1.3 Establishing national institutional	Professional	2018	S	Guide on STG	NHM
	framework and methodology for collating,	bodies			development is	
	developing and commissioning evidence	MoHFW/DGHS			endorsed	
	based STG's for Indian context.	NHSRC				
	3.1.4 Developing and implementing	MoHFW/DGHS	Ongoing	M-L	Unified national	NHM
	unified national STGs for each	(vertical	process		STGs are available	
	disease/condition (through	programmes)			for all	
	collation/revision of existing and	Professional			diseases/conditions	
	development of new ones)	bodies				
		NHSRC				
3.2	3.2.1 Develop/adjust the Patient Safety	Leading agency:	2018	S	Patient Safety pre-	Professio
Improving	pre-service educational curricula/training	Professional			service educational	nal
the	modules through mapping and converging	councils			curricula/training	councils
understandin	the available materials with their further				modules	
g and	institutionalization at undergraduate and	Contributing			developed/adjusted	
application	postgraduate level (reference to WHO	agency: Academic				
of patient	Patient Safety Curriculum Guide)	institutions				
safety and		NIHFW				
risk						
management						
in health						
care						
	3.2.2 Incorporate patient safety basic	Lead agency:	Ongoing	S	Patient safety basic	Employe
	principles and practice in all in-service	Employer	process		principles and	r
	education/on job training for all				practice are	
	categories of health workforce	Contributing			incorporated in all	
		agency: NIHFW			in-service	

[				T	1	
		DGHS/vertical			education/on job	
		programmes			training for all	
		Accreditation			categories of health	
		agencies			workforce	
	3.2.3 Introduce elements of Patient Safety	Health	2019-20	М	Elements of Patient	Not
	job descriptions of different categories of	Directorates			Safety incorporated	required
	health workforce and ensure their usage				in job descriptions of	
	for monitoring performance at different	Employer			different categories	
	levels, and linking that to promotion and				of health workforce	
	financial incentives					
	3.2.4 Organize Patient Safety weeks/days	MoHFW/DGHS	2018	S	Patient Safety	Central/s
	across the country to promote different				weeks/days	tate
	components of patient safety.				organized	govt.
						Employe
						r
	3.2.5 Develop a IT based learning	MoHFW	2018	S	IT based learning	NHM
	solutions for disseminating information on	NHSRC			solutions developed	
	patient safety				for patient safety	
	JECTIVE 4: To prevent and control healthcare		1	T		ſ
4.1	4.1.1 Develop national level IPC	MOHFW (NACA/	2018	S	National IPC	MOHFW
Strengthenin	strategy/plan/programme (link to	Patient Safety			strategy/plan/progra	with
g infection	National Action Plan on AMR NAP-AMR)	Unit)			mme available	other
prevention						global
and control						agencies
structure and						
programmes						
across all						
healthcare						

services and						
all levels of						
care						
	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 NABH	2018-19	S	Existing IPC frameworks, programmes and best practices in selected hospitals reviewed and scaled up (through the	NHM in collabora tion with the NABH
					national IPC programme)	
	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	М	SpecialCommitteesfortheIPCprogrammeatinstitutionallevelsestablished, operateandmonitoredbasedonSOPs(throughthenationalIPCprogramme)	
	4.1.4 Improve effectiveness of the Hospital Infection Control Committees that is presently mandatory in accreditation programme/s	MoHFW in collaboration with NABH	2018	S-M	1. Standardized forms	Funding by NABH
	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	М	Amendment of act	Clinical Establish ment cell

	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	MoHFW
	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)	MoHFW
	4.1.8 Establish a system for HAI surveillance and consider its phased introduction and implementation	ICMR/CDC Project scale up		Long Term	Surveillance system of HAI established and implemented	MoHFW
	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	MoHFW
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	NHM, Central & State Government	2018		Specific IPC budget line is incorporated in PIPs,	
4.3 Providing a safe and clean environment by improving the general	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	S-M	Hand-Hygiene programme scaled up at all levels of care (through IPC national programme or separately)	

hygiene sanitation and management of healthcare waste in healthcare facilities	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 OB programmes	JECTIVE 5: To improve implementation of	global patient safet	y campaigns a	and streng	then patient safety in	all health
5.1 Safe surgical care	5.1.1 Uniformly adopt surgical safety checklist that cover elective and emergency surgeries at first referral units (FRU)	DGHS/State dte. Of Health services	2020	M-L	Surgical checklist adopted uniformly across the country	No
	5.1.2 uniform adopt WHO 24X7 Emergency and Essential surgical norms in all institute which provide surgical care 5.1.3 Adopt the appropriate anesthetic and sterilization practices within National	DGHS/State Dte. Of Health services	2020	S/M	Essential and emergency surgical norms	NHM
	Trauma Care and National Burns Programme					Trauma and Burns Progra Program division
	5.1.4 Improve public awareness across diverse groups on what constitutes safe surgery	Directorate Central /state/institute	2022	M	Awareness raising activities implemented	MoHFW
	5.1.5Carry out regular monitoring and		2020	М	Surveillance system	

	surveillance of SSI				of SSI in place	
	5.1.6 Develop and introduce guidelines on prevention of Venous Thromboembolism (VTE)	DGHS	2020	S-M	Guidelines on prevention of Venous Thromboembolism (VTE) in place	no
5.2 Safe childbirth	5.2.1 Review and update available standards regularly for greater efficiency	NHM/MoHFW	ONGOING			N/A
5.3 Safe injections	5.2.2 Expand and reinforce the available standards to private sector as well as to all levels of care	MoHFW/NHM	2022	M	At least 80% of the MNH care providers are included under the scope	N/A
	5.3.1 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		Mechanisms for uniform adherence to and compliance with the available injection safety guidelines and standards, including BWM rules, in place	Respecti ve ministry
	5.3.2 Ensure all healthcare providers are vaccinated against Hepatitis B in addition waste handlers against tetanus to ensure occupational safety concerns among healthcare providers	MoHFW (NHM/ Dte.GHS)	2018	S	Mechanisms established for mandatory vaccination of health care providers	NHM
	5.3.3 Mandate post-exposure prophylaxis (PEP) for needle stick injuries at all causalities/OTs and other intervention sites	NACO/ MoHFW/ Hospitals	2018	S	Mechanisms established for post- exposure prophylaxis for needle stick injuries	Hospital budget
	5.3.4 Facilitate inclusion of the injection safety module in the MBBS course.	MCI	2022	М	MBBS course contains injection	MCI

					safety module	
5.4 Medication Safety	5.4.1 Develop SOPs for disposal of discarded/expired drugs as per standard guidelines.	Hospital Pharmacy Committee, Hospital management	2020	S-M	SOPs for disposal of discarded/expired drugs developed	Hospital budget
	5.4.2 Ensure implementation of surveillance of adverse drug reactions universally	Pharmacology Departments, CMSS, State Health Departments, National Pharmacovigilanc e Cell, Patient Groups, Private Hospital Chains, IMA Drug Controllers Drug Manufacturers Development Partners	2019		Surveillance system of adverse drug reactions in place and operational	CDSCO
5.4 Medication Safety 5.5 blood safety	5.4.3 Incorporate pharmacovigilance within all national vertical programme	National Pharmacovigilanc e Programme/ National Programmes	2019	S-M	All national vertical programmes include pharmacovigilance component	CDSCO
	5.5.1Ensure implementation of surveillance of adverse blood reactions universally	NACO	2019	S/M		

	5.5.2Develop/revise SOPs for ensuring healthcare workers' safety and disposal of discarded blood and consumables in accordance with BMW Rules	NACO	2022	S/M	SOPs for ensuring healthcare workers' safety and disposal of discarded blood and consumables developed/revised	
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	
	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 atHICC and filled	DGHS/DS HS
	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	<ol> <li>Updated SOPs for utility; breakdown; monitoring of medical devices, restricting access of single-use devices for reuse purposes available</li> <li>SOPs of calibration for electronically operated medical devices available</li> </ol>	DGHS/DS HS

5.7 Safe organ, tissue and cell transplantati on and	5.7.1 Reinforce the deceased donor programme and modify as necessary	MoHFW/DGHS/N OTP	2022	S/M	3. Policy on condemnation of equipment in place Deceased donor programme modified and reinforced	MoHFW
donation	5.7.2 Scale-up IEC for organ donation, training of personnel in addition to registration of organ retrieval centers	MoHFW/DGHS/N OTTO	2022	S/M	IEC for organ donation, training of personnel in addition to registration of organ retrieval centres scaled up	MoHFW/ DGHS/N OTP
	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/N OTP	2022	S/M		MoHFW/ DGHS/N OTP
STRATEGIC OB	JECTIVE 6: To strengthen capacity for and im	prove patient safety	y research			
6.1 Consolidatio n of patient	6.1.1 Establish a repository of all good quality research on patient safety and allied themes.	Lead agencies: ICMR, NML	2017-19	м	Repository on good quality research on patient safety and	Not required

safety research and utilization for decision- making		Contributing agencies: Professional colleges Department of Health Research			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	2017-22	M-L	Study/ies on burden of unsafe care available	Multiple agencies
	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	Multiple agencies

### 7 Human resources

Implementation of the patient safety framework largely will not require additional human resources. Most of the interventions will be implemented within the existing programmes and by well-established organizations and institutions. Additional training initiatives as per thematic areas might be considered for the health workforce for taking forward patient safety initiatives. Though there are some exceptions as indicated in the framework itself regarding establishment of new departments/positions). 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.

## 8 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, inflectional 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 NHM as well institutional budgets of hospitals.

# 9 Monitoring and evaluation

Strategic Objective	Intervention	Indicator	Baseline	Target
Strategic Objective 1				
Priority area 1	Policy and Strategy on patient safety	National Policy and Strategy on patient safety	Nil	National policy available
Priority area 2	Accreditation systems	Proportion of public health facilities accredited		80%
Priority area 3				
Priority area 4				
Strategic Objective 2				
Priority area 1	System of surveillance for adverse events	Proportion of facilities reporting monthly on adverse events		80%
Priority area 2				
Priority area 3				
Strategic Objective 3				
Priority area 1	Training of healthcare workers on patient safety	Proportion of states with state level trainers on patient safety		80%
Priority area 2	STGs & SOPs for diseases and Training manual on	Standardised National level Training manuals	Not available	Available

	patient safety	on patient safety		
Strategic Objective 4				
Priority area 1	Surveillance of HCAI	Proportion of facilities reporting HCAI monthly		80%
Priority area 2				
Priority area 3				
Priority area 4				
Strategic Objective 5				
Priority area 1	Adoption of Surgical Safety Checklist	Proportion of health care facilities implementing safe surgical checklist		80%
Priority area 2	Improving implementation of BMW Rules	Proportion of facilities with satisfactory implementation of BMW Rules		80%
Priority area 3	Promote Non Mercury devices	Certification of non mercury medical devices	Not mandatory	Mandatory
Priority area 4	Strengthening the NOTTO	Operational Regional Centres		4-5
Priority area 5				
Priority area 6				
Priority area 7				
Strategic Objective 6				
Priority area 1	Estimation of burden of unsafe care (point survey of HCAI)	Proportion of states with Survey estimates available	nil	50%
Priority area 2				

# 10 Communication strategy

Communication strategy for patient safety has to consider the following aspects:

*I Overall purpose and key issue:* Patient safety related issues have to be linked to the behavior or 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.

*III Audiences* (Primary, secondary and/or influencing audiences): Communication strategy for patient safety has to 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)

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

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

*VI Channels and Tools:* The communication tools and channels have to 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.

*VII. 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.

*VIII. Timeline for Strategy Implementation:* If the communication strategy is to 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.

*IX. Budge:* Developing a detailed budget ensures that there will be available the financial resources to carry out your communication strategy in all its parts. The budget for communication strategy on patient safety has to be linked to the overall budget for patient safety framework and be reflected in PIPs, for example. Alternatively, separate budget has to be established for communication strategy.

### References

Annexes