REPUBLIC OF KENYA

MINISTRY OF HEALTH

NATIONAL POLICY ON PATIENT SAFETY, HEALTH WORKER SAFETY AND QUALITY OF CARE

AUGUST 2022

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Patient Safety, Health Workers Safety and Quality of Care are integral components of health care systems. In developing countries, 3 in 10 patients experience adverse events and harm in hospitalized care settings. Available evidence reflects that 15% of hospital expenditure is directed to addressing the issues related to safety failures. Prevention, and reduction of adverse events and injuries arising from or during the process of healthcare is a priority in ensuring optimal patient outcomes and protecting the health worker.

The Constitution of Kenya and the Kenya Health Policy, 2014–2030 demonstrates the health sector's commitment, under the government's stewardship, to ensuring that the country attains the highest possible standards of health, in a manner responsive to the needs of the population. Universal Health Coverage (UHC) is a priority at both the national and global level. The goal of UHC is to ensure that every citizen has access to quality healthcare services that they need without getting into financial difficulties or, worse, pushed into poverty. To ensure safety and quality of care, many interventions have been undertaken within the Ministry of Health under the following initiatives: the Kenya Quality Model for Health, the Kenya Quality of Care Framework, the Joint Health Inspection Checklist, the National Infection Prevention and Control Strategy, the National Policy and Action Plan on the prevention and containment of antimicrobial resistance and the Categorization guidelines.

This policy provides a comprehensive framework through which the health care system will be transformed to deliver high quality & safer patient and family centered services. The policy also provides for health workers safety, wellness and capacity building in compassionate care; adhering to clinical and evidence-based practices promoting social medicine and community practice.

The current Kenya Quality of Care Accreditation Framework under implementation lacks the pre-requisite structures to guarantee independent, accountable and credible evaluation of safety and quality of care provided.

This policy seeks to bridge this gap by proposing the establishment of a suitable independent entity to oversee and advise government on matters safety and quality in health care. This will guarantee a certification with a mark of quality for global recognition. This endeavor will further position Kenya as a medical tourism destination as envisioned in vision 2030.

This first Patient Safety, Health Worker Safety and Quality of Care Policy, envisions a Nation where safety and quality is valued and promoted, to ensure the provision of respectful and responsive quality health care for a healthy, productive and globally competitive country. I call upon all stakeholders to commit and invest in these strategic actions to address safety and quality in health care for a healthy nation.

Sen. Mutahi Kagwe, EGH

Cabinet Secretary, Ministry of Health

The Kenya Health Policy, 2014 – 2030 gives directions to ensure the well-being of Kenyans in line with the country's Vision 2030 and the Kenya Constitution, 2010. This is a sector commitment under government stewardship in ensuring the Country attains the highest possible standards of health, in a manner responsive to the population needs. It focuses on ensuring equity, people centeredness and participatory approach, efficiency, multi-sectoral approach and social accountability in delivery of health care services.

The National Patient Safety, Health Workers Safety and Quality of Care Policy and the accompanying Action Plan, provides for a framework on interventions for safe and quality health care provision for all.

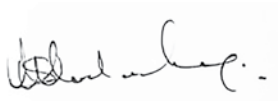
The Policy embodies the spirit of the Constitution of Kenya 2010, Vision 2030, the Kenya Health Policy (2014-2030) and the global commitments as envisioned in the Global Patient Safety Action Plan endorsed at the 74TH World Health Assembly by member states. Article 43 (1a) of the Constitution of Kenya 2010, provides that "every person has the right to the highest attainable standard of health, which includes the right to healthcare services".

This first National Patient Safety, Health Worker Safety and Quality of Care Policy is a commitment to pursuing policy measures and strategies for achieving optimal health status and capacity of each individual. The policy aims at building a resilient health care system with an excellent culture of safety and quality of care with minimal risks and free from preventable harm through appropriate strategies, actions, positive client experiences, and partnerships. The policy provides a pathway through which optimal levels of patient safety will be achieved as we strive towards attainment of Universal Health Coverage.

This policy was developed through a rigorous consultative process involving the public at all levels of government, private, professional associations and unions, regulatory bodies and non-state actors including patient representatives under the stewardship of the Ministry of Health. The policy recognizes that it is the responsibility of every person in the public and private sector to ensure the objectives are attained and calls for a multi-disciplinary and inter-sectoral approach in its implementation.

The government is committed to implementing this policy and it is therefore my belief that collectively we can make a difference. Let us all join hands in embracing the culture of safety and quality to build a safe, respectful and responsive quality health care system for a healthy, productive and globally competitive nation.

Susan Mochache, CBS



Principal Secretary, Ministry of Health

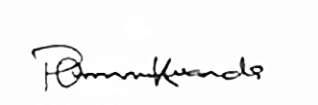
The National Policy on Patient Safety, Health Worker Safety and Quality of Care 2022-2027 was developed through a consultative process of key health stakeholders whose inputs contributed significantly in a variety of ways towards its planning and development.

Foremost, we acknowledge the Cabinet Secretary for Health whose leadership and guidance ensured that all the necessary resources and technical inputs were provided for effective planning and development of the Action Plan. We thank the technical teams from the Ministry of Health headed by the Directorate of Health Standards Quality Assurance and Regulations and support from all heads of directorates in the Ministry of Health under the leadership of the Director General for Health.

We would like to thank the Council of Governors, who through the secretariat supported and gave significant inputs to the development of the policy. The contributions from Health Professional Associations and Unions, Regulatory Boards and Councils, development and implementation partners and patient representatives brought the multisectoral approach and commitment.

Special thanks to the Division of Patient and Health Workers Safety and the Division of Quality Assurance and the technical working group, who spearheaded the whole exercise. We acknowledge the World Health Organization (WHO) for technical and financial support toward the development of these documents.

Dr. Patrick Amoth, EBS



Ag. Director General, Ministry of Health

ADE	Adverse Drug Event
AMR	Antimicrobial Resistance
CASIC	County Antimicrobial Stewardship Interagency Committee
CIPCAC	County Infection Prevention Control Advisory Committee
FBO	Faith Based Organization
GPSC	Global Patient Safety Collaborative
HAIs	Healthcare Associated Infections
HCW	Healthcare Workers
ICAN	Infection Control Africa Network
IPC	Infection Prevention Control
IPNET	Infection Prevention Network Kenya
KQMH	Kenya Quality Model for Health
LMIC	Low- and Middle-Income Countries
ME	Medical Errors
MOH	Ministry of Health
NPSAC	National Patient Safety Advisory Council
NASIC	National Antimicrobial Stewardship Interagency Committee
NGO	Non-Governmental Organization
OSH	Occupational Safety and Health
PPB	Pharmacy and Poisons Board
QI	Quality Improvement
QoC	Quality of Care
UHC	Universal Health Coverage
WASH	Water Sanitation and Hygiene
WHA	World Health Assembly
WHO	World Health Organization
WPSD	World Patient Safety Day

1. **Adverse event** - An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable.
2. **Culture of safety** - an integrated pattern of individual and organizational behavior based upon shared beliefs and values, that continuously seeks to minimize patient harm which may result from the processes of care delivery
3. **Harm** - temporary or permanent impairment of the physical, emotional or psychological function or structure of the body and/or pain resulting therefrom requiring intervention
4. **Hazard** - Any threat to safety, e.g., unsafe practices, conduct, equipment, labels, names.
5. **Health worker** - A health worker is anyone who works in a healthcare setting, including community health units, students on clinical placement at health facilities, frontline health workers and other health workers not in direct patient contact but offering health related services
6. **Healthcare Associated Infection** - localized or systemic condition that was not present or incubating at the time of admission into the healthcare setting and was acquired in the process of providing or receiving care
7. **Occupational diseases** - adverse health conditions the occurrence or severity of which is related to exposure to factors on the job or in the work environment
8. **Patient Safety** - A framework of organized activities that creates cultures, processes and procedures, behaviours, technologies, and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur
9. **Patient safety incident** - any unintended or unexpected incident(s) that could have or did lead to harm for persons receiving healthcare
10. **Quality of care** - the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes
11. **Risk** - probability that a person will be harmed or experience an adverse health effect if expose a hazard

The right to health is a fundamental human right guaranteed in the Constitution of Kenya. Article 43 (1) (a) of the Constitution provides that every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care. In addition, Article 46, specifies that consumers have the right to protection of their health, safety, and economic interests. Similar provisions are also contained in international and regional human rights instruments of which Kenya has ratified.

There is an increasing effort towards the achievement of Universal Health Coverage (UHC) with safety and quality as an essential feature, based on years of recognition that patient safety is a global concern (World Health Assembly (WHA 72.6), 2019). The Kenyan government has embarked on ensuring the provision of Universal Health Coverage as a priority being part of the Big 4 agenda items, the other 3 being affordable housing, food security and local manufacturing.

UHC is focused on ensuring that all people can access promotive, preventive, curative, rehabilitative and palliative health services they need in a safe environment and of sufficient quality to be effective. In order to deliver on the promise of providing quality health care, treatment, and services in a safe environment free of errors and harm, various elements should be applied across the continuum which include assessing, planning, providing, and coordinating care to address patient needs. The WHA resolution 72.6 of 2019 recognized patient safety as a global health priority and endorsed to observe September 17 annually as World Patient Safety Day (WPSD), to raise awareness and understanding about patient safety and to galvanize global actions for safer systems, services, procedures and practices in healthcare to eliminate harm.

Healthcare worker safety cannot be separated from patient safety as health and safety risks to healthcare workers directly affect and impact on patient outcomes. In 2020, the toll of the COVID-19 pandemic brought increased recognition of risks to patients and healthcare workers. The physical and psychological safety of healthcare workers was greatly compromised due to the risk of exposure to infection, together with the capacity and financial stability of health care systems. Situational factors, such as staffing shortages, shortages of PPEs, inadequate skills to deal with unfamiliar scenarios, all disrupted existing care processes in most health systems. In recognition of this challenge, the World Patient Safety Day, 17 September 2020, was dedicated to the theme "Health worker safety: a priority for patient safety".

The safety and protection of healthcare workers is key to ensuring the safety of patients as well as a well-functioning health system and society. Workers in hospitals encounter unique risks that are uncommon in other industries. In particular, hospital workers lift, reposition, and transfer patients who have limited mobility. Heavy patients can pose particular challenges for safe handling. Workers may have to interact with potentially contagious patients, hazardous materials and sharp devices contaminated with bloodborne pathogens. Hospitals serve patients with physical or mental health challenges, some of which increase the likelihood of violent outbursts. Caregivers feel an ethical duty to "do no harm" to patients and often feel compelled to put patient safety above all else. Indeed, some will put their own safety and health at risk to help a patient. Without adequate safeguards for workers, an increased emphasis on patient safety can potentially increase risks for workers *(https://www.osha.gov/sites/ default/files/1.2_Factbook_508.pdf)*

1.1 Background

Patient safety is a framework of organized activities that creates cultures, processes, procedures, behaviors, technologies and environments in health care that consistently and sustainably lower risks during health care delivery. It aims to prevent and reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur (WHO Global Patient Safety Action Plan 2021-2030)

The World Health Organization defines Patient safety as "The avoidance of unintended or unexpected harm to people during the provision of healthcare" (The WHO & NHS Improvement). The Canadian Patient Safety Dictionary also defines

practices shown to lead to optimal patient outcomes." (The Canadian Patient Safety Dictionary, October 2003).

Patient safety can also be defined as the absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighted against the risk of non-treatment or other treatment. (https://www.who.int/initiatives/medication-without-harm)

Quality of care is defined as "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes." (Agency for Healthcare Research and Quality).

There is no single definition for patient safety and quality of care, and no approaches appear to be more successful than others. However, what is clear is that to consider patient safety and quality of care as separate entities would be a misunderstanding of their concepts entirely as they are intrinsically linked.

There are aims for improvements to achieve the ideal healthcare system. These aims are often used within the quality improvement process and are described below (Delivering quality health services: a global imperative for universal health coverage. *Geneva: World Health Organization, Organization for Economic Co-operation and Development, and The World Bank; 2018.)*

1. Effective - Offered based on scientific knowledge and evidence-based guidelines.
2. Safe - Minimizes harm, including preventable injuries and medical errors, to the patient.
3. People-centered - It respects and responds to the patient's preferences, needs and values.
4. Timely – It keep delays in providing and receiving services to a minimum.
5. Equitable – Does not vary according to personal characteristics such as gender, race, ethnicity, geographical location and socioeconomic status.
6. Integrated – Care received across facilities and providers would be coordinated. that offer dementia-related care and other services as needed.
7. Efficient Avoids waste of resources, including equipment, medicines, energy and ideas.

The above dimensions of quality have been adopted by the Kenya Quality Model for Health (KQMH) with the addition of Accessibility and Acceptability.

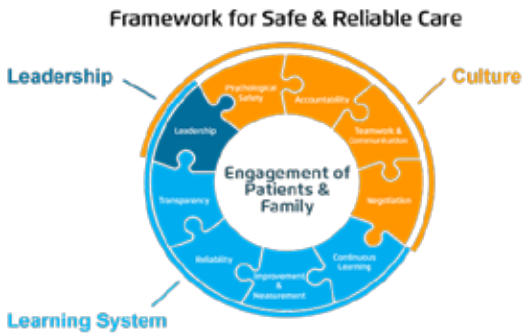


Figure 1-Framework of safe and reliable care

The Kenya Health Policy 2014-2030 highlights the importance of Quality, Patient and Health worker safety including organizational considerations at all levels of health care. Patient safety has been well articulated in the revised Kenya IPC Policy (2020-2025) and IPC Strategy (2020-2025), several IPC trainings packages and tools. Medication and patient safety are a core component of pharmacovigilance as outlined in the Kenya Guideline on the Safety and Vigilance of Medical Products and Health Technologies 2019. In addition, health worker safety is well articulated in the Occupational Safety and Health Act No. 15 of 2007, the National Occupational Safety and Health Policy (May 2012) and the Occupational Safety and Health Policy Guidelines for the Health Sector (July 2014). Quality of care is also well articulated in the Kenya Quality Model for Health (2014), the KQMH Quality Core Standards for Quality Healthcare (March 2018), the Kenya Quality of Care Accreditation Framework 2019 and related Joint Health Inspection Checklists (Feb 2015) which promote compliance to minimum standards of quality and safety in health service provision. However, Kenya lacks an integrated comprehensive Policy on patient safety, quality and health worker safety and hence the need for this policy.

1.2 Rationale

The patient safety call for action emerged in the first decade of the 21st century following the release of the report by Institute of Medicine (IOM) To Err Is Human: Building a Safer Health System. The report, which dramatically raised the profile of patient safety, showed that errors are common, they are costly, systems-related problems cause errors, errors can be prevented, and safety can be improved.

Globally, hundreds of millions of people are affected every year by avoidable infections in health care settings (Allegranzi, 2011)and this does not take into account the additional harm caused by outbreaks and pandemics such as COVID-19. The WHO report highlights that at any given time, 7% of patients in developed countries and 10% in developing countries will acquire at least one health care-associated infection (HAI) and this can contribute to avoidable death. Patients who acquire infections while receiving care tend to have longer hospital stays and be treated with less effective drugs that are more toxic and/or more expensive. Some of these patients will not recover and others may develop long-term complications. Fortunately, most of these errors result not in serious harm but in near misses.

Patient harm during healthcare is a leading cause of morbidity and mortality internationally. Harmful patient incidents are also a major financial burden for healthcare systems across the globe. It is estimated that 10-15% of healthcare expenditure is consumed by the direct sequelae of healthcare-related patient harm *(Panagioti et al., 2019)*. The patient safety situations causing most concern include:

	Patient Safety Area of Concern	Burden of Harm/Impact
1	Medication errors	Estimated to cost US$ 42 billion annually
2	Health care-associated infections	Occurs in 7 and 10 out of every 100 hospitalized patients in high-income countries and low- and middle-income countries respectively
3	Unsafe surgical care procedures	Cause complications in up to 25% of patients
4	Unsafe injections practices	Estimated at 9.2 million years of life lost to disability and death
5	Diagnostic errors	Occur in about 5% of adults in outpatient care settings
6	Unsafe transfusion practices	Data on adverse transfusion reactions from a group of 21 countries show an average incidence of 8.7 serious reactions per 100 000 distributed blood components
7	Radiation errors	Overall incidence of errors is around 15 per 10 000 treatment courses over a 30-year study
8	Sepsis	Affects an estimated 31 million people worldwide and causing over 5 million deaths per year
9	Venous thromboembolism (blood clots)	Contributes up to one third of the complications attributed to hospitalization

Table 1-Safety situations causing most concern (Source: WHO)

The rates of HAIs are disproportionately higher in African countries, estimated to range from 2.5% to 14.8%. In Kenya, the rate of HAIs is estimated to be 4.4 per 100 patient admissions(Odoyo et al., 2021).

A Ministry of Health study published in 2016 on occupational exposure to blood and body fluids and HIV post exposure prophylaxis in Health Care Facilities in Kenya 2011-2014, showed that of 1665 reports analyzed, needle stick injuries (NIS) contributed 77%. There have also been reports of serious adverse events following injections of medications. It is not easy to establish the full magnitude of the safety challenge with certainty since the health care sector does not routinely identify and collect information on errors.

Violence against health workers, burnout, and musculoskeletal disorders are all widespread occupational health problems in strained health care facilities, many of which also face acute shortage of competent health workers. Health worker absenteeism and attrition, resulting in suboptimal care outcomes, are aggravated by poor physical and mental health of health workers. The COVID-19 pandemic has exposed and sometimes exacerbated underlying challenges facing the health workforce, the safety of healthcare and the overall health system. Preserving the physical and mental health of health workers is essential to ensuring the delivery of safe care and avoiding patient safety incidents. Physically and psychologically sound health workers are less prone to make errors, contributing to safer care. the safety of health workers therefore directly impacts the safety of patients(WHO).

World Patient safety day, calls on governments and those running health services at local levels to take actions to better protect health workers. These steps include: protecting health workers from violence, improving their mental health and protecting them from physical harm and biological hazards.

The WHO Global patient safety action plan includes seven strategic objectives as below:

i. Make zero avoidable harm to patients a state of mind and a rule of engagement in the planning and delivery of health care everywhere

ii. Build high-reliability health systems and health organizations that protect patients daily from harm

iii. Assure the safety of every clinical process

iv. Engage and empower patients and families to help and support the journey to safer health care

v. Inspire, educate, skill and protect health workers to contribute to the design and delivery of safe care systems

vi. Ensure a constant flow of information and knowledge to drive the mitigation of risk, a reduction in levels of avoidable harm, and improvements in the safety of care

vii. Develop and sustain multisectoral and multinational synergy, partnership and solidarity to improve patient safety and quality of care

2.1 Legal, regulatory, policy framework, institutional mechanisms and stakeholder involvement

2.1.1 Legal and regulatory framework

There exists laws, regulations, policies and strategies that support patient and healthcare worker safety as well as quality of care at all levels. The Constitution of Kenya Article 43(1) (a) states that every person has the right to the highest attainable standard of health, which includes the right to health care services. The Constitution envisions that the two levels of government collaborate, cooperate and consult to ensure quality health services to all Kenyans, where the national government is responsible for policy formulation and capacity building whilst the county governments are responsible for delivery of healthcare services.

The Health Act No. 21 of 2017 provides mechanisms for implementation of health services in the country. This includes regulation of healthcare professionals and health products and technologies. The Occupational Safety and Health Act 2007 and the Public Health Act CAP 242 provide for safe infrastructure and safe workplaces for workers, which includes health care workers while the Work Injury and Compensation Act 2007 provides for compensation of workers for workplace related injury.

2.1.2 Policy framework

Notable policies and strategies that provide guidance on safety and quality of health services include the National IPC Policy of 2015, the National AMR Policy of 2017, the Guidelines on vigilance and safety of medical products and health technologies- 2019, Occupational Safety and Health services guidelines of 2018, Kenya Quality Model for Health 2018, Norms and Standards for Human resources for health (HRH) staffing, schemes of service for HRH, Quality of care certification framework of 2020 and various service and patient rights charters

However, despite the existence of the above legal and regulatory frameworks, there exist glaring gaps in addressing patients and health worker safety and quality of care. These gaps include:

i. The existing legislations, policies and guidelines have not been adequately synergized to address patients and health worker safety and quality of care.

ii. Where legislation, policies and guidelines exist, implementation is poor owing to inadequate dissemination, access, and adherence.

iii. Inadequate monitoring and evaluation of implementation of the existing laws, policies and guidelines.

2.1.3 Coordination mechanisms

National level

At the national level under the Directorate of Health Standards, Quality Assurance and Regulation the department of standards and quality assurance is tasked with coordinating infection prevention and control and antimicrobial stewardship, as well as promoting patient safety, health worker safety and quality of care.

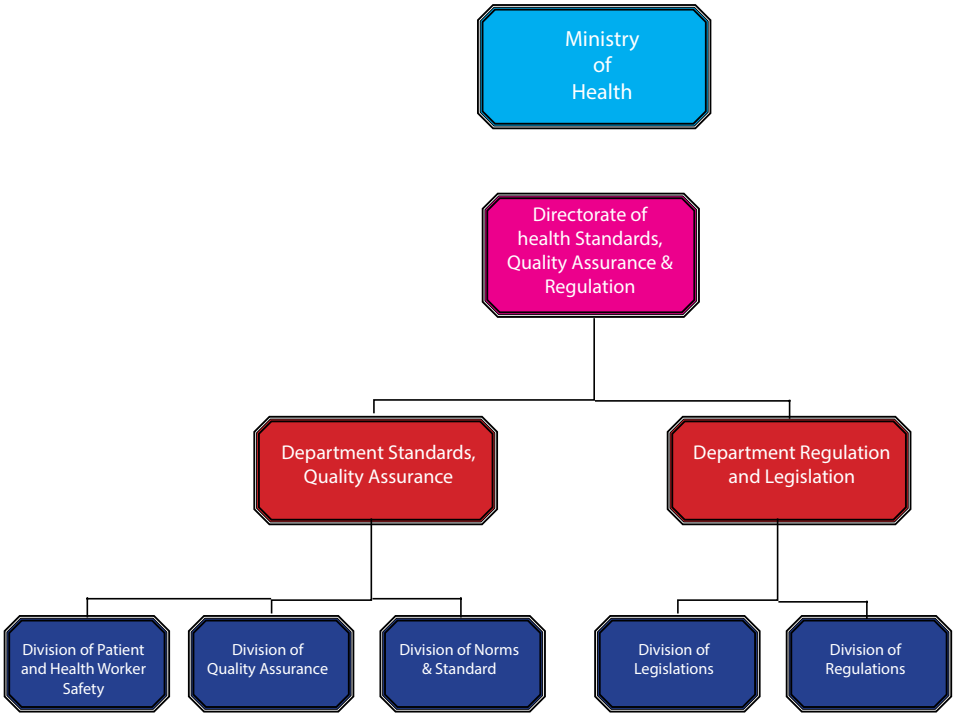


Figure 2-Organizational Structure of the Directorate of Health Standards, Quality Assurance and Regulation

There is the National Patient Safety Advisory Committee (NPSAC) is tasked with overseeing matters pertaining to patient safety. However, a gap exists in mechanisms for addressing matters concerning health worker safety in the health sector which are currently under the umbrella of the Division of Occupational health and safety.

There is need to develop a linkage between the NPSAC and the Division of Occupational health and safety to ensure issues of patient and healthcare workers safety are addressed as an entity.

2.1.4 Stakeholder involvement

To ensure patient safety, healthcare worker safety and quality there is need to have a multisectoral approach to all necessary interventions. Key stakeholders include but not limited to:

Ministries' Departments and Agencies (MDAs) at the National and County Governments

1. Develop policies on safety and quality of care
2. Provide resources (financial, human and physical) in support of safety and quality of care interventions

National Patient Safety Advisory Committee (NPSAC)

1. Promote safety and quality of health care at all care levels
2. Monitor safety and quality of health care at all levels, including coordination of the process of national patient safety situation analysis and collection and analysis of other designated patient data
3. Track available human, material and financial resources of the country
4. Promote development of safety and quality of care human resources
5. Promote safety and quality of care research

1. Technical advice and support on safety and quality of care
2. Supplement governments provision of resources

Professional associations and regulatory bodies

1. Provided direction for healthcare workers by developing such items as practice standards and guidelines and ethics statements

Service providers (Public, Private and Faith Based)

1. Conduct regular safety situation analyses.
2. Develop an annual plan for safety improvement activities.
3. Develop written safety policy and protocols aligned with national policy.
4. Each health care institution will develop a plan for sensitization campaigns for health care workers aligned with the national policy.

Professional Training institutions

1. Professional training instructions will integrate safety and quality of care content in the training and education programme

Other key stakeholders include Non-Governmental Organizations (NGOs), Private sector, Civil Society Organizations, Judiciary, National Antimicrobial Stewardship Interagency Committee (NASIC), National IPC Advisory Committee IPC, County Antimicrobial Stewardship Interagency Committee (CASIC), County IPC Advisory Committees (CIPCAC, Infection Prevention Network Kenya (IPNET), Infection Control Africa Network (ICAN), Global Patient Safety Collaborative (GPSC).

Despite having multi stakeholder involvement coordination is still a challenge, leading to duplication of interventions and sub-optimal uptake of recommendations.

2.2 Healthcare worker education, training, performance and protection

To protect healthcare workers and to ensure enhanced patient safety and quality of care, education, training and capacity building for personnel in the health sector is imperative.

The Ministry of Health has developed training curricula on IPC and OSH for all healthcare workers at all levels of care.

Pharmacovigilance and OSH are advanced disciplines with training provided up to Master's level. However, training is only for some healthcare cadres and there is a need to incorporate elements of this training across all health worker training.

Training has been ongoing on IPC, WASH and OSH however there is low coverage, inadequate monitoring and impact assessment of the primary level facilities.

It is difficult to estimate the number of appropriately trained and skilled staff in IPC, WASH and OSH. Multiple trainings take place within the frames of different programs and projects, at different levels of care both at the national and county government and in many cases, they are not well documented.

Periodic assessments of knowledge and skills of IPC, WASH and OSH practices among different cadres of healthcare workers has not been done in the entire health sector. Curricula on patient and health worker safety and quality of care have not been developed. However, a module on patient safety has been incorporated within the IPC curriculum.

2.3 Health facility infrastructure.

Infrastructure in the health sector refers to four main components, namely Buildings (Medical and Non – Medical), Equipment (Medical and Hospital Equipment), Information Communication and Technologies (ICTs) and Transport Services of various categories. Majority of the physical buildings are dilapidated, inadequate space and not prioritized by national /counties as areas of critical investments but influenced by political leaders.

Patient safety relies on more than just internal operations and care, it spans all the way to the infrastructure of the healthcare facility itself. Having standard and conforming infrastructure in place helps create a safe environment which ensures better outcomes for health workers, for patients and their families.

Notable gaps include inadequate number of healthcare facilities, inadequate equipment and supplies as well as nonconformity with norms and standards(MOH, 2014).

2.4 Key Safety Concerns

2.4.1 Prevention and control of healthcare associated infections (HAIs)

Health care-associated infections (HAIs) are those infections that patients acquire while receiving health care. The term HAIs initially referred to those infections linked with admission to an acute-care hospital (earlier called nosocomial infections), but the term now includes infections developed in various settings where patients obtain health care (e.g., long-term care, family medicine clinics, home care, and ambulatory care). HCAIs are infections that first appear 48 hours or more after hospitalization or within 30 days after having received health care(Haque et al., 2018). There must be evidence that the infection was not present or incubating. They also include infections acquired by patients in the hospital or facility but appearing after discharge, and occupational infections among staff.

HAIs occur globally and account for infections with an incidence of 7% in developed and 10% in developing countries *(Khan et al., 2017)*.

HAIs endanger the safety of anyone who enters the health care setting: patients and their families, clients, health care workers (HCWs), and support staff.

Organization for Economic Co-operation and Development (OECD) suggests that 15% of hospital expenditure and activity in OECD countries can be attributed to treating safety failures, including health care–associated infections. These failures result in lost capacity and productivity of patients, HCWs, and communities, as well as a loss of trust in health systems, governments, and social institutions

In addition to physical risks, the COVID-19 pandemic has placed extraordinary levels of psychological stress on health workers. Before COVID-19 hit, medical professionals were already at higher risk of suicide in all parts of the world. A recent review of health care professionals found one in four reported depression and anxiety, and one in three suffered insomnia during COVID-19. WHO recently highlighted an alarming rise in reports of verbal harassment, discrimination and physical violence among health workers in the wake of COVID-19. (WHO 2020).

Kenya has developed a national HAI surveillance guidance on the common HAIs in the patient population which include device associated and procedure associated while the occupational health policy guidelines for healthcare sector in Kenya 2014 has featured the protection and promotion of workers' health by preventing and controlling occupational diseases and accidents as a basic element.

To ensure compliance with evidence-based best practices in care delivery processes, quality improvement acts as a prevention mechanism against HAI outbreaks stemming from poor quality care. It addresses this issue by placing quality at

need every time they need it and at the same time ensuring the safety of the caregivers.

2.4.2 Prevention of occupational hazards

Occupational diseases in healthcare workers are adverse health conditions the occurrence or severity of which is related to exposure to factors on the job or in the work environment. These factors can be physical, chemical biological, ergonomic, psychosocial, mechanical. (WHO, EM/OCH/085/2000)

The World Health Organization (WHO) estimates that sharps' injuries contribute 30% of new cases of HBV and 2.5% of annual infections of HIV among health care workers in Sub-Saharan Africa (WHR 2002).

Occupational Exposure to Blood and Body Fluids and HIV Post-exposure Prophylaxis in Health Care Facilities in Kenya 2011 – 2014 report indicates that exposure to HIV and other bloodborne pathogens is high and that access and adherence to postexposure prophylaxis is suboptimal. The emergence of highly infectious diseases increases the infection risk dramatically.

In addition to this, healthcare workers are confronted with hazards unique to their work environment. For instance, lifting and rolling immobilized or disabled patients exposes workers, especially nurses to back injuries. Hazard identification, risk assessment evaluation and management, medical surveillance of occupational wellbeing and compensation mechanisms are fundamental in addressing healthcare workers' plight (Occupational safety and health policy guidelines for the health sector in Kenya).

Violence against health personnel is a widespread problem, with more than 50 per cent of health-care workers having experienced violent incidents at work (International Council of Nurses et al., 2002). Within the health sector workers may suffer violence at the hands of either patients or others outside the service but patients may also be the victims of health workers, and this means that violence is not only a safety issue but also a threat to delivery of quality care. The impact of this is that it affects not only the victim but the work environment as a whole, causing unease, insecurity, and fear even among staff or patients who are not the direct victims; the impact on efficiency and working conditions can be significant.

Currently, the implementation of occupational and safety health guidelines has not been uniformly implemented across the health sector therefore exposing health care workers to occupational and mental health hazards.

CARE SETTINGS

The main goal of safety and health programs is to prevent workplace injuries, illnesses, and deaths, as well as the suffering and financial hardship these events can cause for workers, their families and patients. However, in the Kenyan Health sector, individual programs have quality improvements (QI)/ Quality of care (QoC) embedded in their programs. Some programs like HIV and TB have continued to involve their clients on adherence to medication by encouraging them to have "drug buddies" and enhancement of pharmacovigilance in therapy, the introduction of safety engineered needles and deployment of technology in surveillance of occupational exposures and PEP uptake for the Healthcare worker.

Physical and psychological safety of the healthcare worker is an important aspect and should be a core component of the quality of care & safety in healthcare settings. As healthcare workers provide care, they are exposed to physical injuries from patients and psychological disorders resulting from the fear of being attacked by the patients as well as stress attributed to the lack of required resources to provide care. Ministry of health has developed structures for psychosocial support for healthcare workers at different levels of care for both the patient and the caregivers.

This cascading of safety and Quality improvement principles have resulted to increased safety and quality of care within specific programs. However, there has not been a significant horizontal spread of these principles resulting in some programs performing well in the quality of care and others being left behind. Therefore, there is a need for mainstreaming Quality and Safety activities across to the entire health sector.

3.1 Patient and healthcare worker safety and quality research

Research has not been prioritized in this domain. More research is crucial for the transformation of low-quality health systems to high-quality ones. Health care professionals in Low- and Middle-Income Countries (LMIC) are mostly preoccupied with care of the patients with limited time to engage in systematic health research. This is worsened by the biomedical approaches to research, with little scale in implementation research, which could help/ motivate HCW to contribute to what works in their settings.

Time and resources for research in Kenya are scarce for HCW. Data collection, analysis, dissemination and publishing are not factored in routine health facility budgets.

Data sources are in some instances incomplete, not comprehensive and not easily retrievable because of the lack of digitalization. In some cases, the hard copies are kept at home with patients. The formal structure for persons identification and civil registry makes population health research difficult. Rigorous research in quality improvement is low, and more synergy between quality improvement and systematic measurement of health outcomes need to be strengthened.

3.2 Quality of care

Quality of care is fundamental in delivery of Universal health coverage. It is estimated that 60% of deaths in lower and middle-income countries (LMICs) are due to poor quality of care. About 8 million deaths per year in LMICs are the result of poor-quality care indicating that poor quality care in the health system is responsible for a greater number of deaths than insufficient access to care. The total number of deaths from poor-quality care is estimated to be five times higher than annual global deaths from HIV/AIDS (1 million), and over three times more than deaths from diabetes (1.4 million) *(Kruk & Pate, 2020)*.

User experience, system competence, confidence in the system, and the wellbeing of people, including patient- reported outcomes are key pillars in quality of care but have not been prioritized. A global study found that only 28% of Kenyans believed their health system works well and only requires minor changes. For health systems to be responsive and resilient to shocks, inbuilt quality controls and monitors are essential *(Kruk & Pate, 2020)*.

developed a training curriculum on patient safety to address this.

Adherence to clinical standards is key to provision of quality care. It was however noted that only 44% of providers complete recommended clinical actions during sick child visits on(Kruk et al., 2018). A study on medical errors at Kenyatta national Hospital indicated that out of 927 medication errors the most common error-type was inappropriate duration which contributed to 71.2% while the least was inappropriate indication (1.4 %) *(Huldah et al., 2015)*.

The incidence and epidemiology for Medical Errors (ME) in the country is largely unknown. Despite the awareness of the need for medical error reporting being high in most Kenyan institutions, a great proportion of the errors go unreported. (WHO). Kenya lacks a comprehensive national incident and reporting system for ME however, the Pharmacy & Poisons Board (PPB) pharmacovigilance website offers a platform for Adverse Drug Events (ADE) reporting.

Timeliness of health care provision is of great importance in offering quality services, however, a study showed that only 43% of women delivering in a facility had a provider check on them within one hour of delivery, a critical window for detecting complications. Breast, cervical cancer and TB treatment is often delayed by many weeks. Surgical procedures result in infections for one in ten African patients(Kruk et al., 2018).

To address the above and other issues, the Ministry of Health developed several standards including the Kenya Quality Model for Health. This is a conceptual framework with an integrated approach to improving quality of care to regulate the health services provided within the Kenyan health sector in terms of patient and health worker safety, quality of care and client satisfaction. Further to this, the Ministry developed a Quality-of-Care Framework for the Kenyan Health Sector (Ministry of Health, 2020) that provides standards for health facilities to holistically and systematically address organizational quality issues with the main aim of delivering positive health impacts. Despite the obvious benefits of regulation of the quality-of-care provision, health facilities in the country have not followed a defined structure for Certification and Accreditation with very few health facilities seeking to continuously improve quality of care.

4.1 Vision

A safe, respectful and responsive quality health care system for a healthy, productive and globally competitive nation

4.2 Mission

To build a resilient health care system with an excellent culture of safety and quality of care with minimal risks and free from preventable harm through appropriate strategies, actions, positive client experiences, and partnerships.

4.3 Goal

To improve patient and health workers safety and quality of care at all levels of the health system across the continuum of care.

This policy shall provide guidance for improving the healthcare delivery environment to ensure safety and quality of health care services provided and establishing a strong governance and coordination mechanism.

This policy will be guided by the following objectives;

5.1 Policy objective 1: to strengthen governance and coordination mechanisms

This policy aims to establish effective and responsive leadership, governance and coordination mechanisms to deliver on patient and health workers safety and quality of care.

The priority policy strategies include the following:

i. Strengthen leadership, governance, and coordination structures at all levels of care

ii. Develop, review and implement laws, policies, guidelines, strategies and frameworks for patient and health worker safety and quality of care

iii. Allocate a budget to support patient and health worker safety and quality of care programs at all levels of care.

iv. Strengthen Implementation of the M&E framework for patient and health workers safety and quality of care

v. Establish an independent entity to oversee patient and health workers safety and quality of care at all levels

vi. Establish a system to provide consumer information on availability and quality of healthcare services

5.2 Policy objective 2: To protect the patient from avoidable harm while undergoing care.

This policy aims to prevent and reduce risk, errors and avoidable harm that occurs to patients during the provision of health care. The priority policy strategies include the following:

i. Build reliable and resilient systems to support patient safety

ii. Promote safe clinical processes

iii. Improve patient and family centered care

iv. Enhance health worker education including pre-service training, skills and competencies

v. Build capacity for research, risk management and information sharing

5.3 Policy objective 3: To maintain health and promote the overall wellbeing of health workers by protecting them from occupational hazards

The policy will provide guidance on protection of health care workers from occupational risks, hazards and accidents at the workplace. The priority policy strategies include the following:

i. Strengthen Occupational Safety and Health (OSH) Services at all levels

ii. Promote transparency, openness and no blame culture at the workplace for incident learning and reporting

iii. Ensure a safe working environment through identification and control of hazards and risk management

documentation and claim processing

5.4 Policy objective 4: To ensure provision of quality healthcare services

This policy provides guidance for the provision of quality health care services which are safe, effective people centered, timely, integrated, efficient and equitable.

The priority policy strategies include the following:

i. Include quality and safety standards as regulatory requirements for registration and accreditation

ii. Empower health workers through training on safety and quality of care

iii. Establish structures to support quality and safety of care in health systems

iv. Strengthen professional competency in healthcare safety and quality of healthcare

v. Enhancing positive experiences for clients and patients during utilization of health and related services

vi. Strengthen information management and research in safety and quality of care

These define how the health sector will be structured to facilitate the attainment of the four policy objectives for patient and health workers safety. The key action areas, where investments will need to be made to facilitate the attainment of the policy objectives as follows:

6.1 Health leadership and governance:

Oversight required for delivery of services. This relates to how the oversight of the delivery of safe and quality health and related services shall be provided. The policy aspiration is for a comprehensive leadership that delivers on patient and health workers safety. The policy focuses on six priority areas under leadership and governance in as follows:

i. Governance, management systems and functions shall be established to support patient and healthcare workers safety interventions

ii. Partnership and coordination of healthcare delivery

iii. Engaging of public and private services providers to ensure functional strategic partnership and coordination mechanisms in support of patient and health workers safety.

iv. Planning and monitoring systems and services

v. Health regulatory framework and services

vi. Governance structures for safety and quality management shall be established and aligned with national, county and facility operational and accountability channels.

6.2 Organization of service delivery:

Organizational arrangements required for delivery of safe and quality services;

i. Health services shall continuously be well-coordinated while promoting smooth transitions across the continuum of care.

ii. Health services shall be well coordinated to ensure risks are minimized, while ensuring that preventable harm is eliminated during care provision.

iii. Care shall be provided in line with best practices, ensuring that inputs, processes standards are established, implemented and monitored for desired outcomes.

iv. Organization-wide Quality Assurance and Quality improvement programs shall be developed and implemented.

v. Quality and Safety indicators shall be determined, reported and documented at all levels.

6.3 Health workforce:

Human resources required for provision of safe and quality services;

i. Reviewing and applying evidence-based health workforce norms and standards for the different tiers of services delivery

ii. Advocate for recruitment, support, management and retention of health care workers appropriate skills and competencies

iii. Strengthen intersectoral collaboration on health worker and patient safety, with appropriate worker and

iv. Establish a blame-free and just working culture through open communication, supported by legal and administrative protection from punitive action when reporting adverse safety events;

v. Provide access to mental well-being and social support services for health workers, including advice on work–life balance and risk assessment and mitigation.

vi. Strengthen Occupational incident reporting, documentation and management for healthcare workers safety and protection in accordance with regulations.

6.4 Financing for the patient and health workers safety policy:

This policy shall guide the process of:

i. Mobilizing and managing required finances to ensure provision of safe and quality health care services.

ii. Progressively facilitating access to safe and quality services through adequate mobilization, allocation, and

iii. efficient utilization of financial resources to support patient and health workers safety

iv. Progressively build a sustainable political, national, and community commitment to resource allocation for patient and health workers safety.

6.5 Health products and technologies:

Essential medicines, medical supplies, vaccines, health technologies, and public health commodities required for provision of quality services;

This policy aims at ensuring that effective, safe, quality and affordable health products and technologies are available, safely and rationally used at all times.

6.6 Health information:

Establish Systems for generation, collation, analysis, dissemination, and utilization of health-related information to enhance patient and health workers safety;

The policy aspires for adequate health information from incident reporting and learning to provide an evidence-base for corrective action and decision making.

The target consumers include health workers, health managers, policymakers, clients and all other actors in the health sector, with a view to guiding their decision-making processes. This will be attained through focusing on implementation of the following strategies:

i. Develop integrated metrics of patient safety, health worker safety and quality of care indicators, within health information systems providing comprehensive data

ii. Collaborating, harmonizing, and integrating data collection, analysis, storage, and dissemination mechanisms on patient and health workers safety to ensure availability of adequate and complete information for decision making;

iii. Continued strengthening of accuracy, timeliness, and completeness of health information from incident reporting and learning systems;

iv. Generating and managing information to guide evidence-based decision making in the provision of safe and quality health care services at the national and county levels.

through established channels in a manner that meets safety and confidentiality requirements, in accordance with the health research and information policies, regulations, and standards.

vi. Putting in place health surveillance, response and reporting mechanisms to ensure patient and health workers safety;

vii. Progressive utilization of information and communication technologies to aid service delivery;

viii. Facilitating access to safety and quality information to the public while protecting privacy and confidentiality of data.

6.7 Health infrastructure:

Physical infrastructure, equipment, transport, and information communication technology (ICT) needed for provision of services;

Health infrastructure relates to all the physical infrastructure, non-medical equipment, transport, and technology infrastructure (including ICT) required for effective delivery of services by the national and county governments and other health service providers.

The goal of this policy is to:

i. Guide the provision of adequate, safe and appropriate health infrastructure.

ii. Ensure a network work of functional, efficient, safe, and sustainable health infrastructure based on the needs of the clients and existing norms and standards

6.8 Research and development:

Creation of a culture in which research plays a significant role in guiding policy formulation and action to improve

the quality of care in all levels.

i. Health care research shall be resourced and prioritized as an enabler for information and knowledge generation for Safer and Improved health.

ii. Routine incident reporting on patient safety and Healthcare worker incidence shall inform areas of emphasis for systematic measurement and possible intervention

iii. Health care workers skills in operational research shall be enhanced, while enhancing the ability to address the know-do gap in the priority Quality and Person safety areas at the National, county and facility level.

iv. Develop integrated metrics of patient safety, health worker safety and quality of care indicators, within health information systems providing comprehensive data

6.9 Patient centered care

For the investments in the WHO building blocks to assure desired outcomes, there is need to create an enabling environment. This will require that patients are engaged, at various levels, given that responsiveness as an outcome, is from the patient's perspective. Addressing access and coverage of care, assures that families do not suffer catastrophic health expenditure when seeking care. Quality and safety of care will ensure that the patients will access care that is effective, efficient while not suffering harm.

Policy shall further outline the strategies that enable optimal engagement of patients, design, delivery and evaluation of health services.

7.1 Institutional framework

This policy will be implemented within the context of the existing Health Policy (2014-2030) and other relevant policy documents. This policy is also alive to the functional assignments between the two levels of government with respective accountability, reporting, and management responsibilities.

The successful implementation of this policy will be dependent upon the collaborative efforts and synergies of all the stakeholders and actors.

Under the existing legal and other government policy frameworks, this policy will be implemented through five-year National Strategic Plans, Multi-year County Sectoral Plans, and Annual Plans.

7.2 Stakeholders in patient and healthcare worker safety and quality of care

The policy implementation process will adopt a multisectoral approach involving different stakeholders—state actors (government ministries and agencies) at the national and county levels; clients/consumers (individuals, households, communities); regulatory bodies; professional associations; health workers unions; non-state actors (civil society organizations [CSOs], FBOs/nongovernmental organizations [NGOs], the private sector); and development partners.

The following are the key health sector actors and their respective roles in implementing this policy:

No	Stakeholder	Roles
1.	National government ministry and semi-autonomous government agencies (SAGAs) responsible for health	Establish and facilitate an institutional and management structure to coordinate and manage delivery of the constitutionally defined health mandates and services at the national level while championing the implementation of this policy Allocate adequate resources for implementation of the policy
2.	County government departments and entities responsible for health	Establish and facilitate an institutional and management structure to coordinate and manage delivery of the constitutionally defined health mandates and services at the county level while championing the implementation of this policy Allocate adequate resources for implementation of the policy
3.	Clients/consumers	Adoption of appropriate health practices and healthcare-seeking behaviors. Demand for quality health care services and providing feedback on experience of care.
4.	Non-state actors (Private sector, NGOs, FBOs, CSOs, Media, Insurance providers) and Development partners	Compliment government in health service delivery while implementing the policy, advocacy & demand creation for safety and quality of care. Mobilizing resources for health service delivery, designing and implementing interventions. Promote transparency and accountability in healthcare provision.
5.	Training Institutions	Capacity building conducting relevant research in patient and healthcare worker safety and quality of care

Table 2-Key health sector actors

A comprehensive M&E framework shall be developed. Programmed monitoring and evaluation at management and technical levels through a Monitoring and Evaluation Framework is necessary to ensure that objectives are met. The M&E framework is expected to utilize the relevant provisions of the National Integrated Monitoring and Evaluation Systems (NIMES) and have clear terms of reference for relevant stakeholders in data collection and reporting at all levels.

The implementation of this policy will be tracked using a set of targets and indicators that will be elaborated in the National and County Multi-year Plans. These plans will be implemented and monitored through annual work plans and medium-term plans.

The policy will also be reviewed through a mid-term review. The targets will be benchmarked against best practices from across the globe.

The policy will capture and share knowledge generated during the design and implementation phases, ensure that related activities build on each other's efforts to make a significant difference, identify gaps that may need further research, facilitate evidence sharing that will enable the programme to adapt and apply best practices.

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