**TITLE OF PROPOSAL**

Standardization of Patient Safety in Healthcare Service Sectors

**Presenters**

1. Francis Mose Lead Auditor -Lead Auditor

Moi Teaching and Referral Hospital

[ntabomose@gmail.com](mailto:ntabomose@gmail.com)

0722902067

1. Flora Kibet Lead Auditor – Lead Auditor

Moi Teaching and Referral Hospital

[Florahkibe10@gmail.com](mailto:Florahkibe10@gmail.com)

0726017454

**Scope of proposed project**

New Document

**Purpose and justification:**

Patient safety is a framework of systematized activities that forms cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks during conveyance of health care. It intentions to prevent and reduce the prevalence of avoidable harm, make error less likely and reduce its effect 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 Canadian Patient Safety Dictionary also defines Patient safety as the “*reduction and mitigation of unsafe acts within the healthcare system, as well as through the use of best practices shown to lead to optimal patient outcomes*.” (The Canadian Patient Safety Dictionary, October 2003).

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).

The Institute of Medicine has identified six aims for improvements to achieve the ideal healthcare system as outlined below.

**key dimensions of healthcare quality**

1. **Safe:** Avoid injuries to patients from care that is intended to help them. ​
2. ​**Effective**: Provide care based on scientific knowledge regarding who will likely benefit, and restrain from providing care when it is not likely to benefit a patient.
3. **Patient-Centered:** Care is respectful and responsive to patient preferences, needs, and value.
4. ​**Timely:** Wait times and harmful delays for those who receive and provide care are eliminated.
5. ​**Efficient:** Care is provided in ways that avoid waste, including waste of equipment, supplies, ideas, and energy. ​
6. ​**Equitable:** Care does not vary in quality because of the patient’s personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

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 (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.

The following gaps were identified despites existing laws:

1. The existing, legislations, policies and guidelines have not been adequately synergized to address patient safety and quality of care
2. Where legislation, policies and guidelines exist, implementation is poor owing to inadequate dissemination, access, and adherence.
3. Inadequate monitoring and evaluation of implementation of the existing laws, policies and guidelines
4. That only 44% of providers complete recommended clinical actions during sick child visits on average (Kruk, Global Lancet Quality Commission 2018).
5. The incidence and epidemiology for Medical Errors 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. Kenya lacks a comprehensive national incident and reporting system for medical errors however, the Pharmacy & Poisons Board pharmacovigilance website offers a platform for Adverse Drug Events (ADE) reporting.
6. Timeliness of health care provision is of great importance in offering quality services, 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, Global Lancet Quality Commission 2018).

In addressing the above including 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. Additionally, the Ministry developed a Quality of Care Framework for the Kenyan Health Sector in 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.

**Global Perspectives**

The occurrence of adverse events due to unsafe care is likely one of the 10 leading causes of death and disability in the world. In high-income countries, it is estimated that one in every 10 patients is harmed while receiving hospital care. The harm can be caused by a range of adverse events, with nearly 50% of them being preventable.

Each year, 134 million adverse events occur in hospitals in low- and middle-income countries, due to unsafe care, this result in 2.6 million deaths annually.

Globally, as many as 4 in 10 patients are harmed in primary and outpatient health care. Up to 80% of harm is preventable. The most detrimental errors are related to diagnosis, prescription and the use of medicines. It is estimated that, 15% of total hospital activity and expenditure is a direct result of adverse events.

Investments in reducing patient harm can lead to significant financial savings, and more importantly better patient outcomes.

**Causes of patient harm**

An established health system takes into account the growing complexity in health care settings that make humans more prone to mistakes. Example,

a patient might receive a wrong medication due to mix-up in packaging similar drugs. In this case, the prescription passes through different levels of care starting with the doctor, pharmacy and finally to the nurse who administers the wrong medication to the patient. Had there been safe guarding processes, this error could have been swiftly identified and corrected.

In this situation, a lack of standard procedures for storage of similar medications, poor communication channels, non-existence of verification systems to administration of drugs and not involving patients in own care giving might be underlying factors leading to errors.

Usually, the provider who actively made the mistake would take the blame for such an incident and as a result might also be punished. Regrettably, this does not take into account factors in the system that led to the occurrence of latent errors. It is when multiple latent errors align that an active error reaches the patient.

To error is human, and expecting flawless performance from human beings working in complex, high-stress environments is unrealistic. Assuming that individual perfection is possible will not improve safety. Humans are guarded from making mistakes when placed in an error-proof environment where the systems, tasks and processes they work in are well designed. Therefore, focusing on the system that allows harm to occur is the beginning of improvement, and this can only occur in an open and transparent environment where a safety culture prevails. This is a culture where a high level of importance is placed on safety beliefs, values and attitudes and shared by most people within the workplace.

**The burden of harm**

Millions of patients die or suffer injuries annually due to poor and unsafe health care. The emerging risks and medical practices associated with health poses a major challenge for patient safety and this gives a burden of harm due to unsafe care.

**Patient Safety Errors of Concern in Health Care Setting**

* 1. **Medication errors**; they are the leading cause of avoidable harm and injury in health care setups, globally it is estimated that every year the cost associated with medication errors is US$ 42 billion.
  2. **Health care-associated infections.** In High and low income countries, 7 and 10 out of every 100 hospitalized patients get infections during Health care giving.
  3. **Unsafe surgical care procedures.** Up to 25% of patients complications and almost 7 million surgical patients suffer with complications associated every year.
  4. **Unsafe injections practices** This may transmit infections, HIV and hepatitis B and C, and this dangers patients and health care workers*.*
  5. **Diagnostic errors** occur in about 5% of adults in outpatient care settings, more than half of which have the potential to cause severe harm
  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** involve overexposure to radiation and cases of wrong-patient and wrong-site identification
  8. **Sepsis** is frequently not diagnosed early enough to save a patient’s life. Because these infections are often resistant to antibiotics, they can rapidly lead to deteriorating clinical conditions*.*
  9. **Venous thromboembolism (blood clots)** is one of the most common and preventable causes of patient harm, contributing to one third of the complications attributed to hospitalization.

Patient Safety is a fundamental component for Universal Health Coverage in Kenya. Safety of patients during the provision of health services that are safe and of high quality is a prerequisite for strengthening health care systems and making progress towards effective universal health coverage (UHC) under Sustainable Development Goal 3.

Provision of safe services will a reassure and restore communities’ trust in their health care systems.

Recognizing Patient Safety as a global health priority, the World Health Assembly adopted a resolution on Patient Safety which endorsed the establishment of World Patient Safety Day to be observed annually by Member States on 17 September.

The Patient Safety and Risk Management unit at WHO has shaped the patient safety agenda globally by focusing on driving improvements in some key strategic areas through:

1. providing global leadership and fostering collaboration between Member States and relevant stakeholders
2. setting global priorities for action
3. developing guidelines and tools
4. providing technical support and building capacity of Member States
5. engaging patients and families for safer health care
6. monitoring improvements in patient safety
7. conducting research in the area

**Feasibility of the activity**

There are no known factors that could hinder the successful establishment or global application of the standard.

**Timeliness of the standard to be produced:**

Technology is practically stabilized and the advances in technology may not render the proposed standard out-dated. If the standardization activity is, or is likely to be, the subject of regulations or to require the harmonization of existing regulations, this should be indicated. If a series of new work items is proposed having a common purpose and justification, a common proposal may be drafted including all elements to be clarified and enumerating the titles and scopes of each individual item.

**Relevant documents and their effects on global relevancy:**

WHO has developed guidelines on patient safety but lacks a standard way of implementation of the set guidelines**.**