

NATIONAL PATIENT SAFETY FRAMEWORK

ENSURING QUALITY & SAFETY



QUALITY ASSURANCE AND REGULATION DIVISION,
MINISTRY OF HEALTH IN COLLABORATION WITH WHO MALDIVES



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FORWARD

It is undeniable, that issues related to quality of care have implications beyond health. The economic impact of adverse patient events are immense, costing billions of dollars a year, much of which is hidden having devastating emotional and financial effects, and can be deadly.

Establishing patient safety mechanism is expensive. The government of Maldives believes that it's high time to invest in quality health care. If not done today, this will increase the cost to government in the future in-terms of lives lost, medical litigations, reduced public confidence in the system.

We must understand that patient safety cannot be achieved without system accountability and system competence, this summit highlights some of the most vital areas required to address patient safety. Emphasis needs to be made on innovation, reviewing policies to align with patient safety. Governments should focus on modernizing delivery through digital health, investing in science and research.

The government of Maldives is commitment to not only ensure access to healthcare but to aspire towards a health system that is centered around patient safety and quality of care. The future of health care is not in quantity but in quality and safety. Therefore commit to mainstreaming patient safety as the fundamental cornerstone of health care delivery system.

Minister of Health
Ahmed Naseem



ACKNOWLEDGEMENT

Ensuring safety and quality in health services provision is the main foundation in improving health services. This also remains to be one of the major challenges due to the scarcity of resources committed to its practical application, although the importance of patient safety has grown immensely.

One of the main aim of creating this patient safety framework with doable and achievable implementation plan is to approach patient safety in the perspective of risk at all levels including; patient, provider, entity, and system. The principle behind the framework entails providing high-quality care with the fundamental medical mantra of “do no harm.” There is global evidence of death and disability due to unsafe care and avoidable harm. One of the main step to establish a culture of safety is to ensure that leadership and the whole organization understand the basis for a focus on patient safety. This will enhance policies by introducing and sustaining safety cultures in planning and service delivery with improved patient outcomes.

In this regard I would like to acknowledge everyone who had contributed to this commendable work. We are indebted to the Honorable Minister of Health, for his commitment and dedication in providing the best possible care to the public and aligning national health policies towards achieving this goal. We would like to express our gratitude to WHO Representative, Dr Nazneen Anwar and former WR, Dr Arvind Mathur who have extended their support to in this endeavor. Our sincere appreciation to the quality improvement experts Dr J N Srinivastav and Dr Nikhil Prakash, two people who knows the inside and local context of the system due to the extensive work that they have contributed in developing Maldives Healthcare Quality Standard. This framework and implementation plan takes into consideration the challenges in our system, overcoming the barriers and implementing the framework.

We are especially thankful to all stakeholders who were involved in making this a reality. Lastly, my team at Quality Assurance and Regulations Division at the Ministry of Health, I would like to acknowledge the immense efforts, involvement, timely comments, collaboration and the dedication of the team. Finally, my sincere request to all healthcare workers is to involve patients and families as partners in the implementation of National Patient Safety Framework to achieve results and make care safe. To utilize this framework to analyze and share data to generate learning and translate evidence into actionable and measurable improvement.

Thasleema Usman
Commissioner of Quality Assurance



PAGE OF CONTENT

SECTION A	01
Background	01
Situational Analysis	03
Patient Safety Assessment Methodology	03
Current Situation of Patient Safety in Maldives	04
SECTION B	11
Aim	14
Application	14
Guiding Principles	14
Strategic Objectives	16
Key requirements to meet Strategic objectives	17
SECTION C	43
Action Plan for implementation of patient safety framework	43
Patient Safety Assessment Tool	69
Patient Engagement Assessment Tools	89
List of Abbreviation	101



SECTION A

BACKGROUND AND SITUATION ANALYSIS

A.1 Background

Patient safety is the keystone of high-quality health care and is defined as ‘processes that reduce the probability of potential harm or adverse events viz. morbidity and mortality associated with exposure to the health care within the institutions’. It is one of the core dimensions of Quality of care and comprises of multiple elements viz. medication safety, injection safety, blood safety, prevention of hospital acquired infections, safe disposal of healthcare waste, medical device safety and much more.

Global estimate shows that adverse events or patient harm is one of the 10 leading causes of death and disability worldwide and about two third of the global burden on account of the adverse events happens in low and middle-income countries. Commonly occurring situations leading to harmful and unsafe care can be through multiple channels, such as medication error, Health care associated infections, unsafe surgical care, unsafe injection practices, diagnostic errors, unsafe transfusion, venous thrombosis, etc. It could be one at a time or more than one situation happening simultaneously. Various Studies have shown prevalence of health care-associated infections about 7.6% and 10.0% in high-income countries, and higher figures in low- and middle-income group countries. Complications arising due to unsafe surgical procedures are around 25%, abnormally very high and puts extra burden on the health systems. Approximately 7 million surgical patients annually suffer from significant complications and 1 million of them die during or immediately after the surgery. Unsafe injections practices account for an estimated 9.2 million disability-adjusted life years (DALY) lost per year worldwide. Other than this, Medication errors and Venous thromboembolism are other common and

preventable adverse events. Venous Thrombosis contributes to one third of the complications annually which lead to hospitalization of patients. Medication errors are expected to cost about 42 billion US dollars annually.

There are many factors which contribute to unsafe care. These have been broadly grouped under following three broad heads.

- a. Amalgamation of unfavourable conditions of facility's operations viz. understaffing, inadequate structures and overcrowding, non-availability of equipment, poor hygiene and sanitation, etc. specially in low- and middle-income group countries,
- b. Weak quality and safety culture, and disinterested leadership further weaken the ability of health systems to provide safe care. It gets further aggravated due to poor clinical governance. And
- c. Increasing complexities of health system environment - Poor Capacity to absorb newer investigation and treatment modalities

Treating, caring and protecting the patients from health care-related avoidable harm require concerted efforts at both national and international level. In the year 2002, WHO member states agreed in World Health Assembly for resolution on patient safety. WHO in collaboration with its member states provide overall leadership and guidance to develop and implement interventions that reduce risks and improve safety. One of such interventions are through implementation of 'Global Patient safety' challenges. Till now, three such challenges have initiated that is: **Clean Care is Safer Care, Safe Surgery Saves Lives and Medication Without Harm**. These challenges have started action to reduce health care infection, risks associated with surgery and unsafe medication practices and errors respectively.

Current year (2019) is the historic year in the journey of patient safety movement globally. Initially, the WHO Executive Board (EB) in its 144th session deliberated on the agenda item 'Global action on patient safety' on 31 January 2019; and adopted the EB Resolution 'Global action on patient safety'. Subsequently, 72nd World Health Assembly (WHA), in the month of May 2019 adopted the WHA Resolution (WHA72.6). A decision has also been taken by the member countries to have annual World Patient Safety Day on 17 September.

Various studies have also shown that health related SDGs cannot be achieved by reliance on disease specific interventions and achievements of financial reforms. Attainment of the goals will require commitment to deliver the safe and high-quality care. In this context, recently Patient safety and Quality of care have been recognized as critical components for achieving the Universal health coverage (UHC).

A.2 Situational Analysis

Patient safety is fundamental to healthcare and is a major concern for the Republic of Maldives. For strengthening the patient safety framework, Ministry of Health (MOH), Republic of Maldives had requested the WHO for assistance in assessing prevalent the status in the year 2016.

Now the Ministry of Health has decided to develop the National Strategic plan for the Patient Safety in the country. Previous findings have been validated by undertaking field visits, discussion with practitioners, and focused group discussions.

Areas focused during situation analysis:

- Legal and regulatory framework, National policies and strategies, structural system and involvement of stakeholders.
- Nature and Scale of Adverse events and surveillance system
- Competent & Aware Workforce
- Infection Prevention and control (IPC)
- Implementation of Global Patient Safety Campaigns
- Capacity for research on Patient Safety

2.1 Patient Safety Assessment Methodology

Following strategic objectives are recommended by the 'Regional strategy for patient safety - WHO South-East Asia Region':

1. To improve the structural systems to support quality and efficiency of health care and place patient safety at the core at national, sub-national and healthcare facility level.
2. To assess the nature and scale of adverse events in healthcare and establish system of reporting and learning.
3. To ensure a competent and capable work force which is aware and sensitive to patient safety.

4. To prevent and control Healthcare associated infections (HAI).
5. To Improve implementation of Global patient safety challenges and strengthen patient safety in all health programmes: safe surgery, safe childbirth, safe injections, medication safety, blood safety, medical device safety, safe (organ, tissue and cell) transplantation
6. To strengthen capacity for research on Patient Safety and ensure patient safety in research

The strategy also acknowledges that patient safety cannot be assured, unless health system is in place in a country. WHO SEARO Patient Safety assessment tool was used for the situation analysis in Republic of Maldives in the year 2016. The tool had questions for undertaking assessment across all levels of health systems including vertical programmes. Such assessment is aligned with the strategic objectives. Extent of compliance is made in each area, on a scale of 0-4 (0=not present, 1=present but implementation less than 25%, 2= present and implementation is between 26-50%, 3=present and implementation between 51-75 %, 4=fully functional or implementation above 76%).

2.2 Current Situation of Patient Safety in Maldives

Following observations are specific to the strategic objectives for the patient safety in the country.

2.2.1 Legal and regulatory framework, National policies and strategies, structural system and involvement of stakeholders'

- 'Right to Life' has been enshrined under the Article 21 of the Constitution of Republic of Maldives and the country has passed various acts, which are supported by commensurate regulations and other legal provisions. Few such examples are Medicines Act, Drug Control Act, Environment Protection Act, Health service Act, Public Health Protection Act, Health Professional Act, etc. Following acts exemplify commitment of the Government in this direction.
 - **Health Services Act of the Maldives:** This act provides broad regulatory framework for strengthening of the National Health Services in the country. The act proposes the institutional framework of the National Health Services, registration & licencing requirements, penalties, etc. **The act also provides provision of Health Services Safety and Quality Assurance in the country and states it would be administered by**

'Commissioner of Quality Assurance', who would be custodian of all such requirements, actions and investigations, as deemed appropriate.

- **Public Health Protection Act:** Public Health Act covers all dimensions of work, living and recreation in the country. For administration of the Act, 'Health Protection Agency (HPA) is in place. Under the Section 10 of the Act, the Civil Services Commission has been mandated to create positions in twelve categories to meet the Human Resource (HR) needs of the country's Health System. Section 44 of the Act empowers the Agency to develop Hygiene Standards for the Hospitals.
- **Health Professional Act:** Health Professional Act lays down institutional framework for the professional regulatory bodies and their operational matters. This act gains importance since the country has substantial presence of expatriate professionals working in the health system, both government and non-government as well.
- **Regulation of Drugs and Consumables - Food and Drug Administration Authority:** Maldives Food and Drug Authority has been designated as a nodal agency responsible for quality and safety of drugs, consumables and food products. Presently, the State Trading Organization (STO) is the nodal agency for the Public Procurement in the country. The Ministry of Health does not own and administer Hospital Pharmacies, which are either owned by the State Trading Organisation or by Private bodies.
- **Maldives Health Master Plan 2016 – 2025:** For meeting aspiration of citizens of country and commitment of the Government, the Ministry of Health has conceptualized developed 'Maldives Health Master Plan. The Master plan acknowledges current weaknesses in the health system with regards to Quality Assurance and reiterates the Government's commitment for strengthening the Quality of Care.
- **Non-operationalisation of Structured Quality Assurance and safety supporting Institutional Framework:** Quality Assurance & Improvement Division within the Ministry of Health has been established in the country. The major activities/responsibilities of Quality Assurance & Improvement Division (QA&I) is to undertake the assessment of public health facilities using a set of checklists. In the checklist, there is no provision of scoring based on assessment criteria. There is a single common checklist for all health centres and hospitals, irrespective of their roles, and responsibilities. The process for subsequent action planning and gap closure following an assessment is non-evident. Assessment activities do not involve assessment of tertiary care institution. Though Maldivian Health Quality Standards were developed with support of the WHO, it has not yet been institutionalised

across all health facilities. There are no Programs for capacity building of the Quality Assessors and Service Providers.

- Apart from assessment of Public Health facilities for the quality assurance and improvement purposes, the QA&I division also inspects private healthcare facilities and resort clinics for licensing and monitoring purposes. These inspections are done usually at the time of granting and renewal of the licenses and. Any structured checklist, having pre-defined criteria for this purpose has not been developed.
- **Quality Assurance at Indira Gandhi Memorial Hospital** – IGMH is the apex secondary and tertiary care hospital in the country. It has established its own Quality Assurance structure. The quality team performs quality assurance related activities such as Infection Control Audit, Medical and Death audits, and also measuring quality Indicators. The quality assurance team has also developed SOPs for few departments and is in the process of developing SOPs for remaining departments. The Hospital laboratory follows ISO-15189 Standards. The laboratory was also certified to ISO 9001 Standards. However, the certified status could not be maintained subsequently.
- **Registration of Private health care facilities:** Though there is a system of registration of Private Health Facilities for licensing, which looks largely at 'minimum' requirement, mainly on structure component (Infrastructure, HR & Equipment) of the Quality of Care. There is no system of evaluating the processes & outcome components. The health facilities in government and private sector are not quality certified for the care, provided there.
- **Quality Assurance at Private Hospital:** The biggest private hospital, ADK Hospital Male has a dedicated Quality Assurance cell with a full time professional for leading the QA activities in the Hospital. The Hospital is working for getting JCI accreditation. Other than this most of the public hospitals and health centres beyond Male don't have quality assurance system, though some of the facilities have Standard Operating Procedures for certain departments and functions.
- **Institutional Framework for development of Standard Treatment Guidelines (STG) and its periodical review:** MOH along with Maldives Medical Association has created task force for development of STGs on 72 identified disease conditions. In the first phase, guidelines for 42 clinical conditions have been developed.
- **Quality Indicators and Performance Measurement:** Health Information System has been implemented by the Ministry of Health for public Hospitals and health centres. There is a single format applicable to all level of facilities from Grade I Health Centre to Grade III Hospital. Most of the current data elements measure volume indicators only. The data

elements are reported through a monthly report of activities, generated in a Microsoft Excel Format. A dedicated HMIS application is not available, so collating and analysing data from all the facilities having a challenge in the country.

- Since 2017, the WHO has been supporting the ministry of health in developing and implementation of health information management platform called District Health Information System (DHIS2). Currently the first phase is nearing completion. In the second phase, more Programmatic focus areas such as surveillance, reproductive health, nutrition, NCD etc. will be included. The MOH is currently in process of developing data entry forms to be included in the DHIS2 platform. Routine health information, such as Outpatient form, Bed form, Birth form, HR form, Death form, Monthly report (8 forms) (Outpatient, Observation, Inpatient census and occupancy, Obstetrics, Surgeries, Lab and diagnostics, Procedures and service, Referrals and others) would be captured in phase 1 of DHIS2.
- Although few indicators viz. bed occupancy and Inpatient days are part of DHIS2 but there is hardly any indicator pertaining to the Quality of Care such as patient satisfaction level, hospital acquired infection rates, adverse events, medication errors etc. and Average Length of Stay (ALOS) get reported across all health facilities.
- There is absence of a credible system of performance measurement. Comparison of the health facilities and their ranking in term of quality of care have not been possible. There is also no formal system of taking feedback from the patients and health system beneficiaries.

2.2.2 Nature and Scale of Adverse events and surveillance system

- System for on-going assessment patient safety is almost non-existent in the country. Although MFDA's Medicine and Therapeutic Division has a system in place for ADR monitoring, medication errors, efficacy and quality of drugs, etc. still the reporting under existing system is negligible (as per Medicine in Healthcare – Maldives Situational analysis -2014.)
- There is no system of incidence surveillance, reporting and learning at the National and atoll level. IGMH conducts regular perinatal mortality and morbidity review meetings with all relevant stakeholders. The adverse events and 'near-misses' are analysed as case to case basis, more on receipt of such complaints. Most of the institutes do not have institutional arrangement for review of such happenings, nor, there is a regulatory requirement.

2.2.3 Competent & Aware Workforce:

- **Absence of a System of Competency Assessment and Credentialing of Health Professionals:** Substantial number of Health Professionals in Maldives are expatriate. Initial registration of the expatriate staff with their respective professional bodies (councils) and subsequent renewal take place on submission of requisite documents. There is no formal procedure to test their skill and knowledge after they arrive in the country.
- **No System of Capacity Building and Continual Medical Education:** Staff at the health centres and hospitals do not undergo any structured training for updating their knowledge and skills. There is no system for continuous professional education and development (CME and CPD) and professional certification and re-certification for different categories of health workers.
- **Absence of Training Need Assessment of Different Category of Staff:** There is no system of assessing understanding and practices of patient safety among healthcare workers both in public and private sector.

2.2.4 Infection Prevention and control (IPC)

- **Infection Control Committee:** There are functional infection control committees at the IGMH and ADK hospital (Non-government hospital). A senior nurse has been designated as the focal point for the IPC in the peripheral hospitals. Although, National Guidelines for Infection Control in Health Facilities were released in the year 2008, but over the period of time, the guidelines have become outdated and the recommendations are not practiced uniformly. Health facilities are using different international guidelines as per their preferences.
- **Hand Hygiene:** There has been some efforts undertaken for establishing the hand washing protocols such as the WHO five moments and steps of hand hygiene etc. Hand washing facilities are adequate viz. availability of soap and alcohol-based hand rubs. Single use towels and tissue papers are available in most of the institutions. But compliance to hand washing was relatively poor. It was observed to be around 60% among nurses and only 40% among doctors.
- **Personal Protective Equipment & Other Sterile Services:** Gloves and masks are available in most of the health facilities. Isolation rooms were available at IGMH; but other referral hospitals did not have separate isolation wards /rooms. The N95 masks were available at IGMH, but not in other hospitals. Autoclaves were available at IGMH, regional and Atoll

hospitals. But there is no Central Sterile Service Department (CSSD) even at IGMH. The ward staff usually clean the instruments etc. and send it for sterilization. The health centres have small bench type autoclaves. Reusable instruments are usually boiled on site.

- **Training** in infection control is conducted in ad-hoc manner. There is no system for training need assessment as well as there is no defined training guide / module for IPC.
- **Surveillance** of healthcare associated infection (HAI) is conducted at IGMH and regional hospitals. However, there is no defined reporting system of HAI and no institutional system is in place for collection, analysis and reporting of HAI nationally. Antibiotic policy is not in place at the visited facilities. Culture Surveillance of critical area such as ICU, OT, Labour room, etc. is not practiced in most of health facilities.
- **Standards for Healthcare Waste Management:** Minimum standards for health care waste management at health facilities has been released by the Ministry of Health. These standards define category of health waste and its management through seven steps. This includes waste minimization, segregation, intermediate storage, internal transport, centralized storage, treatment, external transport and final disposal. The document does not define colour coding for segregated collection of the health care waste, while National Standards for clinical laboratories provides colour coding of health waste according to its categories.
- **Waste Management Practices:** For segregation of healthcare waste, bins, liners and sharps containers are available. But, after segregated collection, hazardous and non-hazardous waste are burnt in the open. Incinerators at Atoll Hospitals were found to be obsolete. There is a higher chance that hospital waste is mixed with the general municipal waste. Generally, health facilities do not have a system of safe disposal of liquid waste. The country's fauna and eco-system is delicately balanced. Existing system of Healthcare waste management does not have sustenance.

2.2.5 Implementation of Global Patient Safety Campaigns

- **Surgical Safety.** The WHO safe surgery checklist is being used in the IGMH. Other hospitals have their own checklists, but their applicability is limited.
- **Blood Safety** - The disease burden on account of Thalassaemia and related disorder is significantly high in the Country. At Maldivian Blood Services (MBS), quality assurance related activities are being undertaken. The laboratory services in MBS has established Standard Operating Procedures (SOPs) for its various functions and activities. The

laboratory also participates in NRL External Quality Assurance Scheme (EQAS). The national blood policy has not been implemented yet.

- **Safe childbirth** The WHO safe childbirth check list is not being used. However, usage of partograph has been found.
- **Medicines safety:** In Maldives, all medicines are imported from other countries. Maldives Food and Drug Authority (MFDA) is designated as nodal agency responsible for quality and safety of drugs, consumables and food products. State Trading Organisation (STO) is the nodal agency for the procurement in the country. There are regulations for medicine safety. Pharmacovigilance is in place for reporting of adverse events, but it needs to be further strengthened. Laboratory for testing quality of medicines has not been established.
- **Device safety:** The responsibility of device safety has given to MFDA recently. Equipment are procured by the MOH and there is significant delay in the procurement process. Assistance in procurement is often requested from external partners such as WHO and UNICEF. A system of break down maintenance is available but there is no system for preventive maintenance of available equipment at the hospitals and health centres. The equipment are not calibrated periodically to ensure their correct functionality and output.
- **Regulatory Framework for Radiation Safety in Health Facilities:** The country does not have regulatory framework for Radiation Safety in the Hospitals and Health Centres. Nor there is a system of monitoring of staff for cumulative exposure to ionising radiations.
- **Injection safety:** There is no National policies for safe and appropriate use of injections. Only IGMH has institutional guidelines on safe injections.

2.2.6 Capacity for research on Patient Safety

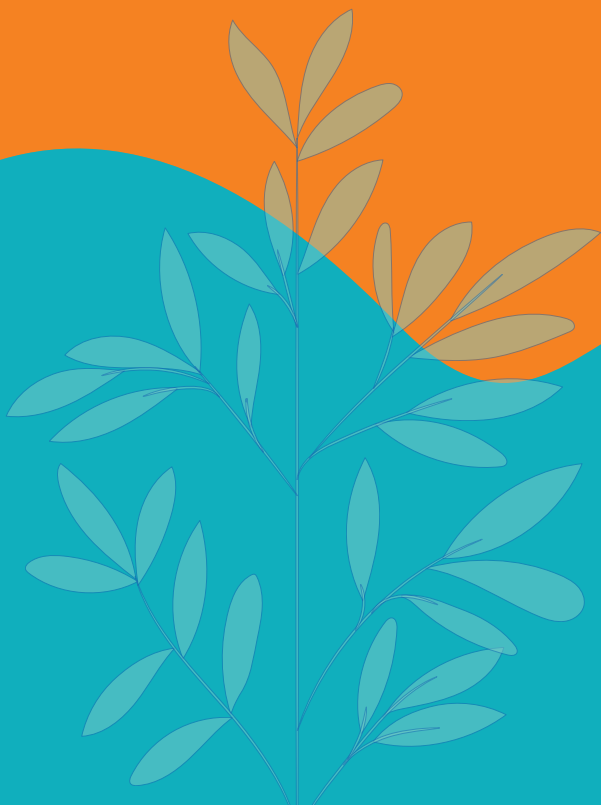
- Ministry of health has identified 'National health research priorities' in 2013. Quality of care in hospitals is identified as one National health research priority.
- The country has National Research Ethics Committee as national body that decides on the ethical aspects of the research. The IGMH also has its own Ethics Review Committee, but it needs prior approval from the national research ethics committee.

SECTION B

NATIONAL PATIENT SAFETY FRAMEWORK

AIM

“THE AIM OF NATIONAL PATIENT SAFETY FRAMEWORK IS TO CREATE AN INSTITUTIONAL FRAMEWORK FOR DELIVERY OF HEALTH CARE, WHICH IS SAFE AND RESPONSIVE”



GUIDING PRINCIPLES

Focusing on Health System Approach

Establishing priorities

Monitoring, reporting and learning

Ensuring sustainability

Prompting Collaborations

Instigating Patient centred approach

Engaging of all levels of Healthcare

Using evidence-based Interventions

STRATEGIC OBJECTIVES

To establish the institutional arrangements and strengthen the clinical governance to place patient safety at core of national, subnational and facility priorities

01

To ensure competent and capable work force sensitive to patient safety needs

02

To implement patient safety in its all modalities that is prevention, diagnosis, treatment and follows up across all levels of care and programs.

03

To reduce patient harm generated by unsafe medication practices and errors

04

To engage the patient and patient groups to improve patient safety and quality

05

To establish Patient safety event reporting system and promote patient safety research

06

B.1 Aim:

The aim of National Patient Safety framework is to create an institutional framework for delivery of health care, which is safe and responsive. It supports assimilation of international best practices and helps in creating an open environment for continual learning and professional excellence for better health outcomes. It can be achieved through bringing patient safety at the centre functioning of all types of healthcare facilities (Primary, secondary, tertiary). This complements efforts of the country in with attaining Universal Health coverage by improving the quality and safety of the health care.

B.2 Application:

Patient Safety framework provides standards and guidance to implement Patient Safety Program within the health system, so it is applicable at the national, sub-national and facility levels both in public and private sectors as well as in all National health programmes and schemes. It also envisions collaboration within and outside health sectors including public-private, national- international stakeholders.

B.3 Guiding Principles:

Focusing on Health System Approach: Multi-dimensional approach will be ensued to strengthen the patient safety across the health system and its core components. It includes

- Strengthening the governance and leadership for the patient safety in the country. It is expected to ensure that there is effective oversight and regulation. Efforts are undertaken for the coalition building and ensuring the system's accountability.
- Design mechanism for health system financing so that adequate and dedicated funds are allocated for planned activities of patient safety and individuals have access to the quality services.

- Ensure health services delivered are based on scientific knowledge, safe, respectful and responsive to patient's need, reduce unwanted waits/ delays, equitable and avoiding waste of resources. It also ensures equitable access to essential medical products, devices, vaccines and technologies of assured quality and cost effectiveness.
- Ensure adequate health workforce, which is fairly distributed and are competent, responsive and achieve best possible outcomes. Also, focus in building their competencies and skills through continuous education and training.

Using evidence-based Interventions: Identify, prioritize and implement the interventions those are proved to be effective and efficient. Continue proactive efforts are undertaken to generate the evidences and required adaptation can be ensured during implementation.

Engaging of all levels of Healthcare: Engage all types of healthcare facilities and bring Patient safety at the core of healthcare because of its cross cutting nature.

Ensure health services delivered are based on scientific knowledge, safe, respectful and responsive to patient's need, reduce unwanted waits/ delays, equitable and avoiding waste of resources. It also ensures equitable access to essential medical products, devices, vaccines and technologies of assured quality and cost effectiveness.

Instigating Patient centred approach: Engage the patient as equal partner in patient safety by active involvement and empowerment for ensuring that provided healthcare is respectful and responsive to their preferences, needs and values.

Prompting Collaborations: Involve all stakeholders those within or outside the system for improving the patient safety. Along with health workers and decision makers, it is equally important to have a system of engagement with the patients, their families, civil societies, professional organizations, media, etc. It is also significant to recognize their roles and responsibilities.

Establishing priorities: Establish priorities and define clear cut timelines and responsibilities for implementation by incremental approach.

Monitoring, reporting and learning: Create an enabling environment for monitoring, measuring and learning as these are critical to minimize the risk and play vital role enhancing Quality of care.

Ensuring sustainability: Make patient safety interventions sustainable by addressing it as policy objective. Ensure the institutional arrangement and monitoring at National, atoll and facility level on mutually agreed indicators. Also create an enabling environment to support the meaningful reporting.

B.4 Strategic Objectives

National Patient safety implementation requires integration of health system components with patient safety policies so that culture of patient safety is in-built within the health system. Six strategic objectives have been prioritized for this purpose after reviewing the global and regional frameworks as well as by due consultation with Ministry of health, relevant stakeholders and implementation partners. Strategic objectives identified have been detailed in terms of priorities and interventions. Priorities are further divided into core and advance priorities.

Following are the strategic objectives:

1. To establish the institutional arrangements and strengthen the clinical governance to place patient safety at core of national, subnational and facility priorities.
2. To ensure competent and capable work force sensitive to patient safety needs.
3. To implement patient safety in its all modalities that is prevention, diagnosis, treatment and follow up across all levels of care and programs.
4. To reduce patient harm generated by unsafe medication practices and errors.
5. To engage the patient and patient groups to improve patient safety and quality.
6. To establish Patient safety event reporting system and promote patient safety research.

B.5 Key requirements to meet Strategic objectives

OBJECTIVE 1

To establish the Institutional arrangements and strengthen the clinical Governance to place patient safety at core of National, subnational and facility priorities

For ensuring universal access to quality services, Republic of Maldives has passed various acts, regulations and legal provisions which directly or indirectly impact their citizen's health. In order to provide financial protection, the Government runs an insurance scheme which covers medical expenditure of its all natives. The Public health care sector of Maldives has maximum share in terms of coverage and services provision. Although private sector is small in size and volume, it is growing exponentially. Maldives has a growing healthcare sector and its major challenges include

- a. scattered and small units of habitation in atolls and islands
- b. High dependence on expatriate health professionals, who come with diverse background and have limited tenure
- c. Absence of Quality and safety culture
- d. Absence of certification & accreditation system for measuring and validating quality and safety in health system as well as expanding private sector

OBJECTIVE 1

To establish the institutional arrangements and strengthen the clinical governance to place patient safety at core of national, subnational and facility priorities.

Core Priority:

- Establish the Structural System to support Patient Safety and Quality in Healthcare
- Strengthen the regulatory framework for patient safety
- Improve the responsiveness and effectiveness of clinical Governance system
- Establish mechanisms for independent assessment and accreditation of health care facilities

Advance Priority

- Strengthen the regulatory framework for patient safety

In this context, a rational approach would be to have an overarching National Framework that covers institutional mechanism and all modalities for quality & safety in public and private sector. Other than establishing institutional arrangement, objective is also focused on defining regulatory mechanism, improving the clinical governance and starting a formal accreditation programme to assess the compliance against quality and safety standards.

Core Priority 1.1: Establish the Structural System to support Patient Safety and Quality in Healthcare

Establishment of institutional arrangement is the most critical component of patient safety and quality for addressing the system issues and support to create an enabling environment within the existing policy, regulatory and programme management framework. Following is proposed institutional framework for patient safety in Maldives.

1. **National Level:** National Patient Safety Committee will be constituted under aegis of Ministry of Health and it will be an integral part of Maldives Quality Commission (As mandated under the Health Services Act and Health Master Plan 2016 – 2025). Since at present Maldives Quality commission is not notified, an Interim committee could be constituted at in the Ministry of Health for Patient Safety.
2. The Interim committee of Patient safety will have experts of IGMH, representatives from Maldives Medical Association, Maldives nurse association, Health protection agency, state trading organization, Maldives Blood services, regulatory authorities, insurance agencies, patient / civil society organization, private institutions, representatives from at least two atoll hospitals and two health centres and other relevant stakeholders. The detailed TORs for National Patient Safety committee are given in Annexure 'A'.
3. To accomplishing the responsibilities of Patient Safety framework, Interim committee will further be divided into Technical Advisory Subgroups having mix of experts and relevant stakeholders. These subgroups can provide technical inputs for Infection prevention, Biomedical waste management, radiation safety, formulation/adoption of minimum Quality & safety standards for facilities, laboratories, Blood banks and other relevant areas, development of patient safety capacity building modules, defining core KPIs for Quality and safety, mechanism for reporting of adverse events, framework for reporting and learning systems and defining the legal & regulatory requirements for quality and safety, etc.

4. The Committee will be supported by its secretariat at QA&I Division of the MOH. The secretariat will provide support for implementing patient safety, coordinating different sub groups for drafting technical guidelines, developing training material, etc.
5. **Regional Level:** Considering the geographical spread of the country, it is recommended to have a focal point for patient safety at Atoll level. The focal point will be responsible for effective implementation of Patient safety framework goals in their respective Atolls as per directions of National Patient Safety Committee/ Interim committee. The regular functions can be later subsumed under Atoll level quality committee.
6. **Facility Level:** For assuring the patient safety it is very much important to timely detect the errors and analyse them. Periodical feedback is given to the staff for focused and continual improvement. So, it is required to designate a focal point for patient safety at facility level also. If facility have Quality team/circles, infection control committee, clinical/ medical audit committee at place, the focal point can be designated from the existing structure.
7. Institutional framework for patient safety will have many stakeholders such as regulator, accreditation, licensing agencies, training, professional councils, evaluation agencies, and health administration, civil societies etc. To define the clear demarcation of authorities & responsibilities, channels of reporting, communication and conflict resolution, terms of reference and process flow for co- ordination will be defined and shared consensus would be arrived at beforehand.
8. Patients safety concepts and principles should be integrated in all disease control program considering safety of both providers and patients. Some important aspects are injection safety and reporting of AEFI in immunization programs, infection control under Tuberculosis control program, Blood Safety, etc. So, integration of critical components of patient safety will be ensured in all existing programs & schemes.
9. Govt. 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 etc.
10. As a start point for sensitisation on patient safety and quality, it is suggested to have a TOT. Suggested topics for the TOT are given in Annexure 'B'.

Advance Priority 1.2 Strengthen the regulatory framework for patient safety

1. As mandated under Health Services Act Maldives, Quality Commission would be constituted at the National level within the Ministry of Health. This commission will be headed by a Quality Commissioner with eligibility and stature as mandated in Health Services act. Roles & responsibilities of the 'Maldivian Health Quality Commission' would be decided by the Government. However, among many functions, it would be made responsible for core Patient safety activities in the country.
2. For accomplishing the responsibilities of Quality and safety in country, proposed quality commission will be adequately staffed to create certain new technical units. Existing support units will be realigned or subsumed within the Quality commission to establish technical Advisory committee, Licencing unit, Accreditation units, Quality Assurance & Improvement unit, Patient safety unit, etc.
3. Regulatory Framework for reporting of the notifiable diseases, processing and disposal of hazardous and biomedical waste, radiation safety in the health facilities will be established using or adopting International frameworks.
4. Special clause in existing legal documents/ Provision of Legal remedies for ensuring patient rights and safety related issues will be established. It will include well laid out processes for ensuring patient rights and addressing grievances through consumer and civil judicial mechanism. It should define the time guarantee for actions to be taken in case of medical negligence.
5. Legal and administrative provisions will be developed to protect the health workforce, patient safety data or its reporting from any litigation and punitive actions. The provision should address the limited/ restricted access to patient safety data to enable fearless and blame free reporting of adverse events.
6. Awareness and capacity building programme for patient safety laws and regulations will be developed.

Core Priority 1.3 Improve the responsiveness and effectiveness of clinical Governance system

For improving the clinical Governance, the most critical requirement is use of evidence based standard treatment guidelines. In this context, Ministry of Health along with Maldives Medical

Association has created task force for development of STGs on identified disease conditions. This work will be continued. Simultaneously an institutional structure would be developed for continual revision of developed guidelines periodically.

1. A methodology guideline will be developed for drafting, adopting and commissioning of evidence-based STG. It will also include mechanism of updating, collating reviewing and disseminating of STGs, clinical-care pathways, standards, outcomes etc.
2. Implementation tools for use of clinical guidelines such as care pathways, patient safety and quality standards, patient information etc. will be developed. Digital aids will be used for assuring implementation the clinical guidelines and care pathways.
3. A mechanism/framework will be established for updating and enhancing clinical skills of Health workforce through continual medical and nursing education programmes. The Ministry of Health will identify Institutions at National /Atoll level for continues education and capacity building of healthcare staff both in public and private sector.
4. Clinical audit guidelines will be developed and disseminated. Clinical audits will be done for internal quality and safety improvement purpose. It will not be used for external evaluation or appraisal of performance etc. Guidelines can be a compendium of processes for medical record audits, prescription audit, death audits (maternal and child death reviews), nursing care audit, referral audits and other clinical review for safety or quality of care.

Core Priority 1.4 Establish mechanisms for independent assessment and accreditation of health care facilities

At present the Health System in Maldives does not have a structured approach for Quality of Care in the services offered at the Health Facilities. Ministry of Health only ensures that private health facilities are licensed before they commence their operations. To assure the patient safety at point of delivery require establishing Quality assurance and accreditation mechanism for public and private healthcare facilities. Following measures are proposed in this direction:

A mechanism/framework will be established for updating and enhancing clinical skills of Health workforce through continual medical and nursing education programs.

1. Quality of Care Standards and their assessment tools for each level of the Health Facilities will be developed and notified. Quality of Care Standards should be notified for each type of Public Health Facilities, Hospitals, Stand-alone Clinics, Speciality Hospitals, Laboratories, Blood bank, Dental Clinics, etc.
2. Minimum patient safety standards and norms should be incorporated in the Quality of care Standards. The standards should be capable of measuring patient safety issues objectively and adequately such as fire safety, structural safety, seismic safety, medical device safety, etc.
3. Mechanism for independent assessments and Quality accreditations will be established under Maldives Health Quality Commission. For undertaking accreditation and assessment activities, a separate independent accreditation unit will be instituted. The unit may be made responsible for receiving and processing of the applications for accreditation, training and empanelling the quality assessors, conducting assessment for the accreditation and submitting recommendations for accreditation to the quality commissioner.
4. Both public and private healthcare facilities will be encouraged to achieve quality accreditation. Provision for financial incentives in reimbursement from insurance providers will be made for accredited hospitals.
5. A set of Key performance indicators that measure different dimensions of quality and safety will be defined at the national level through a consultative process. The indicators will vary according to the level and type of healthcare facility. Reporting of these quality and safety indicators on monthly basis should be made mandatory. A performance dashboard based on these indicators can be defined.
6. A System of periodic internal or peer/ independent review of healthcare facilities for safety and quality will be established to ensure continual improvement. The results of review can be used for internal improvement, benchmarking & ranking of the facilities.

OBJECTIVE 2

To ensure competent and capable work force sensitive to patient safety needs.

Availability of adequate and competent health workforce is an essential component for ensuring the delivery of responsive and safe services at the health facilities. Poor staffing norms and under performance by the health workers compromises the patient safety. It is important to ensure that adequate number of the staff are deployed at the required delivery points and such care providers have required knowledge and competencies, and they are sensitive to patient safety issues. The competent and sensitized health professionals can help in creating an error free care environment. The Patient safety framework focuses on incorporating patient safety concepts in professional education as well as ensuring that such skills are sustained through continual medical education and on the job trainings. It also emphasizes on creating blame-free, positive work culture with flexibility of having open communication to ensure the staff safety and security. Few of such priorities are given below:

OBJECTIVE 2

To ensure competent and capable work force sensitive to patient safety needs.

Core Priority:

- Strengthening of HR norms and link it with Service provision
- Ensure staff safety and promote safer work culture
- Promote safety through health care support processes
- Implement physical safety and environment control measures

Advance Priority

- Integrate patient safety in professional education (medical & nursing schools) and in-service training

Core Priority 2.1:

- 1. Strengthening of HR norms and link it with Service provision:** Strengthening of the Human resource norms in respect of Clinical, Nursing, para-clinical and support staff for different grades of hospitals and health centres according to changing needs is essential. Maldives has defined their HR needs as per patient load in "Criteria for Grading of Health Facilities". As documents have been published some time back, it needs to be updated and will be published as a comprehensive document, which defines service package and commensurate Infrastructure, equipment, drugs, consumable and human resources.
2. Code of practice for various cadre of clinical, nursing and para-clinical professionals will be developed and promoted.
3. Elements of patient safety will be introduced in Job Specifications of health workforce. Its practice and monitoring would be used to evaluate performance of different categories of health care professionals.
- 4. Establish system for Competence assessment and Credentialing of all Health Professionals:** Maldives has substantial presence of expatriate health professionals and they possess formal educational qualification of their countries. Minimum professional qualification and licencing requirement for offering medical, nursing or any other clinical services have been defined. A formal procedure for testing their skill and knowledge will be introduced.
5. Patient safety skills should be incorporated in the evaluation criteria for licencing and re-licencing assessment for healthcare professionals
6. Based on credentialing & competence assessments, a need based capacity building program will be designed for eligible professionals to make them aware of local diseases, their management protocols, quality, patient safety issues and other managerial/administrative issues such as referrals etc.
7. Private health facilities are licensed before they commence their operations. However, there are no explicit objective criteria for licensing of such health facilities. It is proposed to strengthen licencing norms for private health facilities and it will include explicit norms for infrastructure, equipment, safety, no. of professional staff and their qualification & experience required to deliver the committed services and critical processes, etc.

Code of practice for various cadre of clinical, nursing and para-clinical professionals will be developed and promoted

Advance Priority 2.2: Integrate patient safety in professional education (medical & nursing schools) and in-service training

1. **Establish Competency and skill mix for patient safety:** Staff competency matrices with patient safety attribute will be defined for all health care cadres. Based on matrices, it would be ensured that core skills for patient safety practices are imparted in various trainings and orientation programme.
2. For strengthening the imparted patient safety skills, Practice Guidebook on Patient safety targeting different healthcare providers will be developed and disseminated.
3. Patient safety will be promoted within broader in-service professional development programme or on job training for all categories of health care staff. To ensure regular training program, institutions or agencies level will be identified to conduct TOT's at the national and atoll levels. TOTs will include healthcare workers from both public and private health facilities.
4. For ensuring sustenance of the program in long run, Patient safety will be introduced in the educational curriculum (as separate module) of health care professionals viz. nursing, para medical etc. as ongoing education and capacity building of next generation health professionals.
5. Specific number of mandatory credit hours will be introduced for patient safety and linked with re-licencing norms of all category of health workers.

Core Priority 2.3: Ensure staff safety and promote safer work culture

1. Adequate measures will be taken for strengthening the safety and security in the work environment to health facilities. Such measures would include availability of adequate resources like personal protection equipment, security arrangements, surveillance equipment, etc.
2. Standardise policies and SOPs will be made available in healthcare facilities to ensure safe and secure work environment. It can include restricting entry of visitors, mechanism for preventing sexual harassment at work place, norms for personal protection, standard procedures for safety and security in healthcare facilities etc.

3. Minimum Health Workers safety requirements will be issued by MOH which will be incorporated in all licensing and accreditation programs also.
4. A structured mechanism will be established to develop, introduce and implement continuous improvement tools such as establishing internal patient safety goals or participating in external patient safety benchmarking schemes, organising team-building activities and simulation exercises for patient safety at the facilities and use of quality tools such as PDCA, mistake proofing, Lean etc. for the improvement
5. Positive team work culture will be promoted in healthcare facilities to improve patient safety and quality. It will be achieved by institutionalising multidisciplinary patient centred teams in patient care units as well as promoting intradepartmental teams' coordination or using existing committee such as Quality improvement team, Clinical audit committees, Infection prevention and control committees, Drug and therapeutic committee and Facility management committee etc. for patient safety and its activities.
6. Mechanism for feedback on satisfaction and grievance redressal of healthcare staff will be introduced at facility level for promoting blame free culture.
7. Health care staff will be supported for financial and legal liabilities in case of patient safety event and/or in case of patient safety reporting. This will be achieved through providing indemnity cover.

Core Priority 2.4: Promote safety through health care support processes

1. Electronic health records system will be promoted at all levels of healthcare with provision of extraction for patient safety information from administrative and clinical records. EHR data will also be used for detecting patient safety triggers. Management of electronic health records will include use of standardized format, meta-data standards and standards for health data security and privacy.

Health care staff will be supported for financial and legal liabilities in case of patient safety event and/or in case of patient safety reporting. This will be achieved through providing indemnity cover.

2. The Existing Waste Management guidelines will be strengthened and periodically updated as per change in practice and evidences. It would be instrumental for improving Quality of care and safety.

3. Implementation of Waste management practices such as segregation, handling, transportation and disposal will be streamlined in all level of healthcare facilities through ensuring availability of adequate facilities for segregation, treatment and disposal of waste, SOPs for handling of infectious waste, checklists, periodic monitoring of waste management practices, etc.
4. Awareness about scientific management of BMW will be raised with broader scope, than what is practiced and propagated now.
5. A comprehensive program for preventive maintenance & calibration of equipment will be established and implemented.
6. SOPs for equipment management including labelling and isolation of malfunctional equipment, monitoring down-time of equipment, breakdown maintenance, restricted access used single-use devices, condemnation policy, etc. will be developed and implemented at the facility level.
7. Training of staff will be ensured for safely operating the equipment, trouble shooting and daily cleaning and maintenance of equipment at the time of commissioning. Existing procedures and guidelines for the same will be strengthened.
8. Guidelines for the facility management including civil maintenance, housekeeping, water supply, medical gas supplies, laundry, dietary and other services will be developed and implemented.
9. Minimum standards and norms for support process should be incorporated under the Quality of care Standards. It will be ensured that standards are capable in measuring patient safety issues in support processes adequately.

Core Priority 2.5: Implement physical safety and environment control measures

1. Structural Safety Requirements for healthcare facility will be defined, collated and implemented. Guidelines can include guidance on layout and design of health care facilities and clinical departments, which takes into account the health facility design principles and ergonomics to mitigate risks of errors. Guidelines will also advocate conducting human factor and ergonomic (HFE) analysis before introducing new technologies, IT systems and devices in the health system.
2. Hospital planning and designing norms will include recommendation on Illumination levels at various patient care and procedure areas, norms for air quality including ventilation and

air exchanges at specially in department prone for infections and optimal temperature, humidity in care environment, etc.

3. Ensuring fire and electrical safety measures for all type of health care facilities will be of paramount importance. Existing norms will be re-defined and implemented. Such measures would also include provision of periodic assessment of healthcare facilities based on fire safety preparedness.

OBJECTIVE 3

To implement patient safety in all dimensions of prevention, diagnosis, treatment and follow-up services

Health-care settings are complex in terms of its complicated infrastructure, dynamic environment and unpredictable nature and it can pose sufficient threat to patient, their families, staff and even to community. It has potential to cause major complications and adverse events that may lead to death, disability and high level of dissatisfaction. Therefore, it is imperative that patient safety should be integrated in all programmes at all types of healthcare delivery institutions. Keeping the complexity of healthcare in mind, objective is focused on ensuring safety during high-risk services, avoid unintended harm due to medical devices, implementation of infection prevention practices, etc.

Core Priority 3.1: To ensure safety in high risk clinical services

1. Safe surgery checklist will be used in the secondary and tertiary care hospitals and it will be ensured that all elective and emergency surgeries are performed using safe surgery checklist.

2. WHO 24X7 Emergency and essential surgical norms will be adopted in all healthcare facilities providing surgical care.
3. Indicators for Surgical surveillance will be established and regularly measured and monitored at the national level. It would include indicators on utilisation, surgical site infection, perioperative mortality, etc.
4. Guidelines for proactive measures to make surgeries safer and guidelines for prevention on venous thromboembolism will be developed and implemented.
5. International standards for safe practice of anaesthesia and use of safe anaesthesia checklist will be promoted.
6. Safe child birth checklist will be used to improve safety during delivery and post-partum care both in Private and public sector.
7. Standards for Safe surgery checklist, Safe birth checklist, anaesthesia and resuscitation will be developed and incorporated in the quality accreditation programme.
8. National haemovigilance system with standardised channels of reporting, analysis and feedback will be established. Adverse transfusion reactions surveillance will be implemented and incorporated within National Blood Policy Maldives to prevent occurrence or recurrence of any adverse events.
9. External quality assessment process and accreditations standards (including haemovigilance) will be established for the blood banks and laboratories.

OBJECTIVE 3

To implement patient safety in its all modalities that is prevention, diagnosis, treatment and follows up across all levels of care and programs.

Core Priority:

- To ensure safety in high risk clinical services
- To avoid unintended harm due to medical devices
- To implement core components of infection prevention

Advance Priority

- System and procedures for ensuring safety during all stages of patient care

Core Priority 3.2: To avoid unintended harm due to medical devices

1. Safety standards for medical devices will be defined or adapted for procurement of medical devices.

2. Training needs will be assessed for optimal use of existing equipment as well as training will be provided to relevant staff on installation of new equipment.
3. SOPs will be developed and disseminated for utility; breakdown; monitoring of medical devices, restricting reuse of single-use devices etc. Clear policies on calibration of electronically operated medical equipment, and condemnation will be developed and implemented.
4. Regulatory framework for Radiation Safety in the Hospitals as per recommendation of International Atomic Energy Agency (IAEA) will be developed including provisioning for monitoring of staff for cumulative exposure to ionising radiations.

Core Priority 3.3: To implement core components of infection prevention

1. National Guidelines for Infection Prevention and Control in Health Facilities will be revised and disseminated. The guidelines would provide latest work-instructions and norms for the infection prevention practices and standard precautions to be followed in the hospitals and health centres. It can include relevant information about HAI surveillance mechanism, its implementation, rational use of antibiotics, etc.
2. Institutions, which have successfully implemented the infection prevention programs, will be identified and their best practices will be disseminated for evidence-based learning and scaling-up.
3. A National level strategic plan for infection prevention will be prepared and it will be linked with other related programs such as Antimicrobial Resistance Program, safety, quality, WASH, etc.
4. Functioning of infection control committees at facility level will be strengthened, and SOPs and indicators will be developed for implementation of IPC program
5. Surveillance system for Healthcare Associated Infections will be established and HAI data will be collected and analysed by the units responsible for patient safety reporting.
6. Regular audit, feedback and reporting of infection prevention practices will be implemented at all health facilities in the country.

Regulatory framework for Radiation Safety in the Hospitals as per recommendation of International Atomic Energy Agency (IAEA) will be developed including provisioning for monitoring of staff for cumulative exposure to ionizing radiations.

7. Hand Hygiene program will be further reinforced in continued medical and nursing educations program and in-service training at health care facilities.
8. Hand Hygiene day or week will be celebrated to raise awareness about the hand hygiene.
9. Infection control activities will be integrated in various national health programs.
10. Laboratory capacity and network will be strengthened for AMR activities. This will also include periodical analysis of prescribing patterns and AMR prevalence in the country.
11. Standards and practice guidelines for safe injection practices will be defined and disseminated. It will include vaccination of healthcare providers, mandatory post exposure prophylaxis in needle stick injuries, etc.
12. Guidelines and SOPs for sharp management will be included as an integral part in Bio medical waste management guidelines.

Advance Priority 3.4: System and procedures for ensuring safety during all stages of patient care

1. Guidelines, SOPs and checklists will be developed and disseminated for error prone processes in all areas of health care facilities viz. clinical handover and inter departmental transfers, follow-up, discharge, referral, shifting of patients in step-down wards, intensive care units, etc. to ensure unambiguous communication among the care providers. It will help to promote patient safety initiative at different levels of care.
2. A comprehensive communication strategy, which promotes patient safety within the health facility, will be developed involving all stakeholders. The communication strategy will be targeting both patient, carer, community as well as care providers.
3. Risk Assessment tools, grading as per severity, protocols for prophylaxis and management guidelines will be made available to healthcare providers to identify and mitigate the risks

OBJECTIVE 4

To reduce patient harm generated by unsafe medication practices and medication errors

WHO has initiated Medication safety as the third Global Patient Safety Challenge. The challenge is focused on improving medication safety by strengthening the systems for reducing medication errors and avoidable medication-related harm. In Maldives, all medicines are imported, Maldives Food and Drug Authority has been designated as a nodal agency responsible for quality and safety of drugs, consumables and food products. State Trading Organisation (STO) is the nodal agency for the public procurement in the country. The STO supplies the controlled drugs, the hospital drugs and drugs for national disease control programs to the government Central Medical Store (CMS) which then distributes them to all the public hospitals in Maldives. Health Department does not own and administer Hospital Pharmacies, which are either owned by the State Trading Organisation or by Private bodies. Therefore, this objective is focused on having pharmacovigilance systems, ensuring safety of drugs during transportation, storage etc., adoption of safe medication practices and reduce inappropriate polypharmacy.

Advance Priority 4.1: To establish mechanism for ensuring safety of medicines through regulatory, control and pharmacovigilance systems

1. A system will be established to issue instructions to manufacturers to improve the naming, labelling, packaging, formulation and presentation of medicines, which contribute in improving the medication safety.
2. Risk management measures to reduce errors such as identification and communication, look alike and sound alike drugs, storing look alike medicines, ensuring availability in paediatric formulations, etc. will be employed. Existing guidelines for naming, labelling, storing, preparation and administration of drugs at facility level will be strengthened.

3. Advisory/alerts on lookalike and sound alike medicines to healthcare providers will be issued.
4. The Monitoring and Surveillance Unit in Medicine and Therapeutics Division of the MFDA is in charge of pharmacovigilance and it covers ADR monitoring, unexpected lack of efficacy, quality defects and medication errors but there is negligible reporting under the existing system. Surveillance program for Adverse drug reaction will be strengthened and implemented across all public and private health care facilities in coordination with health departments, State Trading Organisation (STO), private bodies owning pharmacies, professional associations and drug manufacturers.
5. ADR reporting will be improved by continuous sensitization campaign, targeting the doctors, nurses, community health workers, pharmacists, etc.

OBJECTIVE 4

To reduce patient harm generated by unsafe medication practices and errors.

Core Priority:

- To avoid unintended harm due to medical devices

Advance Priority

- To establish mechanism for ensuring safety of medicines through regulatory, control and pharmacovigilance systems

Core Priority 4.2: To ensure safety of medicines during Storage and Logistics

1. Guidelines and Standards for optimal storage of medicines will be defined. It would essentially include guidance for storage and inventory management medicines at the health facility level including storages and management of medicines that require specialised handling such as cold chain, lock & key facility, etc.
2. All stores' personnel will be trained and supervised for ensuring use of drug management information system, correct data entry and monitoring of stock levels. A system for annual quantification based on past consumption data taking into account stock-out days and balance will be developed. MoH will undertake steps for developing close linkages with the organisations responsible for drug procurement, quality monitoring and distribution.

Core Priority 4.3: To make medication use process safer through focused interventions

1. National list of high alert /high risk drugs will be identified and disseminated.
2. National guidelines for medication use processes including prescription, preparation, dispensing, administration and monitoring will be developed and circulated.
3. System for prescription audits will be established and its implementation will be ensured at all level of healthcare facilities including private sector.
4. A National workshop on medication safety will be conducted to sensitise healthcare workers.
5. International best practices/ tools such as medication pass port, medication list and 5 Movements of medication safety will be introduced in phases for encouraging patients' participation in the medication safety.

Advance Priority 4.4: To reduce inappropriate Polypharmacy

1. National guidelines for management of patients on polypharmacy especially risk assessment of elderly patients will be developed.
2. A process of mandatory medication review and optimization for patients on polypharmacy will be established. It would include Identifying needs of patients, identifying essential and non-essential medicines in current therapy and Identify ADR risk and cost implication etc.

OBJECTIVE 5

To engage the patient and patient groups for improving patient safety and quality

Patient engagement in healthcare delivery system means involving patients, families, communities and patient partners in clinical care and decision making. It includes involving them proactively in managing their health and also contribute in designing, delivering and evaluating the health services. The healthcare industry and their stakeholders agree that engaging patients, families and patient partners are not only important for ensuring safe and quality care, but it is a way to show respect, value their insights and experience. Their participation in the care empower them. It can be done by involving patient /patient partner in sharing their care experience or demonstrating impact of patient partnerships, etc. in ensuring the patient safety

and quality. The objective is focused on aligning and entrenching patient engagement in structures, policies, and processes that help to achieve patient safety & delivery of high-quality care.

OBJECTIVE 5

To engage the patient and patient groups to improve patient safety and quality.

Core Priority:

- To make medication use process safer through focused interventions

Advance Priority

- To reduce inappropriate Polypharmacy

Core Priority 5.1: Ensure healthcare delivery processes are patient centred

1. A comprehensive program to measure the patient experience during the care delivery process will be established. It can be in form of hospital specific patient satisfaction surveys and patient reported experiences.
2. For having a meaningful concurrent feedback system, an IT based tools for Patients' Satisfaction Survey and patient reported experience will be developed. Methodology for collection of patients' feedbacks, analysis, discussion, and subsequently use it for improvement in safety and quality will be defined and implemented.
3. Guidelines of privacy, confidentiality and dignity of patients will be strengthened and updated with inputs from patients and communities.
4. Capacity building to raise awareness of service providers on respectful care, visual and speech privacy, maintaining confidentiality of patient information and records, special considerations for patients with social stigma and empathic behaviours will be undertaken for knowledge and skills.
5. Adequate resources will be allocated to make healthcare facility access friendly. Measures will be taken for improving the physical access. It can include ramps, lifts and escalator, Wheelchairs and stretchers, Disabled friendly facilities such toilets and tactile guidance sign language for the hearing impaired, etc.
6. Definitions of high risk and vulnerable patients along with guidance for care will be agreed upon, documented and disseminated.

Core Priority 5.2: Promotion of information and education about Patient care and safety

1. Citizen charter will be strengthened, and patient safety will be included as integral part of the patient rights in the country. It would broadly include right to be treated without any actual or potential harm, right to know safety and quality performance, right to refuse and ask for a second opinion, etc. Citizen's charter will be disseminated through health system channels as well as through public display, mass media channels, etc.
2. Standardised guidance on identifying hazardous activities and risk areas in health care settings will be developed and implemented uniformly across all types of healthcare facilities. These can be in form of signs and precautions such as slippery or wet floor,

infectious waste, radiation hazard, fire safety, electrical safety, access to restricted areas, etc.

3. A comprehensive Information, Education and Communication (IEC) plan to raise awareness of masses on patient safety issues will be developed. Information will be disseminated through multiple channels viz. mass media, celebrating patient safety day/week, public displays and through development of dedicated patient safety portal/ Application.
4. Rating/ ranking of healthcare facilities based on safety and quality performance will be undertaken at regular interval. It will be linked with compliance to patient safety standards, quality accreditation status and patient safety key performance indicators
5. Patient safety portal/patient safety app. will have multiple interfaces such as safety information regarding specific procedures, advisory to healthcare professionals on specific high-risk practices, new treatment modalities, regular on line capacity building about safety information and their implementation.

Advance Priority 5.3: Involving patients in their care and shared decision making

1. The situations and procedures, where taking informed consent is mandatory by MOH, will be reviewed and updated. Guidelines for taking various types of consent including high risk consent will be strengthened. It will include specific consent formats and instructions to fill the formats. Consent form would explicitly mention about the procedures and specific risks and adverse event that may occur during the procedure or treatment.
2. A web based / mobile based system for registering the patient safety events with properties of ensuring anonymous reporting, easy to use and access will be established. It can be part of overall incident reporting system or can be standalone reporting system for the patients and public.
3. Practice of involving patient and families in their care and decision making will be promoted through various strategies. This can be through involving campaigns, instituting practices

Rating/ ranking of healthcare facilities based on safety and quality performance will be undertaken at regular interval. It will be linked with compliance to patient safety standards, quality accreditation status and patient safety key performance indicators

like birth companion, involving family members in counselling, informed decision making, second opinion as patient right, etc.

4. Patient and family engagement tools will be developed and disseminated. It could be developed de-nova or can be adopted from global best practices/ evidence-based tool released by as WHO such as 5 moments of patient safety, communication tool for safe surgery, tips for patient before appointments, self-care after discharge, 5 moments of medication safety, etc.
5. Guidelines for self-managed care like as palliative care, care of elderly people with special needs, long term self-management of chronic diseases and rehabilitation will be developed. This would also include roles and responsibilities of health care providers, involvement of community, referral systems, quality and safety of services and support mechanisms, etc.

Advance Priority 5.4: Partner with patient & patient groups in improving safety & quality

1. Formal process to recognise/ recruit the patient groups working in general or for specific disease conditions will be established. This would also include explicit criteria for recognising and recruiting such groups. A registry of patient groups listed and recognized with Govt. will be developed.
2. A process to identify and recruit the local patient partners at facility level will be evolved. It can be individuals who has experienced the facility-based care (as a patient, family member or caregiver) and who can be helpful in improving the patient engagement and safety in the hospital. The qualification criteria, and role and responsibilities of patient partners would be defined.
3. Mechanism will be in place to ensure patient partners or groups are used to spreading health literacy, educating community about safer care, educate patients and family about their rights and responsibilities in hospital and also brief them about do's and don'ts for ensuring the safer care.
4. Ensure Patient support groups will be available for peer support, counselling services and assistance in case of a patient safety incident at facility. It also includes that information on various patient safety groups and the assistance offered by them to the patients with specific disease conditions can be displayed at relevant places. Attempt will be made to ensure that patient groups are true representative of patient interest, not for mere 'tokenism'

Advance Priority 5.5: Establish mechanism for Communication, Appraisal and Grievance Redressal for patient safety issues

1. A dedicated unit will be established to take-up complaints regarding improper care including ethical and safety issues. Adequate resources in terms staffing and financial resources will be made available for proper functioning of unit. It will be either part of National patient safety committee or may have close working relationship with the committee. The unit will be mandated to accept grievances from all health facilities including private hospitals.
2. A dedicated grievance redressal officer or a suitable staff for receiving and processing the grievances related to services will be designated. The designated officer would be expected to have adequate time, office resources and skills to do justice with the expected task.
3. Channels for grievance registration will be established. It could be through web portal, toll free phone, emails, physical letters, etc.
4. Process for registering, processing, codifying, escalating and taking action on the reported complaints will established and defined by the grievance redressal unit. This includes informing and coordinating with other agencies such health administrators, accreditation and licencing agencies, concerned hospitals, patient groups and law enforcement agencies, professional councils, etc. based on merits and scope of case. Such agencies will keep track of progress made on complaints and will inform patient / aggrieved family about the actions taken.
5. Positive resolution of all valid complaints will be ensured. Corrective action will include compensation to aggrieved person(s). A system for systematic analysis of the complaints will be operationalised. This would also include making recommendations for improvement in service delivery and safety.
6. An operational framework, laying down the procedures will be developed for enabling healthcare providers to disclose unexpected events and possible harms to patients/ families in transparent and empathetic manner. Capacity of care providers for effective communication and positive resolution of such cases will be built.

OBJECTIVE 6

To establish Patient safety event reporting system and promote patient safety research

Any process, act of omission or commission that results into unintended harm or hazards to patient is known as patient safety event. To improve patient safety, it is imperative to report patient safety events as it helps to improve the safety as well as learning from the errors. The objective is focused on establishing adverse reporting system with features of anonymous reporting, meaningful feedback, ease of reporting, etc. Collecting adverse events and 'near-misses' in healthcare, their reporting enables the system to analyse events, identify possible underlying factors, and generate knowledge for mitigating the risk. It also focuses on building learning and reporting system which is resilient and promotes culture and practices that will reduce harm to patients.

Advance Priority 6.1: To establish system for adverse events reporting

1. Developing system for reporting of errors, near-misses and adverse events from facilities to national level through a dedicated web based adverse event reporting system. Such system will ensure data entry from all

OBJECTIVE 6

To establish Patient safety event reporting system and promote patient safety research.

Core Priority:

- Ensure healthcare delivery processes are patient centred
- Promotion of information and education about Patient care and safety
- To generate patient safety information and evidence through assessments, surveillance and research for policy makers

Advance Priority

- Involving patients in their care and shared decision making
- Partner with patient & patient groups in improving safety & quality
- Establish mechanism for Communication, Appraisal and Grievance Redressal for patient safety issues
- To establish system for adverse events reporting

- types of health care facilities both in public (peripheral health centres to IGMH) and private.
2. Reporting system will also host existing mandatory adverse events reporting under the National health programs viz. immunization, NACP etc. to establish a streamlined and comprehensive patient safety surveillance system.
 3. A consultative meeting will be organized to define key patient safety terms, taxonomy and categories of the events to be reported. Consultation will be followed by development of guidelines for inclusion criteria in terms of error, adverse event and near-misses and Standardised reporting format for capturing structured information. Also, alignment with WHO minimum information model (MIM) for learning and reporting system will be ensured.
 4. Adequate resources will be provided to operationalise reporting system, performance analysis and learning functions. A multi-disciplinary team of professionals will be constituted to assess and analyse the patient safety data.
 5. Annual reports on quality of care and patient safety will be released by the Ministry of Health based on the data available from patient safety surveillance system.

Core Priority 6.2: To generate patient safety information and evidence through assessments, surveillance and research for policy makers

1. As Limited information is available about the possible unsafe care in Maldives, it would be prudent to evaluate its burden. Scope of errors and adverse events will be defined based on internationally agreed benchmarks and best practices. A baseline assessment of public and private healthcare facilities will be conducted for estimating the extent of errors and adverse events and also to define scope. Such survey could be conducted by autonomous professional agencies having relevant experience in field patient safety and health quality.

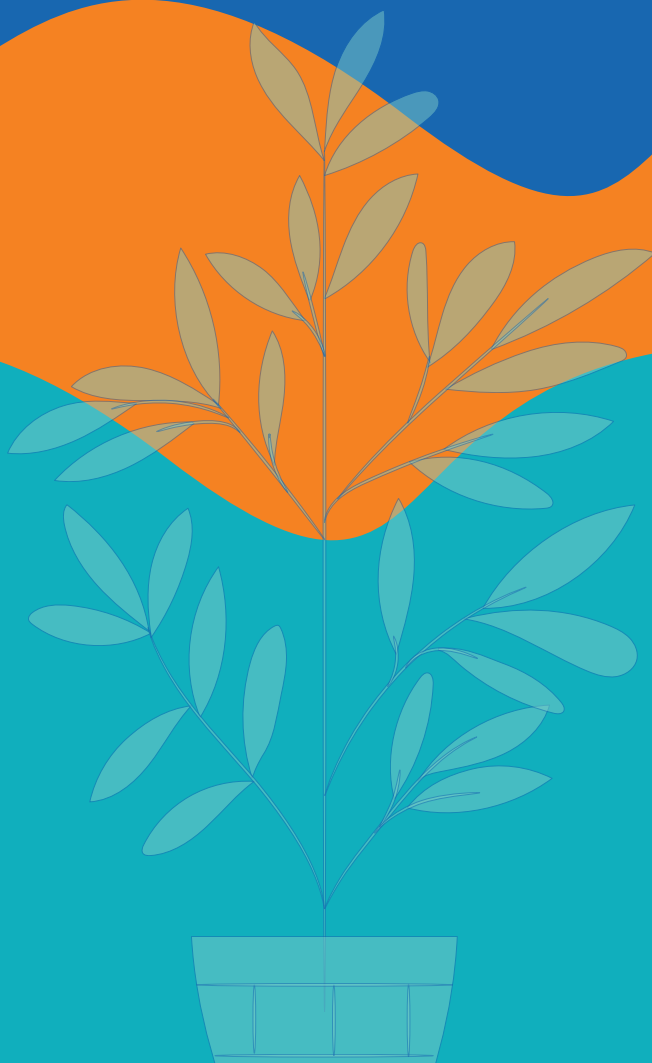
Reporting of priority Patient safety indicators through health management information system or equivalent platform will be strengthened. A dedicated dashboard for patients and key health quality indicators will be established to get regular estimates about the improvement.

2. Focused studies/ surveys for estimation of harm in focused areas such as HAI, medication safety, primary care, child birth, radiation safety, laboratory safety, blood safety, etc. will be commissioned.

3. Reporting of priority Patient safety indicators through health management information system or equivalent platform will be strengthened. A dedicated dashboard for patients and key health quality indicators will be established to get regular estimates about the improvement.
4. A repository of good quality research on patient safety and allied themes will be established.

SECTION C

ACTION PLAN FOR IMPLEMENTATION OF PATIENT SAFETY FRAMEWORK



STRATEGIC OBJECTIVE 1

To establish the institutional arrangements and strengthen the clinical Governance to place patient safety at core of National, subnational and facility level

	Priority Area	Interventions	Desired Output /Expected Result	Time Frame*
1.1	Establish the structural system to support patient safety and Quality in healthcare.	Constitute the National Level Patient Safety committee at MoH (or any other institution) for coordination of patient safety mechanism	National Patient Safety Committee is established at Central Level & made functional	S
		To start with constitution of an interim committee for Patient safety at IGMH with technical advisory subgroups (later subsume with Maldives Quality Commission)	Interim National Patient safety committee & technical advisory subgroups are established at IGMH	S
		Designate a patient safety focal point at Atoll and facility level	Focal points for patient safety are designated at Atolls	S
		Incorporate patient safety principles and concepts in National Disease Control Program	Patient safety is addressed in all National Health Programmes	M
		Streamline the patient safety in different insurance schemes and link it with pay for performance	Insurance mechanism at National level consider payment for better performance, based on patient safety indicators	M

		Development of training Module for Principles and concepts Quality and Safety	Training module is developed and TOT is conducted for creating the awareness	S
1.2	Strengthen the regulatory framework for patient safety	Institute the Quality Commission at National level as mandated under Health Service Act	Maldives Health Quality Commission is established at National level & made functional	M
		Establish framework for reporting of notifiable disease, processing and disposal of hazardous and biomedical waste, radiation safety using international framework and best practices	Regulatory framework for notification of diseases, Bio medical & Hazardous waste management and radiation safety is developed	M
		Incorporate a special clause in existing legal documents for patient rights and safety related issues (Mechanism to address grievances & define the time and guarantee for actions in case of medical negligence.)	Special Clause on patient rights and safety issues are incorporated	M-L
		Enact a law/ incorporate special clause in existing legal documents to protect the health workforce and Patient safety related data or its reporting from any punitive action and litigation on disclosure/ reporting of information	Special law/ clause to protect health work force, Patient safety related data and its reporting from any punitive action and litigation is enacted	L

		Development of capacity building program for patient safety laws and regulations	Programme on enhancing awareness on patient safety laws and regulations is developed	L
1.3	Improve the reliability of clinical Governance system and its operations	Establish National institutional framework and methodology for collating, adopting/adapting, reviewing and commissioning of evidence based STGs	Methodology Guidebook on STG is developed	S
		Develop clinical guidelines implementation tools such as care pathways, patient safety and quality standards	Implementation tools and digital aids for STGs are developed.	S
		Develop Compendium of clinical audit/review (including medical, prescription, death audit, nursing audits, quality and safety audits etc.) for internal Quality improvement.	Clinical audit guidelines for internal quality Improvement is developed	S
1.4	Establish mechanisms for independent assessment and accreditation of health care facilities	Development of Quality of care Standards and assessment tools for public healthcare facilities', private institutions, clinics, speciality hospitals, blood banks, laboratories etc.	Quality of care standards are developed & notified	S-M
		Incorporate fire safety, seismic safety, device safety, structural safety of health facilities into the Quality of Care standards	Critical component of Patient safety is incorporated in the Quality of care standards for healthcare facilities	S

		Establish special mechanism for independent assessments and Quality & safety accreditations based on adherence to Quality of care standards	Independent assessments and Quality accreditations mechanism is established under the Quality commission and has been made functional	S
		Streamline accreditation program for availing incentives in reimbursement benefits the insurance provider	Provision of incentive for accredited facilities	S
		Define and develop Patient safety and Quality KPIs for different level of facilities through consultative process	A set of Key performance indicators and Dashboard measuring Quality and safety are developed	S-M
		Establish a system of internal & peer assessments for improvement in healthcare safety using Quality of care standards	Hospital performance/ ranking system is introduced and it incorporates the patient safety indicators	S

S= Short term

M= Medium term

L= Long term

STRATEGIC OBJECTIVE 2

To ensure competent and capable work force sensitive to patient safety needs

	Priority Area	Interventions	Desired Output /Expected Result	Time Frame*
2.1	Strengthen the human resources for Patient safety	Strengthen the Human resource norms for different grades as per service package	Existing document related to HR norms - 'Criteria for Grading of Health Facilities' is updated and linked with the service package	S
		Develop Code of practice for professionals for various cadre	Code of practice for professionals viz. clinical, nursing and para-clinical, etc. is developed and promoted	S
		Introduce patient safety in Job Specifications and it is used as a parameter to evaluate the performance	Patient safety is incorporated in Job specifications of all categories of health care professionals	S-M
		Establish a system for competency assessment and credentialing of all health professionals	A formal procedure to test skill and knowledge of health professionals is introduced.	M

		Incorporate patient safety as evaluation criteria for licencing and re-licensing assessments of healthcare professionals	Patient safety is introduced in licencing and re-licensing assessments of professionals	M
		Design a need based capacity building program for professionals	Capacity building program is introduced for newly inducted eligible professionals	M
		Develop explicit norms for infrastructure, equipment, Safety, HR their qualification, experience, no. of professional staff, etc. for private sector	Licencing norms for private health facilities are strengthened	L
2.2	Integrate patient safety in professional education (medical & nursing school) and In-service training	Define Competency and skill mix for patient safety for all health care cadres & ensure skill imparted	Core skills for patient safety practices are defined and imparted	M-L
		Develop a Guidebook on practical issues of Patient safety and its management, targeting different healthcare providers	Practice Guidebook on patient safety for health professionals is developed & disseminated	S
		Identify institutions or agencies to conduct patient safety TOT's at the National and regional levels	Regular training program is conducted for both public and private health care providers	S
		Introduce patient safety in the educational curriculum (as separate module) of health care professionals viz. nursing, para medical, etc.	Advance Capacity building of forthcoming healthcare professionals	M

		Introduce mandatory credit hours for patient safety with re-licencing norms of all category of health workers	Credits hours on patient safety is introduced as re-licencing norm	M
2.3	Ensure staff safety and promote safer work culture	Strengthen the arrangements and resources for safe and secure work environment	Adequate resources and measures are made available at healthcare facilities	S-M-L
		Develop policies and SOPs for ensuring safe and secure work environment	Standardise Polices and SOPs are available with healthcare facilities	S
		Develop a system for ensuring health worker safety	System of health worker safety is established and incorporated in the Quality of care standards	S
		Establish a mechanism for development and introduction of improvement tools for patient safety	Patient safety improved tools viz. simulation exercises, use of PDSA, mistake proofing etc. are introduced and implemented	S-M
		Promote positive team work culture healthcare facilities	Multidisciplinary patient centred teams in patient care units/or existing committee such as Quality improvement team, Infection prevention and control committees etc. are institutionalized for patient safety activities as well	S
		Introduce Mechanism for feedback on satisfaction and grievance redressal of healthcare staff	Employee satisfaction and grievance redressal mechanism are introduced	S

		Introduce indemnity cover or 'no-fault' compensation scheme for patient safety legal or financial liability of health professionals	Indemnity cover is introduced for the health professionals of the country	L
2.4	Promote safety through health care support processes	Promote Electronic health records system with provision of extraction for patient safety information	Electronic health records are introduced using standardized format and options for detecting patient safety triggers	M
		Strengthen the Bio medical waste management practices	Existing Waste Management guidelines are updated	S
		Availability of adequate facilities for waste management including SOPs monitoring of waste management	Resourcing including SOPs, monitoring checklists etc. are available and revised, and waste management takes place as per revised SOPs	S
		Establish a comprehensive program for maintenance and calibration of equipment	Comprehensive Program for equipment is developed and operationalised	S
		Develop SOP for routine cleaning, trouble shooting, monitoring of down time, etc.	Standardise SOPs are available with healthcare facilities.	S
		Strengthen the existing processes with introduction of mandatory training of end-users for safely operating the equipment at the time of commissioning	Mandatory training of end-users for safely operating the equipment is introduced in existing curriculum	S-M

		Develop facility management guidelines viz. civil maintenance, housekeeping, water supply, medical gas supply, etc.	Facility management guidelines are developed and available with facility	S
2.5	Implement physical safety and environment control measures	Define, collate and implement Structural safety requirements for healthcare facility	Structural safety requirements for healthcare safety is defined	M
		Introduce norms for Illumination levels, air quality (including ventilation and air exchanges) and optimal temperature and humidity in facility's environment, etc. Such norms are taken into the account as time of Hospital planning and designing	Norms are introduced in Hospital planning and designing manual and followed	M
		Define fire and electrical safety measures for all type of health care facilities	Fire and electrical safety measures are defined and implemented	S

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S= Short term

M= Medium term

L= Long term

STRATEGIC OBJECTIVE 3

To implement patient safety in its all modalities that is prevention, diagnosis, treatment and follow up across all the programs

	Priority Area	Interventions	Desired Output /Expected Result	Time Frame*
3.1	To ensure safety in high risk clinical services	Uniformly adopt surgical safety checklist for both elective and emergency surgeries	Surgical Checklist is adopted uniformly across the Nation	S
		Uniformly adopt WHO 24X7 Emergency and essential surgical norms in all institution, providing surgical care	Essential and emergency norms are followed	S
		Establish Indicators for Surgical surveillance and carry-out regularly monitoring from National level	Surveillance System for Surgeries is in place and functional	M
		Develop guidelines for proactive measures for safer surgeries (including prevention on venous thromboembolism)	Proactive measures for safer surgeries guidelines developed, and preventive measures for venous thromboembolism are in place	M
		Adoption of safe practice of anaesthesia and use of safe anaesthesia checklist	Safe practices of Anaesthesia as per international standards are adopted	S

		Reinforce use of Safe birth checklist both in public & private sector	Safe birth checklist is followed by all MNH care providers	S-M
		Incorporate Adverse transfusion reactions in National blood policy Maldives	Adverse event reporting is strengthened in National blood policy and implemented	S
		Ensure implementation of surveillance of adverse events and transfusion reactions	All blood banks report adverse events	S
3.2	To avoid unintended harm due to medical devices	Define/ adapt safety standards for medical devices, its procurement, authorization of medical devices for use	Safety standards for medical devices are defined	M
		Develop SOP for utility; breakdown; monitoring of medical devices, restricting reuse of single-use devices, etc. Formulate a clear policy on calibration for electronically operated medical devices and condemnation of equipment	SOPs on calibration are made available with Healthcare facilities. Policy on condemnation of equipment in place	S
		Establish regulatory framework for Radiation Safety in the Hospitals as per recommendation of International Atomic Energy Agency (IAEA) including provisioning for monitoring of staff for cumulative exposure to ionising radiations.	Regulatory framework & mechanism for radiation safety in hospital & monitoring of staff for radiation exposure is in place	M

3.3	To implement core components of infection prevention	Review and update National Guidelines for Infection Prevention and Control in Health Facilities (include relevant information about HAI surveillance mechanism its implementation and rational use of antibiotics)	National Guidelines for Infection Prevention and Control have been revised	S
		Review the existing best practices in existing key hospitals, which have successful IP Program and scale up their experience	Existing IPC best practices are reviewed and scaled up	S
		Develop National level strategic plan for infection prevention Programme (Link with AMR, Safety, Quality etc.)	National IPC strategy plan is available	M
		Strengthen infection control committees at facility level & develop mechanism for implementation of IPC	Infection control committee at facility level are strengthened. SOP & indicators are developed & implemented	S-M
		Establish system for HAI surveillance & data is collected, analysed at National level by patient safety reporting unit	Surveillance System for HAI is in place and operational Patient safety reporting unit collect and analyse data regularly	M-L

		Implement mechanism for regular audit, feedback and reporting of infection prevention practices	Regular audits of IP practices are conducted by internal/ peer assessment	M
		Reinforce Hand Hygiene program in continual medical and nursing education programs and in-service trainings	Hand hygiene program scale up at all levels of care	S
		Celebrate Hand Hygiene day or week to raise awareness about the hand hygiene	Hand hygiene week/day is observed	S-M
		Integrate Infection Control activities in all national health programs	Component of IPC are integrated in all disease control programs and other priority interventions (wherever relevant)	S
		Strengthen the Laboratory capacity and network for AMR activities	Laboratories are identified and strengthened to ensure analysis available on prescribing patterns and AMR prevalence.	M
		Define the Standards and practice guidelines for safe injection practices(including vaccination for healthcare providers, mandatory PEP in needle stick injuries etc.)	Safe injection practices guidelines developed and implemented	S
		Integrate sharp management with waste management guideline	Sharpe management becomes integral part of waste management guidelines for healthcare facilities	S

3.4	System and procedures are to ensure safety during all stages of patient care	Streamline standardization of patient safety initiative at different levels of care through SOP, policies and checklists etc.	SOPs , algorithms checklists are developed and followed	S
		Develop comprehensive communication strategy for patient safety	Communication strategy is in place	M-L
		Define risk Assessment tools, grading as per severity, management guidelines to be used to identify & mitigate risks	Checklist for patient safety risk assessment at healthcare facility level is developed	M

STRATEGIC OBJECTIVE 4

To reduce patient harm generated by unsafe medication practices and medication errors

	Priority Area	Interventions	Desired Output /Expected Result	Time Frame*
4.1	To establish mechanism for ensuring safety of medicines through regulatory, control and pharmacovigilance systems	Establish a system for issuing necessary instructions to suppliers to improve the presentation of medicines which can attribute in medication errors.	Instructions are issued to suppliers to improve the naming, labelling, packaging, formulation and presentation of medicine	M
		Employs risk management measures to reduce errors because of naming, packaging, formulation	Existing guidelines for naming, labelling, storing, preparation and administration of drugs at facility level are strengthened	S
		Develop a system for issuing advisories/alerts on lookalike and sound alike medicines to healthcare providers	Advisories are issued and being followed, which are verified	S
		Encourage reporting the Adverse drug reactions by all stakeholders	Improve the ADR reporting	S-M

4.2	To ensure safety of medicines during Storage and Logistics	Define guidelines for storage, inventory management and management of medicine requiring specific handling	Drugs logistic management guidelines are developed and followed	M
		Establish drug management information system for all level of healthcare facilities (features of inventory management including essential medicine list and minimum stock level)	Drug management information system in place (in coordination with organisations, managing health facilities' pharmacies)	M
		Training & supervision of pharmacist/ drug store keeper for correct use of drug management information system	Training program is conducted for all pharmacist and store keepers	M
4.3	To make medication use process safer through focused interventions	Identify National list of high alert /high risk drugs	Such drugs are identified and listed, followed by dissemination of the list	S
		Develop National guidelines for medication use processes including prescription, preparation, dispensing, administration and monitoring	National guideline of medication use processes are developed and followed	S
		Establish process of prescription audit for all level of healthcare facilities including private sector	Prescription audits are done regularly in all healthcare facilities	S

		Conduct a National workshop on medication safety to sensitize the healthcare professionals	National workshop on medication safety is conducted	S
		Identify and follow International best practices/ tools for medication safety (for both patient and service providers)	Tools are identified, people are trained and start utilizing	S
4.4	To reduce inappropriate Polypharmacy	Develop guidelines for management of patients on polypharmacy especially for elderly patients	Guidelines on management of patient on polypharmacy will be developed	M
		Establish processes of mandatory medication review and optimization for patients on polypharmacy	Identification of patients on polypharmacy and optimization of their medication is done and a system for the review is established	M

STRATEGIC OBJECTIVE 5

To engage the patient and patient groups to improve patient safety and quality

	Priority Area	Interventions	Desired Output /Expected Result	Time Frame*
5.1	Ensure healthcare delivery processes are patient centred	Establish comprehensive program to measure the patient experience during the healthcare delivery process	Hospital specific Patient satisfaction surveys are conducted regularly	S
		Develop methodology and an IT based tool for Patients' Satisfaction Survey/ patient reported experience	IT based tool is used for reporting of patient experience Methodology for feedback collection, analysis and improvement is developed	S
		Strengthen Guidelines for privacy, confidentiality and dignity of patients with inputs from patients and communities.	Privacy, confidentiality and dignity guidelines are updated	S
		Impart Knowledge and skill for respectful care, Visual and speech privacy, maintaining confidentiality of patient information and records, etc.	Impart training to all healthcare professional	S
		Ensure incorporation of budget for ensuring patient friendly access in facility	Proposal can be incorporated in the annual financial planning	M

		Define of high risk and vulnerable patients along with guidance for care agreed upon	Guidance for high risk and vulnerable groups is available	M
5.2	Promotion of information and education about Patient care and safety	Incorporate patient rights and safety as part of the citizen's charter	Citizen charter is disseminated through health system channels as well as through public display etc.	M
		Develop standardised signage for identifying hazardous activities and risk areas in health care settings	Signage are developed and used uniformly across the health care facilities	S
		Develop a comprehensive Information, Education and Communication plan to raise awareness of masses on patient safety issues	Information disseminated through multiple channels viz. mass media, celebrating patient safety day/week, public displays and through dedicated patient safety portal/ application	S
		Establish mechanism for Rating/ ranking of healthcare facilities based on safety and quality performance	Rating /ranking of facilities is done at pre-defined intervals	M-L
		Legal provision to get access to patient care information i.e. care provided	Patient information is accessible to patient/their family within stipulated time frame	M
5.3	Involve patients in their care and shared decision making	Review and update guidelines for taking informed consent (specific consent formats , explicitly mention about	Updated guidelines are available and are followed	S

		procedures, specific risks and adverse events)		
		Establish a system for registering the patient safety event	A web based / mobile based system is established with features of ensuring anonymous reporting, easy to use and access, etc.	M
		Establish strategies for promotion of practice of involving patient and families in care and decision making	Involving campaigns, birth companion, family members in counselling, follow informed decision making and second opinion etc. is encouraged	S
		Develop Guidelines for self-managed care like as palliative care, care of elderly people with special needs, long term self-management of chronic disease, rehabilitation, etc.	Guidelines are developed and are followed	M
5.4	Partner with patient & patient groups in improving safety & quality	Establish a formal process to recognise/ recruit the patient groups working in general or for specific disease conditions	Explicit criteria for recognising and empanelling such groups are developed and periodically notified	L

		Evolve the process to identify and recruit the local patient partners at facility level	Process to recruit local patient partners is developed. The qualification criteria, role and responsibilities of patient partners are defined	L
		There is a mechanism in place for ensuring that patient partners/ groups are used to spread health literacy, educate community about safer care, etc.	Patient partners/ groups are used by hospital to educate patient, family and community	L
		Display the information about patient safety groups and the assistance offered by them	Information about patient safety groups and the assistance offered by them is available in public domain	L
5.5	Establish mechanism for Communication, Appraisal and Grievance Redressal for patient safety issues	Establish a dedicated unit to take-up complaints regarding improper care including ethical and safety issues	A dedicated unit is established under direct supervision of National Patient safety committee A dedicated grievance redressal officer is designated for management of grievances	M
		Establish Channels for grievance registration	Multiple Grievance registration channels are in place	M

		Establish process for registering, processing, codifying, escalating and taking action on the reported complaints	Processes of Grievance redressal unit are defined & followed	M
		Mechanism for corrective action & positive resolution of valid complaints is in place	There is functional system to analyse the complaints, and make recommendations for enhancement of safe delivery Compensation to aggrieved person is ensured	L
		Develop a transparent mechanism to enable healthcare providers to disclose the case-details to patient/ family in case of unexpected harm	A uniform policy is in place to disclose patient/family in case of any unexpected harm Capacity of healthcare professional built up for effective communication	L

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S= Short term

M= Medium term

L= Long term

STRATEGIC OBJECTIVE 6

To establish Patient safety event reporting system and promote patient safety research

	Priority Area	Interventions	Desired Output /Expected Result	Time Frame*
6.1	To establish system for adverse events reporting	Develop a patient safety incident surveillance system at National & facility level	Web based patient safety incident surveillance system is established	L
		Streamline reporting on patient safety related events within existing program	Periodic reports on patient safety initiative are available	L
		Organize a consultative meeting to define key patient safety terms, taxonomy and categories of events to be reported	Guidelines for inclusion criteria of error, adverse event and near misses along with Standardised reporting format to capture the information are developed	S-M
		Operationalise reporting system along with performance analysis and learning functions	Patient Safety incident reporting & learning system is operationalized	L
		Release annual reports on quality of care and patient safety	Annual reports are released and actioned	L

6.2	To generate patient safety information and evidence through assessments, surveillance and research for policy makers	Conduct a baseline assessment of overall burden of unsafe care in country including public , private sector	Baseline of overall burden of unsafe care is assessed	M
		Commission focused studies/ surveys to estimate unsafe care in HAI, medication safety, primary care, radiation safety, etc.	Focused studies/survey is conducted to assess the burden	L
		Strengthen the reporting of patient safety indicators through Health information system	Identify key patient safety indicators Ensure reporting and collation of such indicators at central level (Patient safety surveillance system) Development of Dashboard to get regular estimations	M
		Establish a repository of research on patient safety and allied themes	Repository of good Quality research on patient safety is established	L

Patient Safety Assessment Tool

PS 1

Safety of high risk clinical services has been ensured

Ref No.	Requirement	Description	Assessment Guidance
PS1.1	Safe surgery is promoted at system level and practiced during surgical care processes	<p>Healthcare facility has implemented following measures to make surgeries safer-</p> <ul style="list-style-type: none"> • Implementing WHO safe surgery checklist for all surgical procedures • Following the universal protocol for verification, marking and time out to ensure correct patient at the correct site. • Risk assessment for large-volume blood loss before anaesthesia and skin incision and conforming the availability of blood products • Assessing the drug allergies and ensuring safe delivery of medication • Administering prophylactic antibiotics within 1 hour of incision 	<ul style="list-style-type: none"> • Interact with team at operation theatre to understand their practices on use of safe surgery checklist, identification of patients and site, blood loss assessment, prophylactic antibiotics, performing counts and maintain asepsis. • Review the records to understand adequacy if surgical note, and safe practices have been recorded adequately

		<ul style="list-style-type: none"> • Using indicators to ensure sterility of the surgical instruments • Practicing surgical scrub and skin preparation with antiseptic • Performing full count of sponges, needles, sharps, instrument at least beginning and end of each case • Establish practice of effective communication and record keeping with adequate operation note • Collect and analyse the data of surgical safety 	
PS1.2	Safety measures have been implemented in anaesthesia care process	<p>Healthcare facility ensures safety of anaesthesia procedures. This includes -</p> <ul style="list-style-type: none"> • Ensure the continuous presence of a vigilant, professionally trained anaesthesia provider • Continuous Monitoring of vitals using a pulse oximeter • Continuous monitoring of adequacy of the airways and of ventilation Performing an objective evaluation of airway before induction of anaesthesia • Use of anaesthesia safety checklist 	<ul style="list-style-type: none"> • Interact with the staff available for understanding the safety practises in operation theatre. • review anaesthesia records for assessment and monitoring details

		<ul style="list-style-type: none"> • Conducting pre-anaesthesia assessment for elective surgery 	
PS1.3	Policy, technical guidelines and haemovigilance system is in place to ensure blood transfusion safety .	<p>Healthcare Facility ensures the blood transfusion safety through-</p> <ul style="list-style-type: none"> • Adhering to donor selection criteria • Performs all mandatory tests for transmissible infections as per national norms. • necessary licences for operation • Collecting all or majority of blood through voluntary donations. • Establishing quality management system for documenting standards operating procedures, participating in external quality assurance program haemovigilance • Reporting adverse events to national haemovigilance system • Constituting a blood transfusion committee and designating as transfusion safety officer • Accreditation of blood bank lab 	<ul style="list-style-type: none"> • Check with concerned staff regarding awareness and practice of donor selection criteria, testing, clinical use of blood and standards for transfusion services. • Review the records regarding collection and reporting of adverse events, standard operating procedures, licences, accreditation and external quality assessment. • Check weathers all / majority of blood is collected through voluntary donation.
PS1.4	Initiatives have been taken to	<p>Healthcare facility implements measures to ensure safety in birthing processes. This includes –</p> <ul style="list-style-type: none"> • Implementation of safe child birth checklist 	<ul style="list-style-type: none"> • Interact with hospital leadership and staff engaged in maternal and child health care

	<p>make child birth process safer.</p>	<ul style="list-style-type: none"> • Use of Partograph for all normal deliveries. • Rational use augmentation and surgical interventions (C- Section) • Encouraging birth companions • Implementation of Infection prevention and control protocols • Discontinuing of not recommended processes such as shaving of cervical area, excessive episiotomy and fundal pressure • Recording and reporting adverse events and near miss in labour rooms 	<p>regarding use of safe birth checklist, partograph</p> <ul style="list-style-type: none"> • Check doctors and birth attendants are aware of safe practices, standards, clinical and infection protocols. • Check if birth companion is allowed during delivery process.
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PS1.5	<p>Safety Standards and practise are in place to limit the harm due to medical use of ionic radiations.</p>	<p>Healthcare facility has taken adequate measures to ensure safety of patient as well as staff working in radiation units. This includes</p> <ul style="list-style-type: none"> • Confirming to the national standards, structural requirements and staffing norms • Obtaining necessary licence for operating the unit • Providing personal protection and radiation exposure measuring devices (dosimeters) • On job training of relevant staff on radiation safety • Appointing or designating one of the trained staff as radiation safety officer • Establishing as radiation safety manual / SOP and defining the role and responsibly radiologist, radiographer and medical physicist as applicable • Established quality assurance mechanism through periodic internal radiation safety audits, equipment maintenance and calibration and participating in external clinical audit programs • Ensuing justification and optimization principles while recommending for radiation exposure for diagnosis or therapeutic purpose. 	<ul style="list-style-type: none"> • Interact with hospital administration and in charge of radiology/ radiotherapy/ Nuclear medicine unit for status on meeting licencing norms. • Interact with clinical staff for their awareness on justification and optimization principles and how they are implementing them in practice • Check if there are defined and implemented criteria for radiation exposure to pregnant women and children is practiced. • Check if caution signage such as radiation hazard and advisory for pregnant women are displayed • Personal protection and radiation surveillance devices has been provided to all staff working in radiology unit • Review records for clinical audits and quality assurance mechanism. • Check if a radiation safety officers has been designated and if any training on radiation safety has been provided
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		<ul style="list-style-type: none">• Following criteria and Ensuing minimum exposure to vulnerable patients such as pregnant women and paediatric patients• Recording and reporting any patient or occupational adverse event such as over exposure and wrong site/ patient• Restrict the entry of imaging area and displaying hazard signage in the vicinity	
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PS 2

Systems are in place to avoid unintended harm due to medication and medical devices

PS2.1	There is an established mechanism for ensuring safety of medicines through regulatory, control and pharmacovigilance systems	<p>Healthcare facility employs risk management measures to reduce errors because of naming packaging, formulation.</p> <ul style="list-style-type: none">• This includes• Identifying look alike and sound alike drugs and communicating to the relevant departments• Storing look alike medicines separately, with visibly distinguishable labels• Practicing "Procurement for safety, to minimise the look alike and sound alike drugs• Preferring ready to administer medicines at point of use wherever possible• Ensuring medicines intended to be given to children are available in paediatric formulations• Communicating additional technical information on medicine products where it's not provided by	<ul style="list-style-type: none">• Interact with responsible staff to understand their strategy to minimise and distinguish look alike and sound alike drugs.• Check at medicine dispensing counters as well as nursing station that look alike drugs have been separately stored and labelled• Check medicines are available at point of use in ready to administer formulations• Check medicines in paediatric dosage in departments treating children• Check if there is hospital wide written policy / SOPs for managing look alike and sound alike drugs
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PS2.2	Standard practices are in place to ensure safety of medicines during Storage and Logistics	<p>Healthcare facility takes adequate measures for safe storage of medicines in the facility. This includes-</p> <ul style="list-style-type: none"> • Ensuring medicines are stored in their original packing at point of use • Defined the minimum order level and alerts for shortage of drugs • Preparing a hospital formulary • Implemented a scientific inventory managements system • Ensuring medicines are stored at recommended temperature • Controlling storage and distribution of high risk medicines and narcotic substance • Ensuring safe disposal of discarded medicines as per national protocols 	<p>Observe if</p> <ul style="list-style-type: none"> • medicines at patient care areas / nursing stations are not repacked / pooled • There are no expired medicines and near expiry drugs have been marked • A standard operating procedure for storage and inventory management is available • Narcotics and controlled drugs are kept at lock and key • Interact staff to understand the inventory management practices and recorder level • Revie records of temperature monitoring if any
PS2.3	There are focused interventions to make medication use process safer	<ul style="list-style-type: none"> • Healthcare facility ensures implementation of safe medication use processes. This includes • Communicating list of error prone abbreviation and methods of expressing dosages in prescription 	<ul style="list-style-type: none"> • Review the relevant guidance document on medication use process such as SOP, list of high risk and high alert drugs, dosing guidelines paediatric patients, patient

		<ul style="list-style-type: none"> • Guidance on calculating correct dosages specially for paediatric patients • IT enabled tools such as CPOE (Computerized Physician Order Entry) has been implemented • Identified high risk/ high alerts drugs available in the facility communicated to all the department • The calculation of dilution and administration of high alert medicines are verified by second person • Patient is identified with help of at least two identifiers before administration of medication • Practice for obtaining allergy information before administration • Discouraging verbal and telephone orders wherever possible and ensuring their accuracy if these are unavoidable. • Implementing Standard operating procedures for medication use process 	<p>identification policy and instructions for verbal orders.</p> <ul style="list-style-type: none"> • Interact with patient care staff is aware of safety aspects in medication use including how to administer high alert drugs. • Check if IT tools such as CPOE are available and used
PS2.4	System are in place to reducing inappropriate Polypharmacy	Healthcare facility systematically identifies the patients on pharmacy and optimise their medication through periodic medication review proceeds Mediation review process includes –	<ul style="list-style-type: none"> • Interact with clinical staff if there how they identify inappropriate polypharmacy and what is the medication review and optimization process

		<ul style="list-style-type: none"> • Identifying need of patient • Identifying essential and non-essential medicines in current therapy • Identify ADR risk and cost implication • Patient willingness to take medicines 	<ul style="list-style-type: none"> • Review sample patient records where medication review has been preformed
DS2.5	<p>Medical Device Safety program is in place at system and healthcare facility level</p>	<p>Healthcare facility ensures safety of medical devices. this involves</p> <ul style="list-style-type: none"> • Using only authorized devices that meets the prescribed safety standards • Ensuring periodic maintenance and calibration of equipment • Providing training of relevant staff on using if equipment • Ensuing operating manual and safety instructions of equipment is always available at point of use. • Participant in the medical devices safety surveillance program 	<ul style="list-style-type: none"> • Interact with hospital administration or relevant department staff to about adhering to authorization and safety requirements of medical devices before procurement • Review records for pertaining specification, maintenance and calibration and operating manual • Check safety instructions are displayed at point of use

PS 3

Core Components for Infection Prevention and Control has been implemented

PS3.1	There is an established infection prevention and control program at health system and facility level	Healthcare facility has implemented an infection prevention and control program. This includes <ul style="list-style-type: none">• A functional infection control committee• Defined infection control objectives• Regular training of staff on IPC• Surveillance of Hospital Acquired Infections• Regular monitoring/ audit of infection control practices such as hand hygiene assessment• Ensure optimal bed occupancy and bed to bed distance• Ensures adequate supply for material and equipment for infection control	<ul style="list-style-type: none">• Interact with hospital leadership and designated IPC officer for functioning of infection control committee.• Review the records to understand functioning of IPC committee,• Review the records for training, surveillance and monitoring activities• Observe that more than patients are not occupying one bed and bed to bed distance is optimal (>1 M)• Interact with patient care and cleaning staff if they have received any training and• Check with staff if they are getting adequate supply such as gloves, masks, hand rub and disinfectant solutions.
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PS3.2	<p>Technical guidelines for IPC are in being developed and practiced at facility level</p>	<p>Healthcare facility implements the national technical guidelines on Infection prevention and control. This includes</p> <ul style="list-style-type: none"> • Defining and communicating the standard operating procedures and protocols • Ensuring adequate hand hygiene practice • Ensuring staff is using appropriate personal protection as per their work processes • Adequate environmental ventilation specially in high risk areas such as OT, Operation theatres and infectious wards • Adequate arrangement for decontamination, disinfection and sterilisation of equipment 	<ul style="list-style-type: none"> • Review the standard operating procedures / protocols available for IPC and available at point of use. • Interact with staff if they are aware of IPC protocol and practice them • Check if staff is using personal protection equipment • Check if staff follow the hand hygiene guidelines and aware of 5 moments of hand hygiene • Isolation and barrier nursing is practiced for infectious patients • Check Equipment to ensure circulation and air quality functioning in areas such as OT and ICU • Observe Equipment for sterilization are available and • validation of sterilization is done
PS3.3	<p>Hand hygiene promoted are implemented through</p>	<p>Healthcare facility ensures hand hygiene practices are being followed at point of care. This includes-</p> <ul style="list-style-type: none"> • Providing had washing facilities with running water, soap at all point of use 	<ul style="list-style-type: none"> • Observe if adequate hand washing facilities such as wash basins, soap and alcohol based hand rub are available at point of use

	multimodal strategy	<ul style="list-style-type: none"> • Making available alcohol-based hand rub at all point of use and ensuring the constant supply • Training the staff for hand hygiene steps and five moments of hand washing • Monitoring of hand hygiene practices using assessment tools and providing feedback • Placing reminders at work place to prompt hand hygiene • Promotion activities such as hand hygiene day or week 	<ul style="list-style-type: none"> • Review records of training and onsite monitoring of hand hygiene practices • Observe if posters for steps of hand hygiene and 5 moments of hand hygiene have been displayed at relevant places • Check if health care facility conduct any promotional activities such as hand hygiene day
PS3.4	Anti-Microbial Resistance has been prioritised as patient safety issue and implemented across all component of health system	<p>Following action has been taken at healthcare facility level to address AMR</p> <ul style="list-style-type: none"> • Developing and communicating an antibiotic policy to all clinical staff • Defining process for surveillance and reporting of AMR with laboratory support • Monitoring of prescription patterns and feedback to physician • Training of clinical staff on use of antibiotics and AMR 	<ul style="list-style-type: none"> • Check if there is any documented antibiotic policy • Interact with physicians if they are aware of antibiotic policy and how they implement it • Interact with relevant staff to understand how AMR surveillance is done and communicated to different clinical departments

PS3.5	Injection Safety guidelines and practices are in place	Healthcare facility ensures injection safety through following actions <ul style="list-style-type: none"> • communicating safe injection practices guidelines including do's and don'ts to healthcare staff • Use of AD/RUP/SIP synergies • Ensuring single of use of syringe • Making available good quality puncture proof box for collection of sharp waste at point of use • Encouraging procurement and prescription of single use vials as much possible • Training of staff on safe injection practice and disposal • Ensuring sharp waste has been injection waste has been mutilated on site of given to authorised agency so it is not reused • Providing protective clothing e.g. heavy duty gloves and boots to waste handlers • Preventing multiple use of single dose vials • Establishing needle stick injury reporting and PEP protocols 	Observe the safe injection practices e.g. <ul style="list-style-type: none"> • Washing hand before injection • Disposal of syringe after single sue • Discard of syringe and needle into sharp and container • Avoid recapping of syringes • Interact with staff to understand their aware of safe injection practices, disposal of sharp and needle stick injury protocols • Interact hospital administration how sharp waste disposed securely
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PS 4

System and procedures are for ensuring safety during all stages of patient care

PS4.1	There are established procedures for ensuring safety of patient during transition of care within the hospitals	Healthcare facilities have defined established processes for safe care during handovers. This includes- <ul style="list-style-type: none">• Healthcare facility has defined explicit criteria for admission and transfer between department• Practice of assigning doctor and nursing staff at all point of care• Establishing interdisciplinary teams for care of patients• Using SBAR (situation, background, assessment, recommendation) during handover or other critical communication• Practice of giving patient side handovers and documentation• Establishing process and formats for handover during inter departmental transfers• Defining responsibility and accountability for communication during handovers	<ul style="list-style-type: none">• Review any SOPs protocols available for handover• Observe and interact with staff to understand current process of handover during interdepartmental transfers and change in the shifts• Review handover records
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PS4.2	<p>Discharge and follow-up process are standardised to ensure patient safety</p>	<p>Healthcare facility ensures safety in discharge and follow-up processes. This includes -</p> <ul style="list-style-type: none"> • Standard operating procedure for Discharge planning, discharge documentation, and follow up • Educating patient for identifying and reporting high risk symptoms (red flags) • Formal processes for obtaining the list of medication patient were taking previously and reconcile it with that has been prescribed during current care to avoid omission. Duplication and contradiction and • Implementing Electronic health records and personal health records systems 	<ul style="list-style-type: none"> • Interact with clinical staff to understand process of discharge planning, communication and follow up process. • Check if medication reconciliation is done during admission and/ or discharge process,
PS4.3	<p>There established process to ensure safety of referral and emergency medical services</p>	<p>Healthcare facility has implemented</p> <ul style="list-style-type: none"> • a referral checklist to patient preparedness for referral • advance communication is made to referral hospital including any specific requirements such as procedures, specialist and blood • Has established for criteria referral of patients and for level of life support required (Basic or advance) during transportation 	<p>Interact with clinical staff for availability and practice of checklist, criteria and procedure for referral of patients</p> <p>Review records on sample bases to ascertain protocols have been followed.</p>

		<ul style="list-style-type: none"> • Ensure patient is accompanied by a trained healthcare professional as per need • Referral/ discharge card with details of history, treatment given and reason for referral • Ensure assigned ambulance is fully equipped • Establish process of follow up of referred patients 	
PS4.4	Patient safety measures are in place for intensive and critical care	<p>Healthcare facility has taken adequate measures to ensure safety in critical and intensive care</p> <ul style="list-style-type: none"> • Define list urgent critical results and establish channels for communication • System to ensure hospital wide recognition and response to clinical deterioration • Process of screening and prevention of risk related with pressure ulcers and falls • Established procedure for Cardio Pulmonary resuscitation • Standard operating procedure for triage, rapid assessment and response in emergency 	<ul style="list-style-type: none"> • Interact with the clinical staff about list of critical diagnostic values those has to be reported immediately • Review relevant standard operating procedures • Interact with patient care staff how risk assessment for fall and pressure ulcer is done and what actions are taken to reduce the risk

PS4.5	<p>Focused interventions for awareness, assessment, prevention of Venus thromboembolism are in place</p>	<p>Following measures has been taken to reduce the risk of VTE</p> <ul style="list-style-type: none"> • Risk assessment tool is available • All patient at risk are assessed and graded as per severity • Protocols for prophylaxis and reduction are available 	<ul style="list-style-type: none"> • Interact with clinical staff if they are aware of risk assessment criteria and regularly use it • Check records for patient at risk for assessment being done
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PS 5

System and practise are in place to ensure patient safety in Primary Care

PS5.1	There are established processes to ensure safety in immunization program	<p>Healthcare facility –</p> <ul style="list-style-type: none"> • Has made staff immunization aware about safety aspect for vaccination • Made reporting formats available • Ensure vaccines are stored at recommended environment • Following proctors for post vaccination counselling and observation protocols • Train vaccination staff to recognise the adverse event and management if required • Making emergency drug tray available at immunization point 	<ul style="list-style-type: none"> • Interact with staff involved in immunization for their understanding of adverse events , how to report them and managing the adverse events
PS5.2	Initiatives have been taken to make ambulatory care safer	<p>Healthcare facility has established patient safety process in ambulatory care department. This includes -</p> <ul style="list-style-type: none"> • Standardising formats for patient records in ambulatory care • Use of electronic health records and CPOE in OPDs 	<ul style="list-style-type: none"> • Interact with hospital administration for efforts made to implement EHR and CPOE in OPD services • Check availability any decision support system for physicians

		<ul style="list-style-type: none"> • System to make request diagnostic and receiving test report without errors • follow-up of patients after diagnostic tests report has been received • Communicating with care providers at hospital while referring the patient • Establishing a patient registration system with unique identifier linked will all processes and services • Including OPD services in incident reporting system • Providing clinical decision support tools to physicians 	<ul style="list-style-type: none"> • Review recorded if errors in OPD services are reported in patient safety reporting system
PS5.3	There are focused efforts to minimise harms due to diagnostic errors	<p>The clinical leadership of the health care facility acknowledges diagnostic errors as important patient safety issue and takes actions such as</p> <ul style="list-style-type: none"> • Use of decision support system and EHR • Approaching diagnosis as team process with involvement patients and nursing staff • Obtaining opinion in case of diagnostic dilemma. • Conducting Root cause analysis on identified errors and use for learning 	<ul style="list-style-type: none"> • Interact with clinical leadership, physicians and diagnostic services staff for their understating of diagnostic errors and steps being taken to reduce address them. • Check availability of decision support tools, checklist, diagnostic pathways to assist physician in arriving to diagnosis

		<ul style="list-style-type: none"> • Providing feedback to previous physician when there is significant change in diagnosis • Process of following up for abnormal case results • Implementing internal quality control, external quality assurance and accreditation programs in laboratory and imaging services • Measuring the diagnostic safety indicators including timeliness of diagnosis • 	<ul style="list-style-type: none"> • Interact with physicians to understand practises such as second opinion, follow-up and learning from errors. • Interact with the clinical staff about list of critical diagnostic values those has to be reported immediately and how these are communicated
PS5.4	Steps has been taken to make palliative care and of end of life care safer	<p>Healthcare facility has effectively communicated to carer safety issues in palliative care. This includes care</p> <ul style="list-style-type: none"> • Patient attendant or carer has been given counselling and given hands-on demonstration on care of patient including • How to safely operate medical devised • infection prevention measures such as hand hygiene and personal protection, infectious waste disposal, safe storage of medicines specially opioids • identifying danger sign and report it to treating clinical staff 	<p>Interact with clinical staff to understand how patient attendant/ carer are counselled for safer care at home</p> <p>Review if any standard operating procedure is available for end of life care</p>

		<ul style="list-style-type: none"> • Documented and established the standard procedures for pain management, opioid use and advance care planning and end of life decision making 	
PS5.5	<p>Mental health</p> <p>patient safety issues has been identified and integrated with patient safety program</p>	<p>Health care facility implements-</p> <ul style="list-style-type: none"> • Evidence based risk assessment tools for suicide, aggression, restraint use) • Reporting mechanism for adverse event in mental health patients 	<p>Interact with concerned clinical staff understanding risk assessment tools in use and reporting of mental health indicators</p>

Patient Engagement Assessment Tool

PE 1

Healthcare delivery processes are patient centred

Ref No.	Requirement	Description	Assessment Guidance
PE1.1	There is mechanism to factor in the preferences of patients/ community while designing healthcare delivery processes	Healthcare facility encourages the patient and family to express their preferences, any religious or cultural requirements and what health outcomes matter to them. These preferences are analysed and factored in while designing the patient care process and environment or even while modifying them	Interact with facility leaders and care providers how patient preferences are factored in the service delivery
PE1.2	Patient experience is measured and improved through	Healthcare facility has formal processes in place that were co-designed with patients/community for sharing patient and family experience, concern and solution. These feedbacks are adequately recorded	Interact with hospital administration to understand the process of patient feedback measurement, analysis and improvement

	systemic patient feedback program	<p>analysed and used to develop improvement efforts in partnership with patients and community. The feedback experience is more than just satisfaction level. This includes sharing observations, needs, expectations, ideas for improvement and peculiar safety concern</p> <p>Patient and family is made aware of action taken of their feedback provided</p>	
PE1.3	Health care system and providers ensures privacy, dignity and confidentiality of patients	<p>Facility makes adequate arrangements to ensure privacy, confidentiality and dignity of patients. This includes –</p> <ul style="list-style-type: none"> - Visual and speech privacy - Confidentiality of patient information and records - Special considerations for patients with social stigma - Empathic and respectful behaviours of staff - Clean and hygienic care environment 	Interact with hospital administration and care providers about measures taken to maintain privacy, confidentiality and dignity of patients
PE1.4	Adequate measures have been taken to ensure that there are	<p>Health care facility has provided adequate physical access without any barriers. This includes</p> <ul style="list-style-type: none"> - Ramps, lifts and escalators as applicable 	Check if healthcare facilities are barrier free with special provisions for persons with disabilities

	no physical barriers to access	<ul style="list-style-type: none"> - Wheelchairs and stretchers - Disabled friendly facilities such toilets and tactile guidance 1. sign language for the hearing impaired. 	
PE1.5	There are well-defined processes for care of high risk and vulnerable patients	Health care facility identifies high risk and vulnerable patients and ensure their proper care	Interact with care providers how high risk and vulnerable patients are identified and measures taken for their safe care

PE 2

Information and Education about care provision and safety are readily available

PE2.1	Information of patient rights and service availability and entitlements	<p>Facility prominently displays the patient right charter at all critical places in local language</p> <p>Patient safety has been explicitly mentioned as patient right</p> <p>Facility administration and staff is thoroughly aware of patient rights and how to secure them.</p> <p>Patient are proactively informed and educated about their rights while availing services in facility.</p> <p>Patient rights also include rights of family/ attendants.</p> <p>Information should be available in local language and in form that can be readily understood by patients and their family.</p>	Check if citizen charter is available and prominently displayed at the health care facility
PE2.2	Safety and security information has been standardised and made available	Healthcare facility identifies all areas which require proactive display of information about safety precautions. Such radiology units, infectious waste handling areas, electricity panels, fire hazards,	Check adequate information and signage have been placed all risk prone areas in standardised form as mandated by national guidelines

		slippery floor, restricted areas having highly infectious patient or high risk patients, security hazards etc.	
PE2.3	Health system educates the patients and communities on patient safety issues	Healthcare facility provides Information patient safety education through various communication materials and patient safety campaigns. These may be posters, videos, brochure etc.	Check if patient safety information and education material is available in the facility
PE2.4	Safety information regarding specific procedures , healthcare settings is provided to the patient and family	Healthcare facility informs patients about procedure and expected outcomes including risk involved. Patients and families are also counselled for use of medication information sheet is readily available for specific precautions	Check with care providers about safety information about procedures/ treatment to patient and family
PE2.5	Systems are in place to insure the access to information regarding to patient and community	Hospital defines the procedures on how information can be accesses especially regarding the health records. This includes list of records can be shared, average time, who can access the information, how request to be made, responsible person to authorize access and provide the information, and usual time taken. Bed side handover	Interact with facility administration for policy on access to records Review the documented procedure

PE 3

Patients are involved in their care and shared decision making

PE3.1	Established process for informed consenting procedure	<p>Facility wide consenting policy has been defined, documented and disseminated to relevant departments. Policy explicitly mentions the situations and procedures and type of consent required. Consent policies and procedures should be in adherence with national policies and applicable laws.</p> <p>Consent includes mention of specific risks and adverse event that may occur during the procedure or treatment.</p> <p>The consent should be available in the language understood by the patient and explained to him or her by authorized person. Neutrality of consent is ensured through and independent observer</p>	<p>Review the hospital wide policy manual of consenting procedures</p> <p>Verify sample patient records for consent and their completeness.</p> <p>Check if Consent forms for general as well as high risk consent are available at all point of use.</p>
PE3.2	Patients are involved in incident reporting	Patient is made aware and encouraged to inform any safety incident may or may not lead to ham, to care givers or hospital authorities. These may be in	Check if there is mechanism for systematic collection of patient reported incidents.

		<p>terms of medication error, such as wrong drugs, reporting any medical condition arising, any unsafe staff behaviour such as not washing hand before touching patient or physical safety issues such as electrical and fire safety has been over looked.</p> <p>Facility should ensure the anonymity of the reporting person</p>	<p>Check is there is any material such poster, pamphlet, video etc. that educate patient / family about their responsibility of reporting the any unsafe behaviour or incident</p> <p>Review the records that for understating if the system is used for reporting adequately</p> <p>Interact with some patient if they aware about this role and what they perceive by safety incident</p>
PE3.3	<p>Patient & Family engagement tools have developed and implemented</p>	<p>Facility ensures availability of patient engagements tools such as WHO such as</p> <p>5 moments of patient safety, medication passport, communication tool for safe surgery, tips for patient before appointments, self-care after discharge etc.</p> <p>These should be made available patient in print or electronic form. For example in OPD area facility may keep a brochure with blank space and pend about what question you should during the consultation with doctor</p>	<p>Check if patient engagement tools are being made available to patient and family.</p> <p>Discuss with hospital administration / care providers about how patients are educated and encouraged to use these tools.</p> <p>Interact with some of the patients if they understood the purpose of tool and whether these have been for them.</p>

PE3.4	Patients and family are involved in decision making about their treatment	<p>Patient is encouraged to communicate their expectations.</p> <p>Facility should develop / implement decision making tools to help patients and healthcare professional discuss treatment options.</p> <p>Facility support involvement of family in management of care and decision making, where ever possible a member of family should be physically present during the care. Such as birth companion during delivery, during discharge counselling and taking informed consents.</p>	<p>Interact with hospital administration and care providers for measures taken to involve patients and family decision making.</p> <p>Check if some decision making tools for patients are available and practiced.</p> <p>Interact with patients if how they have been involved in decision making.</p>
PE3.5	Norms and practices for self-care and self-Management are defined and practiced	<p>Healthcare facility has counsels and trained patient and family members for self-management and safer care.</p> <p>This may be in terms of counselling for self-medication, home care during rehabilitation after discharge and regular review of self-management process.</p>	<p>Check with care providers for any practice counselling for self-care.</p> <p>Interact with patients if they have sensitised for self-care and follow up</p>

PE 4

Patient and Patient Groups are Partnered in improving safety and quality

PE4.1	The system for identifying and recruiting patient groups and partners has been implemented	Facility identifies and recruits the local patient partners. Patient partners are individuals who experienced care (as a patient, family member or caregiver) and who can be helpful in improving the patient engagement and safety in the hospital The qualification criteria, and role and responsibilities of patient partners have been defined.	Interact with facility leadership and admiration of any such policy or program to recruit patient partners. Review role and responsibility if those have been documented Interact with patient partners if any recruited.
PE4.2	Patient groups and partners are involved in policy design and patient safety improvement initiatives	Facility involves / patient partners as advisors or advisory council members in organisation, design, governance. They should also involve as partners / advisors on specific patient safety initiatives and quality improvement projects	Interact with facility leadership and administration about how patient groups/ partners are involved in design and governance functions. Also patient partners have involved in planning and implementation of patient safety initiatives and quality improvement projects.
PE4.3	Patient groups are partners involved in	Facility utilises patient partners for educating staff members on patient centred care and communication. Patient partners are also used to	Interact with hospital administration as well as patient partners to understand how they are

	education and research activities	educate patients and family about their rights and responsibilities in hospital. and do's and don'ts for safer care	involved in education activities for staff as well as patients
PE4.4	There is formal process peer support of the patient through patient group	Healthcare facility provides patient access to patient support groups for peer support and counselling services. This includes assistance in case of a patient safety incident.	Interact with hospital staff of any such mechanism available for per support
PE4.5	Adequate resources are made available for enabling patient as partners and leadership role	Healthcare facility compensates the patient partners for their time and efforts. This may be in terms of honorarium or they can engaged as salaried staff	Interact with hospital administration for understanding if there is any mechanism to compensate patient partners for their contributions. Patient partners can also be interacted for same.

PE 5

Mechanism for Communication, Appraisal and Grievance Redressal is established

PE5.1	There is dedicated agency , unit or person to handle the grievance related processes	<p>Facility has appointed ad dedicated grievance redressal officer or designated a suitable staff for receiving and processing the grievances related to services provided including safety issues.</p> <p>The designated office has adequate time, office resources and skills to do justice with task.</p>	<p>Interact with hospital administration about grievance redressal officer.</p> <p>Review records regarding his/her appointment and role and responsibilities. Interact with the designated officer regarding his ability to perform responsibilities.</p>
PE5.2	Channels for grievance registration are established and easily accessible to patient and public	<p>Facility offers user friendly and multiple ways to register the complaints including complaint boxes, emails and through face to face interaction with grievance redressal officer</p> <p>The information about where and how to register complaint is prominently displayed and printed in information material.</p> <p>Facility also displays information about national/ sub national level grievance redressal mechanism</p>	<p>Discuss with responsible officer or hospital administration about modes and modalities of registering the complaints and how it is disseminated to users.</p> <p>Observe if information is displayed prominently in hospital.</p>

PE5.3	There is established criteria and mechanism for categorising the complaints and escalating it to different agencies	Facility has defined and established procedures for categorising complaints and escalating them to different departments / responsible personal for actions. Complaints can be categorised based severity of complaint, urgency of action required, level of actions and efforts required to resolve the complaint.	Interact with responsible officer to understand the process of grievance processing and corrective action taken. Review if any SOP / circular is available defining the process. Review the record to how actions are taken, tracked and communicated to aggrieved patient/ family
PE5.4	Corrective action including compensation are has been integrated with grievance redressal system	Facility plans for corrective action and track action taken of them. Action taken may be in term of <ul style="list-style-type: none"> • Verbal or written apology • Improvement in work processes of relevant departments • Providing additional human resources / equipment/ supplies • Providing information and transparency in service delivery • Training and counselling for relevant staff • Better monitoring / assurance of staff and delivery process 	Interact with responsible officer for action taken on complaints received. Review the records to understand the action taken were adequate and reflect systematic approach of compliant management and learning

		Facility analyses the complaints use them for improving safety and quality in the processes	
PE5.5	There is established procedure for disclosure and resolution in case of unexpected harm to patient	Facility implements comprehensive mechanism for identifying, disclosing and resolution of unexpected patient safety events that has caused severe harm to the patient. Facility should constitute communication teams and train them for effective, empathetic and transparent disclosure of such events to the patient and their family.	Interact with hospital leadership and administration on action taken in this regard Review any circular; SOP or training material has been developed for this purpose.

List of Abbreviation

ADR	Adverse Drug Reaction
AMR	Anti-microbial Resistance
CPOE	Computerized Physician Order Entry
DHIS	District Health Information System
EPA	Environment Protection Agency
EQAS	External Quality Assurance Scheme
HAI	Hospital Acquired Infection
HFE	Human Factor & Ergonomics
IAEA	International Atomic Energy Agency
IGMH	Indira Gandhi Memorial Hospital
IPC	Infection Prevention and Control
KPI	Key Performance Indicator
KPI	Key Performance Indicators
MBS	Maldivian Blood Service
MFDA	Maldives Food and Drug Authority
MHS	Maldivian Health Standard
MIM	Minimum Information Model
MNH	Maternal & Newborn Health
MOH	Ministry of Health
NACP	National Aids Control Programme
PDSA	Plan-Do-Study-Act
PEP	Post Exposure Prophylaxis
QA&I	Quality Assurance & Inspection
QOC	Quality of Care
SOP	Standard Operating Procedure
STG	Standard Treatment Guidelines
STO	State Trading Organisation
TOT	Training of Trainers
VTE	Venous Thromboembolism

WASH	Water and Sanitation & Hygiene
WHA	World Health Assembly
WHO	World Health Organisation





NATIONAL PATIENT SAFETY FRAMEWORK

QUALITY ASSURANCE AND REGULATION DIVISION, MINISTRY OF HEALTH IN COLLABORATION WITH WHO MALDIVES