A MODEL OF PAIN MANAGEMENT USING OPIOID ANALGESICS IN PALIATIVE CARE NURSING IN KENYA

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A model of pain management using opioid analgesics in Palliative Care Nursing in Kenya

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DECLARATION

This Thesis is my original work and has not been presented for a degree in any other University.

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DEDICATION

This work is dedicated to all the nurses and other healthcare professionals who commit to provide care to cancer patients and others suffering from life- limiting illnesses. It is also dedicated to patients who struggle to find comfort and hope to enjoy their final days as well as their family members and care givers who provide constant presence and support to the patients to add life to their days as opposed to days to their lives.

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LIST OF ACCRONYMS AND ABBREVIATIONS

AIDS- Acquired Immunodeficiency Syndrome

APCA- African palliative Care association

BMC- Biomedical Central

BPS- Behavioral Pain Scale

CPD- Continued Professional Development

EAPC- European Association of Palliative Care

FLACC- Face, Leg, Activity, Cry, Consolability Scale

HIV- Human Immunodeficiency Virus

ICN- International Council of Nurses

ICU- Intensive Care Unit

IMMPACT- Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials

LMIC- Low & Middle Income Countries

KEHPCA- Kenya Hospice and Palliative Care Association

KNWR – Kenya Nursing Workforce analysis Report

KRSP- Nurses' Knowledge and Attitude Survey Regarding Pain

MOH- Ministry of Health

MTP- Mid Term Plan

NACOSTI- National Commission for Science, Technology & Innovation

NCD- Non Communicable Diseases

NHIF- National Hospital Insurance Fund

NICE- National Institute for Health and Care Excellence

PAINAD- Pain Assessment In Advanced Dementia scale

PC- Palliative Care

PCAU- Palliative Care Association of Uganda

POS- Palliative Outcome Scale

PQRST- Palliative/ precipitating factors, Quality, Region/ radiation, Severity & Timing.

SDG- Sustainable Development Goals

UHC- Universal Health Coverage

USDHHS- United States Department of Health and Human Services

WHO- World Health Organization

WMA- World Medical Association

OPERATIONAL DEFINITION OF TERMS/NOMECLATURES

Chronic illnesses- It is a disease that has slow onset and progression and is characterized by periods of remission and exacerbation (Lewis et al., 2016).

Impeccable pain assessment- This is a faultless, flawless evaluation of the reported pain and the factors that alleviate or exacerbate it, as well as the response to pain management interventions, in accordance with the highest standards of propriety (free dictionary).

Innovation- an innovation is an idea, practice, or project that is perceived as new by an individual or other unit of adoption" (Wayne, 2019).

Life- limiting illness- a condition where it is anticipated that death will be a direct consequence of the specified condition. Such illnesses may include, but are not limited to: carcinoma, cardiovascular disease, chronic obstructive pulmonary disease, dementia, cardiac failure, neurodegenerative disease (Macauley, 2019).

Metaparadigms- A set of theories or ideas that provide structure for how a discipline should function. For a nursing discipline, these theories consist of four basic concepts that address the patient as a whole, the patient's health and well-being, the patient's environment and the nursing responsibilities (McEwen & Willis, 2014).

Model- Models are schematic representations of some aspect of reality. **Nursing models** are constructed of **theories** and concepts used to help **nurses** assess, plan and implement patient care by providing a framework within which to work (McEwen & Willis, 2014).

Oncology and Palliative care nurse specialists- These are nurses who hold a Master's degree in Oncology and /or palliative care.

Pain An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage (International Association for the Study of Pain, 2020).

Pain management- for purposes of this study constitutes the process of assessing for pain by collecting both objective and subjective data from the patient where possible and choosing the most appropriate intervention to manage the symptom as well as monitoring for the outcome.

Palliative care - an approach whose aim is to improve the quality of life of patients and their families facing serious issues associated with life-threatening illnesses, through the prevention and relief of pain and suffering by means of early detection and impeccable assessment of pain and other problems to include physical, psychological and spiritual issues (WHO, 2018).

Palliative care experts- For purposes of this research these are healthcare workers who hold a basic degree in a health related field or a post basic diploma in palliative care and are in clinical practice or teaching.

Palliative care nursing is the holistic care of patients with advanced progressive illness who are unresponsive to curative treatment which involves management of pain and other symptoms as well as the provision of psychological, social and spiritual support (Schroeder, 2018).

Universal Health Coverage- Means that all people have access to the health services they need, when and where they need them, without financial hardship (WHO Fact Sheet, 2021).

ABSTRACT

Satisfactory pain management is an essential component of palliative care which emphasizes on pain and symptom management in life-limiting disease. The three phased descriptive, analytical cross sectional research aimed at developing a Model of pain management by use of opioid analgesics in palliative care (PC). It was conducted in Machakos and Embu county referral Hospitals located in Eastern Kenya which were purposively sampled. In phase one, participants were systematically sampled from nurses working in the two hospitals. Data was collected by use of questionnaires, cleaned, coded and entered in Epidata 3.1 then and analyzed using Stata version 14.0. This phase adopted Diffusion of Innovations theoretical framework. In phase two and three qualitative data was collected via key informant interviews and thematically analyzed based on Classical Grounded theory. Presentation of results was done by use of tables, charts and narratives. The results showed that the level of knowledge of nurses on pharmacology of opioid analgesics was low. Hypothesis testing showed no significant relationship between knowledge of general pharmacology of opioids and education level of the nurses. Most respondents reported lack of awareness of the recommended pain management guidelines. Commonly used pain assessment tools included history taking and physical examination and use of numerical rating scales, Wong's Faces and Palliative/ precipitating factors, Quality, Region/ radiation, Severity & Timing (PQRST) methods. The most preferred pain management tool was the World Health Organization (WHO) analgesic ladder. Gaps identified in the pain assessment tools included lack of provision for monitoring of & management of side effects and inability to assess pain in special populations. There was no standard recommended Model of pain management in PC hence participants recommended need to address the identified gaps. In conclusion there exist many barriers to pain management by use of opioid analgesics hence there is need for continued professional development for healthcare professionals. Additionally, the Government needs to develop sound policies to govern the use of opioids. Gaps identified in pain management guidelines such as lack of capacity to manage special populations and monitor treatment outcomes can be addressed by use of the appropriate tools like Behavioral Pain Scale (BPS), Face, Leg, Activity, Cry and Consolability (FLACC) plus the emergent Model.

CHAPTER ONE

INTRODUCTION

1.0 Background information

Pain is an enormous problem affecting most people especially those suffering from life- limiting conditions. Globally, it has been estimated that about 20% of adults suffer from pain while another 10% are diagnosed with chronic pain each year. It affects all populations, regardless of the socio- demographic and economic status (Goldberg, 2011). Pain is a chief concern in medical care, and its influence has been well recognized, to an extent where it is considered one of the ‘‘vital signs’’ in some countries for example in America while in some European countries it is used as an indicator for the quality of medical and nursing care (Morone & Wainer, 2013).

The International Association for the Study of Pain (IASP) defines pain as “An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage (IASP, 2020). Globally about 60 million people are estimated to have chronic pain prevalence closer to 20-25 percent in some countries and regions (Jackson & Stabile, 2015). Studies performed in different settings have revealed that chronic pain affects between 10% and 30% of the adult population in Europe (Reid et al., 2011). Indeed, a recent study showed a 16.6% prevalence of this condition among the general population in Spain, with at least one person affected in every four Spanish homes (Dueñas et al., 2016).

A study conducted to estimate the pooled prevalence of chronic pain in the general population in Low and Middle Income Countries (LMICs) revealed that overall pooled prevalence was 18% (Sá et al., 2019). Similarly, a systematic review by Morris et al. investigating the prevalence of low back pain in Africa revealed that the life time prevalence of low back pain among African populations was substantially higher than the revealed global low back pain prevalence estimates (Morris et al., 2018).

In Sub- Saharan Africa studies have shown a high prevalence of pain among cancer patients. For instance a study done among cancer patients in South Africa and Uganda revealed a pain prevalence of 87.5% despite their participation in palliative care services. Over and above patients with fatal malignancies, patients with chronic conditions also experience untreated pain. For instance a study conducted in Kwazulu – Natal, revealed the prevalence of pain to be 59% to 98% among HIV/AIDS patients in South Africa, Uganda, and Kenya (Bhengu et al., 2011). Additionally, low back pain which is a major cause of chronic pain has been shown to have an estimated lifetime prevalence of 50 to 80% (Kahere, 2020).

In Kenya a study conducted in a referral hospital in Western Kenya revealed a chronic pain prevalence rate of 80.5% among the hospitalized patients with 30% of them reporting moderate to severe pain. It also showed that 66% of those with moderate to severe pain had undertreated pain (Huang et al., 2013).

Good health as enshrined in Sustainable Development Goal (SDG) number 3 is essential to sustainable development and the interconnectedness between the two is reflected in 2030 Agenda for sustainable development. It takes into account the emerging burden of non-communicable diseases such as cancer among other challenges. Target 3.8 of SDG 3 aims to achieve Universal Health Coverage (UHC), including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines for all which has implications for a wide range of Non Communicable Diseases (NCD)- related promotion, prevention and treatment interventions. Universal Health Coverage therefore is considered integral to achieving SDG 3 (Singh Thakur et al., 2021).

Enshrined in the Sustainable Development Goals (SDGs), Universal Health Coverage aims to provide health security and universal access to essential care services without financial hardship to individuals, families and communities (WHO-Organization for Economic Co-operation and Development (OECD), 2018; pp16, para 1). Universal Health Coverage means that all people have access to the health services they need, when and where they need them, without financial hardship. It includes the full range of essential health services, from health promotion to

prevention, treatment, rehabilitation, and palliative care (WHO fact sheet, 2020). The World Health Organization (WHO) definition of Universal Health Coverage (UHC) includes 'palliative care' as an 'essential health service'. The safe, effective, quality, and affordable essential medicines needed for palliative care include internationally controlled medications such as morphine, unavailable in more than 80% of the world (Fraser, 2017).

As nations commit to achieving Universal Health Coverage by 2030, it should be acknowledged that improvement in health care delivery requires a deliberate focus on quality of health services, which involves providing effective, safe, people-centred care that is timely, equitable, integrated and efficient. Quality care aims at increasing the likelihood of desired health outcomes in line with the current professional knowledge (WHO, OECD, 2018; pp11, para 1).

Worldwide 20 million people are estimated to require Palliative Care at the end of life (EOL) every year, of which 69% are adults over 60 years old (United Nations population Fund, 2012). The prevalence of most of the life limiting illnesses increases markedly with age. Under current trends, increased longevity in Low and Middle Income Countries is likely to triple the number of people who live to the age of 65 years by 2050 (Worldwide Palliative Care Alliance, 2017). The global movement to achieve UHC, and SDG3, which focuses on ensuring healthy lives and wellbeing for all people and at all ages, provides new opportunities to expand access to palliative care at a time when need is increasing rapidly (WHO UHC Fact Sheet, 2021).

World Health Organization (WHO) has defined 'palliative care' as an approach that aims at improving the quality of life of patients and their families facing serious problems associated with life-threatening illnesses, through the prevention and relief of pain and suffering by means of early identification and impeccable assessment of pain and other problems to include physical, psychological and spiritual issues (WHO Factsheet, 2020).

Publicly funded palliative care services integrated into primary care under Universal Health Coverage, an objective under Target 3.8 of the Sustainable Development

Goals (SDGs), is both ethical and sustainable. It aligns with the 2030 Agenda, adopted by all UN member states in 2015, and offers a "best buy" for member states. According to the 2018 Lancet Commission Report, "Alleviating the access abyss in palliative care and pain relief- an imperative of universal health coverage," most governments, including the Low and Middle Income Countries (LMICs), can afford to make that choice and provide what has been defined as an "essential package" of palliative care to address serious health related suffering (Knaul et al., 2018).

Kenya's Vision 2030 which was launched in 2008 as a development blueprint covering the period 2008 to 2030 was aimed at making Kenya a newly industrializing, "middle income country providing high quality life for all its citizens by the year 2030." The Social Pillar of the Kenya Vision 2030 seeks to invest in the people in order to improve the quality of life for all Kenyans by targeting a cross-section of human and social welfare projects and programmes with Health as a key sector. To improve the overall livelihoods of Kenyans, the country aims to provide an efficient integrated and high quality affordable health care system. Improved access to health care for all will come through provision of a robust health infrastructure network countrywide as well as improvement of the quality of health service delivery to the highest standards among others (Electronic project Monitoring Information System Kenya, 2015).

During the third Mid Term Plan (MTP), Kenya conceptualized the big Four agenda with an aim to accelerate the achievement of the country's Vision 2030 aspiration, by focusing on those issues that would have the greatest impact on the well-being of the people. One of the pillars of the big four agenda is affordable health care. The aim is to increase the current Universal Health Coverage (UHC) from 36% to 100% by the year 2022 through scaling up National Hospital Insurance Fund (NHIF) uptake, increased budgetary allocation to health and adoption of low cost service delivery models. This agenda conforms to the third Sustainable Development Goal (SDG 3) - To ensure Good health and well-being for all, at every stage of life (Mutinda, 2020).

In the year 2010 Kenya promulgated a new constitution in which the government provided the necessary legal framework for guaranteeing a comprehensive and

people driven health care delivery aimed at enhancing access to quality and affordable health care. The Constitution introduced a devolved system of governance with two tier government systems namely the County and National government with the goal of enhancing utilization and geographical access to quality care by all Kenyans (Oketch, 2018).

With the implementation of the new constitution the Government has adopted initiatives aimed at realization of Universal Health Coverage to include abolition of user fees in primary health care facilities as well as free maternal health care services. Recently, the government made a concerted effort to implement Universal Health Coverage and settled on National Hospital Insurance Fund (NHIF) as a vehicle towards the realization of the UHC. Unlike most insurance companies, NHIF provides medical cover for all cases including patients requiring hospice and palliative care (Okech & Lelegwe, 2016). Good as they were these initiatives were faced with challenges to include inadequacy of finances, supplies and equipment as well as drugs procurement challenges which affected health care provision in the devolved system of government (Kirwa & Letting, 2017).

Millions of people suffering from Non communicable diseases (NCDs) e.g. cancer live and die with severe pain and other debilitating symptoms which can be effectively treated and managed at affordable cost. The annual incidence of cancer word wide is estimated to be 14.1 million. Of these 4.7 million are in High Income Countries while nearly 5.3 million are in Low and Middle income countries. In High Income Countries, cancer is ranked as the second most common cause of death with cardiovascular conditions taking the first position. Epidemiological evidence points to the emergence of a similar trend in Low and Middle Income countries ((WHO-NCD facts, 2018).

Pain has multiple, serious sequelae including but not limited to physical effects such as immobility, psychological effects such as depression and suicidal thoughts; occupational problems such as inability to work, and disrupted social relationships. It affects the psychological wellbeing causing fear ,anxiety , demoralization, a feeling

of helplessness, depression, fatigue, loss of control and sleep disturbances which may contribute to the patients' overall pain experience (Goldberg, 2011)..

Pain has an economic impact as shown by evidence from studies carried out in different countries which revealed that patients who are affected by pain present with problems of absenteeism from work. Additionally they may be forced to change their occupational duties or post, or even end up being laid off from their jobs as a result of their pain symptoms. Absenteeism may also affect satisfactory performance at work thereby lowering productivity and adversely affecting the ability to fulfill certain obligations (Gaskin, 2012; Dueñas, et al., 2016).

Pain has also been shown to lead to social isolation owing to the fact that the effects of chronic pain are not independent to the patient, but also extend to their family and significant others. Intractable pain can demoralize and depress the patient, relatives and caregivers, especially when there is no effective pain control or hope for relief. This has been shown to cause family members to stop participating in social activities (Cosia, 2019).

Pain has persistent and untreated effects on most of the systems of the body where it results in development of complications, chronic pain, and increased length of hospital stay. Of particular importance to nursing care, undertreated pain causes patients to be immobilized which may result in complications such as deep vein thrombosis, pulmonary embolus, decubitus ulcers and pneumonia (Shahriari et al., 2015).

Pain management is an essential part of caring for people with a life- limiting illness hence relief of pain is a human right. The goal of pain management throughout the life cycle is to address the various dimensions of pain and to provide maximum relief with minimum side effects (Fishman, 2013). Pain management involves assessment of pain intensity and carrying out interventions. Pain intensity as reported by the patient is the gold standard for pain assessment. The three most commonly used scales are the numeric rating scale (0 to 10) whereby 0 represents no pain while 10 indicates worst possible pain; The patient is asked to rate their pain on a scale of 0 –

10: 0 = no pain; 1-3 mild pain; 4- 6 = moderate pain; 7- 10 = severe pain (Hui & Bruela, 2014).

In Africa and especially the sub Saharan Africa there are enormous looming epidemics of cancer and other non-communicable diseases. Most of these patients experience moderate to severe pain during the diseases trajectory. Unfortunately, most of these people typically lack access to medication, appropriate technology and palliative care services (Kamonyo, 2018).

Health care puts emphasis on acute care and care of chronically ill patients with stable conditions but patients with progressive illness are generally a neglected group. According to WHO, one reason why pain control has been relatively slow to develop is that opioid analgesics, while considered by international health authorities to be essential medicines, have had stringent regulations governing their use as narcotic drugs, by government law enforcement and drug regulatory agencies to prevent diversion and abuse. This has led to over 80 percent of the world's population having no access to opioid pain relief, even though morphine is included on the World Health Organization (WHO) list of essential medicines (WHO Palliative care Fact sheet, 2018). Consequently, the cancer and palliative care population is faced with a unique challenge regarding how to cooperate with government drug control and law enforcement agencies, leading to reform of excessively restrictive opioid control policies at every level- International, National, and State/ county where applicable (MOH Kenya, 2013).

There are two known approaches in the strategy for pain management, and in palliative care: evaluation of the pain, and the treatment (management) of the pain. To adopt the appropriate management, it is important to determine: the origin of the pain, the situations in which the pain is more intensive, the quality of the pain, the route of propagation of the pain, and the degree and the intensity of the pain. Additionally, successful Pain management interventions depend on the choice of method used which could be pharmacological or non- pharmacological (Sholjakova et al., 2019).

Many medications are available to block pain at various pain pathways. Types of chronic pain medication used include Non-steroidal anti-inflammatory drugs and opioid analgesics and steroids (for management of pain accompanied by inflammation). Opioid analgesics are indicated for the control of moderate-to-severe pain among patients with life threatening illnesses to include HIV&AIDS, cancer and other painful disease conditions **(**Morelli, 2017).

Opioids have been regarded for long as among the most effective drugs for the treatment of pain. Their use in the management of acute severe pain and chronic pain related to advanced medical illness is considered the standard of care in most parts of the world. A study conducted in Norwegain hospitals revealed that most patients with life limiting illnesses use opioids during the end of life to manage distressing symptoms (Wergeland, 2019). Strong opioids are a cornerstone of pain treatment, of which morphine is considered essential by the WHO. In 2007, the International Association for Hospice and Palliative Care (IAHPC) developed a list of Essential Medicines in Palliative Care, which includes opioids for the treatment of pain and other symptoms (Lima, 2014).

Literature has also shown that opioids are commonly prescribed for pain in the United States whereby an estimated 20% of patients presenting with non-cancer pain symptoms or pain-related diagnoses (both acute and chronic pain) receive an opioid prescription. Unfortunately prevention, assessment, and treatment of chronic pain are challenges for health providers hence pain might go unrecognized, and patients, especially the elderly, persons with cognitive impairment, and those with cancer and at the end of life, can be at risk for inadequate pain treatment. Patients should receive appropriate pain treatment based on a careful consideration of the benefits and risks of treatment options (Dowell et al., 2016).

The long-term administration of an opioid for the treatment of chronic non-cancer pain however continues to be controversial (United States Department of Health and Human Services, 2015). This is despite the fact that the Center for Disease Control and Prevention's 2016 guidelines for prescribing opioids for chronic pain state that

"clinicians should consider opioid therapy only if expected benefits for both pain and function will outweigh risks to the patient (Guy et al., 2017).

Commonly used opioids globally are morphine and Dihydrocodeine. Morphine, an opioid agonist, derived from the opium poppy has long been known to relieve severe pain with remarkable efficacy. It remains the standard against which all drugs that have strong analgesic action are compared. Dihydrocodeine is a semi-synthetic opioid analgesic prescribed for pain or severe dyspnea either alone or compounded with Paracetamol or aspirin (Rana et al., 2011).

Morphine is a full agonist at the μ (mu) opioid receptors, the major analgesic opioid receptor producing analgesia, as well as the euphoria, respiratory depression, sedation and physical dependence. Dihydrocodeine is a semi-synthetic opioid analgesic prescribed for pain or severe dyspnea either alone or compounded with Paracetamol or aspirin. Dihydrocodeine is metabolized to Dihydromorphine a highly active metabolite with a high affinity for μ opioid receptors. The analgesic properties of Dihydrocodeine are believed to come from its conversion to morphine. It is used for the treatment of moderate to severe pain, including post-operative and dental pain. It can also be used to treat chronic pain, breathlessness and coughing. In heroin addicts, Dihydrocodeine has been used as a substitute drug (Trevor et al., 2014).

The WHO Analgesic Ladder provides a step -wise approach to pain management**.** The main principles of analgesic choice to achieve efficacy are based on the analgesic ladder. This staged approach to the prescribing of analgesia allows flexibility for different intensities of pain as it increases the analgesic effect (Raffa, 2014). The ladder as reported by Stjernswärd specifies treatment on pain intensity, from simple analgesics for mild pain to opioid analgesics for moderate and severe pain. Its four steps are: Step 1 Non-opioid plus optional adjuvant analgesics for mild pain; Step 2 Weak opioid plus non-opioid and adjuvant analgesics for mild to moderate pain; Step 3 Strong opioid plus non-opioid and adjuvant analgesics for moderate to severe pain (Yang, et al., 2020). Step 4 includes numerous non-pharmacological procedures that are robust recommendations for treating persistent

pain, even in combination with the use of strong opioids or other medications (Pergolizzi & Raffa, 2020).

Like all pain medications, opioids come with side effects, the most common of which include: Constipation, nausea, sedation, and increased risk of falls and fractures in the short term and depression and/or sexual dysfunction after prolonged use (Manchikanti, 2011). With repeated use, a high degree of tolerance occurs to all of these effects. Despite the side effects the benefits of morphine in chronic pain management cannot be ignored. Effective and safe titration of opioid analgesics has a major impact on patient comfort. It also prevents respiratory depression (Rana, et al., 2011).

Palliative care (PC) aims at improving quality of life for people who have serious or life-threatening illnesses. It affirms life hence regarding dying as a normal process; it neither hastens nor postpones death. The end goal is to preserve the best possible quality of life until death i.e. adding life to the days of the patients as opposed to adding days to their life. The goal of palliative care is not to cure but to prevent or treat, as early as possible, the clinical manifestations and side effects of the disease and its treatment, in addition to the related psychological, social, and spiritual problems. Palliative care is not offered as a replacement to primary medical treatment instead it is provided to complement the other forms of treatment (Luo et al., 2016).

Palliative care is distinguished from comprehensive care in progressive disease by its clinical dimensions, particularly in control of pain and other distressing symptoms. It also differs from hospice in that it is provided at any time during a life- limiting or life-threatening illness, while hospice care is available only at the end of life. This kind of care is provided when curative or life-prolonging treatments have been stopped. Therefore, palliative care is not restricted only to those in the hospice (Connor & Cecilia, 2014). Additionally, Palliative care can address a broad range of concerns, incorporating an individual's specific needs into care. The physical and emotional effects of cancer and its treatment as well as other life limiting illnesses may greatly differ from person to person. For instance, differences in age, cultural

orientation, or support systems may lead to very different palliative care needs. Comprehensive palliative care should therefore, take into account the physical, emotional and spiritual aspects of a patient (Rome, 2011).

In the context of palliative care Virginia Henderson (1997) defined nursing as: 'primarily assisting the individual in the performance of those actions contributing to health and its recovery, or to a peaceful death.' The statement suggests three concepts: partnership, helping and dignity which are central to the palliative care approach to nursing (Saba et al., 2012).

In Kenya palliative care is offered in homes, Hospitals and hospices depending on the client's preferences and affordability. There are more than 70 institutions providing palliative care, including hospices for home care, inpatient units in government hospitals, private hospitals, faith-based institutions, and community-based centers distributed across the country (Kamonyo, 2017). Palliative care is provided by a multidisciplinary team, which is usually composed of doctors, nurses, physiotherapists, occupational therapists, and pharmacists, social workers, specialists, spiritual advisors, dieticians, massage therapists, home health aides, volunteers, and others (Bowen, 2014).

Kenya Hospices and Palliative Care Association (KEHPCA) is a National association formed to represent all palliative care service providers in Kenya. The mission of Kenya Hospice and palliative Care Association (KEHPCA) is to scale up palliative care services focusing mainly on integrating palliative care into the health care system at all levels of care, improving national policies, ensuring access to essential medicines, improving education and training, and advocating for the legal aspects of palliative care (Fraser et al., 2018).

To achieve this Mission KEHPCA has been working with the Government Ministries and Departments to ensure that Palliative Care is integrated into both legal and healthcare related policies to include National Palliative care guidelines, legal aspects in palliative care among others. Additionally KEHPCA advocated for inclusion of palliative care training in the curricular of all health professionals (Kamonyo, 2018). However efforts to advocate for change of legislation (in collaboration with the

Nursing Council of Kenya) to allow nurses to prescribe opioids in order to increase the pool of prescribers which has been a success story in Uganda, were unfruitful.

Optimizing quality of life for patients and their families through the use of symptom control and good supportive care may be significant at any point along the disease continuum. Palliative care may therefore be a good option for those with serious conditions requiring help to manage pain or other symptoms or to understand and cope with their conditions (Harding & Bonsall, 2019). However, limited access to palliative care services in Kenya is a major public health concern which calls for urgent attention. More than 80% of people living with cancer and other chronic illnesses can benefit from palliative care services if the nurses are empowered to assess pain and administer opioid drugs (Ministry of Health, Kenya, 2013).

Impeccable assessment of pain levels and monitoring of treatment outcomes is crucial in facilitating successful pain control in palliative care (Morreli, 2017). This is due to the fact that Palliative care patients especially those taking other medications e.g. chemotherapy suffer from many other side effects which can affect treatment compliance. It should be noted that monitoring of the effects of the medications by the nurse will also ensure that the side effects are noticed early and action taken. It is imperative for the care providers of patients on opioids to have sufficient knowledge on opioid pharmacology to include treatment side effects and how to manage them so as to ensure better pain control and adherence to treatment (Regnier, 2011).

Pain management is an integral part of the practice of nursing hence patient's pain cannot be left untreated. A study conducted in a hospital in Ethiopia revealed that nurse-based pain management programme positively influenced patient-reported pain intensity. Despite this, inadequately managed pain is highly prevalent in most hospitals and palliative care centres, due to a lack of appropriate care (Germosa, 2019). Despite the fact that pain management is a multidisciplinary process, nurses play a key role in pain management; Jeannine Brant described pain as a nurse-sensitive indicator (Brant, 2017). This implied that nursing interventions have a

direct impact on patient outcomes for pain and the quality of pain management that is delivered (Narsavage, 2017).

Although Palliative care requires a multidisciplinary approach with varied care teams depending on patient needs and available resources, the presence of a nurse is constant and constitutes the first link between team, patient and family. Thus, nurses play a central role in palliative care, acting in the best interest of patients and their families and providing care on a continuous basis (Pereira et al., 2018).

Nursing care of people living with and dying from life-limiting conditions is undertaken by mostly nurses who form majority of healthcare workforce in all settings and possess varying levels of expertise. In many clinical settings, nurses have a vital role in assessment of pain as well as monitoring for outcome of treatment. Literature has shown that Palliative care nurses strongly support the availability of comprehensive hospice and palliative care in all settings (Canadian Hospice Palliative Care Association, 2014).

In Kenya, the Ministry of Health in collaboration with Médecins Sans Frontières (MSF) introduced the concept of task shifting in management of non- communicable diseases. A study conducted in Kibera slums in 2016 demonstrated that nurses working within a resource-constrained, primary care and HIV setting can successfully follow protocols managing stable patients with multiple NCDs. This was a clear indication that nurses are able to adhere to protocols for managing stable NCD patients based on clear and standardized protocols and guidelines, thus paving the way towards task shifting of NCD care (Some et al., 2016).

The Nurses' model of pain management by use of opioids will be a conceptual model that prescribes various steps on how to assess and manage a patient on treatment with opioids in palliative care using the nursing process approach. These include history taking, impeccable pain assessment for all populations as well as administration of opioids specifically morphine and DF118, patient monitoring and management of treatment outcomes/side effects using a multidisciplinary approach.

1.1 Statement of the Problem

Pain is a major concern among those affected by life-limiting illnesses whose number has been shown to increase owing to increased longevity. Interestingly, despite the increased availability of strong opioid analgesics in most parts of sub-Saharan Africa pain resulting from advanced illnesses remains under- treated. This is attributed to difficulties in assessing pain, and ineffective monitoring of symptoms, fear of opioid analgesics effects and lack of access to drugs (Scarborough & Smith, 2018).

Untreated or poorly executed pain management plans put people at risk for depression, irritability, fatigue and an overall diminished quality of life. Further, it leads to increased cost of living by prolonging hospital stay as well as reducing productivity of individuals and families (Goldberg, 2011).

In Kenya, like in most African countries, studies have shown evidence of pain being undertreated due to the existence of barriers to pain management (Ali et al., 2011 & Al- Marhezi, 2017; Huang et al., 2013). However, the barriers to pain management using opioids in palliative care among nurses have not been studied. Additionally although poor performance in pharmacology has been recorded in nursing examinations, no specific assessments have been conducted to determine general knowledge on opioid pharmacology.

Despite the fact that nurses play a vital role in pain control, in Kenya nursing management of patients on opioids has not been standardized owing to lack of comprehensive guidelines and models on assessment and management of pain and other symptoms. The available guidelines to pain management in Kenya include the MOH palliative care guidelines which do not give a clear direction on monitoring and management of outcomes of opioid analgesics to avoid complications of therapy. Additionally, the Nursing models that have relevance in palliative care identified from reviewed literature including Virginia Henderson's need based theory, Jean Watson's theory of human caring, Faye Abdellah and Dorothea Orem's self- care deficit are not specifically tailored for Palliative care and especially for pain management by use of opioids (Craig, 2014).

The prevalence of most of the life limiting illnesses increases markedly with age. Under current trends, increased longevity in low and middle income countries is likely to triple the number of people who live to the age of 65 years by 2050 (World Palliative Care Alliance, 2014). This demographic shift is compounded by the entrenchment of modifiable risk factors such as smoking, sedentary lifestyle and obesity in most of the low-and middle income countries. In 2014 the estimated number of people in need of palliative care at the end of life was 20.4 million (Macaden et al., 2014).

1.3 Study justification

Nurses are deployed to work in all health facilities including the hard to reach areas where they provide care to patients with various conditions including those requiring home based care. Inadequate pain assessment is believed to be the leading barrier to adequate pain management. Recognition of pain should begin at pre-diagnosis and its assessment should include a detailed history, psychosocial evaluation and physical examination (Shute, 2013). One of the main reasons for poor pain management practices in Kenya has been due to lack of clear guidelines and Models, limited knowledge and access to opioids among other barriers.

By empowering nurses with knowledge, policies and guidelines to administer opioid analgesics, palliative care services will be easily accessible to ensure widespread pain and other symptoms control, and improvement in general care, support and quality of life for patients and families facing life limiting illnesses in Kenya.

Conceptual models articulate nursing issues and provide a theory-based nursing care for evidence-based nursing practice. They also enable nurses to organize an approach that maximizes use of nursing time, interventions and resources thereby improving patient health outcomes. A conceptual model will enable nurses to stop using medical models which limits nurses' critical thinking and creates dependence in the profession hence killing autonomy. Additionally it will provide a clear guideline and ensure standardization of pain management practice in palliative care. The study therefore wishes to address the gaps/limitations by developing a comprehensive

model of pain management to facilitate a seamless assessment and management of pain in palliative care.

It is envisaged that the Model of pain management by use of opioids will provide nurses working in Hospitals, hospices, palliative care units and home based care settings with useful tips that will help them manage pain for patients on opioids under their care. This will facilitate task shifting in care of patients with advanced NCDs to nurses to help relieve the significant healthcare gap created by shortage of specialists in low and middle income countries. Sound pain management practices will also go a long way to facilitate the achievement of SDG 3- To ensure Good health and well-being for all, at every stage of life.

Lastly, over the last five decades of theory development, review of the health care literature demonstrates that changes in health care, society, and the environment, as well as changes in population demographics such as aging and urbanization, have led to a need to renew or update existing theories and to develop different theories that fit contemporary issues. Furthermore Nursing scientists are finding that the theories that have guided practice in the past are no longer sufficient to explain, predict, or guide current practice (McEwen & Willis, 2014).

It was against this background that this research was undertaken with the aim of developing a conceptual model of pain management to guide palliative care. It is envisaged that adoption and utilization of a standard model of pain management that is customized to the Kenyan palliative care context, as well as implementation of the sound recommendations from the study would improve pain management practice in Palliative care.

1.4 Anticipated benefits of the study

The conceptual model will help nurses articulate nursing issues and provide a theory-based nursing care for evidence-based nursing practice. The successful adoption and use of this model will therefore empower nurses to administer opioid analgesics in a safe and competent manner in order to improve pain management in life limiting illnesses. Additionally recommendations from the findings of the research will be

utilized in advocating for sound policies aimed at improving pain management practices in Kenya. The model will generate further research in the area of palliative care and provide a tool for use in both classroom and clinical teaching.

1.4 Objectives of the study

1.4.1. Main objective

The aim of the study was to develop a model of pain management using opioid analgesics in palliative care.

1.4.2. Specific objectives

1. To determine the level of knowledge on general pharmacology of opioids among nurses working in Embu and Machakos County referral Hospitals.
2. To establish the barriers encountered by nurses working in Embu and Machakos County referral Hospitals while managing pain using opioid analgesics in palliative care.
3. To determine the modalities/guidelines of pain management used in palliative care in Embu and Machakos County referral Hospitals.
4. To establish gaps in the pain management guidelines used that contribute to inadequate pain assessment and management in Embu and Machakos County referral Hospitals.
5. To develop a Model of pain management using opioid analgesics for use in Palliative care.

1.5 Research questions

1. What is the level of knowledge on general pharmacology of opioids among nurses working in Embu and Machakos County referral Hospitals?
2. What are the barriers encountered by nurses working in Embu and Machakos County referral Hospitals while managing pain using opioid analgesics in palliative care.
3. What are the modalities/guidelines of pain management used in palliative care in Embu and Machakos County referral Hospitals?

4. What are the gaps in the pain management guidelines used that contribute to inadequate pain assessment and management in Embu and Machakos County referral Hospitals?
5. What is the suitable Model of pain management using opioid analgesics for use in Palliative care?

1.6 Hypotheses

The hypotheses for the study were:

H_o1: There is no relationship between nurses' level of education and level of general knowledge on pharmacology of opioid analgesics.

H_11: There is relationship between nurses' level of education and the level of general knowledge on pharmacology of opioid analgesics.

Ho2: There is no relationship between nurses' education level and the level of knowledge on recommended pain management guidelines.

H_12: There is relationship between nurses' education level and the level of knowledge on recommended pain management guidelines.

H_o3: There is no relationship between nurses' length of work experience and level of knowledge on recommended pain management guidelines.

H_13: There is relationship between nurses' length of work experience and the level of knowledge on recommended pain management guidelines.

1.7. Study limitations

The study had some limitations and hence adopted the delimitations indicated below:

1. Phase one of the study did not target opioid prescribers but the researcher relied on reports given by nurses who administer the prescribed medication. To mitigate this limitation medical doctors who are the opioid prescribers were interviewed in phase two and three to give their views on pain management guidelines and the Model respectively.

2. The study focuses only on two counties in the Eastern region of Kenya which were purposively sampled hence findings may not be generalizable to the entire country. The study population from these two counties had similar characteristics to those in other counties in Kenya hence the researcher believed participants from the other counties were likely to give similar results.
3. Some key players e.g. pharmacists were not interviewed as it was believed that they were not involved in direct care of patients.
4. The model of care may not address all the barriers to pain management as some require change of policy and legislation. Recommendations (not addressed by the model) were shared with policy makers in both counties and the National Government hence it is envisaged they will be addressed.

CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

This chapter which is organized into three sections gives a detailed explanation of the theoretical and conceptual frameworks guiding the research and on how this study fits into the current body of literature. It also gives a description of the philosophical perspective which determined the choice of paradigm of inquiry, epistemology and ontology of the research as discussed. The literature review discusses the relevant existing information relating to this study under the appropriate subheadings in accordance with the research objectives to include a review of the legislative imperatives governing handling of opioid analgesics in Kenya.

The review provides a detailed narrative on the literature that was studied to provide information on the research questions as well as to guide the development of the model. It also provides detailed information on the current pain management and the barriers that have caused a hindrance to effective practice. It also provides information about the conceptual models relevant to palliative care to include their nature and the argument about their usefulness in nursing practice and palliative care. This information is intended to provide insight on why it was necessary to conduct the current research and by extension develop the Model.

Sources of information included responses given by the participants regarding barriers to pain management as well as the commonly used, or institutional recommended pain management guidelines. Other literature sources involved the study and critical analyses of the commonly used pain management guidelines as reported by the participants as well as the Acts of parliament that regulate the handling and use of opioid analgesics.

Thorough literature review of textbooks and web information gave a detailed description of the existing nursing models as well as the guidelines that are applicable in the fields of palliative care. These were scrutinized to establish the

weaknesses/ gaps that justify the development of the Model of pain management by use of opioid analgesics in Kenya.

2.1 Theoretical framework

2.1.1 Introduction

A Theoretical framework is the structure that can hold or support a theory of a research study. The theoretical framework introduces and describes the theory that explains why the research problem under study exists (Kivunja, 2018). The importance of a theoretical framework is that it allows the reader to conceptualize the study in a broader context thus it should bring out detailed information to support the purpose of the research. Adoption of a theoretical framework also promotes rational and methodical practice by challenging and validating intuition (Grant, 2014).

2.1.2. Philosophy and Paradigm of inquiry

Scientific research philosophy is a system of the researcher's thought, in which new, consistent knowledge about the research body is obtained. It is the basis of the research, which involves the choice of research strategy, formulation of the problem, data collection, processing, and analysis (Žukauskas et al., 2017). The term "paradigm" on the other hand refers to the philosophical assumptions or to the basic set of beliefs that guide the actions and define the worldview of the researcher (Lincoln et al., 2011).

In educational research according to Mackenzie & Knipe, the term paradigm is used to describe a researcher's 'worldview'. This worldview is the perspective, or thinking, or school of thought, or set of shared beliefs, that inform the meaning or interpretation of research data. A paradigm tells us how meaning will be constructed from the data to be gathered, based on individual experiences (Kivunja et al., 2017).

Pragmatist philosophy holds that human actions can never be separated from the past experiences and from the beliefs that have originated from those experiences. Pragmatism is concerned with action and change and the interplay between knowledge and action. This makes it appropriate as a basis for research approaches

aiming at explanation & prediction, interpretation & understanding and Intervention & change (Kaushik, 2019).

As a research paradigm, pragmatism is based on the proposition that researchers should use the philosophical and/or methodological approach that works best for the particular research problem being investigated. According to Creswell and Clark (2011) pragmatic paradigm is often associated with mixed-methods or multiple-methods (Kaushik, 2019). Additionally according to Charmaz (2014) and Bacon (2012) Grounded Theory has been influenced by the Pragmatist philosophical tradition (Timonen et al., 2018). Considering that the researcher adopted a mixed method research design as well as Grounded Theory it was prudent to adopt pragmatism which is the recommended paradigm of inquiry.

2.1.3 Epistemological perspective

Epistemology as described by Levers (2013) is the theory or philosophical study of knowledge that is concerned with the grounds upon which we believe something to be true. Moreover, epistemology explains why our minds relate to reality and how these relationships are either valid or invalid. Epistemology is concerned with all aspects of the validity, scope and methods of acquiring knowledge, such as a) what constitutes a knowledge claim; b) how can knowledge be acquired or produced; and c) how the extent of its transferability can be assessed (Jackson, 2013).

Nursing epistemology has been defined as “the study of the origins of nursing knowledge, its structure and methods, the patterns of knowing of its members, and the criteria for validating its knowledge claims.” Like most disciplines, nursing has both scientific knowledge and knowledge that can be termed conventional wisdom i.e. knowledge that has not been empirically tested (McEwen & Willis, 2014).

Epistemology can be objective or subjective. A "subjectivist epistemology" is one that implies the standards of rational belief are those of the individual believer or those of the believer's community. Thus, subjectivism can come in either an individualistic form or a social form. Objective epistemology on the other hand is associated with critical practicality and proposes that knowledge is often used to explain, predict, and control events (Levers, 2013). Pragmatism is a research

philosophy based on the epistemology that there is no single way to learning but many different ways of understanding because there are multiple realities (Saunders, et al., 2012 & Collis, et al., 2014).

The research adopts mixed method approach hence both objective and subjective (pragmatic) epistemology were adopted owing to the fact that the participants would be required to be objective and factual in order to give their subjective views/ experience regarding use of opioid analgesics in the course of pain management endeavors which formed the basis of the study process. This was also guided by the pragmatic philosophical perspective and paradigm of inquiry which proposes use of both subjectivist and objective epistemology.

2.1.4 Ontological perspective

Ontology is the philosophical study of the nature of reality and how there may be different perceptions of what is known. Ontology is concerned with what actually exists in the world about which humans can acquire knowledge (Kaushik, 2019). It helps researchers recognize how certain they can be about the nature and existence of objects they are researching. Ontology views reality from two perspectives: The positivist ontology that believes that the world is external and that there is a single objective reality to any research phenomenon or situation regardless of the researcher's perspective or belief; and Relativist ontology the belief that reality is a finite subjective experience. Relativist ontology is based on the philosophy that reality is constructed within the human mind hence it is multiple and relative (Levers, 2013).

The research adopted pragmatic ontology based on the paradigm of inquiry. This was guided by the fact that some research questions aimed at collecting both quantitative and qualitative data which required one to apply dichotomous reality while others involved collection of qualitative data with multiple realities since the healthcare professionals have different levels of knowledge and understanding as well as views regarding pain management policies and interventions.

2.1.5 Research implication

Based on the choice of the paradigm of inquiry, philosophical, ontological and epistemological perspectives one would comfortably conclude that the perspectives were congruent with the qualitative and quantitative research methodology which were adopted in data collection in phase one (partially quantitative) and in phase two and three (fully qualitative). This is owing to the fact that the purpose of quantitative research is to generate knowledge and create understanding about the subject matter whereas qualitative research method gives the participants an opportunity to express their views regarding the subject matter in question.

2.1.7 Diffusion of innovations theory

Everett M. Rogers diffusion of innovations (1995) Model is the theoretical framework that underpins the first phase of the study. The theoretical framework was adopted with an understanding that the Model would be an innovation to the field of palliative care. The Diffusion of innovations theoretical framework was linked to a nursing theory (Classical Grounded theory) so as to bring a nursing concept into the research process during the development of the Model. Grounded theory has been an important methodology for nursing research since 1970 (Mediani, 2017).

Rogers describes diffusion as “the method by which an innovation is disseminated through certain means among the members of a social system over a given period of time. As articulated in this definition, innovation, communication channels, time, and social system are the four key constituents of the diffusion of innovations (Wayne, 2019).”

Diffusion of Innovations is a borrowed theory as it does not owe its origin to nursing practice. Borrowing theory from other disciplines is not unique to the nursing profession (Masters, 2015; Rodgers, 2018). Furthermore, advocates of borrowed or shared theory believe that, like other applied sciences, nursing depends on theories from other disciplines for its theoretical foundations. Some of the commonly borrowed theories and frameworks that have influenced the development of nursing theory include: General systems theory, social cognitive theory, stress and coping theory, general adaptation theories, and developmental theories. Villarruel and

colleagues as reported by Mete and Gocke, argued that borrowed theories "can be placed within a nursing context only if linked with a nursing frame of reference, that is, a conceptual model of nursing" (Mete & Gocke, 2014). The research therefore adopted Diffusions of Innovations theory upon linking it to Classical Grounded theory.

Diffusion of innovation theory explains how an idea for instance the model for pain management is disseminated throughout the population of interest. For purposes of this research the population constitutes the healthcare professionals working in nurse training institutions, hospitals, hospices and palliative care units. According to Rogers' definition of an innovation, the nurses' model of pain management by use of opioid analgesics in palliative care could be considered a good example of an innovation in palliative care.

2.1.17.1 The Mechanism of Diffusion

Rogers describes diffusion as the process by which an innovation is disseminated through a range of channels over a period of time among members of a social system. The theory is based on the fact that most innovations do require a long time from the time of dissemination to the time they gain full adoption and implementation in the relevant field. So diffusion is a form of social activation that may or may not occur after the dissemination of information has occurred. Diffusion can also occur without organized, intentional dissemination (Dearing & Cox, 2018).

The model of pain management in Kenya may not be an exception to the challenge of adoption. The researcher therefore appreciated the fact that the model was likely to take time before gaining full adoption in the palliative care setting which may be as a consequence of uncertainty. To mitigate this possibility there was clear communication to create understanding by the managers and the users detailing the use of the model as well as its positive attributes.

Diffusion being a process, by which an innovation is conveyed through certain channels over time among the members of a social system, has various mechanisms.

Each member of the social system faces his/her own innovation- decision that follows a 5-step process

- Knowledge – Creating awareness in a person regarding an innovation, who forms some idea about it but lacks complete information about its functioning.
- Persuasion – Individual becomes interested in the new idea and seeks additional information.
- Decision – He/ She decides either to accept or decline to adopt the innovation.
- Implementation – The person goes on to implement their decision by putting the innovation into use.
- Confirmation – One finally undertakes an evaluation of the results of the decision already made regarding the innovation (Kaminski, 2011).

It was envisaged that the nurse managers and palliative care specialists as the major adopters of the model would portray similar characteristics when the model is introduced to them. The five steps of the Innovation Process were adopted during dissemination and evaluation of the Model as follows: During evaluation process awareness was created to the healthcare professionals (who participated in the evaluation process) on the concept of the Model and how to apply it in the pain management practices. Generally they were convinced of its usefulness and were willing to apply it in practice and for clinical instruction. Upon accepting the Model it is envisaged that all the healthcare professionals will adopt it for use during pain management and for instructing students. Issues of concern were raised during the evaluation process to include insertion of a key to clarify the abbreviated terms plus another type of pain. With continued use the Model will be open for further research to determine its usefulness and value in palliative care.

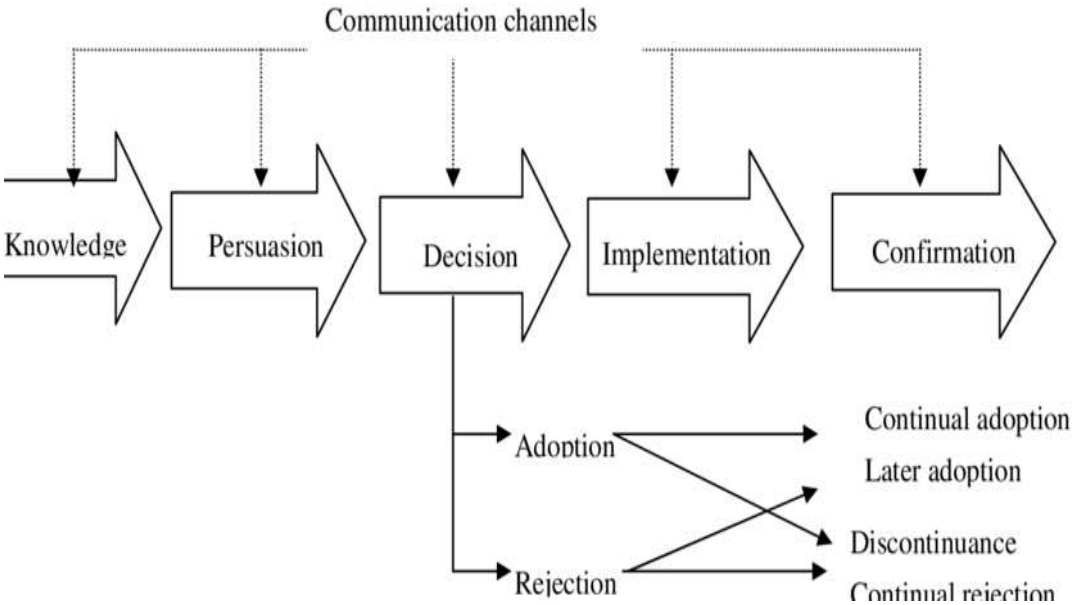

Figure 2.1: Illustration of 5 stages of Diffusion of innovations theoretical framework (adopted from research gate.net).

2.1.17.2 Factors influencing the diffusion of innovations process: There are four major interconnected factors that influence the diffusion of innovation. These are:

i) **The characteristics of the innovation**: The innovation refers to an idea or a practice that is considered as new by an individual. Rogers argues that the newness of an innovation is not determined by how long it has been in the field since its first use but rather by an individual perception as demonstrated by his /her reaction to it at first contact. If the individual considers the idea as new to them, it is believed to be an innovation (Johnson, 2013). In the context of this research though there has been existing policies and guidelines that guide pain management that nurses in Kenya have been using over time, the quest for clear guidelines outlining the distinct role of the nurse in this practice has not been adequately addressed. This model can therefore be considered an innovation in this practice.

ii) **The channel of communicating the information concerning the innovation**: Rogers defines communication as the process by which participants create and share information to be able to reach a common understanding. Diffusion refers to a unique form of interpersonal communication which is concerned with dissemination

and sharing of new innovations though most people do not evaluate the positive attributes of an innovation scientifically. He observes that instead they depend on subjective evaluation from those who previously adopted or rejected the innovation. This means that when opinion leaders adopt an innovation, social systems convert from one normative state to another (Readiness & Cox, 2018). Interpersonal communication was adopted during the results dissemination process in which the Emergent Model was communicated to the nurse administrators and users in the clinical area. Further, evaluation of its usefulness was done by conducting sensitization of the healthcare professionals in the clinical area.

iii) **Time:** Time is a very vital element in the diffusion process and should be observed any time communication is taking place. Rogers considers time as an aspect of every activity though ignored in most behavioral researches (Kaminski, 2011). In this research time was allocated for every activity. Care was also taken to ensure that time for research does not interfere a lot with the time allocated for patient care or interfere with office work during Key informant interviews. The Model was not complex hence it took little time to train the users and consequently little time will be required to implement it once internalized by all the users.

iv). **Nature of the social system into which the innovation is to be introduced**: Rogers defines the social system as a set of interrelated units that are engaged in joint problem solving to accomplish a common goal. Understanding this social system and the role of each team player is important in gaining insight into how diffusion of the model will take place (Eck et al., 2011). In the context of this research the social system refers to the health care team involved in provision of care to patients on opioid analgesics for pain management in life limiting illnesses. It is believed that these members share a common goal of ensuring that patients do not live or die in severe pain.

Rogers further refers to the system norms as patterns of behavior that are enshrined in any social system which can influence the acceptability of an innovation. He describes certain individuals who play a key role to affect diffusion of ideas in the

social system. These individuals are: opinion leaders and change agents (Masullo, 2017).

Opinion leaders are those who are regarded as informal leaders in that they are able to exert influence over others' attitude. This position is acquired through an individual's ability to socialize as well as to conform to the norms of the system (Eck et al., 2011).

Change agents on the other hand have been defined by Rogers as individuals whose ability to influence innovation is motivated by their educational preparation and social status within the social system. They may choose to work with the opinion leaders to influence acceptance of an innovation (Masullo, 2017).

The current guidelines on opioid use in palliative care settings mostly give direction on the practice of the Doctors who are prescribers of opioids but there is little or nothing to guide the nurse. A new model that is oriented to nursing practice and values may receive acceptance but this is yet to be established. For purposes of this research opinion leaders and change agents were the nurse managers and palliative care specialists and experts. During key informant interviews these professionals gave their views concerning the gaps in the commonly used pain management tools and guidelines and recommended the need for a Model over and above other recommendations to improve on the practice of pain management. Later the Model was delivered to them for approval to be used by other professionals in the clinical areas.

2.1.17.3 Strengths and limitations of the framework

Strengths -Diffusion research has been widely used by scholars, students and practitioners. This is because the diffusion model had a conceptual approach with significance in many professions nursing included.

Factors that influence adoption highlight the importance of the innovation itself, communication channels that spread information about the innovation and influence the adoption decision-making process as well as the nature of the society to whom it is introduced and its influence on adoption of decision-making.

Though the Roger's theoretical model is not nurse based, the 5 stages of the innovation adoption decision-making process mimic the five steps of the nursing process (assessment, nursing diagnosis, planning, implementation and evaluation) which would be adopted in the development of the Model of pain management.

Limitations -The framework is not originated to nursing hence it lacks the four metaparadigms common to all nursing theoretical models.

Its application in nursing has also not been verified.

2.1.8 CONCEPTUAL FRAMEWORK

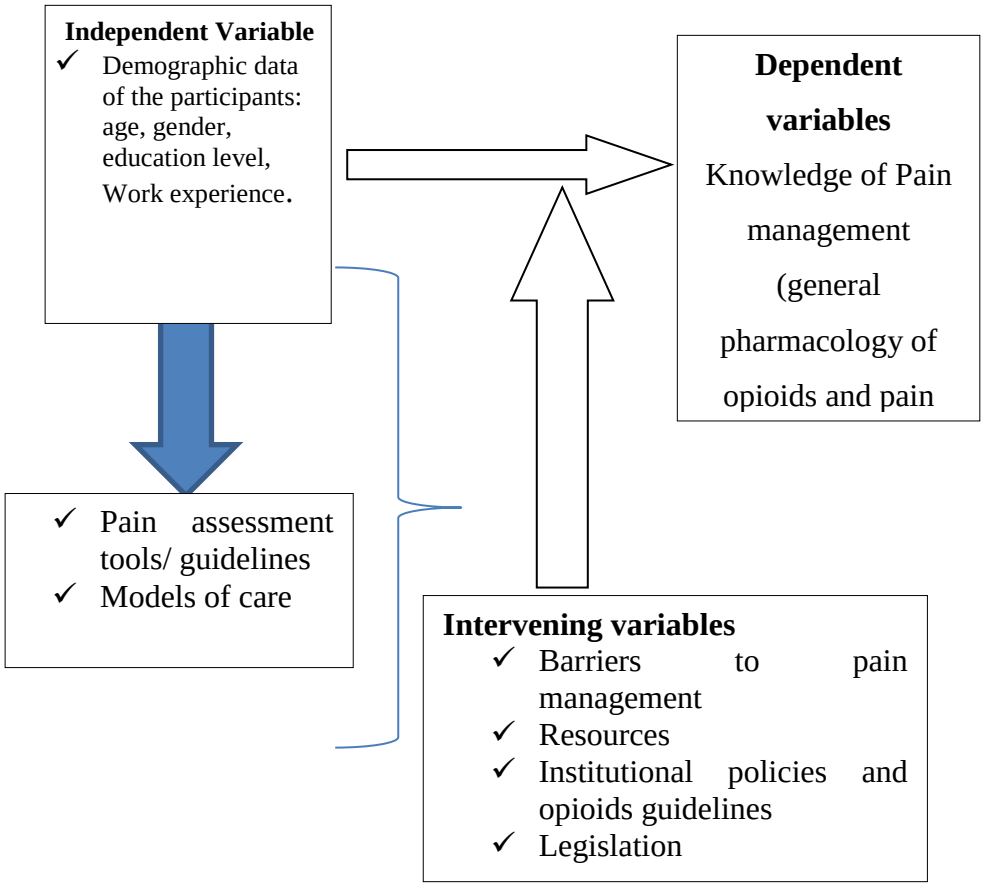

Figure 2.2: The conceptual framework to guide phase one of the study

2.1.9 Description of the conceptual framework

A conceptual framework has been defined as a visual or written product indicating either graphically or in narrative form, the main issues to be studied with an emphasis on the key factors, concepts, or variables and the presumed relationships among them (Jones & Montana, 2014). Research Variables can be classified into dependent, independent and confounding variables. An independent variable is the variable that is controlled in a scientific experiment to test the effects on the dependent variable while a dependent variable is the variable being tested and measured in a scientific study. It is usually manipulated to determine the value of dependent variable. It is affected by the independent variable (Kaur, 2013). A confounding variable also referred to as a mediator variable, can adversely affect the relationship between the independent variable and dependent variable if not well controlled (Shuttle worth, 2017).

2.1.10 Relationship between conceptual framework, theoretical framework & study objectives

The first phase of the study was based on a conceptual framework that is, Diffusion of Innovations theory. The baseline research aimed at establishing the nurses' level of knowledge on general pharmacology of opioids, barriers to pain management plus the commonly used guidelines for pain management. The results of this phase of the research were used to guide the development of the model.

According to Wejnert (2002), as cited by Hayward (2018) the Diffusions of Innovations conceptual framework groups the variables into three major components: characteristics of the innovation, innovators and the environmental context (Hayward, 2018). For purposes of this research the first and second components formed the Independent variables. These included: characteristics of the innovation itself, whose variables constituted the commonly used/ institutional recommended guidelines/tools and Models for pain management. The second component which involves the characteristics of innovators (actors) that influence the probability of adoption of an innovation, constituted the demographic characteristics of the nurses and other healthcare professionals who are presumed to be the users of the model

(actors). The third component involves characteristics of the environmental context that modulate the innovation process. Success in pain control by use of opioid analgesics is influenced by various factors. The research considers these as the intervening/ confounding variables to include policy and legislation, resources, personal values regarding opioids and other barriers to pain control. Knowledge of pain management being the outcome/dependent variable was considered a central concept in provision of palliative care to patients suffering from life-limiting illnesses. The outcome is dependent majorly on the characteristics of the actors and other variables. Successful pain management was attributed to knowledge of opioid pharmacology and that of recommended pain management policies. The first three objectives of the research aimed at collecting data as reflected in the study variables. The last two objectives were addressed during the subsequent phases of the research.

2.1.11 Interactions between the variables

Literature has revealed that the independent factors influence the magnitude of barriers to pain management. For instance the myths and misconceptions nurses hold towards administration of opioid analgesics to manage pain in palliative care may depend greatly on their level of training or years of work experience. Additionally, the confounding factors can affect the relationship between the dependent and independent variables. The researcher observed that institutional policies may stipulate some guidelines on pain management which may negate the role of the nurse in opioid administration. Personal, values of the health professionals regarding use of opioids and availability of the drugs may also influence their pain management practice. The legislative imperatives on the other hand may forbid the administration of opioid analgesics by some cadres in the health profession. All these factors affect the outcome which is effective pain management process.

2.1.12 Grounded theory

Grounded theory (GT) is an inductive research method that provides for the systematic generation of theory using qualitative and/or quantitative data generated from interviews, observation, or written sources such as documents (Mediani, 2017). The Grounded theory has proved to be very vital in development of both formal and substantive theories. A Substantive theory is developed from research conducted in

one specific area or contextual situation, such as patient care. Grounded theory further provides a particular set of systematic methods, which support perception from the data in order to develop a theory that is grounded in the empirical data (Vollstedt & Rezat, 2019).

Grounded theory was developed in California, USA by Glaser and Strauss during their study (Noble & Mitchell, 2016). Grounded theory is the methodology most-often cited by authors of qualitative studies in medicine especially in developing Models for medical practice or nursing care (Sbaraini et al., 2011). Glaser and Strauss originally worked together in a study examining the experience of terminally ill patients who had differing knowledge of their health status. During this investigation, they developed the constant comparative method, a key element of grounded theory (Tie et al., 2019).

2.1.12.1. Features of Grounded Theory

Openness- Grounded theory methodology emphasizes inductive analysis. This means that grounded theory studies tend to take a very open approach to the process being studied. Data collection and analysis occur simultaneously.

Data analysis- It involves the following steps:

a) **Coding and comparing**- Data analysis relies on *coding* - a process of breaking data down into much smaller components and labeling those components; and *comparing* - comparing data with data, case with case, event with event, code with code, to understand and explain variation in the data. The constant comparative method developed by Glaser and Strauss is deemed an original way of organizing and analyzing qualitative data. Coding is the pivotal link between collecting data and developing an emergent theory to explain these data (Tie et al., 2019). Straus and Corbin advocate for three stages of data analysis/ coding process as follows:

i) Open coding- this involves line by line coding where concepts and key phrases are identified, highlighted and moved into subcategories, then categories. This breaks the data down into conceptual components and the researcher can start to theorize or reflect on what they are reading and understanding hence making sense of the data

(Vaismoradi et al., 2016). Open coding allows the researcher to see the direction in which to take his/her research so as to become selective and focused conceptually on a particular problem.

ii) Axial coding- To develop a grounded theory, the emerging relationships between the elaborated concepts are integrated into an overarching framework with one core category. At this stage relationships are identified between the categories and connections identified (Vollstedt & Rezat, 2019).

iii) Selective coding- this involves identifying the core category and methodically relating it to other categories. The relationships must be authenticated and categories refined. Categories are then integrated together and a Grounded Theory established (Maupa, 2020).

b) Memo writing/ drawing diagrams- The analyst writes many memos/notes throughout the project. Memos can be about events, cases, categories, or relationships between categories. They are the storehouse of ideas generated and documented through interacting with data hence they provide detailed records of the researchers' thoughts, feelings and contemplations (Tie et al., 2011).

c**) Theoretical sampling used to refine categories**- By carefully selecting *participants* and by modifying the *questions* asked in data collection, the researchers fill gaps, clarify uncertainties, test their interpretations, and build their emerging theory. Theoretical saturation occurs when all of the concepts in the substantive theory being developed are well understood and can be substantiated from the data (Esperiera & Restrepo, 2018).

d) **Production of a substantive theory**- Categories are integrated into a theoretical framework; a set of concepts that are related to one another in a cohesive whole (Esperiera & Restrepo, 2018).

2.1.12.2. Classical Grounded theory- Glaser and Holton who are the proponents of classical Grounded theory advocate for 2 stages of coding: Substantive and theoretical coding. These coding stages are imperative to Classic Grounded Theory as they bind all the concepts of the methodology together in the

entire research process from conception to conclusion (Kenny & Fourie, 2015).

1. **Substantive coding**- this is divided into open and selective coding:

a) Open coding: - As data are collected and analyzed line-by-line, each incident is coded with a key word, which summarizes sections of data. Coded segments are fragmented from the transcript, compared to each other, and grouped conceptually/ categorized (Quresh &Unlu, 2020).

b) Selective coding: - the collection and coding of incoming data is selectively restricted to focus exclusively on relevant data (Quresh & Unlu, 2020).
2. **Theoretical coding** - the researcher conceptualizes the inter-relationships of the substantive concepts. This gives rise to an emerging grounded theory that can "account for the relationships between the concepts thereby explaining the latent pattern of social behavior" (Kenny & Fourie, 2015).

2.1.13 Justification for using Grounded theory

The research adopted classical Grounded theoretical framework. Grounded theory provides a methodology to develop an understanding of social phenomena that is not pre-formed or pre-theoretically developed with existing theories and paradigms (Engward, 2013).

Grounded theory provides tools to discover the participants' core problem and to generate a theoretical conceptualization derived from living phenomena. By developing a theory, researchers seek to understand the problem situation as experienced by a group of participants and how they deal with this problem (Tie et al., 2019).

The theory gathered by Grounded theory approach can be clarified and refined by asking questions which can provide more in-depth knowledge about categories (Sbaraini, 2011).

2.1.14 Challenges of using Grounded theory

Grounded theory (GT) is a widely applied research method that is spelled out in several books including the foundational work by Glaser and Strauss (1967); the current editions of path breaking works by Charmaz (2014), and Corbin and Strauss (2015); and the comprehensive outline by Bryant (2017). In these and other contributions, the GT method takes a number of different forms, which appear to be partly in contradiction or even dispute with each other (Timonen et al., 2018).

2.1.15. Pain

The International Association for the Study of Pain (IASP) defines pain as "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage. Over and above the definition it is emphasized that Pain is always a personal experience that is influenced to varying degrees by biological, psychological, and social factors. Additionally, Pain and nociception are different phenomena hence pain cannot be inferred solely from activity in sensory neurons. Through their life experiences, individuals learn the concept of pain hence a person's report of pain experience should be respected. Verbal description is only one of several behaviors to express pain; inability to communicate does not refute the possibility that a person is in pain. Although pain usually serves an adaptive role, it may have adverse effects on function and social and psychological well-being (IASP, 2020).

Pain control is a vitally important goal because untreated pain has detrimental impacts on the patients such as hopelessness which impede their response to treatment, and negatively affect their quality of life. Over the years it has been observed that having been diagnosed with terminal illnesses patients often struggle to find the strength and hope to enjoy their last moments. It is therefore the duty of palliative care team members to ensure that such patients receive the best possible treatments to relieve their pain and other distressing symptoms (Bleicher, 2011).

Physiology of pain- Pain receptors, located in the skin and other tissues, are nerve fibres with endings that can be excited by mechanical, thermal, and chemical impulses. Chemical substances produced by the body that excite pain receptors

include bradykinin, serotonin, and Histamines. Prostaglandins released following inflammation can heighten the pain sensation. The experience of acute pain is mediated by two types of primary afferent nerve fibres that transmit electrical impulses from the tissues to the spinal cord via the ascending nerve tracts (Ganong, 2013 p. 169**).** The A delta fibres are the larger (2-5 micrometers in diameter) and the most rapidly conducting of the two types, because of their thin myelin covering, and, therefore, they are associated with the sharp, well-localized pain that first occurs. They are usually activated by mechanical and thermal stimuli. The C fibres are smaller (0.4-1.2 micrometers in diameter) and unmyelinated. They respond to chemical, mechanical, and thermal stimuli and are associated with the lingering, poorly localized sensation that follows the first quick sensation of pain. Pain sensation therefore involves an initial fast, sharp pain and a later slow, dull, long lasting pain which is due to the difference in the speed of the nerve impulses in the different types of nerve fibers (Yam et al., 2018).

Pain impulses enter the spinal cord, where they synapse primarily on the dorsal horn neurons in the marginal zone and substantia gelatinosa of the gray matter of the spinal cord, the area responsible for regulating and modulating the incoming impulses. Two different pathways, the spinothalamic and spinoreticular tracts, transmit impulses to the brainstem and thalamus. Spinothalamic input is thought to effect the conscious sensation of pain, and the spinoreticular tract is thought to effect the arousal and emotional aspects of pain (Guyton & Hall, 2015, pp 613 para 4).

Pain pathways involve both the peripheral and central nervous system. The presence of the two pain pathways mentioned earlier therefore explains the physiologic observation that there are two kinds of pain as described above. Following an injury some chemical transmitters are released which influence the degree of nerve activity hence the intensity of pain sensation. The transmitter secreted by primary afferent fibers in fast mild pain is glutamate while the transmitter secreted in slow severe pain is substance P (Bisanth et al., 2014).

2.1.15.1. Types of pain-

Pain can be experienced in various forms to include:

i.Acute pain is short-term pain that comes on suddenly and has a specific cause, usually tissue injury or illness. The location and cause of this type of pain can be identified easily, and it usually has a predictable course with the expectation to diminish as the injury heals. It lasts less than 3 months without long-term effects on the patient's quality of life. Acute pain resolves once the underlying cause is treated (Noroozian et al., 2018).

ii. Chronic pain on the other hand persists for more than three months, even after the original injury has healed. Chronic pain can last for years and range from mild to severe, sometimes without an apparent cause (Gatchel et.al., 2018). Anatomically, chronic pain can be classified into receptive (nociceptive) and non-receptive (neuropathic) subgroups. Nociceptive pain is the most common type of pain. It's caused by stimulation of nociceptors (somatic or visceral pain receptors). It is felt with any type of injury or inflammation. Nociceptive pain can be either acute or chronic. It can also be further classified as being either visceral or somatic (Noroozian et al., 2018).

iii. Visceral pain -results from injuries or damage to the internal organs. It's felt in the visceral structures and it is often hard to pinpoint the exact location. Visceral pain is often described as pressure, aching, squeezing or cramping in nature. It may also be accompanied by other symptoms such as nausea or vomiting, as well as changes in body temperature, heart rate, or blood pressure (Weatherspoon, 2018).

iv. Somatic pain- results from stimulation of the pain receptors in the body tissues, rather than the internal organs. This includes the skin, muscles, joints, connective tissues, and bones. It is usually characterized by a constant aching or gnawing sensation. Somatic pain can be further classified as either deep or superficial. Causes of somatic pain include: skin or bone cancer, fractures, muscle sprains, osteoporosis, arthritis, cuts and burns (Lewis et al., 2014, pp 119 para 1).

2.1.15.2. Causes of pain-

Pain have different causes to include physiological and environmental factors as well as cancer. Pain in cancer patients can be caused by the disease itself, treatment, or autoimmune antibodies associated with the malignancy. There are various causes of pain the largest being cancer (Blyth & Noguchi, 2017, p. 1).

Other than cancer there exist other life- limiting conditions to include musculoskeletal disorders, injuries, and spinal problems, which make the etiology of pain a complex affair. Musculoskeletal conditions which cause chronic pain are prevalent and their impact is enormous (Ngoie et al., 2021). The conditions are the most common cause of severe chronic pain and physical disability, affecting millions of people around the world. They include a spectrum of conditions, from those of acute onset and short duration to lifelong disorders, including osteoarthritis; rheumatoid arthritis, osteoporosis, and low back pain which is the most prevalent among a variety of other musculoskeletal disorders. Globally, low back pain is a major public health problem affecting mainly adults of the working class and is the leading cause of disability (Kahere, 2020).

2.2. Nurses' level of knowledge regarding opioid pharmacology

Pain management is an essential process for nurses because they spend most time of the day with the patients. Success in pain control by use of opioid analgesics is influenced by various factors to include the socio demographic characteristics of the nurses especially their education level. These factors determine pain management knowledge and practices aspects of palliative care. Therefore, nurses' level of knowledge and positive attitudes toward pain management reflect this vital and significant role played by the nurse hence pain management becomes a prerequisite knowledge for nurses to acquire (Salameh, 2018).

Nurses and other healthcare providers need to be knowledgeable about the pharmacology of opioid drugs for effective and safe administration of the medications. In order to avoid errors, the nurse must demonstrate medication competence. Safe medication administration practices are linked to medication

competence that relies heavily on the nurse having the requisite pharmacology knowledge (Kumar & Koleen, 2015).

Knowledge deficit on opioid pharmacology has been reported among nurses who are the majority care givers. A systematic literature review done on sixty four studies identified from 12 African countries, comprising 13, 911 Healthcare professionals, mostly nurses/midwifes and physicians revealed a low level of medication knowledge across different disease areas, countries and Healthcare professionals (Behre, 2018).

Knowledge deficit has also been manifested by previous studies which have shown that: nurses are likely to be influenced by the patient's reaction to pain than his/her self-report of pain, especially when it relates to deciding on opioid administration (Desai et al., 2014). Additionally it has been shown that nurses are more likely to manage a previously safe but ineffective dose of opioid for a frowning patient than a smiling patient. Survey results also reveal a tendency for nurses' personal opinions and lack of understanding about the patients' pain, rather than their assessments, to influence choice of opioid dose and to contribute to insufficiency of managing pain (Craig, 2014).

Review of other literature from previous studies conducted in other countries showed some disconnect between opioid prescription and administration whereby majority of patients do not receive adequate pain management even where opioids are available. Evidence has shown that when physicians prescribe a dose range for analgesia, most nurses tend to give lower doses. For instance, a study conducted in North Dakota to determine the factors that affect the dosage of opioids nurses give, revealed under treatment of acute pain (oligo-analgesia) which was attributable to knowledge deficit. This can have many negative effects on patient recovery and satisfaction. The problem of under treatment of pain also remains, and is confounded by significant increases in opioid adverse events (Pearson, 2016).

Another study conducted in Cyprus to determine Healthcare professionals' perceptions on the use of opioid analgesics for the treatment of cancer-related pain established that nurses working in oncology wards, due to lack of knowledge, did not

administer the opioids as indicated with the inevitable result that the patients suffered. The Nurses had difficulty in recognizing the correct doses of opioids hence creating a problem with their administration (Charalambous, 2019).

In Kenya a study conducted at Kenyatta National Hospital emergency Department revealed that nurses feared to administer opioids via intravenous route due to fear of drug reaction which was attributed to lack of knowledge on pharmacology of opioids (Gathiri, 2012).

2.3.Barriers to pain management in palliative care

Mismanagement of pain includes both over treatment and under treatment of pain. In 2001, the US Joint Commission rolled out its Pain Management Standards, which helped grow the idea of pain as a "fifth vital sign." This however led to over use of opioid analgesics which led the advocates to urge the Joint Commission to scrap the standards (Fiora, 2016).

Inadequate pain management affects 80% of the global population, and poses a serious problem in many countries. Patients especially the vulnerable groups such as the elderly, pregnant and breastfeeding women, children, people with substance abuse, and the mentally ill are at greater risk for undertreatemnt of pain due to a variety of barriers to include: system-related, staff-related, nurse-related, physician-related, and patient-related **(**U.S. Department of Health and Human Services, 2019). The barriers have been known to hinder the health care professionals from achieving optimal pain management. System-related barriers include a lack of clearly defined standards and pain management protocols, and limited access to pain specialists and analgesics. Staff-related barriers include inadequate knowledge and skills, and lack of team-work. Lack of knowledge and false concerns about addiction and overdosing are examples of physician-related barriers (Al- Marhezi, 2017). Review of literature revealed several barriers to include:

2.3.1. Nurses' misconceptions about pain management

Other than knowledge deficit which poses a barrier to pain management in palliative care there exists various myths and misconceptions about pain among nurses and

other health care providers which if ignored can pose a great hindrance to pain management. It is widely believed that nurses working in various settings where terminally ill and other patients requiring palliative care are monitored and followed up do find difficulties in administering opioid analgesics to manage pain. This has been attributed to various beliefs, myths and misconceptions among the nurses and other healthcare professionals (Nuseir et al., 2016).

Misconceptions about pain assessment and management could be attributed to the nurses' cultural backgrounds. Culture has been shown to influence many pain-related factors, including but not limited to, how an individual communicates pain, an individual's emotional responses to someone else's pain (empathy), pain intensity and tolerance, beliefs about and coping with pain, as well as pain management. Healthcare professionals therefore need to examine their own cultural beliefs about pain (Sharma, 2018).

The notable misconceptions about pain include beliefs that: Physical or behavioral signs of pain are more reliable indicators of pain than what the patient verbalizes and a misconception that pain does not exist in the absence of physical or behavioral signs or detectable tissue damage hence pain killers should be withheld until the cause of the pain is established. Pain without an obvious physical cause, or that is more severe than expected based on findings, is usually thought to be psychogenic (Katz et al., 2015). Other misconceptions noted among nurses and other healthcare providers include beliefs such as: Pain medications always cause heavy sedation, some types of pain cannot be relieved and that many patients, especially those on opioid analgesics will exhibit 'drug-seeking' behavior (Nuseir et al., 2016).

Some of the myths that have been recorded include beliefs that: elderly or patients with impaired memory are not able to correctly verbalize pain intensity, there exists a uniform pain threshold which means that stimuli with similar intensity produce the same level of pain in everyone and that pain due to malignant disorders is always more severe than pain from other causes. Nurses also tend to belief that prior experience with pain creates tolerance in an individual (Richard, 2017).

2.3.2. Shortage of prescribers

Shortage of physicians has been recorded worldwide for different reasons such as emigration, rural/urban mal-distribution, and change in population demography. This is common especially in rural areas and low and middle income countries where the population size is high, and there is already established shortage of the health care professionals (Al-shamsi, 2017).

During a World Medical Association (WMA) meeting held in Santiago in April 2019 it was reported that 76 countries had less than one physician per thousand people and three billion people lacked access to a healthcare professional. The WMA went on to urge Governments to take action aimed at meeting world shortage of health professionals owing to the fact that closing the health workforce gap was essential to achieving universal health coverage (World Medical Association, 2019).

Following the WHO estimation of the need for palliative care as one percent of a country's total population, approximately 9.67 million people need palliative care across Africa. The continent however faces an extreme shortage of healthcare professionals. A study conducted by Miseda et al. revealed that 57 countries majorly African, had a critical shortage of healthcare workers with a deficit of 2.4 million Doctors and nurses. In 2015 Africa was reported to have 2.3 healthcare workers per 1000 population which could be largely attributed to the emigration of their healthcare professionals (Miseda et al., 2017).

In East Africa shortage of physicians has been reported: In Uganda for instance in 2018, 70% of doctors were practicing in urban areas, where only 20% of the population lived leaving the coverage in rural areas with only one doctor for every 22,000 people. This uneven service discouraged patients from seeking out professional care, especially in rural areas (State of Healthcare in Uganda, 2018). Additionally records of workforce in Tanzania and other countries in Sub- Saharan Africa showed that Tanzania had two doctors and 37 nurses per 100,000 people; Mozambique had three doctors, 21 nurses; Cote D'Ivoire, 12 doctors, 60 nurses per 100,000 people (APCA, 2019).

Effective palliative care delivery would address the needs of those Kenyans dying of a life-threatening condition, as well as those of their carers and family members. There are however, considerable challenges to providing this care, which include inadequate numbers of health care professionals. Like in other Low and Middle Income Countries, Kenya is experiencing health workforce shortage particularly in specialized healthcare workers to cater for the rapidly growing need for specialized health care. The Country's health sector is understaffed and characterized by uneven distribution of healthcare workers, with rural areas being the most disadvantaged (MOH Training Needs Assessment report, 2015).

A survey conducted in 2016 revealed that the total number of the health workers currently employed in the County Departments of Health as well as in the public, faith-based organization (FBO), and private-for-profit health facilities was estimated at 31 412 (Training Needs Assessment, 2016). These numbers were below the required number of 138, 266 healthcare workers as per the Norms and Standards Guidelines by the Ministry of Health. This shortage has not only considerably constrained the achievement of health-related development goals but also impeded accelerated progress towards universal health coverage (Miseda et al., 2017).

These challenges have resulted in most of the hospices in Kenya being manned by one or no Doctor at all. Pain assessment is therefore done by nurses who may recommend administration of opioids for the patients who probably had been referred to the facility with a less strong analgesic. Coupled with this is the fact that most Kenyan physicians and nurses just like many health care professionals throughout the world have little training regarding palliative care (Malloy, 2017).

In 2019 the ratio of Doctors to patients was reported to be 1: 16,000, which was way below the World Health Organization recommendation of one doctor for every 1,000 patients. This was an indication that there was a shortage of Doctors in the country and as a result many patients may not get opioid analgesics prescribed to manage their severe pain (Africa Check, 2019).

In Kenya only Medical Doctors are allowed to prescribe Narcotic analgesics. The fact that Doctors are the sole prescribers of opioids according to the law it means that

in healthcare facilities where there is no Doctor patients may have to live with the pain for prolonged periods. Another problem would arise if the patient reacts to the medication since the nurse lacks adequate guidelines to manage the administration of the medication and in most cases they are forced to stop the treatment (Kamonyo, 2018).

It is worth noting however that a different trajectory has been recorded in Uganda whereby in order to mitigate the problem of shortage and to facilitate effective pain management especially in rural Uganda, the Government recommended training of palliative care nurses and clinical officers who were then allowed (through change of legislation), to prescribe opioid analgesics especially morphine (McNeir Jr., 2017).

2.3.3. Inadequate knowledge & fears about opioid analgesics among healthcare professionals

Adequate knowledge among healthcare professionals on opioid action, administration, and management of side effects is Key in pain management by use of opioids. There are rumors and misconceptions among healthcare workers that concern pain management. An example is a misconception that use of opioids in management of pain will lead to drug addiction in the patients; and a prevailing rumor that administration of opioids can cause respiratory depression in the patient. However this concern should not arise as titration of morphine prevents respiratory depression (Berger et al., 2013). Being knowledgeable enables healthcare professionals to dispense rumors which pose as barriers to adequate pain management.

Knowledge deficit about overall pain management is not uncommon among health-care professionals. For instance, a study conducted in the University of Dammam (Saudi Arabia), to get an overview of the knowledge and attitude among health-care professionals in the University Hospital toward pain management, and the need for an educational plan to improve pain service in hospitals showed that knowledge and attitude of pain were deficient and unsatisfactory which was a major obstacles to implementation of an effective pain management initiative (Fallatah, 2017). A similar study conducted in India by Prem and others showed that Nurses' overall

level of knowledge about palliative care was poor. This was attributed to several reasons including inadequacies in nursing education, absence of curriculum content related to pain management, and lack of knowledge related to pain and palliative care (Prem et al., 2012).

Evidence has shown that inadequate knowledge on use of opioids amongst healthcare professionals as well as fear of addiction to users can cause healthcare professionals to shun prescribing these drugs. For instance a study conducted among physicians in the United States showed that among the prescribers, a tension emerged between managing chronic pain and facilitating opioid misuse. The physicians in this group held the belief that opioid prescribing was likely to create "*drug addicts*", leading to the belief that opioid use conflicted with their professional identity in wanting to "*do the right thing*" (Desveaux et al., 2019).

The tendency to undertreat pain has often been attributed to fear of opioid analgesic administration (opiophobia) especially the fear of causing addiction among patients. This appears to be prominent among healthcare providers and it seems to be reinforced through the inadequate training on opioid analgesics. Their poor preparation to appropriately manage opioids in the clinical setting often leads to improper use, leaving the patient in unnecessary suffering **(**Charalambous, 2019).

In contrast to the negative attitudes expressed by physicians and patients toward opioid therapy, evidence has shown that when opioid analgesics are administered under proper physician supervision, treatment is associated with very low rates of opioid misuse (Voon et al., 2017). It has also been proven that adequate assessment in conjunction with opioid titration based on patient response can also provide maximum analgesia without adversely affecting the Central Nervous System or the respiratory status. There is also evidence that medical use of opioid analgesics for pain associated with advanced illness rarely leads to drug abuse or opioid addiction (Kumar, 2020). Therefore, it is unwarranted to under-utilize or withhold opioids from a patient who is experiencing pain based on fear of causing respiratory depression or addiction.

2.3.4. Legal restrictions

Legal restrictions to opioids availability and access have caused people with life-limiting conditions (e.g. cancer and AIDS) to suffer unnecessary pain. The restrictions imposed by the government agencies through the Acts of Parliament create fear of prosecution for handling classified drugs that cause some Doctors to decline to prescribe morphine for relief of patients' pain. The same fears caused some pharmacies and drug stores not to stock the opioid drugs (Dideen & Dubois, 2016).

Most National laws controlling "illegal" drugs are based on the UN Single Convention on Narcotic Drugs (1961) and the Convention on Psychotropic Substances (1971) that define a range of substances that are supposedly sufficiently harmful to be removed from the usual sales regulations. This automatically makes them "illegal," which means that punishments are implemented for sale and, in most cases, possession. However, many "illegal" drugs have medicinal uses: for example, opioids for pain, amphetamines for narcolepsy and attention deficit hyperactivity disorder (ADHD), and even cocaine for controlling blood loss and as local anesthesia in ear, nose and throat (ENT) surgery (Nutt, 2015).

In some countries e.g. the US there exist some guidelines in prescription and titration of opioids. The guidelines provide recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. They also provide directions on: when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use (Voon, 2017).

In Kenya apart from Opioid analgesics being classified as controlled drugs, the fact that opioid analgesics are only prescribed by Doctors further limits their accessibility. The problem has further been compounded by conflicting legislation which governs the use of opioids. Whereas, the Pharmacy and Poisons Act CAP 244 stipulates a broad mandate for the regulation of medicines, the Narcotic Drugs and Psychotropic Substances Control Act (Cap 245) makes provision for the control and possession of, and trafficking in narcotic drugs and psychotropic substances while

the Food, Drugs and Chemical Substances Act (Cap 254) provides for the prevention of adulteration of food, drugs and chemical substances. The three laws have overlapping and conflicting provisions. For example some controlled drugs under Cap 245 also have licit (medicinal) uses, yet in Kenya the heavy penalties associated with handling of illicit drugs deter most pharmacists from stocking any of them, and this limits access for needy patients for instance in palliative care.

Other barriers include policies that inappropriately or excessively regulate the medical use of controlled substances, in particular, the opioids that are essential in pain management as well as lack of data due to few studies done on pain (Lohman & Amon, 2015). These limitations in terms of policy and legislative imperatives deny many patients access to this group of analgesic drugs. It also denies former drug users the right to pain relief even in advanced stages of life limiting illnesses.

2.4 Guidelines on assessment and management of pain

Pain in the absence of disease is not normal yet it is experienced daily by a majority of patients especially those with life limiting illnesses (U.S. Department of Health and Human Services, 2019). It is important for nurses and other health care providers to determine the type of pain experienced by patients since different types of pain respond differently to analgesics. This will provide guidance for one to be able to recommend/ administer the most suitable analgesic. Pain can be classified according to situation, duration and the underlying mechanism (African Palliative Care Association, 2012).

Patients in sub-Saharan Africa commonly experience pain, which often is un-assessed and undertreated. One impediment to routine pain assessment in most settings is the lack of a single-item pain rating scale validated for the particular context (Christin, 2012). Palliative care patients who experience pain and other distressing symptoms are often unable to self-report their pain placing them at increased risk for under-treatment of pain. Use of appropriate pain assessment tools significantly enhances the prospect of effective pain management and improved pain-related outcomes (McGuire et al., 2016).

2.4.1. Pain assessment guidelines

Pain control begins with a thorough assessment, including an extensive history and physical examination. Precise and systematic pain assessment is required to make the correct diagnosis and determine the most efficacious treatment plan for patients presenting with pain. During assessment healthcare providers often seek to understand the level of pain their patients are experiencing. They can observe pain behavior or ask the patients to rate their pain. Pain is therefore measured based on a person's perception of the pain experience (Verson et al., 2015).

This information guides the plan of care, including both pharmacologic and non-pharmacologic therapies. Pain must be assessed using a multidimensional approach, to be able to establish: Chronicity, Severity, Quality, Contributing/ associated factors, Location/ distribution or etiology of pain, if identifiable, barriers to pain assessment (Kim et. al., 2012).

2.4.1.1. Clinical history -Fundamental to pain assessment procedures are the patients' general medical and pain history and a clinical physical examination for both acute and chronic pain. To make a pain diagnosis one has to always obtain a complete history with particular attention to: full pain history, psychosocial, spiritual and family history and medication history. The healthcare provider should seek to establish if the pain is limiting activity, what the patient feels about it, patient's fears and expectations and his/her previous experiences of pain and illness (Dansie & Turk, 2013).

i). Assessing Acute pain-When assessing a patient suffering from acute pain one should consider the location and description of pain. One would therefore seek to establish if the pain is a primary or a secondary complaint associated with another condition, the location of the pain and if it does radiate and how long it lasts (Kim et al., 2016). The assessor would also enquire about the onset and circumstances associated with the pain, intensity and the factors that exacerbate or relieve pain. They should also observe for signs of neuropathic pain including descriptions such as shooting, burning, stabbing as well as pain associated with gentle touch (***Australian and New Zealand College of Anaesthetists,*** 2016).

ii). Assessing Chronic pain- When assessing a patient who is experiencing chronic pain one should seek to establish the location of pain and to ascertain if the onset of pain was related to trauma or if it was insidious. The duration of time one has lived with the pain, effects of analgesics as well as how any injury associated with the pain occurred (Dansie & Turk, 2013). The assessment should also establish presence of referred pain as well as the relieving and exacerbating factors. One can also ask the patient to describe their pain, enquire if it wakes them and if possible identify any psycho- physiological responses that occur following severe pain, for example, lethargy, nausea or changes in mood (Williams, 2013).

iii). PQRST assessment- Comprehensive pain assessment involves a careful inquiry of pain characteristics. In addition to pain intensity one should seek to establish the position/precipitating factors, quality, radiation, severity and timing/ Treatment history (PQRST) can provide important diagnostic clues to the mechanism of pain and inform personalized management (Swift, 2015).

2.4.1.2. Pain scales- Pain intensity as reported by the patient is the gold standard for pain assessment. The three most commonly used scales are the numeric rating scale (0 to 10) whereby 0 represents no pain while 10 indicates worst possible pain; the visual analog scale (0 to 100 mm) whereby 0 indicates no pain while 100 indicates worst possible pain; and the categorical scale: none, mild, moderate, severe (Hui & Bruela, 2014). Pain measures fall into 2 categories: Single-dimensional and Multidimensional scales.

a) Single-dimensional scales- These scales assess a single dimension of pain and, through patient self-reporting, measure only pain intensity. In most cases the scales are useful in acute pain when the etiology is clear. The patient is asked to rate their pain on a scale of 0 – 10: 0 = no pain; 1-3 mild pain; 4- 6 = moderate pain; 7- 10 = severe pain (Palese et al., 2011). Single dimension scales include:

i). Visual analogue scale- A horizontal or vertical line of 10cm anchored by verbal description at each end ii). Verbal description scale- adjectives reflecting extremes of pain are ranked in order of severity.

iii). Pain thermometer- a modified vertical verbal descriptor scale; administered by telling a patient to point to the words that best describe his/her pain (Hjermstad, 2011).

iv). The hand scale- This ranges from a clenched hand (representing 'No hurt') to five extended digits (representing 'Hurts worst'), with each extended digit indicating increasing levels of pain. Cultural consideration is of importance as a closed fist could be interpreted as worst possible pain in some cultures. There is need to explain this to the patient clearly (Blum, et al., 2014).

b) Multi-dimensional pain assessment tools- Multidimensional scales measure the intensity, nature, and location of pain, as well as, in some cases, the impact that pain is having on a patient's activity or mood; multidimensional scales are useful in complex or persistent acute or chronic pain. Multidimensional tools include:

i).Multidimensional Objective Pain Assessment Tool (MOPAT)- It is a multidimensional scale developed and firstly validated to nonresponsive hospice patients who were cognitively impaired or nonresponsive by virtue of terminal illness (McGuire et al., 2011). This instrument is composed of behavioral and physiological dimensions. The behavioral dimension has four indicators of acute pain (restless, tense muscles, frowning/grimacing, patient sounds), which are rated from 0 (none) to 3 (severe). The physiologic dimension has also four indicators (blood pressure, heart rate, respirations and diaphoresis), which are rated as 0 (no change) or 1 (change), according to patients' usual values of these physiologic indicators.

ii). The APCA African Palliative care Outcome Scale (POS) was formulated as a patient- and family-level tool to measure the outcomes of care being provided and to make recommendations on areas for improvement. It can be used within routine clinical care to enhance individual patient management, but also as a quality improvement tool and in research whose findings can help inform policy formation and best practices within palliative care. This scale comprises six cartoon faces, with expressions ranging from a broad smile representing 'no hurt' to a very sad face representing 'hurts worst' (Huang et al., 2012).

iii). Observational tools may be used with patients who are unconscious/sedated and cognitively impaired to assess physiological responses and/or behaviors, for example, facial expressions, limb movements, vocalization, restlessness and guarding (Barsanji et al., 2019). Examples of Multi-dimensional pain measurement tools include: McGill pain questionnaire (short and long), Brief pain inventory (short and long), Behavioral pain scales and Neuropathic signs and symptoms (Leeds assessment of neuropathic symptoms and signs) (Bennett, 2019).

2.4.2. Pain management modalities

Total pain is a concept commonly used in palliative care and encompasses physical, psychological, social and spiritual aspects of pain. Pain requires to be controlled no matter the source or origin of pain. Pain is real and it's physical but everyone experiences pain differently (Brant, 2017). Effective pain management is central to palliative care and it encompasses use of both Pharmacological and non-pharmacological measures. Both a rational pharmacologic approach and non-pharmacologic plan can be developed using the information obtained from the pain assessment. Health care providers are able to control physical pain according to WHO analgesic ladder among using other methods (Marie, 2013).

2.4.2.1. Pharmacologic measures of pain management- Many medications are available to block pain at various pain pathways. Types of chronic pain medication used include Non-steroidal anti-inflammatory drugs and opioid analgesics and steroids (for management of pain accompanied by inflammation). Opioid analgesics are indicated for the control of moderate-to-severe pain among patients with life threatening illnesses to include HIV&AIDS, cancer as well as other painful disease conditions **(**Morelli, 2017).

There are certain guiding principles for effective pain management which one should consider when developing a rational pharmacologic approach to pain management. These include:

- Understanding that pain is a subjective experience which involves the biological, psycho-social, and spiritual components of one’s life.

- Pain usually occurs with other associated symptoms such as dyspnea, nausea and vomiting which also need to be assessed and managed.
- Assessment of pain should be comprehensive, individualized, and holistic; it should take a multidisciplinary team approach
- Patient and caregiver should be involved in the assessment and planning of pain control interventions.
- The oral route should be preferred for administration of analgesia when possible; titration should be done until pain is relieved, with regular administration of the medication when pain is persistent.
- Morphine is considered the standard-of-choice opioid. However, if comorbid illness exists, such as renal insufficiency, other opioid analgesics with less active metabolites may be preferred to reduce side effects.
- Analgesia must be continuous when pain is continuous (Kress et al., 2015).

2.4.2.2. Commonly used opioid analgesics in palliative care in Kenya- Opioids have been regarded for long as among the most effective drugs for the treatment of pain. Their use in the management of acute severe pain and chronic pain related to advanced medical illness is considered the standard of care in most parts of the world. In contrast, the long-term administration of an opioid for the treatment of chronic non-cancer pain continues to be controversial (McMillen, 2011). According to KEHPCA, Morphine & dihydrocodeine (DF118) are the most commonly used opioid analgesics in palliative care set up in Kenya. This study therefore will focus on morphine and Dihydrocodeine as the main opioid analgesics.

2.4.2.3. Pharmacology of Opioid analgesics

Source and classification- Opioid analgesics are a class of drugs naturally found in the opium poppy plant. Opioids can be classified according to their synthetic process into: Naturally occurring e.g. Morphine & Codeine; synthetic e.g. Pethidine, Fentanyl and Methadone; and semi- synthetic compounds e.g. Diamorphine & Oxycodone (Yvette, 2011).

Opioids can also be classified according to their effect at opioid receptors. In this method opioids can be considered as agonists, which interact with a receptor to

produce a maximal response from that receptor e.g. Morphine; partial agonists which bind to receptors but elicit only a partial functional response e.g. buprenorphine; and antagonists which bind to receptors but produce no functional response, while at the same time preventing an agonist from binding to that receptor e.g. naloxone (Pathan & Williams, 2012).

Indications for opioid use- Opioids are prescribed for a range of acute and chronic pain conditions. The clinical indications associated with opioid initiation include but not limited to: pain in cancer/ palliative care, trauma, arthritis, back pain, dental, postsurgical and musculoskeletal pain (Pasricha, et al., 2018).

a) Morphine

Morphine an opioid agonist derived from the opium poppy, has long been known to relieve chronic, moderate to severe pain with remarkable efficacy. It remains the standard against which all drugs that have strong analgesic actions against chronic, moderate to severe pain are compared (Yvette, 2011).

Pharmacokinetics: Morphine is well absorbed when given by subcutaneous, intramuscular, and oral routes. It is well distributed in highly perfused tissues such as the brain, lungs, liver, kidneys, and spleen. Drug concentrations in skeletal muscle may be much lower, but this tissue serves as the main reservoir because of its greater bulk. First-pass metabolism of oral morphine determines its systemic bioavailability. Three major metabolites are produced: normorphine, morphine-3-glucuronide, and morphine-6-glucuronide. The metabolites are principally eliminated by the kidney and accumulate in renal failure (Prommer, 2016).

Pharmacodynamics: Morphine is a full agonist at the μ (mu) opioid receptors, which are widely distributed in the central and peripheral nervous system and gastrointestinal tract. To produce an analgesic effect, Opioids act both presynaptically and postsynaptically. Presynaptically, opioids block calcium channels on nociceptive afferent nerves to inhibit the release of neurotransmitters such as glutamate and substance P, which contribute to nociception. Postsynaptically, opioids open potassium channels, which hyperpolarize cell membranes, increasing

the required action potential to generate nociceptive transmission (Cohen et al., 2021).

The analgesic effect of opioids is brought by the synergy of the two events, namely reduction of pain threshold and emotional detachment from pain. Apart from causing analgesia other opioid effects include sedation, respiratory depression, constipation and a strong sense of euphoria (Ghelardini, et al., 2015). With repeated use, a high degree of tolerance occurs to all of these effects. Despite the side effects the benefits of morphine in chronic pain management cannot be ignored. Effective and safe titration of opioid analgesics has a major impact on patient comfort. It also prevents respiratory depression (Rana, et al., 2011).

Side effects and adverse effects of morphine on body systems- Like all pain medications, opioids come with side effects. Opioids can cause fatal overdose through respiratory depression, especially when combined with other sedatives such as alcohol and benzodiazepines. Use of opioids requires risk benefit analysis (Morelli, 2017).

i. Central nervous system effects- the most common side effects include euphoria, sedation, and increased risk of falls and fractures in the short term, and respiratory depression with prolonged use (Satoskar, 2015). With repeated use, a high degree of tolerance occurs to all of these effects. Morphine is, of course, an addicting drug in that it causes tolerance and dependence (Boyer, 2012).

ii. Peripheral effects- In the cardiovascular system Morphine may cause decreased heart rate. In the gastrointestinal system it causes constipation, nausea as well as biliary colic. It also causes depression of the renal function in the urinary system and/or sexual dysfunction after prolonged use (Baldini, et al., 2012).

b) Dihydrocodeine (DF 118)

Dihydrocodeine (DHC) is a semi-synthetic analogue of codeine, formed by the hydrogenation of the double tie in the main chain of the codeine molecule. Dihydrocodeine is prescribed for pain or severe dyspnea either alone or compounded

with Paracetamol or aspirin. It is also used as an antitussive agent and for the management and opioid addiction especially in heroin addicts (Wojciech, 2015).

Pharmacokinetics-The drug is usually administered orally though it has a low bioavailability of approximately 20%. Dihydrocodeine is metabolized in the liver by liver enzymes to Dihydromorphine a highly active metabolite with a high affinity for μ opioid receptors. It is eventually eliminated via the kidneys (Leppert, 2011).

Pharmacodynamics- Dihydrocodeine is metabolized to dihydromorphine a highly active metabolite with a high affinity for μ opioid receptors. The analgesic properties of Dihydrocodeine are believed to come from its conversion to morphine. Dihydrocodeine has equivalent potency as morphine and the adverse events are similar to other opioids (Leppert, 2011).

2.4.2.4. The WHO Analgesic Ladder- The purpose of using drugs in pain control is to provide pain relief to the patient. The WHO analgesic ladder as reported by Stjernswärd specifies treatment on pain intensity, from simple analgesics for mild pain to opioid analgesics for moderate and severe pain (Prommer, 2015). Since 1986 the WHO ladder has been a three stepped approach to pain management as follows: Step 1 Non-opioid plus optional adjuvant analgesics for mild pain; Step 2 Weak opioid plus non-opioid and adjuvant analgesics for mild to moderate pain; Step 3 Strong opioid plus non-opioid and adjuvant analgesics for moderate to severe pain (Yang, et al., 2020).

The main principles of analgesic choice to achieve efficacy are based on the analgesic ladder. This staged approach to the prescribing of analgesia allows flexibility for different intensities of pain as it increases the analgesic effect (Raffa, 2014). In 2015, discussions were done on this strategy by the scientific community who suggested other classifications based on clinical efficacy or pain mechanisms (International Association for the Study of Pain, 2016).

The modified WHO analgesic ladder- The three-step ladder for cancer pain has also been commonly employed in Chronic Non- Cancer Pain, which very likely contributed to opioid analgesic overuse and escalation. Most pain experts stopped

relying on the WHO pain ladder because it was not designed for highly complex cases, chronic nonmalignant pain and its complications. There also emerged greater recognition of the various types of pain e.g. nociceptive, neuropathic as well as the need of tailoring treatment decisions accordingly. Additionally, owing to the complexity of pain, a number of new pain management strategies, new opioid analgesics and other strategies have emerged. All these led to recommendation for inclusion of a fourth step to form a Modified four stepped WHO ladder (Yang et al., 2020). The modified four stepped WHO ladder recommends use of the following drugs:

Step One: for very mild pain a non-opioid analgesic/ simple analgesics (such as acetaminophen or ASA) may be adequate.

Step Two: if the pain is moderately severe a weak opioid such as tramadol or codeine plus or minus appropriate adjuvant agents e.g. antidepressants and anticonvulsants, may provide adequate analgesia.
Step Three: for severe pain, or when it is expected that pain will become severe, it is best to start with a low dose of a strong opioid and titrate up the dose according to effect. At every step of the analgesic ladder non-opioid analgesics form the basis of the pain management (Anekar & Cascella, 2020).

Step 4: Retaining the use of pain intensity as the differentiator between steps, a fourth step was added to the original pain ladder to accommodate very severe pain, such as occurs in the palliative setting in certain patients with advanced forms of cancer. Step 4 includes numerous non-pharmacological procedures for treating persistent pain, even in combination with the use of strong opioids or other medications (McGuire & Slavin, 2020). This group encompasses interventional and minimally invasive procedures such as epidural analgesia, intrathecal administration of analgesic and local anesthetic drugs with or without pumps, neurosurgical procedures and nerve blocks among others (Anekar & Cascella, 2020).

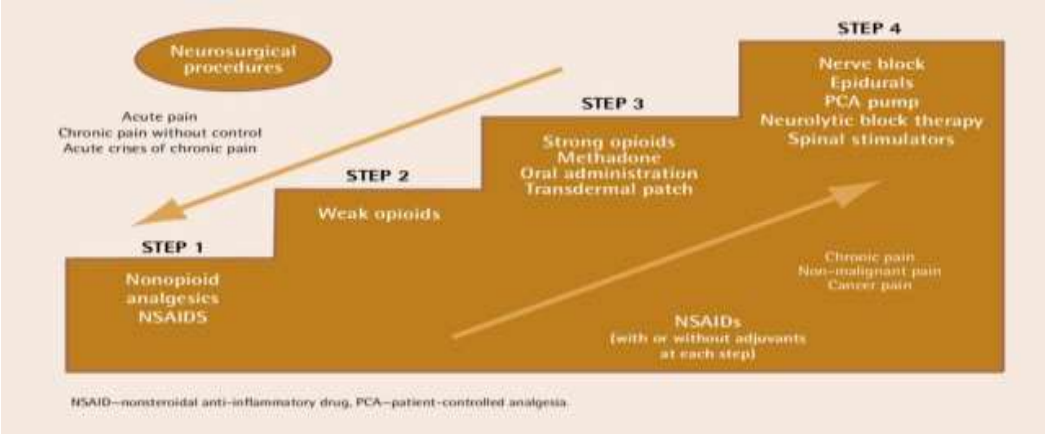

Figure2. 3: A diagram illustrating the Modified WHO analgesic ladder (adopted from researchgate.net).

2.4.2.5. Non- Pharmacological pain management interventions

Therapy- Therapy can be psychological or physical. Therapies deal with various aspects of the human being.

a). **Physical therapy**- This is a very vital part of any pain management program. A person undertakes exercises to help improve movement and strength, and to decrease pain. Pain can be worsened by exercise that is done incorrectly. Therapy should therefore be modified to achieve the right exercise regimen for the client. Proper exercise slowly builds one's tolerance hence reducing pain (Geneen et al., 2017).

i) **Heat and cold therapy**- Heat helps decrease pain and muscle spasms. It may be applied to the affected area for 20 to 30 minutes every 2 hours for as many days as directed. Ice or cold therapy helps relieve pain and swelling as well as preventing tissue damage. Ice should be packed in a plastic bag and covered with a towel then placed on the area for 15 to 20 minutes every hour, or as directed (Lewis et. al., 2019, pp. 132).

ii) **Massage therapy** may help relax tight muscles and decrease pain. It can help relieve chronic muscle pain, and anxiety.

iii) A transcutaneous electrical nerve stimulation (TENS) unit is usually placed over the area of pain. It uses mild, safe electrical signals to help control pain (Lewis et al., 2019, pp. 132.).

b). **Psychological therapies**- Psychotherapy constitutes a valuable modality for addressing the behavioral, cognitive, emotional, and social factors that both result from and contribute to pain-related dysfunction and distress through enhancement of self-management strategies. Recurrent pain may contribute to development of maladaptive cognitions and behavior that worsen daily functioning, increase psychiatric distress, or prolong the experience of pain (Sturgeon, 2014).

i) **Cognitive-behavioral therapy** - Pain is affected by individual cognitions as well as by tissue damage, and the basic principle of Cognitive Behavioral Therapy (CBT) is that maladaptive cognitions contribute to the maintenance of emotional anguish and behavioral problems. In CBT it is assumed that a Patient can identify negative pain related thoughts and replace them with more positive thoughts. Cognitive-behavioral therapy (CBT) is the most common psychological intervention for individuals with chronic pain (Lim et al., 2018).

ii) **Relaxation techniques**- These can help one relax, relieve stress, and decrease pain. Common relaxation techniques include:

- Aromatherapy- a technique in which scents are used to relax, relieve stress, and decrease pain. It uses oils, extracts, or fragrances from flowers, herbs, and trees. The products may be inhaled or applied to the body during massages, facials and baths.
- Deep breathing techniques- These are helpful for relaxation and can decrease pain.
- Guided imagery- Individuals in therapy focus on mental images in order to evoke feelings or relaxation. One learns to focus on the picture instead of his/her pain (Norreli et al., 2020).

iii) Music therapy- may help increase energy levels and improve the mood. It may help reduce pain by triggering the body to release endorphins. Music may be used

with any of the other techniques, such as relaxation and distraction (Lodriguez, 2016).

iv). Self-hypnosis -is a way to direct a person's attention to something other than pain. For example, one may choose to repeat a positive statement about ignoring the pain or seeing the pain in a positive way (Lodriguez, 2016).

2.5. Gaps in the pain management tools and guidelines

2.5.1. Gaps in Pain assessment techniques/guidelines

I. Clinical history- Pain is a subjective experience hence the most reliable method of pain evaluation is the patient's self-report. For patients with dementia, however, communication difficulties experienced because of their state of health hinder patients' ability to provide adequate information about their pain experience. It has also been noted that information given to different members of the healthcare team at different times may be fragmented (Lichtner et al., 2016).

Another category of patients who pose difficulties in pain assessment are the unconscious or the critically ill. Given the inability to self-report in these patients, pain cannot be properly assessed and treated in such patients. The existing barriers to using non-verbal pain assessment scales in these patients can also lead to false evaluations of pain by nurses and consequently unrealistic perception of pain (Deldar & Frotan, 2018). Palliative care patients who have pain at any point during their disease trajectory are often unable to self-report the presence, location, severity, or impact of their pain. This places them at a higher risk for under-recognized and under-treated pain. This challenge applies also in non- communicating patients especially those with cognitive impairment (McGuire et al., 2016).

II. Single dimension scales- These include verbal descriptor scale, visual analogue scale, verbal descriptor scale, Wong Backer's faces pain ration scale and numerical rating scale. Pain scales are based on self-report, observational (behavioral), or physiological data. The disadvantages of using these scales include the fact that they may not be reliable in assessing pain in all populations. For instance the visual analogue scale has a low reliability owing to the patients' need to recall their initial

pain severity before giving an estimate of their pain relief. This poses a gap in conducting assessment for patients with memory impairment (Kumar & Tripathi, 2014).

Use of verbal descriptor scale on the other hand may not be appropriate for patients who are critically ill especially on those with an endotracheal tube owing to their inability to communicate. Additionally these patients may suffer from numerous neurological, physiological, and communicative disabilities arising from a variety of reasons including dependence on a mechanical ventilator and concurrent use of sedatives, which make them unable to accurately estimate the level of their pain (Deldar & Froutan, 2018).

III. Multiple dimension scales - The tools are used to assess pain in nonresponsive hospice patients who were cognitively impaired or nonresponsive by virtue of terminal illness (McGuire et al., 2011). This instrument is composed of behavioral and physiological dimensions. The tools assess pain by monitoring the patient's behavior as well as physiological parameters (vital signs). However use of the tools may pose a challenge when assessing patients with brain injury as vital signs are not recommended as a valid measure to predict the presence of pain in such patients (Azevedo-Santos & DeSantana, 2018).

2.5.2. Gaps in Pain management/ intervention techniques/guidelines

The modified version of the 3-step ladder placed interventional pain management as a fourth step. The perceived priority of medical as opposed to surgical intervention for pain relief indicates that it would be inappropriate to bypass a step and to use pain-relieving interventions, such as surgery, without trying opioids first. However, the opioid epidemic challenges current attitudes toward pain management and necessitates the reexamination of the WHO analgesic ladder (McGuire & Slavin, 2020). Opioid analgesics have been reported to have many side effects to include sedation, euphoria, respiratory depression (Boyer, 2012). Others include constipation, nausea as well as biliary colic. It also causes depression of the renal function in the urinary system and/or sexual dysfunction (Baldini, et al., 2012). Barriers to pain management such as restriction of access to opioids, poor knowledge

about opioid pharmacology as well as myths and misconceptions about opioid use have also negatively affected pain management as earlier discussed.

Specific non- pharmacological pain management strategies that Nurses can use to relief the suffering of patients in the health institution include music therapy, acupuncture, col/hot application, exercise, positioning therapy, massage therapy, social support, spiritual and religious support, hot and cold therapy, relaxation therapy, deep and slow breathing exercise and distraction therapy (Lim et al, 2018; Gennen, et al., 2017; Sturgeon, 2014). However evidence has revealed that nurses do not mostly practice non- pharmacological pain management. The major identified barriers for the practice of non–pharmacological pain management methods include nurses' fatigue, heavy workload, multiple responsibilities of nurses, and insufficient number of nurses per patient ratio as well as negative attitude of nurses on non-pharmacology pain management (Zeleke et al., 2021).

2.6. Nursing Models of care

2.6.1. Introduction

Nursing models are constructed of **theories** and concepts used to help **nurses** assess, plan and implement patient care by providing a framework within which to work. According to Chinn and Kramer a theory has been defined as a "creative and rigorous structuring of ideas that project a tentative, purposeful and systematic view of phenomena" (Chinn & Kramer, 2011, p. 257). It has also been described as a systematic explanation of an event in which constructs and concepts are identified and relationships are proposed and predictions made (Streubert & Carpenter, 2011). The theories used by members of a profession clarify basic assumptions and values shared by its members and define the nature, outcome, and purpose of practice (Butts et al., 2012).

2.6.2. Structure of Nursing Models

A conceptual model has several components, including purpose, concepts and definitions, theoretical statements, structure/linkages and ordering, and assumptions (Knapp, 2011). Creation of conceptual models is also a component of theory

development that is promoted to further explain and define relationships, structure, and linkages.

Purpose- The purpose of a theory explains why the theory was formulated and specifies the context and situations in which it should be applied. The purpose might also provide information about the sociopolitical context in which the theory was developed, circumstances that influenced its creation, the theorist's past experiences, settings in which the theory was formulated, and societal trends (Chinn & Kramer, 2011).

Nursing Metaparadigms- A metaparadigm refers "globally to the subject matter of greatest interest to members of a discipline" (Powers & Knapp, 2011, p. 107). Metaparadigm concepts comprise the central issues in a discipline. Fawcett has named Person, Health, Environment and Nursing as the four main concepts/metaparadigms of nursing that need to be comprehensively defined (Nikfarid et al., 2019).

i.Person (also referred to as Client or Human Beings)- The human metaparadigm refers to the recipient of nursing care to include individuals in a definite culture, family, and society (Deliktas et al., 2019).

ii. Environment (or situation)- is defined as the internal and external surroundings that affect the client. It includes all positive or negative conditions that affect the patient, the physical environment, such as families, friends, and significant others, and the setting for where they go for their healthcare (Bender, 2018).

iii. Health- is defined as the degree of wellness or well-being that the client experiences. The health metaparadigm refers to the harmony between human beings and their environment and to the autonomy of the individual (Deliktas et al., 2019). Health may have different meanings for each patient, the clinical setting, and the health care provider (Kieft et al., 2014).

iv. Nursing- The attributes, characteristics, and actions of the nurse providing care on behalf of or in conjunction with, the client. There are numerous definitions of

nursing, though nursing scholars may have difficulty agreeing on its exact definition, the ultimate goal of nursing is to improve patient care (Nilsen, 2015).

2.6.3. Usefulness of conceptual models in nursing

Nursing conceptual Frameworks have influenced nursing practice in several ways to include:

- Identifying certain standards for nursing practice as well as settings in which the practice should occur and the characteristics of what the model's author considers recipients of nursing care.
- Identifying distinctive nursing processes and technologies to be used, including parameters for client assessment, labels for client problems, a strategy for planning, a typology of intervention, and criteria for evaluation of intervention outcome.
- Directing the delivery of nursing services.
- Serving as the basis for clinical information systems, including nursing orders, care plan, progress notes, and discharge summary.
- Guiding the development of client classification systems.
- Directing quality assurance programs (Fawcett, 2017; Kieft, 2014)

2.6.4. Approaches for developing nursing conceptual models

According to Melesis (2012) different approaches may be used to initiate the process of theory development. She proposed that four major strategies differentiated by their origin (theory, practice, or research) and by whether sources from outside of nursing could be used to develop a theory. These four nursing theory development approaches are theory to practice to theory, practice to theory, research to theory, and theory to research to theory. Melesis then proposed adoption of an integrated approach to theory development (McEwen & Willis, 2014, p. 82).

This research adopted the theory to practice to theory approach, during the process of the Model development. This approach begins with a typically non- nursing theory that describes a phenomenon of interest though the focus of the theory is different from the focus needed for nursing. This methodology assumes that the theory can help describe or explain the phenomenon, but it is not completely consistent with

nursing and/or is not directly designed for nursing practice (Melesis, 2012). The approach was adopted by use of Diffusion of innovations theory which is non-nursing in research, to generate views during the baseline survey which would be used to develop a model of pain management in palliative care (an innovation in nursing practice).

2.6.5 Critique of Nursing Theoretical Models relevant to palliative care

The research analyzed grand theories based on human needs i.e. Paterson's Humanistic theory, Virginia Henderson's need based theory, and Jean Watson theory of caring.

2.6.5.1 The humanistic nursing theory

The main objective of the study was to develop a comprehensive model of pain management by use of opioids in palliative care. The Humanistic Model of Nursing is an approach to nursing that encompasses a number of individual theories, including Patricia Benner's From Novice to Expert Model of Nursing and Jean Watson's Theory of Caring (Pajnkihar et al., 2017).

A study conducted on utilization of nursing models in palliative care identified Paterson's and Zderad's Humanistic Nursing Theory as being a valid and useful model for how to better the quality of hospice and palliative care. The main components of Humanistic Nursing Theory were reported as useful concepts to utilize by those providing hospice and palliative care (Wu & Volker, 2014).

Paterson and Zderald's Humanistic theory has been classified as an interaction theory which revolves around the fact that everyone is a unique person and that the nurse should understand that; no person or experience is the same. This should be respected and reflected in the care provided to the patient. Though the nurse and patient may have different concepts about wholeness they should work towards gaining a common understanding of wholeness. The nurse-patient relationship should not pursue the change in values and customs of the patient, but position the nurse as a witness of the experience of the health and illness process in the patient and family (Molina- Mula & Gallo-Estrada, 2020). The nurse must therefore modify

her/his response in offering a genuine presence (call and response). Additionally, care should be taken that the differences do not create a barrier to nurse- patient interaction to hinder provision of palliative care. Nurses' and patients' cultural values and beliefs can also lead to misinterpretation or reinterpretation of key messages. In line with this study it should be noted that culture influences the perception and reporting of pain hence to understand people from other cultures who are in pain, healthcare providers first need to examine their own cultural beliefs about pain (Givler, 2020).

Metaparadigms of the humanistic nursing Model

i.Person- Human beings are viewed as open energy fields with unique life experiences. As energy fields, they are greater than and different from the sum of their parts and cannot be predicted from knowledge of their parts (Wolf & Bailey, 2013, p. 64).

ii. Environment includes societal beliefs, values, mores, customs, and expectations. The environment is conceptualized as the arena in which the nursing client encounters caring relationships, threats to wellness and the lived experiences of health. Dimensions that may affect health include physical, psychosocial, cultural, historical and developmental processes, as well as the political and economic aspects of the social world (Barveman & Gottlieb, 2014).

iii. Health, a dynamic process, is the synthesis of wellness and illness and is defined by the perception of the client across the life span. The degree or level of health is an expression of the mutual interactive process between human beings and their environment (Bircher & Kurvilla, 2014).

iv. Nursing is defined as an academic discipline and a practice profession. Nurses use critical thinking and clinical judgment to provide evidence-based care to individuals, families, and communities to achieve an optimal level of client wellness in diverse nursing settings/ contexts. Additionally, nurses use critical thinking and current scientific research to facilitate translation of knowledge, skills, and technologies into professional nursing practice (Wolf & Bailey, 2013, p. 339).

Strengths of the Model

- The theory examines the relationship of the nurse to the patient and the important fact that both are unique individuals, but working towards the same end goal to provide effective humanistic nursing care. Every relationship is different and nurses and patients may differ in opinion on a wide variety of topics ranging from values to expectations.
- Additionally it stresses on the Nurse's availability (Call and response) to attend to the patient's need (Wu & Volker, 2014).
- It recognizes nursing as an academic and practice profession in which nurses use critical thinking and current scientific research to facilitate translation of knowledge, skills, and technologies into professional nursing practice.
- It therefore underscores the role of research and evidence based nursing practice.

Limitations of the Model- The humanistic model has been criticized for having the following limitations:

- It emphasizes on client- Centered Therapy which is of limited help for individuals with complex problems as observed in most palliative care patients (Boyd, 2013).
- Additionally the model does not emphasize on the need to work towards a patient/client achieving independence (through self or care provider intervention) but emphasizes the constant presence of the nurse (professional). This may not be practical in the Kenyan context where most of the palliative care services are provided on out- patient basis and care is given by relatives.
- The fact that the model stresses on nurses' constant availability puts a limitation for its use in countries with limited human resource like Kenya.
- The five steps of the nursing process emphasize on the imparting patient knowledge and do not follow the conventional five steps of the nursing process (Assessment, Nursing Diagnosis, Planning, Implementation and Evaluation).

2.6.5.2 Virginia Henderson's need based theory

Concept- Virginia Henderson believed that "the unique function of the nurse is to assist the individual, sick or well, in the performance of those activities contributing to health or its recovery (or to a peaceful death) that he would perform unaided if he had the necessary strength, will or knowledge; And to do this in such a way as to help him gain independence as rapidly as possible" (Nurselabs, 2021).

The theory presents the patient as a sum of parts with bio psychosocial needs, and the patient is neither client nor consumer. She conceptualized the nurse's role as assisting sick or healthy individuals to gain independence in meeting 14 fundamental needs. The first 9 components are physiological; the tenth and fourteenth are psychological aspects of communicating and learning; the eleventh component is spiritual and moral while the twelfth and thirteenth components are sociologically oriented to occupation and recreation (Ahtisham & Jacoline, 2015).

Virginia Henderson recognized the importance of increasing the patient's independence so that progress after hospitalization would not be delayed (Henderson, 1991). Henderson was a nurse educator, and the major thrust of her theory relates to the education of nurses emphasizing that nurses should be educated up to University level. Considering that her concept of nursing was derived from her practice and education; her work is inductive and a careful analysis of the theory by the researcher, in relation to its applicability to palliative care brought out the following concepts, strengths and weaknesses:

Assumptions of the theory- The major assumption of the theory is that nurses care for patients until patients can care for themselves once again assuming that nurses are willing to serve and that they will devote themselves to the patient day and night. Another assumption is that nurses should be educated at the university level in both arts and sciences (Nurselabs, 2021).

Metaparadigms

i. Individual or patients- The theory considers the biological, psychological, sociological, and spiritual components which form the four domains of palliative

care. Patients are also considered to have basic needs that are a component of health and requiring assistance to achieve health and independence or a peaceful death (Gonzalo. 2021).

ii. Environment- It is described as external conditions and influences that affect life and development. This refers to all the settings in which an individual learns unique pattern for living. Basic nursing care comprises providing conditions to enable the patient perform the 14 activities unaided (Kieft, 2014).

iii. Health- Definition is based on individual's ability to function independently as outlined in the 14 components. Nurses need to stress promotion of health and prevention and cure of disease. Health is therefore determined by the individual's ability to meet these needs independently (Bircher & Kurvilla, 2014).

iv. Nursing -Temporarily assisting an individual who lacks the necessary strength, will and knowledge to satisfy the basic needs. A nurse assists and supports the individual in life activities and the attainment of independence (Zamanzadeh et al., 2015). In summary the nurse should supplement a patient's strength will or knowledge according to his needs.

Usefulness- The theory has influenced nursing education and practice as it stipulates the unique role of the nurse and states the 14 activities that form the basis for nursing care.

Testability- the theory can guide research in palliative care considering that the 14 needs fall under the four domains of palliative care (Physiological, psychological, social and spiritual).

Parsimony- Henderson's work is parsimonious in its presentation, but complex in its scope. The 14 activities summarize nursing care actions while the ability to perform them independently forms the complexity of the theory.

Strengths- The strengths of this theory can be described in terms of its applicability to palliative care as follows:

- The unique function of the nurse is "to assist the individual, sick or well, in the performance of those activities contributing to health or its recovery (or to a peaceful death) is a reflection of the palliative care concept concerning patient needs in the course of their illness continuum. Palliative care is not curative and recognizes the fact that death may be inevitable.
- Describing the person as having bio psychosocial needs supports the palliative concept of holistic care.
- The theorist recognized the need for increasing patient independence for purposes of discharge. This compares to palliative care service provision in Kenya as most of the services are provided on outpatient basis due to the chronicity of the conditions and the need to encourage community based approach to care.

Weaknesses- The major weaknesses of this theory lay in its assumptions as follows:

- The theorist focused on ensuring that the patient is helped to gain independence as rapidly as possible which may not be applicable in palliative care owing to the chronic conditions the patients suffer from and the fact that most of the patients need end- of- life care. The goal of palliative care is not to cure but to add life to the days of a patient.
- Another assumption is that nurses should be educated at the university level in both arts and sciences. Most of the nurses providing palliative care services in Kenya and most low and middle income counties are educated up to diploma level hence the assumption may not be valid in the African context.
- The theorist defined health based on individual's ability to function independently as outlined in the 14 components. Additionally, concerning the environment she notes that Basic nursing care involves providing conditions under which the patient can perform the 14 activities unaided. These two targets may not be achievable for most palliative care patients. On assisting the individual in the dying process, there is no explanation of what the nurse does to assist the patient to "peaceful death."
- Finally there is an absence of a conceptual diagram that interconnects the 14 concepts and sub-concepts of Henderson's theory.

2.6.5.3 Jean Watson's theory of Human Caring

The nursing model states that *"nursing is concerned with promoting health, preventing illness, caring for the sick, and restoring health."* It focuses on health promotion, as well as the treatment of diseases. According to Watson, caring is central to nursing practice, and promotes health better than a simple medical cure. She believes that a holistic approach to health care is central to the practice of caring in nursing (Zamanzadeh, 2015).

Watson's theory described ten carative factors/ caring needs critical to the caring human experience that needs to be addressed by nurses with their patients when in a caring role. These were: (1) forming humanistic-altruistic value systems, (2) instilling faith-hope, (3) cultivating a sensitivity to self and others, (4) developing a helping-trust relationship, (5) promoting an expression of feelings, (6) using problem-solving for decision-making, (7) promoting teaching-learning, (8) promoting a supportive environment, (9) assisting with gratification of human needs, and (10) allowing for existential-phenomenological forces (Pajnkihar et al., 2017).

Major Concepts-The Philosophy and Science of Caring has four major concepts: human being, health, environment or society, and nursing.

Society/ environment- According to Watson the Society provides the values that determine how one should behave and what goals one should strive toward. Caring is transmitted by the culture of the profession as a unique way of coping with its environment (Kieft, 2014).

Human being- A Human being is a valued person to be cared for, respected, nurtured, understood, and assisted; in general a philosophical view of a person is a fully functional integrated self. Human is viewed as greater than and different from the sum of his or her parts (Pajnkihar et al., 2017).

Health- Health is the unity and harmony within the mind, body, and soul; health is associated with the degree of congruence between the self as perceived and the self as experienced.

Nursing- Nursing is a human science of persons and human health-illness experiences that are mediated by professional, personal, scientific, esthetic, and ethical human care transactions (Nurseslabs, 2019).

Usefulness –According to Durant and others, Watson's works on the Theory of Human Caring and the Art and Science of Human Caring is applied by nurses in diverse settings; clinical area, schools and community health care. For example, Brockopp and colleagues (2011) details an evidence-based, practice-based practice model rounded in Watson's theory of caring. Furthermore, schools around the world are using Watson's science of caring in nursing education. They include Scandinavia (Wicklund- Gustin & Wagner, 2013), Japan (Ishikawa & Kawano, 2012), and throughout the United States in nursing curricula (Hills et al., 2011). Numerous nationwide community caring projects have made a difference in such areas as immediate care for victims of natural disasters (Durant et al., 2015).

Testability- Testing of Watson's theory and dissemination of findings are progressing. In her research Malone reported that the Watson's paradigm of transpersonal caring was a means to provide the compassionate care needed by patients with chronic pain, who are vulnerable to the comorbidities of depression and anxiety and often have poor outcomes (Malone, 2018).

Parsimony- Watson's theory is comparatively parsimonious. Although a number of new concepts and terms are defined, there are only 10 carative factors or areas to be addressed by nurses.

Strengths- The theory addresses aspects of health promotion, preventing illness and experiencing peaceful death, thereby increasing its generality. The carative factors provide guidelines for nurse-patient interactions, an important aspect of patient care.

Weaknesses- The Human Caring Theory continuously focuses on the "spirit", and has a lack of emphasis on the physical entities of an individual making it difficult to apply in physical care e.g. pain management practice. Additionally considering the number of caritas it takes too much time to incorporate them into practice especially in a resource constraint country.

2.7. Summary and research gaps

Pain management is an essential process for nurses because they spend most time of the day with the patients. Success in pain control by use of opioid analgesics is influenced by various factors to include the socio demographic characteristics of the nurses especially their education level. Knowledge deficit about overall pain management is not uncommon among health-care professionals nurses included.

There are various barriers to pain management which include: Inadequate knowledge, fear and misconceptions regarding opioid analgesics as well as legal restrictions on opioid handling and prescription. The commonly used pain assessment tools include single- dimensional and multi-dimensional scales while the pain management modalities are both non- pharmacological and pharmacological with the latter being guided by the WHO ladder which were found to have gaps when it comes to providing impeccable assessment and management of pain in palliative care.

Gaps- Literature revealed that in Kenya there were no standardized Models and guidelines outlining the comprehensive role of the nurse in the management of patients on opioid analgesics though the nurses are the majority care givers to patients who require palliative care. This calls for development of a nursing care model to guide the practice of pain management by use of opioids which was considered an innovation. The model would provide guidelines on how to assess pain in different population groups to ensure effective management. It was envisaged that the model would gain acceptance among both the change agents and opinion leaders who are the policy makers as it did not reflect any conflict of interest within the professionals. However this was fully not established as there is need to allow users to utilize the Model for some time to be able to evaluate it effectively by use of research. Additionally some of the barriers identified during the research may however not be adequately addressed by development of the Model as they require Policy and legislative shift. The research therefore makes recommendations to the relevant authorities to address them.

CHAPTER THREE

STUDY METHODOLOGY

3.0. Introduction

In this chapter, research methodology is described including application of the Theoretical Framework, Research design, sampling technique, recruitment, data collection, analysis, as well as Ethical considerations in research. To facilitate flow of information, the chapter is organized into three parts which are continuous. The first part gives the background information to include application of the theoretical framework, paradigm of inquiry, philosophical, epistemology and ontological perspectives in the study methodology. The second part describes the methodology phase one while the last part describes methodology for Phase two and three.

The aim of the research was to develop a Model of pain management by use of opioid analgesics in palliative care. To achieve this objective it was important to use the appropriate methodology using participants' views plus literature review as data, hence the use of two theoretical underpinnings. The research adopted a three- phased mixed methods research design. Mixed method research involves collecting, analyzing, and interpreting quantitative and qualitative data in a single study or in a series of studies that investigate the same underlying phenomenon (Schoonenboom & Johnson, 2015).

In phase one descriptive analytical Cross sectional research methodology was adopted guided by Diffusion of Innovations theoretical framework, whose results were used to guide the second and third phases/ the Model development process. Model development was done by applying the Grounded Theoretical framework. Grounded theory was designed for theory development hence it was chosen for this research. Secondly, the choice of nurses (who provide most of care) and other palliative care experts/specialists was necessary because they represented rich sources of data relevant for the study.

3.1. Research design

The first phase adopted descriptive analytical cross- sectional study design. Descriptive cross sectional design was used to determine frequency of commonly encountered barriers in pain management, nurses' knowledge of pain management guidelines and pharmacology of opioids. It sought to address objectives one, two and three. Analytical cross sectional study design was used to test relationship between variables to include participants' level of education/ work experience and knowledge of pain management guidelines.

Phase two and three sought to address objectives four (gaps in the recommended guidelines) and five (Model development process) of the research respectively. To establish the gaps in the pain management tools and guidelines identified during phase one plus the recommendations on how to address the gaps, qualitative research was done by conducting Key Informant interviews. The Key informants were required to state the gaps in the commonly used pain management guidelines and further recommend how they can be addressed. Objective five which involved development of the Model was addressed by use of Classical grounded theory methodology (Interviews, data coding, categorization and crafting of the Model). Figure 4 illustrates the three phases of the study and application of mixed method research.

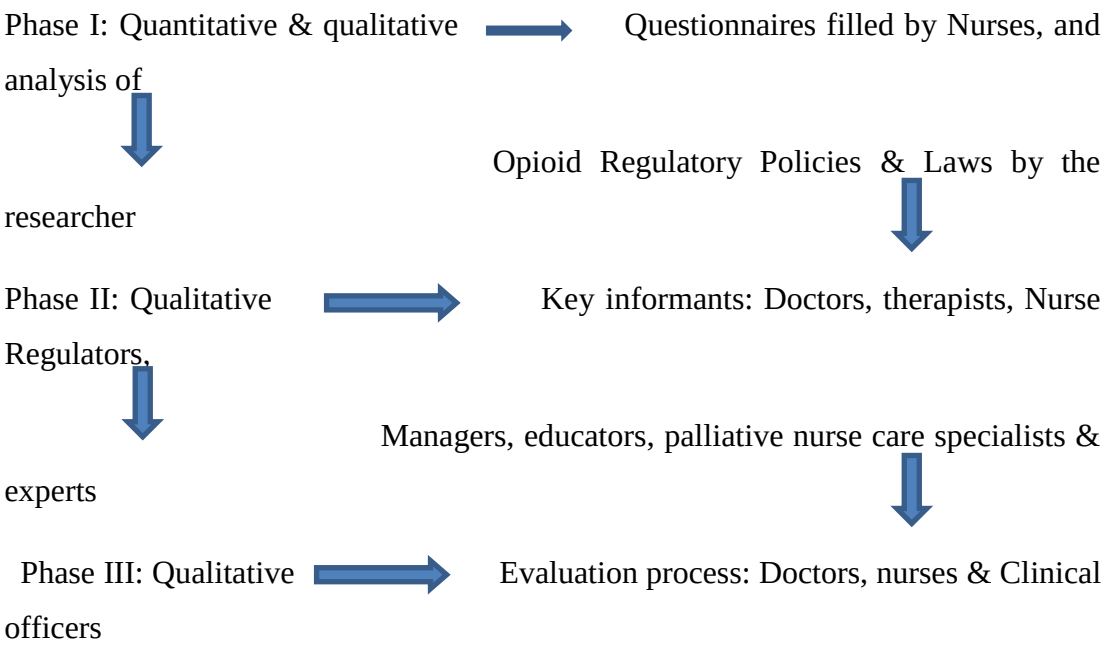

Figure 3.1: Summary of the research design

3.2. Application of the theoretical framework in research methodology

3.2.1. Diffusion of Innovations theoretical framework

Diffusions of Innovations theoretical framework was adopted during Phase one of the research as it supports both quantitative and qualitative research design. The quantitative approach has been justified by its success in measuring, analyzing, replicating, and applying the knowledge gained (Streubert & Carpenter, 2011). This was used to collect data in phase one. Qualitative research arose because aspects of human values, and relationships could not be described fully using quantitative research methods. Qualitative research was adopted in a few questions in phase one. These included questions seeking information concerning the recommended pain management guidelines and knowledge on pain management practice generally. In phase two and three all questions adopted qualitative method. The research also involved scrutinizing the commonly used pain management guidelines and Acts of parliament regulating opioids to collect data which justifies the mixed method approach. Diffusion of innovations theoretical framework was adopted also in data collection process. This is owing to the fact that the research can be compared to an

innovation as it sought to develop a model of pain management by use of opioids which is an innovation in palliative care. The five steps of the Diffusion research process were adopted as follows:

Knowledge – The researcher created awareness of the intention to develop a model to the hospital administrators and the participants who were anticipated to be consumers of the innovation/ model. This was done by explaining concepts, uses and the benefits the innovation was likely to bring to palliative care and nursing in general. Additionally upon completion of the model it was validated in the clinical area following dissemination to the users.

Persuasion – Upon understanding what the research was about and the benefits thereof the administrators were persuaded that there were no negative consequences of the research process. The participants on the other hand understood what was required of them as well as the process of giving consent for the research.

Decision – The hospital administrators went on to allow the research to be undertaken in the institution by allowing access to the participants on condition that the findings of the research would be utilized for the benefits of the institutions and the entire palliative care fraternity. The participants signed informed consent agreeing to participate in the study.

Implementation – the researcher went on to undertake data collection and analysis of the first phase. The results were communicated to the hospital administrators, policy makers and palliative care experts some of whom were recruited as key informants during the second phase of the research.

Confirmation – Findings of the first phase were evaluated some of which formed the basis for development of the Model of pain management by use of opioids in palliative care (in phase two).

3.2.2. Application of Classical Grounded theory framework

Classical Grounded theory methodology was utilized in Phase II and III to generate concepts or categories of the theory from information given by Key informants, and

to guide the Evaluation/ evaluation of the Model. Grounded theory (GT) is a research methodology that is concerned with the generation of theory, which is 'grounded' in data that has been systematically collected and analyzed. It uses a bottom up approach as a way of developing theory empirically (Mediani, 2017). Additionally, the research adopted pragmatic philosophical framework and the paradigm of inquiry which guided the choice of the epistemological and ontological perspectives.

The research process in phase II aimed at scrutinizing the commonly used pain management tools identified in phase one for gaps that could create barriers to pain assessment and control by use of opioids. It also involved generating information concerning the nursing concepts and finally development of the Model.

Phase three involved dissemination of the research findings to the hospital administrators and Evaluation/ evaluation of the Model. Dissemination of the Model was done to hospital administrators and clinical staff while evaluation to assess its parsimony and usefulness was done to Doctors, nurses and clinical officers deployed in the medical, surgical, paediatric wards and palliative care unit.

3.3. Study area

The study was conducted in Embu and Machakos County Referral (Level Five) Hospitals which were purposively sampled owing to the features they had which were relevant to the research. Embu Level Five Hospital is located approximately 160 km form Nairobi. The county is largely cosmopolitan with a population of 608,599 persons (census 2019). The county borders Kirinyaga to the west, Kitui to the east, Tharaka Nithi to the north, Machakos to the south. Embu County referral Hospital provides curative, preventive, promotive and rehabilitative services.

The need for palliative care services in Embu County is evident as shown by a previous analysis of cancer cases which showed that 61 per cent of the women suffered from different strains of cancer compared to 39 per cent of the men (Githinji, 2017). Additionally Embu Level Five hospital (formerly the Eastern Provincial General Hospital) admitted patients from Embu and the neighboring counties hence having a big number of clientele for palliative care.

Machakos level five hospital is situated approximately 60 km from Nairobi Central Business District area. It had a population of 1,421,932 as of 2019. The county borders Nairobi and Kiambu counties to the west, Embu to the north, Kitui to the east, Makueni to the south, Kajiado to the south west, and Murang'a and Kirinyaga to the North West.

Owing to its proximity to Nairobi the Hospital also provided services to many cancer patients from the overstretched Kenyatta National Referral Hospital. Additionally the Hospital has a well- equipped Cancer Care and Research Centre which offers screening, counseling, treatment and palliative care services for most patients from the counties within the South Eastern Kenya Economic Bloc. In 2018 Machakos County was considered a pilot for Universal Health Coverage (UHC) project. It was envisioned that UHC would ensure all Kenyans had access to Palliative, preventive, promotive, curative and rehabilitative health services at minimum financial burden. The 2018 commencement date for UCH pilot in Machakos County was relevant to this study considering that participants were recruited in 2019 following the roll out of the pilot Universal Health Coverage programme which was reported to have benefited about 252,000 patients.

3.4. Study Population

The study population constituted two hundred and seventy nine (279) participants distributed as follows: phase one constituted two hundred and thirty nine (239) nurses working in Machakos and Embu Level Five Hospitals. These were prportinately sampled based on population of nurses in the two hospitals hence a hundred and forty six (146) were from Machakos while ninety three (93) were from Embu Level Five Hospitals respectively. The main survey constituted forty participants: In phase II twenty two (22) key informants were purposively sampled to include Doctors, nurse administrators, Regulators, palliative care educators, specialists and experts. It was believed that the participants would provide a rich source of data based on their qualifications and work experience. In phase III eighteen (18) participants were recruited from the clinical area to participate in the evaluation process.

3.5. Sampling

3.5.1. Sample size determination

i) **Phase one**- Total population of nurses working at Machakos Level Five Hospital was 365 while Embu level five Hospital had 231 nurses. To determine the sample size in phase one, Slovin's Formula was used; Slovin's formula allows a researcher to sample the population with a desired degree of accuracy. Slovin's formula gives the researcher an idea of how large the sample size needs to be to ensure a reasonable accuracy of results (Ellen, 2019).

Slovin's Formula for sample size determination was used as follows: ($n = N/1 + N (e)^2$

n = no. of samples
N = total population
e = error margin / margin of error

Total number of number of nurses working in the hospital targeted areas (N) was 596

Margin of error will be 0.05 based on 95% confidence interval.

Sample size therefore was: 596 /1+ 596 (0.05 x 0.05) = 239 participants,

Number of participants from Embu Level five hospital: 231/596 x 239= 93

Number of participants from Machakos Level Five Hospital: 365/596 x 240 = 146

The total number of participants was two hundred and thirty nine (239) who were then proportionately sampled as per the hospital nursing population as follows: Ninety three (93) nurses were sampled from Embu Level Five Hospital while one hundred and forty six (146) nurses were sampled from Machakos level five hospital.

ii) Phase two (using Grounded theory): **-** According to Charmaz and Morse, 30– 50 participants is the minimum sample size required to reach saturation and redundancy in grounded theory studies that use in-depth interviews. This number is considered adequate for publications in journals because it (1) may allow for thorough examination of the characteristics that address the research questions and to

distinguish conceptual categories of interest, (2) maximizes the possibility that enough data have been collected to clarify relationships between conceptual categories and identify variation in processes, and (3) maximizes the chances that negative cases and hypothetical negative cases have been explored in the data (Dworkin, 2012). Based on this guideline the total sample size for the research was 40 participants recruited as follows: 22 of them were recruited in phase two to give their views during the Model development process while 18 were recruited during the evaluation process in phase III.

Table 3.1: A Breakdown of study participants

Phase	Institution	Total No. of Participants	No. of participants sampled per institution
Phase 1	Machakos Level Five Hospital	365	146
	Embu Level Five Hospital	231	93
Phase 2&3			40
Total			**279**

3.5.2. Sampling procedure

i**) Phase one**- In phase one Systematic sampling method was adopted; the sampling interval was determined by dividing the entire population size by the desired sample size and picking the K^{th} person. Based on the total population of 596 and the sample size of 239 the third person was recruited from the total population (all the nurses working in sampled health care units safe for those meeting the exclusion criteria).

ii) **Phase two and three:** This was done using Grounded Theory. In Classic Grounded theory studies sampling begins purposively, as in any qualitative study followed by theoretical sampling in which case participants are selected based on a set criteria. According to Cresswell & Clark (2011) purposive sampling involves identifying and selecting individuals or groups of individuals that are especially knowledgeable about or experienced with a phenomenon of interest (Palinkas, 2015). Phase two and three therefore adopted Purposive sampling which was done in phase two based on the positions of the participants in the Ministry of Health. The participants were not only from the two counties but also from training institutions, hospices and palliative care units. They were distributed as follows: Nurse Managers at the Ministry of Health headquarters (2), regulatory authorities (1), County offices (2) and Hospital administrative offices (2) who were required to address matters pertaining to policies on palliative care. Further theoretical sampling was done based on the qualifications and expertise of the participants in palliative care who were

required to give input regarding palliative care and pain management concepts that would constitute the metaparadigms of the Model. These were Oncologists/ Doctors (2), palliative care nurse specialists (3), and palliative care experts (9) and a nurse educator (1). Theoretical sampling was also adopted in phase three when further information was collected from the Model users in the clinical setting. These were 1 Doctor, 3 clinical officers, and 14 nurses. The information was used to further make changes to the model to improve on its parsimony.

3.5.3. Inclusion and exclusion criteria

3.5.3.1. Inclusion criteria

To be eligible to participate in Phase one, the participants had to be: Kenyan citizens aged 20 years and above and be Registered/Enrolled nurses working in the selected clinical settings at the time of data collection.

Participants in phases two and three were: Employees under the Ministry of health working in the sampled counties or Ministry of Headquarters, Nurse educators, Palliative care specialists and experts working in KEHPCA, Hospices and palliative care units, medical doctors, nurses, clinical officers working in other clinical areas.

3.5.3.2. Exclusion criteria

Healthcare professionals on annual leave during the time of data collection and those not willing to participate in the research were excluded from the study.

3.6. Data collection Instruments

3.6.1. Development of data collection tools

In phase one the instrument/questionnaire developed for data collection was an attitude and other barriers scale which was meant to collect information on values, beliefs about use of opioids in pain management as well as other aspects of pain management in palliative care. It was a modification of The Nurses' Knowledge and Attitudes Survey Regarding Pain (NKASRP) tool. This tool has been used to assess nurses in hospital settings and as an indicator of nurses' perception of pain management. The NKASRP tool has been revised over the years to reflect changes in

current pain management practices. The content of the tool was derived from current standards of pain management such as the American Pain Society, the World Health Organization, and the National Comprehensive Cancer Network Pain Guidelines (Salameh, 2018).

In this research the instrument was developed/ modified by identifying several themes that represent barriers to pain management in palliative care as identified in literature review. The themes were organized to inform the items for the questionnaire. The preliminary items included 7 demographic questions and 20 attitude and other barriers questions. The other questions requested for information concerning knowledge about opioid analgesics, tools and guidelines used for pain management as well as the gaps/ omissions encountered in the tools used for managing pain on patients who have had opioids prescribed for them.

A likert scale was used as the psychometric response to provide a measure of extremity. The items were coded accordingly: Strongly agree- 5, agree- 4, unsure-3, disagree- 2 and strongly disagree- 1. Some of the questions in the section were used to evaluate the level of nurses' knowledge on pharmacology of opioid analgesics.

In phase two a Key informant interview guide, a static data collection tool was adopted. It constituted fourteen questions distributed as follows: three on views of administrators and policy makers regarding pain management guidelines and recommendations for improvement. Seven questions to palliative care experts and specialists asking their views on commonly used pain management tools and guidelines and recommendations for improvement. The last section had four Questions specific on the nursing metaparadigms directed to the palliative care nurse specialists and experts. The maximum number of questions per participant was eleven. The questions were developed guided by results of the pain management tools obtained in phase one. The development was also guided by the need to address the last objective of the study (developing a Model) which necessitated collection of information pertaining to the concepts of the Model. Phase three involved use of a researcher administered questionnaire seeking to determine the parsimony, testability and usefulness of the Model.

3.6.2. Quality assurance

To ensure quality data was collected, the tool validity and reliability was paramount. Validity of an instrument is a determination of how well the instrument reflects the abstract concept being examined while reliability is concerned with the consistency of the measurement (Mohajan, 2017). To test the reliability of the test items on the questionnaire to assess knowledge level Cronbach's Alpha test was used. Cronbach's alpha is a measure used to assess the reliability, or internal consistency (inter-item covariance), of a set of scale or test items; an alpha of 0.7 indicates acceptable reliability and 0.8 or higher indicates good reliability (Glen, 2014).

Further validity of the entire data collection tool was pre-tested by administering it to nurses working at Thika Level Five Hospital. This was a level Five hospital just like Embu and Machakos; it also had a palliative care unit. Owing to its location Thika Level Five Hospital enjoys accessibility by patients from both Machakos and Embu counties. Views and inputs given by the nurses during pretesting of the questionnaire were used to establish the need for other items to be included in the questionnaire as well as need to expunge or modify the items there in.

3.7. Data collection procedure

3.7.1. Selection and training of research assistants

Four research assistants were selected and trained on the purpose of the research, objectives, ethical guidelines to be followed and how to administer the questionnaire. They were also given a brief explanation of the literature review and the situational analysis to help answer any questions raised during data collection process. The four were Kenya registered nurses, two of whom were holders of Bachelor of Science in nursing while the other two were diploma holders. Diploma holders form majority of the nurses in the hospitals followed by degree holders.

3.7.2. Actual Data collection process

i) **Data collection for Phase one**: - Permission to access participants during phase one was sought from the hospital administration and county directors of health. Permission to conduct research was sought from National Commission for Science,

Technology & Innovation (NACOSTI) and the County Departments of Education. After securing the necessary approvals the research assistants went on to explain the procedure to the participants and request for consent. Those willing to participate in the research upon signing the consent forms were issued with questionnaires to fill in at that time or within a day. Use of self- administered questionnaires saves time as the information is collected simultaneously. To achieve this, questionnaires were administered to respondents and later collected for analysis. Further, review of the existing pain management policies and regulatory Acts of parliament was done to identify more barriers to pain management.

After completion of all the data the research assistants collected the questionnaires, checked for any missing information before allowing the participants to leave then thanked the participants. Questionnaires were then taken for data analysis after which feedback of phase one results was given to the administration prior to commencement of the second phase of the study.

ii) **Data collection in phase two and three: -** This was guided by Grounded theory framework. Grounded theory commonly uses the following data collection methods: Interviewing participants with open-ended questions. Further, it utilizes participant Observation (fieldwork) and /or focus groups discussions (Sbraini, 2016). Data collection or generation and analytical conceptualization need to be rigorous throughout the research process to secure excellence in the final grounded theory (Tie, 2019). This was adopted during the Model development process as follows:

The interview process in phase two took three weeks. The interviews were digitally/ audio recorded by use of a Samsung phone and transcribed in temi. The researcher wrote memos throughout this period. The process of data collection and data analysis which occurred concurrently, continued until theoretical saturation was achieved (consensus building done) meaning that new data did not contribute any longer to a substantial development of the theory.

Phase three involved evaluation of the emergent model. To achieve that, researcher administered semi- structured questionnaires were utilized to collect information

from the clinical area staff regarding the parsimony, testability and usefulness of the Model following sensitization process.

3.7.3. Overcoming bias

Bias relates to methodical sources of error which need to be considered. This is owing to the fact that internal validity of a study depends mostly on the extent to which biases have been accounted for and essential steps taken to diminish their impact (Skelly et al., 2012). The following biases were addressed during the research process:

- Selection bias- could have occurred if the researcher chose to focus on nurses who had achieved a certain level of qualification e.g. those with a higher national diploma in palliative care. To avoid that bias systematic sampling was done and all nurses working in the clinical setting had an equal chance of participation in phase one since they all care for patients with different types of pain.
- Information bias- False information especially on areas related to institutional policies and resources could have been provided if the participants had fear of victimization. To avoid that the participants were assured of confidentiality and names were omitted from the questionnaires.
- Interviewer/ observer bias- recording of exposure information may vary depending on the investigator's knowledge of the variables. To avoid this all the questionnaires administered during baseline survey were to be filled by the participants in their own handwriting and not by the research assistants or the researcher.

3.8. Data analysis

3.8.1 Data cleaning and analysis in phase one

In phase one data from complete questionnaires was coded and entered in Epidata 3.1.for cleaning. Data Cleaning was done by identifying and removing any outliers. Data analysis was undertaken using Stata version 14. This was used to analyze the quantitative aspect of data i.e. participants' demographic characteristics and knowledge of pain management guidelines and tools. The aim of these analyses was

to summarize the nurses' responses on a number of issues within the major areas/ sub themes guided by the objectives of the study. The main quantitative statistics was based on frequencies and percentages of variables. Both Descriptive and inferential statistical methods were used during data analysis. Descriptive statistical method was done to analyze the socio demographic characteristics of the respondents. Analysis of Qualitative data i.e. pain assessment tools and management guidelines was done by coding the data and categorizing it into interrelated themes. It then converted into quantitative measures and analyzed using Excel 2019.

The knowledge, attitude and practice on pain management were assessed by use of questions, scored in a Likert Scale using the responses from the questions asked. Each correct answer scored one point while the wrong responses scored zero. Knowledge scores ranged from 0-5 while attitude and practice scores ranged from 0-5 as well. The total score was 25 marks hence the pass mark was 13 scores. Knowledge level was therefore categorized as "knowledgeable if the score was 13 and above or "not knowledgeable" if the score was below 13. The scores were then converted to quantitative data and analyzed using EXCEL 2019.

Measures of central tendency (mean, standard deviation and interquartile range) were calculated in excel. Inferential statistics were used to compare relationships between study variables. The relationship between variables was determined and expressed by use of chi square method of data analysis with P values set at 0.05. This was done using Pearson' Chi- squared Test statistic. Pearson's chi-squared test is a statistical test applied to sets of categorical data to evaluate how likely it is that any observed difference between the sets arose by chance. The significance of Chi-square value is determined by using the suitable degree of freedom and degree of significance (Turhan, 2020).

3.8.2. Thematic analysis of gaps identified in commonly used pain management guidelines

To establish gaps in pain management guidelines in phase two thematic data analysis method was adopted in six steps as follows:

- ✓ Familiarization- Transcription of the audio recordings was done by use of Temi an automated speech recognition engine that rapidly transcribes audio to text. Following the transcription process, the researcher read through the data to familiarize with the responses.
- ✓ Data coding- Deductive coding was adopted whereby predefined codes were allocated based on study questions and the responses that came from the participants.
- ✓ Identification of patterns was done from the responses.
- ✓ Generating themes- This was done from patterns of responses identified from the coded responses.
- ✓ Naming of the themes- names were given for ease of analysis. These were based on the key words identified in the themes.
- ✓ Writing up- This was done by giving a detailed information on how the data was collected, analysis done and finally conclusions and recommendations of the study.

3.8.3. Data analysis for Model development (in Grounded Theory)

In Grounded theory data analysis commences after initial data has been collected and runs concurrently with data collection process. In grounded theory-based analysis, the researcher generally analyzes the data as follows: finding repeating themes by thoroughly reviewing the data; **coding** the emergent themes with keywords and phrases; grouping the codes into concepts hierarchically; and then categorizing the concepts through relationship. In this research interviews were audio recorded and transcription done in Temi to enhance data review after which the process of analysis commenced. The research adopted two staged coding as recommended by Glaser for Classic grounded theory (Mediani, 2017).

Coding: a) Substantive coding:- During the Model development process substantive coding was done by: i) open coding which involved summarizing of all the audiotaped and transcribed data from the key informant interviews and assigning codes by use of key words. Analysis of each individual segment was done by breaking the transcripts line- by- line.

Examples of open coding of the “Person” Concept

Person

Patient i) With life – limiting illness

ii) Any level of illness

iii) On aggressive cancer treatment

Family: i) Relatives who care for him

ii) Family members

Care givers: Those who care for the patient whether related to him/her or not.

ii) Selective coding:- Through the concurrent process of data collection, cleaning and analysis categories of interrelated sub- themes were developed (selectively coded) from the items of the interview guide as follows: The segments developed from open coding were grouped into categories. Upon consensus building which followed initial interviews a common definition (category) of each concept was arrived at. For instance the metaparadigm of person was defined as “A person with life- limiting illness plus the family and the care givers. This was derived from the three definitions given during the interview process as identified during open coding.

b) Theoretical coding- was done by conceptualizing the inter-relationships of the substantive concepts. The concepts were developed from the collected data and the memos written during the interview process.

Writing Theoretical Memos -In grounded theory Memo writing is the methodological link, through which the researcher transforms data into theory. In the memo writing process, the researcher analytically interprets data. Through sorting, analyzing, and coding the 'raw' data in memos, the Grounded Theorist discovers emergent social patterns. According to Glaser theoretical memos were records of the researcher’s developing ideas about codes and their interconnections. Thus, memos

are informal analytic notes about the data and the theoretical connections between categories (Tie, 2019).

Throughout this study memos were written during interviews for generation of the concepts for Model development and during the evaluation process. The content of the memos included researcher's experiences during interviewers, participants' reactions and information given. Theoretical memos allowed for comparisons between data, and codes in order to establish the issues to be addressed in subsequent interviews. For instance upon interviewing the nurse managers at county level they always directed the researcher to the palliative care experts for further information on the Model development. Additionally the researcher established that the divergent views regarding the four concepts necessitated a consensus building process. Upon analysis of the data, categories and sub- categories which later were used to constitute the nursing metaparadigms were developed as indicated in table 11.

Interactions/ connections between the categories- According to Glaser (1978), Classical grounded theory surrounds a core category, or major theme, that unites all of the conceptual categories (Rieger, 2018). Pain management in palliative care being the main purpose of developing the Model formed the core concept as indicated by the responses from the interviews. The researcher went on through the process of reviewing the records and transcriptions of the interviews, codes as well as memos to bring out interrelationships between the four concepts/ metaparadigms and the core concept as shown in table12.

3.7 Data presentation/ reporting

Results from phase one were presented in charts, frequency distribution tables and narratives. Inputs given in phases two and three were analyzed and reported in narrative form. Inputs from phase two were used to form a draft conceptual model of pain management which was to be completed upon evaluation in phase three. Recommendations were drawn from the report to address the gaps in the commonly used pain management guidelines. They were shared with stakeholders to facilitate improvement of palliative care, nursing education and research.

3.8 Ethical Considerations

Approval to conduct the research was sought from Jomo Kenyatta University of Agriculture and Technology Ethics and Research Committee. Permission to access the participants was sought from the County offices and the Medical officers in charge of the health facilities where the research was conducted.

Consent was sought from the participants based on Declaration of Helsinki Statement of ethical principles for medical research involving human subjects. This involved full disclosure of information concerning the research whereby the participants were given an explanation of what they needed to know about the study to include the purpose and benefits. Components of the questionnaire were explained to create an understanding of the information required and verification to this understanding done to ensure competence. Participation was voluntary without any coercion with participants being free to withdraw at any point. Confidentiality was assured by omitting participants' names on the questionnaires and interview guides to ensure anonymity.

To guarantee confidentiality Qualitative Data was coded for analysis. Additionally, during processing of data and publishing of results the names of the participants were not indicated in the report. Considering that the model was meant to improve on the nursing care of the patients, no interventions were likely to bring harm to the patient and the nurse. All the procedures adopted put into consideration the institutional standard operation procedures to guarantee patient safety.

CHAPTER FOUR

RESULTS

4.0. Introduction

This chapter is organized into seven sections which give a report of the findings/ results of the research. In the first section, profiles of the participants are described while in the other sections the findings of the research are presented progressively according to the research objectives. Knowledge of opioid pharmacology was tested using self- evaluation and by use of specific questions testing on general pharmacology of opioid drugs. The reason for using the two types of assessment is because like most disciplines, nursing has both scientific knowledge and knowledge that can be termed conventional wisdom (knowledge that has not been empirically tested).

The sixth section gives a detailed description of the Model development process to include the theoretical scheme, nursing metaparadigms, as well as the Model diagram that illustrates how the concepts interact. The last section describes the Model evaluation process.

4.1. Demographic characteristics of the participants

The study population constituted 239 participants in phase one, twenty two (22) in phase two and eighteen (18) in phase three. Most of the participants 186 (66.7%) were females while males were 93 (33.3 %) of the study population. The professional qualifications of the participants constituted Doctors, nurses, clinical officers and a physiotherapist with the educational level ranging from certificate to PhD level. Qualifications of the 263 respondents (94.2% response rate) as per the number of analyzed questionnaires were distributed as follows: there was one PhD holder (0.4%); Master's degree holders were 10(3.8%); basic degree holders were 93(35.3%); Higher National Diploma holders-28 (10.6%); Diploma holders 123(46.8%) while certificate holders were 8 (3.1%). Work experience variables were as follows: The total number of participants in phase one who responded to the

question was two hundred and twenty six (226). Coupled with the data from the forty (40) key informants the total number was 266(a response rate of 95.3%). Therefore the distribution was as follows: those who had worked for Zero to five years were 139 (52.5%), 6- 10 years were 43 (16.2%), 11- 15years were 28 (10.5 %) and over 15 years were 55 (20.8%) participants. This breakdown is illustrated in table 4.1.

Table 4.1: Demographic characteristics of the participants

Demographic Variables	Number of responses	Response rate	Percentage
Gender			
Male	93		33.3%
Female	186		66.6%
Total	279	100%	100%
Education level			
PhD	1		0.4%
Master's degree	10		3.8%
Bachelor's degree	93		35.3%
Higher National diploma	28		10.6%
Diploma	123		46.8%
Certificate	8		3.1%
Total	263	94.2%	100%
Work experience			
0-5 years	139		52.5%
6-10 years	43		16.2%
11- 15 years	28		10.5%
Over 15 years	55		20.8%
Total	265	95%	100%

4.2 Nurses' knowledge level on general pharmacology of opioid analgesics

4.2.1. Self- evaluation

The results of self -evaluation as done by 233 participants in phase one (a response rate of 96%) showed that out of the two hundred and thirty three respondents, 28 (12%) reported to be highly knowledgeable on pharmacology of opioid analgesics while 205 (88%) reported to be moderately knowledgeable, slightly knowledgeable or not knowledgeable at all hence requiring further training in the subject.

Table 4.2: Level of knowledge of general opioid Pharmacology by self-evaluation

Knowledge of general pharmacology of opioids	Frequency (N= 233)	Percentage
Not at all knowledgeable	1	0.43
Slightly knowledgeable	50	21.46
Moderately knowledgeable	154	66.09
Extremely knowledgeable	28	12.02
Total	233	100

4.2.2. Use of test questions

To further evaluate the actual knowledge of the respondents about General Pharmacology of opioid analgesics specific questions were asked to test on the actions and effects of opioid analgesics as well as their indications for use in life limiting illnesses. Cronbach's Alpha was used to test reliability of test items and it showed a reliable factor ($\alpha = 0.7549$)- as shown:

Average inter item covariance: .5464703

Number of items in the scale: 5

Scale reliability coefficient: 0.7549

The total score was 25 marks with a pass mark of 16 scores. The test scores were analyzed on Excel with a Likert scale (values of 1- 5). The analysis yielded a mean score of 18.96 indicating that the participants were knowledgeable in opioid pharmacology. The results of individual knowledge assessment showed that 64.3% were knowledgeable while 35.7% of the respondents were less knowledgeable hence they scored less than the pass mark. This was a deviation from the results of self-evaluation as the percentages of the knowledgeable respondents increased while that of the less knowledgeable decreased as shown in table 4.2

Table 4.3: Knowledge on general opioids pharmacology by test

Knowledge of general pharmacology of opioids	Frequency	Percentage
Low knowledge level	150	64.3%
High knowledge level	83	35.7%
Total	233	100%

Measures of central tendency and dispersion

These were calculated on excel measures of central tendency and dispersion yielded the following results: Mean score was18.96, median score 19 and the mode 17. The standard deviation was 4.5, range was 20 while the interquartile range was 5.75.

Hypothesis testing: The first hypothesis for the study was:

H_o1: There is no relationship between level of education of the participants and the level of knowledge on general pharmacology of opioid analgesics.

H_11: There is relationship between level of education of the participants and the level of knowledge on general pharmacology of opioids. The analysis was as shown in table 5:

Decision: Reject H0 if P value is ≤ 0.05. Accept H0 if P value is >0.05.

Table 4.4: Relationship between education level and knowledge of pharmacology

Knowledge of general pharmacology of opioids	Highest of Education Level				
	Certificate	Diploma	Higher Diploma	Degree	Total
Knowledgeable	5	74	17	28	150
Not knowledgeable	3	48	4	54	83
Total	8	122	21	82	233

Pearson chi-squared test at 3 degrees of freedom = 3.3428 P value = 0.342

Conclusion: Based on the above results the Null hypothesis was accepted while the alternative hypothesis was rejected since the P value was 0.342 (Greater than 0.05)

which shows there was no significant relationship between education level of the participants and knowledge on general pharmacology of opioid analgesics.

4.3. Barriers encountered during pain management

The research sought to establish barriers encountered by participants while undertaking pain management interventions. The response rate to this question was 96% (N=226) and the identified barriers to pain management by use of opioid analgesics were broadly categorized into three: Knowledge related, attitude- related and prescriber- related.

4.3.1. Nurses' Knowledge related barriers

Assessment of Knowledge related barriers to pain management focused on Pain assessment and pain management interventions knowledge. Concerning pain assessment guidelines out of the 226 respondents to the question 104(46%) reported lack of awareness of the recommended pain management tools/guidelines. Only 24.5% of the participants reported knowledge of the WHO ladder as a pain management guideline. The notable barriers touching on use of opioids for pain management included misconceptions and fears regarding use of the drugs. These included fears that opioids could cause: decreased pain threshold which was reported by 38 (16%) respondents, addiction by 45(19%); respiratory depression by 75(32%); impaired perception by 30(13%) and tolerance by 85 (36%) of the respondents.

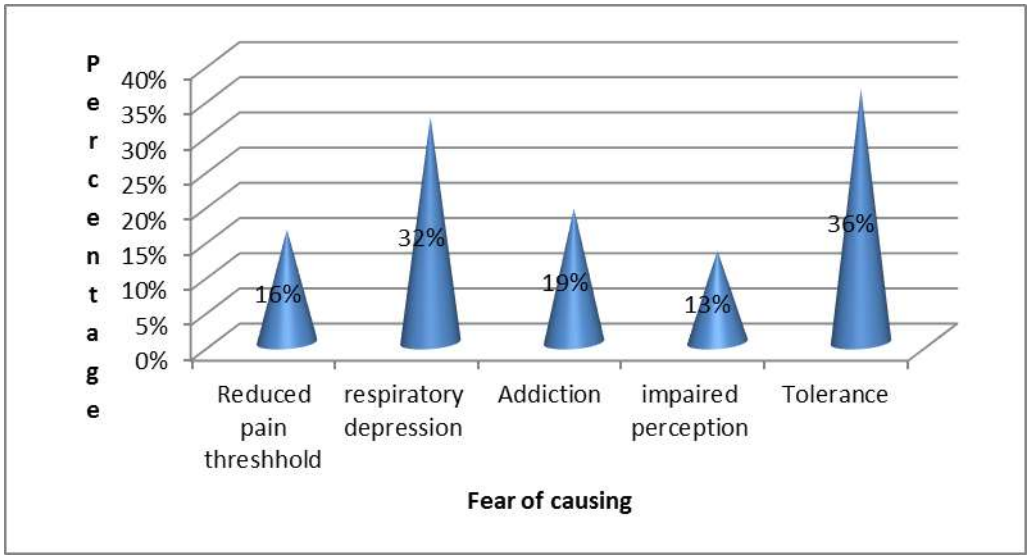

Figure 4.1: Knowledge related barriers

4.3.2. Attitude related barriers

Participants revealed negative attitude towards pain management in general. Attitude related barriers included wrong opinion about pain itself and the patient's perception and reporting of the pain experience as well as a possibility of drug abuse as indicated in figure 5. Attitude to pain was manifested by false beliefs such as pain was a normal experience, and prior experience with pain created tolerance as reported by 134 (57%) out of the 235 respondents. Negative attitude towards patients' perception and reporting of pain were displayed by 228 (97%) respondents. These included beliefs such as pain without an obvious physical cause or that is more severe than expected based on findings, is usually psychogenic; and a belief that patients tend to exaggerate their level of pain. There was also an attitude towards patients and their relatives displayed by a notion that patients and relatives could abuse the opioids once dispensed for pain management (attitude to patient and relatives). This was reported by 90 (38%) respondents.

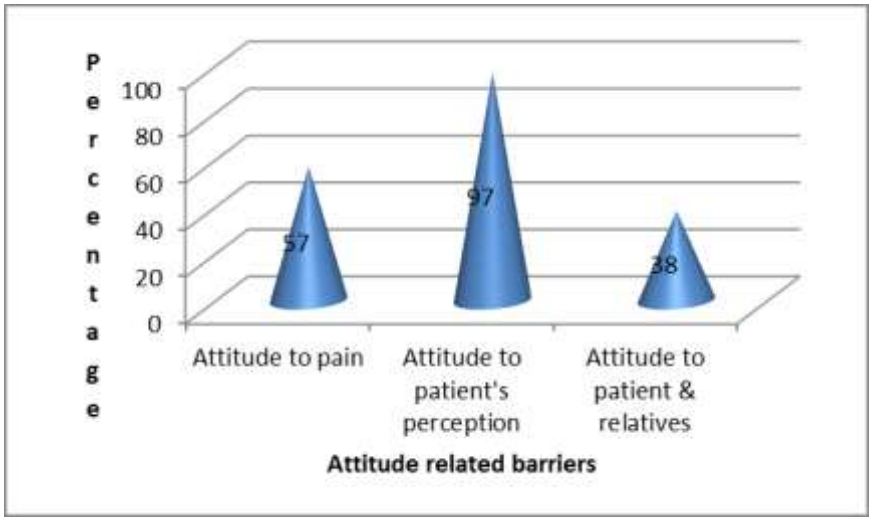

Figure 4.2: Attitude related barriers

4.3.3. Prescriber related barriers

These barriers as reported by 233 (97.5 response rate) respondents included withholding prescription of opioids by the prescribers on pretext that the risks caused by the drugs such as respiratory depression outweigh the benefits as indicated by 61 (26%) respondents; avoiding prescription of opioids to await the cause of pain to be established or for fear of causing drug tolerance as reported by 46(20%) respondents; and conflicting decision to prescribe the analgesics 83 (35%) respondents; other reasons cited for failure to prescribe the drugs were inadequate patient assessment by 136 (58%) respondents as well as shortage of prescribers by 97 (41%) respondents). The distribution of the responses is as given in figure 4.3

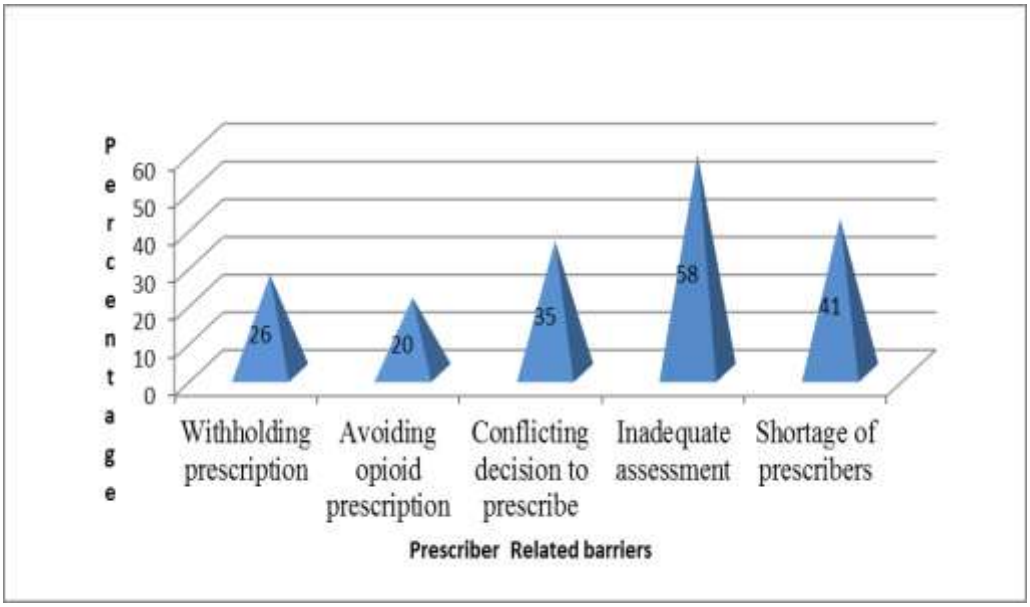

Figure 4.3: prescriber related barriers

4.4. Pain assessment and management modalities

4.4.1 Knowledge/ awareness of the recommended pain management tools/guidelines

Concerning awareness of the recommended pain assessment & management (intervention) tools/ guidelines out of the 226 (96%) respondents to this question, 122 (54%) reported awareness of the available pain management tools. However 104(46%) reported lack of awareness of the recommended pain management tools.

Hypothesis testing: Further, regression analysis of the responses was undertaken by testing the following hypotheses:

Ho2: There is no relationship between nurses' level of education and the level of knowledge on pain assessment guidelines.

H_1 2: There is relationship between nurses' level of education and their level of knowledge on pain assessment guidelines.

This hypothesis was tested using Pearson's Chi squared test at 95% confidence interval to determine the relationship between education level and his/her

knowledge/ awareness of the recommended pain management guidelines; the results showed no significant relationship between the knowledge of recommended pain assessment tools/guidelines, the education level plus the years of work experience as shown in table 4.5.

Decision: Reject H0 if P value is ≤ 0.05. Accept H0 if P value is >0.05.

Table 4.5: Relationship between education level & knowledge of pain management guidelines/tools

	Recommended of pain assessment guidelines		
Awareness of Level of education	**Aware**	**Not aware** **Total**	
Certificate	3	5	8
Diploma	68	44	122
Higher national diploma	9	12	21
Degree	42	40	82
Total	122	111	233
Percentage	52%	48%	100%

Pearson chi-squared test at 3 degrees of freedom = 2.0692 P Value = 0.558

Conclusion: Based on the analysis results (P value of 0.558) the null hypothesis was accepted while the alternative hypothesis was rejected since the P value was 0.558 (Greater than 0.05) which shows there is no significant relationship between the education level of the participants and their awareness of the recommended pain management guidelines.

The third hypothesis was: Ho3 There is no relationship between nurses' level of knowledge on recommended pain management tools and the work experience.

H_1 3: There is relationship between nurses' length of work experience and the level of knowledge on recommended pain management guidelines.

Decision: Reject H_0 if P value is ≤ 0.05. Accept H_0 if P value is >0.05.

Table 4.6: Relationship between work experience & knowledge of pain management tools

	Awareness of recommended pain assessment guidelines		
Years of Work experience	**Aware**	**Not**	**Total**
Zero to five years	57%	43%	
Six to ten years	41%	59%	
Eleven to fifteen years	54%	46%	
Over fifteen years	53%	47%	**100%**

Pearson's chi-squared test at 3 degrees of freedom (chi^2 (3) = 3.4141 P Value = 0.332

Conclusion: Based on the analysis results (P value of 0.332) the null hypothesis was accepted while the alternative hypothesis was rejected since the P value was Greater than 0.05 which shows there is no significant relationship between number of years worked and the participants' awareness of the recommended pain management tools.

4.4.2 Specific Pain assessment tools/ guidelines

The hundred and twenty two (122) respondents who confirmed awareness of the recommended pain management tools/guidelines were further asked to specify the tools they utilized for pain assessment as well as management giving the following responses: Concerning pain assessment tools 110 (90%) respondents reported to utilize pain rating scales to include: verbal descriptor scale and numeric rating scale to assess pain levels; 89 (72%) utilized both history taking and physical examination, 10 (8%) used Wong's faces scale while 17 (14%) used other modes of physical examination such as the Alertness, voice, pain & Vocalization (APVU) and Provoking factors, Quality, Radiation, Severity and Timing PQRST of pain. Others reported to use own knowledge The varied responses were as indicated in table 4.7.

Table 4.7: Commonly used pain assessment techniques/tools

Pain assessment technique	% of respondents
Numerical rating scales	90%
History taking & physical examination	72%
Wong's faces	8%
PQRST , APVU and own knowledge	14%

4.4.3 Pain intervention modalities

The common pain intervention modalities reported by the participants as being used in the facilities were as follows: use of opioid analgesics as reported by 96 (78.6%) respondents; others 50 (40%) reported that pain was managed by use of both Pharmacological and non- pharmacological methods of pain control with some (24.5%) emphasizing on utilization of WHO ladder or by ladder, mouth and clock.

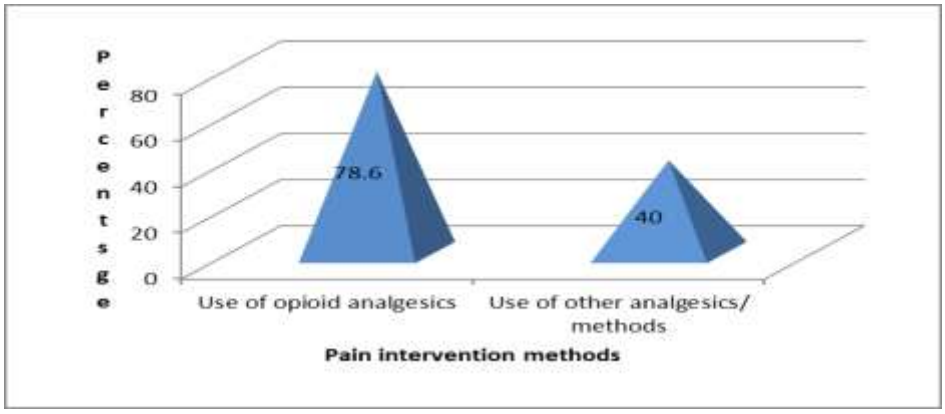

Figure 4.4: Pain management modalities

4.5. Gaps in the pain management guidelines

4.5.1. Gaps reported by participants in phase one

The research went on to establish gaps in the pain management tools/ guidelines that could act as barriers to effective pain management from the participants in phase one; and the results were as shown below: Out of the 122 respondents who reported awareness of availability of pain management guidelines, 116 (95%) respondents attested to the fact that the guidelines/tools did not provide for monitoring of side effects of the medication. Concerning the management of side effects 119 (97%) respondents reported that the tools lacked provision for the intervention (table 4.8)

Table 4.8: gaps in pain management guidelines identified in Phase one :

Do guidelines provide for	**YES**	**NO**	**TOTAL**
Monitoring of side effects?	6 (4.9%)	116 (95.1%)	122
Management of side effects?	4 (3.25%)	119 (96.75%)	123

4.5.2 Gaps identified by key informant interviewees in phase 2

During phase II further scrutiny of the pain management guidelines/tools by palliative care Experts and Specialists revealed some notable gaps since most of them focused on assessing pain and pharmacologic management of the same neglecting holistic patient care that encompasses evaluation of the interventions. Form the baseline survey it was discovered that there was uniformity in the implementation of pain management protocols. The gaps were noted form the inputs obtained from Key informant interviews as summarized in the subsequent results:

Thematic analysis of Key Informant interview results- Data was collected by use of an interview guide consisting of fourteen (14) questions to Key informants. The interview questions sought to establish views of the key informants on pain

management policies and guidelines/tools as well as recommendations for improvement on pain management practice. They also sought to establish the nursing concepts which would constitute the metaparadigms for the Conceptual model.

Pain management policies- The question was directed to participants in policy formulation both at the National and County levels of the Ministry of Health. These included the MoH representatives, The county Chief Nursing Officers, Nursing officers in charge of the two Level Five Hospitals, Nursing Council of Kenya and KEHPCA. All the respondents in this category reported need for improved palliative care policy to facilitate better pain management practice. Respondents form the National Government demonstrated awareness of the National palliative care policy with some of them pointing out that it did not clearly articulate nursing issues.

> *"There is a palliative care policy in existence though it does not clearly articulate nursing issues. It is important to develop guidelines that will improve nursing care" (p11).*

> *"There is need to change legislation to allow nurses who are trained in PC to prescribe opioid analgesics so as to increase the number of prescribers" (P17).*

> *"The Nursing Council has prescribed a syllabus for palliative care but there is no recommended Model to guide training and practice in palliative care" (P20).*

Generally respondents reported a need for improvement of pain management policies which would lead to overall enhancement in nursing care and which all of them seemed to support. There was also a general consensus that owing to nationwide increase in cancer cases there was need for improvement in palliative care.

> *"Any policy that will bring improvement to nursing care is welcome. It is important to improve palliative care since cancer is on the rise. There is need for better policies and guidelines to improve nursing care" (p13, p14, p15& p16).*

"There are no standard guidelines on pain management in the wards. A Model will provide guidance in provision of care for patients requiring palliative care"(P20, P22).

"Guidelines will enhance overall patient monitoring since cancer patients also experience side effects form other treatment interventions e.g. chemotherapy" (P12).

"During my course of practice I have seen Nurses demonstrate competence in pain management by use of opioids but they can only be allowed to recommend use of opioid drugs upon consultation with the oncologists" (P18)

Gaps in Pain assessment tools- The questions were directed to palliative care specialists and experts in clinical practice, training and policy. Regarding the commonly used pain assessment tools most of the respondents agreed that there existed gaps in the tools as they did not provide for impeccable pain assessment. The gaps identified included inability to assess pain in patients with dementia and other forms of cognitive impairment, non- communicative pediatric populations and the unconscious patients.

"There is need to sensitize healthcare workers on how to use the recommended pain assessment tools even for patients in ICU or those unable to communicate"(P17).

"The commonly used tools lack capacity to competently assess all patient populations. Nurses need further sensitization on the recommended tools for total pain assessment" (P9)

"Pain is a major concern in palliative care and pain management requires a multidisciplinary approach. We need to equally come up with the, a better assessment tool" (p4, p22).

"One has to do impeccable assessment which may involve asking several questions."(P 8)

"Commonly used Pain Assessment Tools lack capacity to assess patients with dementia, or a patient with any cognitive impairment or even those with low levels of consciousness. The tools may not be able to assess non- verbal pediatric patients." (P16, P7)

"The commonly used tools for sure have gaps in that the assessor will leave out some patients with special needs." (P8, P10)

"Pain assessment tools lack capacity to assess other distressing symptoms." (P1, P6)

The concern was mostly reported to pose challenge especially to nurses who had not undergone training in palliative care or undertaken Continued Professional Development (CPD) in pain management.

"...Yes I do agree there is a gap especially in areas where people have not been trained on palliative care especially on basic pain assessment & the WHO pain management criteria (P8)

"Pain is not only physical. Other aspects of pain need to be assessed hence proper training is necessary."(P40).

"In PC you have to observe, review, reassess the patient and monitor the outcome of the treatment to be able to tell how the patient's doing while on medication and enhance compliance" (P10).

Gaps in Pain management/ intervention guidelines- In phase one participants indicated that the WHO ladder was the recommended pain management/ control tool. The Kenya Hospital and Palliative Care Association (KEHPCA) had trained some nurses in the healthcare facilities on pain management using morphine by mouth, by ladder and by clock based on the WHO ladder. On scrutinizing the ladder some gaps were also identified which included its inability to provide for total pain assessment as well as monitoring and management of treatment outcomes. Samples of response extracts were as follows:

"WHO ladder does not have the capacity to facilitate assessment or evaluation by the nurse" (P4).

"WHO tool does not provide for assessment of pain and management of treatment outcomes" (P1, p5).

Assessing treatment outcome is also very, very important for us to know patient's progress (P8)

"The WHO ladder does not give provision for impeccable pain assessment and monitoring treatment outcomes." "It's important for healthcare workers to understand the side effects of the medication and how to manage them." (P 16, P17).

WHO ladder is not completely comprehensive since it focuses on physical pain yet pain is not only the physical and you might be having a patient who is having pain because of social issues, psychological issues and all of that in spiritual issues (P5, P8)

"The WHO ladder is a tool for the prescriber, not for the nurse" (p, P9)

"WHO ladder targets prescribers" (p16)

"In PC you have to observe, review, reassess the patient and monitor the outcome of the treatment to be able to tell how the patient's doing while on medication and enhance compliance" (P10).

There was however a dissenting opinion by one of the respondents who felt that the pain assessment tools and the WHO ladder were adequate for the task.

The WHO pain management ladder is what KEHPCA recommends and I feel it is adequate to manage pain since that is what we have used over the years (P21).

Recommended model: The palliative care specialists ascertained that there was no single recommended model for palliative care practice and training.

No recommended model for pain management and training in PC in Kenya (P4, p9).

> *"The Nursing Council has not prescribed any Model to guide training and practice in palliative care" (P20).*

From the responses it was noted that participants working in the clinical areas were able to identify gaps in the pain management tools better than those in administration and teaching. The gaps were an impediment to provision of sound Palliative Care especially by nurses not trained in the area, as well as to home based care providers.

Recommendations for improvement in pain management practice: Majority (97%) of the key informants reported the need for development of comprehensive guidelines to address the gaps identified in the pain management tools in palliative care. Recommendations towards improvement on pain assessment included: need to train/ sensitize nurses on other available pain assessment tools effective for assessing clients with special needs or the critically ill. They needed to be trained on how to use the tools to be able to effectively manage pain among all populations. Owing to lack of a standardized Model in palliative care the need to develop one was also reported.

> *There is need to improve on the guidelines since cancer patients suffer from side effects of other medications hence need for close monitoring (p12).*

> *There is need to sensitize healthcare workers on how to use the recommended pain assessment tools even for patients in ICU or those unable to communicate (P17).*

> *Nurses need to learn how to utilize other assessment tools like FLACC for pediatric patients, PAINAD scale for those with dementia and BPS for those with impaired consciousness (P16)*

> *There is need to develop comprehensive guidelines/model to facilitate pain assessment and management of treatment outcomes (97%).*

Generating Themes on recommendations for improvement on pain management

The interview data was analyzed by first transcription of audio taped information in temi, reading the interviews and familiarizing with the data, generating themes, and noting the themes and concepts that emerged. A thematic framework was developed from the identified themes and sub-themes. Deductive coding and Naming of themes was done. Table 4.9 provides a summary of themes that emerged from qualitative data analysis of the gaps in the pain management guidelines and the recommendations on how to address them.

Table 4.9: Gaps in the pain management guidelines and recommendations to address them

	Theme	Sub-theme
1	Pain management policies	**Policies do not clearly articulate nursing care** **NCK has no recommended Model to guide training and practice in palliative care.**
2	Gaps in Pain assessment tool	**Tools lack capacity to assess special populations** **There are no standard guidelines on pain management in the wards** **Tools cannot assess all types of pain plus other distressing symptoms.**
3	Gaps in Pain managem intervention guidelines (W ladder)	**Who ladder:** **Targets the prescriber only** **Lacks provision for pain assessment and management of treatment outcomes;** **Ladder Not comprehensive.**
4	Recommended model	**No recommended model for pain management and training in palliative care in Kenya**
5	Recommendations improvement in management policy and prac	**There was felt need to:** **Improve on PC policy to adequately address nursing** **Develop guidelines to improve nursing care** **There is need to change legislation to allow more opioids prescribers** **Sensitize healthcare workers on pain assessment guidelines for patients with special needs.**

Develop a model to guide Palliative Care nursing in Kenya.

4.6. Developing the model of pain management by Classical Grounded theory

The methodology adopted Classical Grounded theory method by use of the following package as stipulated by Glaser: data collection, coding and analyzing through memoing, theoretical sampling and sorting to writing, utilizing the constant comparative method.

4.6.1. Coding

Deductive coding was done by use of predetermined codes derived from literature review on nursing theory metaparadigms. These are Person, Nurse/ nursing, Health and Environment.

4.6.2. Generating concepts/ categories of the Nursing Metaparadigms

During the key informant interviews palliative care experts and specialists gave their inputs regarding what would constitute the four nursing metaparadigms. Following analysis of the interview results the following categories and sub- categories were generated to describe the four metaparadigms of the Emergent Model.

Person- Analysis of the Person as a Concept/category under the nursing metaparadigms revealed three sub- categories as follows: The person was described as the patient with life limiting illness hence requiring palliative care by most of the respondents; others described him as a cancer patient requiring end of life care. Most of the respondent also described the Person/ client the patient plus the family and relatives. Lastly the person was described as the patient plus the care givers.

The Nurse- Analysis of the Nurse as a concept/ category revealed three sub-categories as follows: Some respondents described the nurse as a person with a post

basic training in palliative care while others described the nurse as a person who is a competent palliative care giver regardless of the level of qualification. Finally the nurse was described as a member of the Palliative care multidisciplinary team who is trained and passionate about providing care.

Environment – A sound palliative care environment was described by most of the participants as one which the patient prefers whether in the hospital, at home or the hospice. It had to be comfortable, quiet and conducive for palliative care. Additionally, most of the participants reported that the environment had to be free from pain and other distressing symptoms to guarantee improved quality of life. Another view was that that the environment had to have human and material resources especially drugs such as opioid analgesics among others to facilitate freedom form pain and other distressing symptoms.

Health- Health was described in three different ways with most participants emphasizing on freedom from pain and other distressing symptoms. Others were of the opinion that health was a state of wellness whereby a patient enjoyed holistic comfort physically, psychologically, spiritually and socially. In that case the patient had achieved a level of acceptance of the condition to include imminent death. Additionally the optimum health was described as a state when patients achieve the desired quality of life meaning that they were free form distressing symptoms or they could perform some manageable tasks.

4.6.3. Naming of the concepts

Key informant interviews brought out views that were organized into several sub-categories under the four nursing metaparadigms/ concepts. The specific definitions of the concepts were developed following consensus building with the nurse palliative care experts and specialists and summarized as follows:

Patient- A person with life- limiting illness plus the family and the care givers.

Nurse- A trained member of the palliative care team who cares for the patient.

Environment- Where the patient prefers and should be free from pain and distressing symptoms.

Health- Freedom from pain and distressing symptoms for improved quality of life.

The central theme was care/management of pain by use of opioids in palliative care.

4.6.4 Interrelationships between the categories & the core concept

The core concept of the study was pain management by use of opioid analgesics in palliative care. Table 4.11 indicates the interactions between the four categories running from the point the concept emerged to subsequent modifications from similar recurrent views with other interviewees.

Table 4.10- Interrelationships between the Themes/concepts & the core concept

Concepts	Concept description	Initial code	Modified code
Person	A patient living with life limiting illness plus the relatives who care for him.	P2	**P2, P3, P4, p7, P8, P9 & P10**
Nurse	A nurse can be described as anybody with skills to assess and provide care to a patient requiring palliative care	P3	**P5, p9 and p10**
Environment	This is where the patient prefers whether at home or in a hospice/palliative care unit. It should be free from pain and other distressing symptoms	P1	**P4 , P6, P8, P9 and P10**
Health	Health in a palliative care patient means to be free from pain & other distressing symptoms	P1	**P3, P6, P8, P9 and P10**

4.6.3. Integration of the four concepts to the Model

The Model was developed through integration of views from the participants regarding the gaps in the commonly used pain management tools and guidelines as well as the recommendations on how to address the gaps. Of importance was the fact that there was no standard Model to guide pain management in palliative care and the fact that there was felt need to develop one.

The model showed interaction between the concepts to ensure optimum patient health which was described as improved quality of life as demonstrated by absence of pain and other distressing symptoms. The constitution was done in cognizance of the five conventional steps of the nursing process (assessment, diagnosis, planning, implementation & evaluation) and the multidisciplinary team approach to pain management. Patient Assessment considered use of appropriate tools as per patient need as recommended by key informants. The Model also emphasized on the recommended pain management protocol in palliative care (use of the WHO analgesic ladder).

To ensure optimum health the nurse and other members of the palliative care multidisciplinary team play different roles based on their training. These include pain assessment, prescription of the appropriate opioid or other analgesics, administration of the analgesics and evaluation of treatment outcomes to include achieved pain levels, and monitoring and management of side effects. Following evaluation of treatment outcomes, other therapeutic interventions as need be, are carried out by different members of the multidisciplinary team based on the assessment report by the nurse. These may involve administration of medication for breakthrough pain, antiemetic medication, opioid antidotes, antidepressants or Oxygen as prescribed. It may also involve psychotherapy if the pain is suspected to have a psychological component which may interfere with control of physical pain.

The concept of Nurse/Nursing care interventions cut across the five steps of the nursing process (Assessment, Diagnosis, planning, intervention and evaluation). During assessment depending on the condition, the patient could either report pain or show signs that can lead one to suspect pain hence the need for assessment to establish type of pain. To ensure optimum pain management (health) one has to plan for an environment free form pain and other distressing symptoms, by availing opioid analgesics plus other medication for managing side effects and adverse effects of treatment interventions. Once pain is managed evaluation of the outcomes is done which will determine the next course of action.

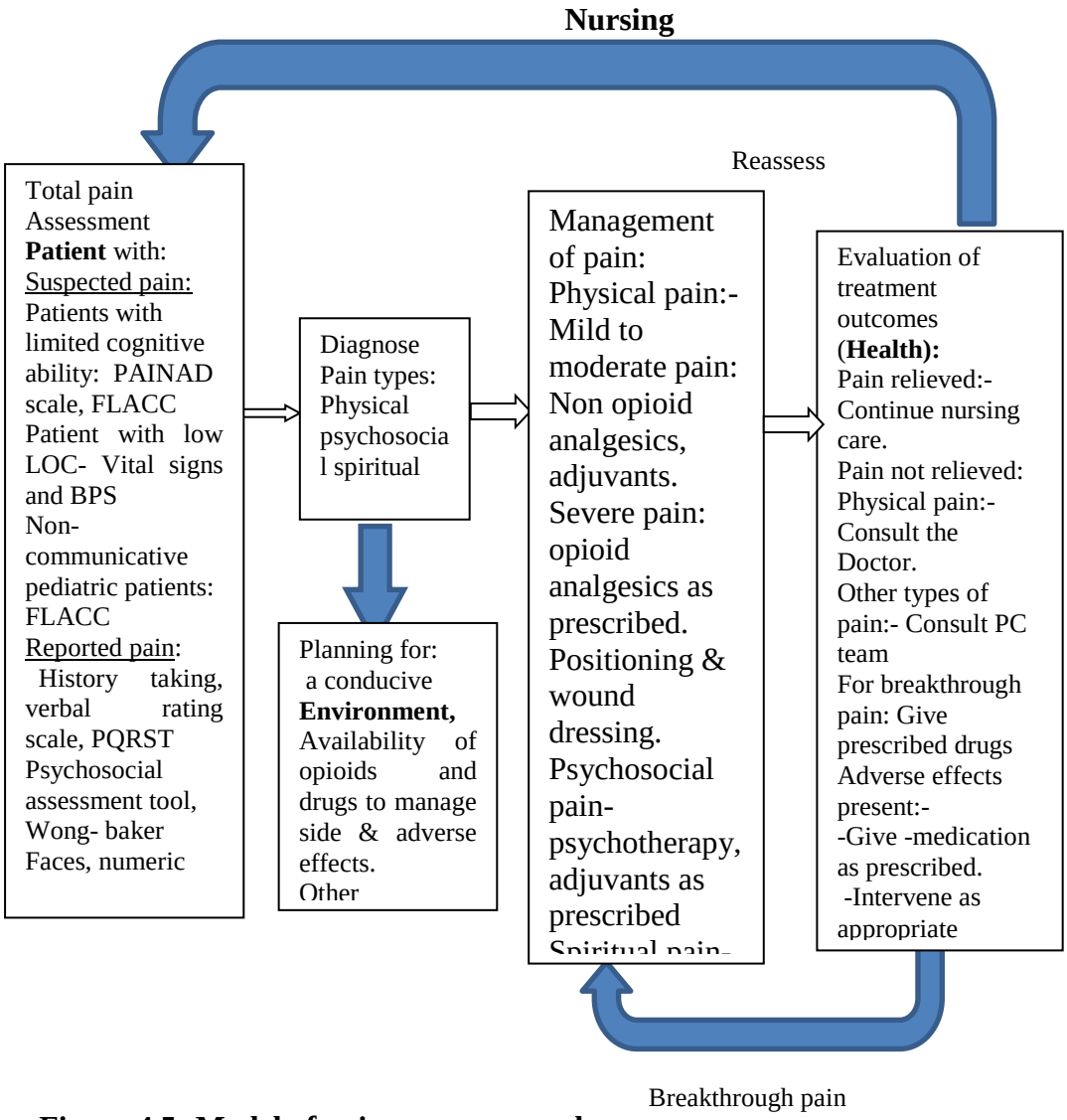

Figure 4.5: Model of pain management by use of opioids

Key: BPS - Behavioral pain Scale

FLACC- Face, Leg, Activity, Cry, Consolability

PAINAD-Pain Assessment in advanced dementia

LOC- Level of consciousness

PQRST- Palliative/ precipitating factors, Quality, Region/ radiation, Severity & Timing

4.7. Evaluation of the Model

Following completion of the Model evaluation was done at Embu and Machakos Level Five hospitals. This was a preliminary evaluation done to confirm if all concepts were well articulated before final completion of the Model. It was done through dissemination and training of Doctors, nurses and clinical officers deployed

in the clinical area on how to use the Model then collecting their feedback regarding its complexity, usefulness and testability. A semi- structured researcher administered questionnaire (Appendix II) was utilized to collect the following information:

4.7.1 Parsimony

Most of the participants attested to the fact that the Model was not complex though it was comprehensive. It was easy to understand, internalize and use without consuming much time. They reported willingness to use especially in nursing care. Below are some of the comments from participants.

> *"The Model is not complex; it is easy to understand." Once you internalize it you may not need to refer to the document while managing pain (P24).*
>
> *"It may however not be so easy to internalize especially for those not trained in pain management or palliative care."(P32).*
>
> *"It is comprehensive as it encompasses all aspects of pain management."(P23 & P26).*
>
> *"It is easy to use as it has adopted the steps of the nursing process apart from planning which is continuous."(P33).*

4.7.2 Usefulness

The model was considered useful for facilitating pain management practice as well as clinical instruction of students. This is because it contained details of most of the aspects of pain and considered team approach to pain management. Examples of interview extracts are as given below:

> *"The Model is very useful as it will create ease of performing pain assessment and management based on availability of drugs." (P23, P24 & P25).*
>
> *"The Model has stipulated the role of various professionals in pain management to include Doctors (prescribers), clinical*

officers, Nurses, spiritual leaders, counselors and psychologists."(P32).

"It is also easy to understand and one can easily use it to instruct students in palliative care." (P24 & P36).

"The Model is very useful as it gives guidance on assessment of patients with dementia who usually have difficulties in communicating pain."

"It is useful in facilitating teaching and research. Metaparadigms are well connected." (P36, P38 & P 39).

4.7.3. Testability

Concerning testability of the Model some participants felt there was need to be allowed time to use it before it is subjected to research. Others felt since research is a continuous process the model can be tested on a continuous basis.

"After using the Model for some time we will be able to do further analysis to identify areas of research just like for all theoretical Models."(P25).

"Research is a continuous process so as we continue using it we can conduct research on any areas requiring further improvement."(P33, P38 & P39).

"Research can be done on the outcome to evaluate the effectiveness of the Model." (P36).

4.7.4. Areas requiring improvement

Some gaps were identified in the Model to include need for consideration of social issues as a source of pain and addition of other interventions for pain management such as patient positioning. They also recommended the need to explain the abbreviations as they may not be understood by all.

"One could be having pain because of social problems. This may require interventions such as group therapy or family counseling."(P24).

"Sometimes a patient may be complaining of pain but once you position them appropriately the pain subsides. You may not have to use drugs always."(P26).

"Some of the abbreviations such as FLACC, PQRST may not be understood by all hence you need to insert a key at the bottom of the Model diagram." (P27).

"Consider other pain management interventions to include wound dressing and positioning." (P32, P37).

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.0 Introduction

This was a three phased study that was aimed at developing a model of pain management by use of opioid analgesics in palliative care. The objectives included establishing the knowledge level of nurses on general pharmacology of opioid analgesics, barriers to pain management by use of opioids, commonly used pain management guidelines, gaps in the guidelines and developing a comprehensive Model of pain management to address some of the identified gaps.

5.1 Discussion

In this chapter the study findings are discussed and interpreted under the following themes: Demographic characteristics of the participants, level of knowledge on opioid pharmacology, barriers to pain management by use of opioids, commonly used pain management tools/guidelines, gaps in the guidelines and the Model development process among other strategies to address the gaps.

5.1.1. Study sample description

Most of the participants were females while males formed a third of the study population. Since nurses formed majority of the participants the results could be supported by the tradition of the nursing profession which has been female dominated. Similar findings were reported in a study conducted in the United States in 2017 by National Council of State Boards of Nursing (NCSBN) which showed that males formed only 9.1% of the nursing workforce in the US though the trend was changing rapidly (NCSBN, 2017).

Concerning education level majority of the participants had been educated up to diploma level of whom a small percentage had acquired a training at Higher National Diploma level; while minority were certificate holders. This could be explained by the fact that most mid- level nurse training institutions in Kenya offered diploma

courses with a few offering certificate courses (Kenya Nursing Workforce Report, 2012). Regarding work experience most of the participants had worked for less than 10 years. These findings are similar to those of a report on Nursing workforce analysis (KNWR) by the Ministry of Health which showed that majority of the nurses (45%) had served for 1- 10 years (KNWR, 2012).

5.1.2. Nurses' level of knowledge of general pharmacology of opioid analgesics

Concerning nurses' level of knowledge of general pharmacology of opioids by self-evaluation, the respondents prominently showed knowledge deficit on the area in which case majority of them reported to be less knowledgeable and possibly requiring further education on the subject. The findings were congruent to those of a study done in 2016 at Jordan University of Science and Technology to evaluate the knowledge and attitudes of healthcare providers toward pain management which showed that only 24% of the nurse participants had adequate level of knowledge (Nuseir et al., 2016). The findings also resonate with those of a systematic literature review done on studies identified from twelve African countries, comprising of Healthcare professionals, mostly nurses/midwifes and physicians which revealed a low level of medication knowledge across different disease areas, countries and Healthcare professionals (Behre, 2018).

The results of individual knowledge assessment by test however showed that majority were highly knowledgeable. This showed a deviation from the results of self- evaluation as the percentages of the highly knowledgeable respondents increased. The findings were contrary to those of previous studies e.g. a study conducted among nurses working in a regional hospital in Mexico in 2015 which reported poor knowledge of pharmacology among nurses (Mario et al., 2015). Another study conducted at Kenyatta National Hospital Emergency Department revealed that nurses feared to administer opioids via intravenous route due to fear of drug reaction which was attributed to lack of knowledge on pharmacology of opioids (Gathiri, 2012). Similar findings were recorded in a study conducted among Saudia nurses which showed a lower level of pain management knowledge compared with nurses from other regions globally. Overall, it was found that nurses were weak in

the pharmacological interventions with regard to appropriate selection, dosing, and converting between different types of opioids (Samarkandi, 2018).

The considerable level of knowledge could be attributed to increasing efforts by KEHPCA in collaboration with national and international training institutions to implement palliative care education and training. For example, in collaboration with Oxford Brookes University in the United Kingdom, Nairobi Hospice offers a postgraduate course in palliative care. This course is designed to educate health care providers in symptom management, bereavement care, and other issues relating to palliative care provision. However despite these efforts to improve palliative care education and training, there remain insufficient numbers of trained palliative care providers in Kenya. This deficit may be the result of a lack of funding for training in palliative care (Fraser et. al., 2018).

Relationships between nurses' level of education and their knowledge of opioid pharmacology: Hypothesis testing was done to determine relationships between the participants' level of education and their level of knowledge of opioid pharmacology. The P value was set at 0.05 (95% Confidence Interval). The results of the hypothesis testing revealed that there was no significant relationship between education level of the participants and knowledge on general pharmacology of opioid analgesics. The results are congruent with those of other studies done in other parts of the world which yielded similar results. For instance, a prospective, descriptive, analytical, and cross-sectional study was conducted to investigate the knowledge and attitudes regarding pediatric pain in two different populations. There results showed a high correlation between the scores of pediatric nurses and nursing students. It was observed that the degree of knowledge about pain and its treatment was very low in both groups with insufficient knowledge being mainly found in the pharmacology of opioids and other analgesics (Ortiz et al., 2015).

The study results however were contrary to those of a previous study conducted among Palestinian nurses in 2019 to establish their knowledge about administration of High alert medications (HAMs) which found that HAMs knowledge score

increased as the educational level increased; nurses with a master degree were the most knowledgeable groups (Zyoud et al., 2019).

5.1.3 Barriers to pain management

Many barriers interfere with the pain and symptom management process, frustrating efforts to assess and control the said symptoms (Rome, Luminais, Bourgeois & Blais, 2011). The study revealed various barriers to pain management notably: **Knowledge related barriers**:- Some of the participants reported lack of awareness of the recommended pain management tools/guidelines. Additionally, most of the participants who reported awareness of the recommended guidelines were not conversant with the WHO ladder as a pain management guideline. These resonates with findings of a study conducted among nurses in selected hospitals in Ekiti State Southwest Nigeria to assess factors influencing utilization of pain assessment tools among the nurses in which 90% of the nurses reported 'unavailability' of pain assessment tools (Ogindan et al., 2018).

Similar findings were also recorded in another study conducted in Bandura hospital (South Africa) in 2016 whose results showed that registered nurses had inadequate knowledge on pain management with a mean knowledge score of 64.5% (Manwere et al., 2016). Another study conducted among Saudia nurses revealed knowledge deficit on pain management with limited knowledge and negative attitudes toward pain management being reported as one of the major obstacles to implement an effective pain management strategy among nurses (Fallatah, 2017).

Another study conducted in King Saud medical City to assess knowledge and attitude towards pain management among critical care nurses in a tertiary hospital revealed low knowledge levels (Issa et al., 2017). Knowledge deficit in pain management could possibly be attributed to deficiencies in the educational nurse training and preparation, lack of exposure to practice as well lack of opportunities to engage in continuing professional development.

Attitude related barriers included: These included attitude to pain and to patients; attitude to pain was reflected by false beliefs such as pain being a normal experience, patients should be able to withstand it and prior experience with pain creates

tolerance in an individual. A notable attitude towards patients was a notion that pain without an obvious physical cause, or that is more severe than expected based on findings, is usually psychogenic and that patients tend to exaggerate their level of pain. Other attitude related barriers included a notion that provision of opioid drugs to patients can create an avenue for abuse by patients and relatives hence the need to consider alternative drugs. Similar barriers were revealed in a study conducted among policy makers in Thailand to assess the attitude of physicians regarding use of opioids for cancer pain management which showed that about one-third of physicians and majority of policy makers/regulators had negative attitudes towards pain (Sirsawang et al., 2012).

Similarly a study conducted in Iran by Kheshti and others in 2016 to assess knowledge, practice and attitude of healthcare workers on chronic pain management recorded similar findings. The report indicated excessive fear of opioid tolerance and addiction with most of the participants indicating that narcotics were not good drugs and that patients had better bear the pain (Kheshti et al., 2016).

Opioid prescriber related barriers- Despite the fact that opioid analgesics use is integral to cancer pain management prescribers still display incorrect beliefs that affect their prescription to those in need. The research identified barriers to include delays in prescription of the drugs with a notion that pain killers should be withheld till the cause of pain is established, failing to prescribe opioids completely due to a false belief that the risks posed by use of the medication outweigh the benefits. Previous research pointed to specific barriers related to health care providers, patients, and existing health care infrastructure. Healthcare provider barriers pertain to attitudes about pain and pain relief, lack of specific education about pain, fear of litigation, and lack of institutional support (Norlan, 2017).

These findings are similar to those reported in a study conducted in Bangladesh in 2014 which showed that 85% of the physicians preferred to prescribe pethidine, when patients needed opioids for severe pain; while 89% of the physicians would restrict opioid dosage in pain management to prevent drug tolerance or addiction (Khan et al., 2014).

Other prescriber related barriers were related to pain assessment which included underestimation of pain intensity due to inadequate patient assessment where the prescriber believed that one could tell a patient in pain just by looking at him/her. The findings compare to those of a study conducted by Ulster Medical Society in 2013 which reported similar findings where inadequate assessment of pain was noted to cause a barrier to pain management (Shute, 2013).

Other barriers related to shortage of prescribers who are mainly Doctors. This could be attributed to the fact that in Kenya opioid analgesics are only prescribed by Medical Doctors. Considering that in Kenya the Doctor – population ratio is 1:16000 which is way below the WHO recommendation of 1:1,000 this further denies accessibility to the medication (Africa Check, 2019). However this is contrary to findings of an earlier study conducted in Uganda whereby a commendable success in pain management by use of opioids has been shown since 1994. This was facilitated by change of legislation to allow nurses and clinical officers who undergo special training in palliative medicine at Hospice of Uganda to prescribe morphine resulting in increased number of prescribers and allowing palliative care to spread throughout all the Districts to ensure availability of morphine to everyone in need (McNeir Jr., 2017).

Conflicting decision to commence patients on opioid analgesics was reported by most of the participants. This could be due to the stringent rules imposed by the regulators and especially the legislative imperatives controlling pharmaceutical products. Additionally Review of literature regarding regulation of opioids in Kenya revealed evidence of conflicting legislation. For instance while Pharmacy and Poisons Act (Cap 244, laws of Kenya) is mandated to control trade in drugs and poisons, the Narcotic drugs and psychotropic substances Act Cap 245, Laws of Kenya section 3(1) prohibits handling of narcotic drugs. This conflicting legislation can scare some pharmacies from stocking opioid drugs hence denying the access of the same to deserving patients. A similar study done in Norwegian Hospitals on opioid use concluded that Strategies that targeted the ordering and monitoring of pharmaceutical care at the end of life could be enhanced by legislation (Wergeland, 2019).

5.1.4. Pain management modalities/guidelines

Concerning awareness of the recommended pain assessment & management tools/ guidelines almost half of the respondents reported lack of awareness of the recommended pain assessment guidelines. The findings are similar to those of a study conducted among Registered Nurses in Bindura Hospital (Zimbambwe) which revealed lack of knowledge on pain assessment as 84% of the respondents failed to give correct tools used for pain assessment, 76% gave incorrect ideal time for pain assessment and 76% failed to identify types of pain measuring scales (Manwere et al., 2015).

Some however reported awareness of pain rating scales to include: verbal descriptor scale and numeric rating scale to assess pain levels. Others utilized both history taking and physical examination, use of Wong's faces scale, the APVU, PQRST and other standard operating procedures. The findings are similar to those of another study conducted in Nepal to determine the utility and validity of pain intensity rating scales for use in Low and Middle Income Countries, which revealed that the commonly used scales were Faces Pain Scale and Verbal Rating Scale (Pathak et al., 2018).

Pain management/intervention modalities involved use of pharmacological and non-pharmacological methods of pain control with majority of the respondents reporting use of opioid analgesics and some emphasizing on utilization of WHO ladder or by ladder, mouth and clock. Similar findings were shared by a study conducted in Illinois to determine effectiveness of WHO cancer pain relief Guidelines. Evidence from the research indicated that 20%–100% of patients with cancer pain, considering their status of treatment or end-of-life care could gain adequate pain relief with application of the WHO guidelines (Carlson, 2016).

Relationship between knowledge of recommended pain management tools and other variables: Relationship between education level of the participant & years of work experience and his/her knowledge/ awareness of the recommended pain management guidelines; was determined using Pearson's Chi squared test at 95% confidence interval. The results revealed no significant relationship between the

variables in both hypotheses. The findings resonate with those of a similar study conducted among graduate nurses in Brazil which revealed that 66% of the nursing graduates were aware of the existence of pain assessment scales but they did not have the ability to perform the assessments (Santos, 2018).

The results could be attributed to lack of exposure to palliative care as well as mal deployment of nurses in the clinical area. Studies have shown that mal- deployment of nurses usually occasioned by staff shortages can lead to loss of efficiency in performance. For instance a study done in south Africa among specialized nurses revealed that lack of recognition of nurses' expertise during redeployment led to improper utilization of staff due to failure to consider their abilities to perform (Mokgadi, 2015). Additionally nurses who undertake further training especially at masters level are deployed in teaching and administrative positions hence they miss the opportunity to apply their knowledge in clinical practice. This can be verified by the demographic characteristics of participants of this study which showed most of the nurse specialists were in teaching or administrative offices.

5.1.5. Gaps in the commonly used pain management guidelines by use of opioid analgesics

A careful scrutiny of the commonly used pain management tools/ guidelines in the health two facilities and with which the participants seemed familiar revealed some notable gaps since most of them focus on assessing pain and pharmacologic management of the same neglecting the patient holistic care that encompasses evaluation of the interventions. The gaps identified in both phases of the research were as follows:

5.1.5.1 -Gaps in pain assessment tools: The identified pain assessment tools could not be used to effectively assess pain in special populations such as: older adults with advanced dementia, infants and preverbal toddlers, critically ill/unconscious patients, persons with intellectual disabilities and patients at the end of life. The nurses were not conversant with pain assessment tools that addressed clients with special needs. The pain assessment tools also focused on physical pain as opposed to other types of pain that could complicate pain management. Similar findings were reported in a

research conducted by Barney and others to establish Challenges in pain assessment and management among individuals with intellectual and developmental disabilities which revealed that Pain assessment tools for this group of individuals have been developed; however, there was little empirical evidence that pain was being better assessed or managed clinically (Barney et al., 2020). Another study done in Norwegian Hospitals pointed out that an assessment tool was needed to indicate the presence or absence of pain in severely cognitively impaired patients (Wergeland et al., 2019).

5.1.5.2- Gaps in Pain management guidelines: Concerning pain management, the most commonly used guide was the WHO ladder. In phase 1 almost fifty percent of the respondents reported that the institution provided/ recommended use of some guidelines (mostly the WHO ladder) for pain management, though a number of them were not conversant with the WHO ladder. Those conversant with the guideline however indicated that the ladder had some gaps including lack of provision for monitoring of drug side effects as well as management of the identified side effects.

In phase two, further scrutiny of the WHO analgesic ladder by key informants revealed more gaps as follows: The tool did not give provision for impeccable assessment of pain as well as for monitoring and management of pain treatment outcomes. The WHO ladder was a tool for use by the opioid prescribers only. It negated the role of the other palliative care team members in patient assessment, monitoring and management of treatment outcomes. The WHO ladder was also reported to focus on treatment of physical pain only without considering other types of pain and /or distressing symptoms that could occur due to pain or treatment interventions and /or aggravate the pain experience. They alluded to the fact that if other distressing symptoms were ignored it could lead to non- compliance with treatment by patients considering that cancer patients usually experienced multiple side effects of the treatment interventions.

The findings concur with those of a study done to assess the appropriateness of the Ladder which revealed that the WHO analgesic ladder, which was designed in the past for cancer pain management, seemed inappropriate for the current updated pain

management situation, especially the control of chronic non cancer pain (Yang et al., 2020). Additionally, a report released by medpro group in 2016 on liability risks in opioid treatment revealed that following the prescribing of opioids, inadequate monitoring occurred in 40% of cases. Examples of inadequate monitoring include failure to (a) reassess the need for opioid continuation, (b) evaluate patient compliance with treatment plans, and (c) review efficacy of treatment. This act of omission often results in opioid crisis raging from patient addiction to death from overdosing; opioid abuse can have tragic outcomes (MedPro Group, 2016).

An integrative review of studies that evaluate the effectiveness of the WHO ladder also showed that the guidelines were not specific to the non- pharmacological and other interventional options used in contemporary pain management practices (Carlson, 2016).

5.1.6. Recommendations on how to address the gaps in pain management

Patient's self- report is the most reliable indicator of the presence and severity of pain. However, a challenge is usually encountered when one is required to assess non- verbal patients such as infants, the cognitively impaired, critically ill or comatose and some patients reaching the end of their life. In these cases the traditional pain measurement tools are often difficult to employ hence the need for alternative approaches. Availability of clear guidelines may provide a solution to this problem.

Participants alluded to the fact that patients with life limiting illnesses especially those suffering from cancer experience side effects of many medications hence holistic care should involve monitoring and management of side effects to enhance compliance to the regimen. Inadequacy or absence of pain management guidelines/tools raises concern about the quality of care provided to patients with life -limiting illnesses.

Regarding strategies to address the gaps identified in the pain management tools in palliative care, other than one key informant the rest recommended for development of comprehensive guidelines to address the gaps. Recommendations towards improvement on pain assessment strategies included need to train/ sensitize nurses on

the recommended pain assessment tools applicable for assessing clients with special needs or the critically ill. These include: Pain Assessment in advanced dementia (PAINAD) scale, Behavioral pain Scale (BPS) for the critically ill and the FLACC for the non- verbal Pediatric patients which is used to evaluate pain based on Facial expression, Limbs movement, Activity, Cry and Consolability.

To facilitate comprehensive pain management and monitoring of outcomes of interventions most of key informants agreed that there was need for a model that could facilitate holistic approach to pain management to improve on the existing pain management tools. The researcher developed a Model for pain management to improve on the WHO analgesic ladder by addressing the role of other Palliative care team members. This was done from inputs collected from the Key Informant interviews. Inputs included the need to specify the assessment tools for particular groups of patients; to specify types of pain and the management interventions and to stress on the need for involvement of the entire palliative care team in management of pain and treatment outcomes. Further data collected regarding the nursing concepts/ metaparadigms of the model was also incorporated.

All the inputs given were organized into a comprehensive Model following consensus building with the palliative care experts and specialists. It was envisaged that use of a model would go a long way to improve clinical practice in palliative care. With permission form the relevant authorities that is, the Ministry of Health Kenya, KEHPCA, and the county Governments the Model can be used in clinical teaching and mentorship of nursing students in palliative care.

5.1.7. The Emergent Model of pain management by use of opioid analgesics

Purpose –The Emergent Model is an example of a descriptive theoretical framework. The purpose of the research was to develop a nursing model of pain management by use of opioid analgesics in palliative care. Decision to develop the model was informed by the fact that the researcher established that in Kenya there was no standardized Model for pain management by use of opioids in palliative care. It was envisaged therefore that the model would provide nurses and other healthcare professionals working in hospices, palliative care units and home based care settings

with useful tips that would help them manage pain for patients on opioids, placed under their care.

Assumptions of the model- Assumptions are beliefs about phenomena one must accept as accurate to accept a theory or the truth about the phenomena. They may be based on accepted knowledge or personal beliefs and values. Assumptions may not be predisposed to testing but they can be argued philosophically (Reiss et al., 2017).

- The major assumptions of this conceptual model is that pain management is a critical component in palliative care hence for optimum health, nursing care should aim at ensuring that patients live in an environment free of pain and other distressing symptoms. Other assumptions are as follows:
- Patients requiring palliative care are characterized by health-related limitations for self-care along the disease continuum.
- Management of pain and other distressing symptoms is very vital in palliative care.
- Pain management requires a multidisciplinary approach with nurses playing a pivotal role.
- Pain perception and reporting is individualized hence the need for multifaceted approach in pain management.
- Opioid analgesics are Key in pain management in palliative care though opioid administration is a highly regulated practice requiring sound policy and guidelines.
- Pain management by use of opioids is limited by barriers that ought to be eliminated for effectiveness.
- Health care providers are characterized by limitations that are associated with their knowledge level, work experience, health state and the patient' care requirements.

Concept- Just like any other nursing conceptual models the Pain management model contains assumptions and four metaparadigms concepts as described in the development process. The concepts were Person/ patient, Nurse/ care provider, a conducive environment and optimum health/ freedom from distressing symptoms.

The central concept which was reported in almost the four metaparadigms was pain management in palliative care. Information concerning what should constitute the four metaparadigms was obtained from the data given by the participants regarding the gaps in the recommended/ commonly used pain management guidelines as well as the recommendations from the key informant interviews in phase two. Following consensus building the four concepts were described as follows:

The person- According to this research the concept of Person in the model was described as the client who includes the patient, family, relatives and care givers. These aspects describe the patient as persons with different roles to play in the disease process. This can be compared with the Rogers' Science of Unitary Human Beings which emphasizes the principle of integrality considering that nothing is a solitary act, involving only one person; others are intimately involved with the patient, whether family, friends or health care providers (Malinski, 2018).

This can be explained by the fact that the family, relatives and care givers who have been depicted as part of the person may not have an illness but they do require psychosocial support just like the patient. Recognition of the human being as a recipient of care at individual, family and community level is consistent with other nurse theorists' views of the human being for example Sister Callista Roy (Alligood, 2014, p. 309). Similarly, Nightingale's environmental theory recognizes the multidimensionality of the human being as the biological, psychological, social and spiritual components (Medeiros et al., 2015; Pirani, 2016).

The Nurse- The participants described a nurse as a member of the palliative care multidisciplinary team who is trained and passionate about providing palliative care. The aspect of training as depicted in this research is in line with Virginia Henderson's value for nursing education especially post basic training. Owing to her passion in education she recommended that nurses needed to be well trained to be able to make critical decisions regarding patient care and face future challenges. The concept of passion in care provision resonates well with the Ronger's theory of human caring which describes the importance of truly listening, sincerely hearing what is being said, and humbly accepting the validity of experiences (Malinski,

2018). Additionally the nurse was described as a member of the multidisciplinary care team. Similar opinions were recorded by Bowen (2014) who noted that palliative care is multidisciplinary because of the multiple dimensions involved in caring for the patients' physical, social and psychological needs, and with close links to the family (Bowen, 2014).

Environment – A sound palliative care environment was described as one in which the patient prefers whether in the hospital, at home or the hospice. It had to be comfortable, quiet and conducive for palliative care. This description indicates that the environment is external and it resonates with many nurse theorists who place a lot of emphasis on the external environment and its effect on the health of the human being (Nursing theories, 2012). Florence Nightngale also emphasized on maintaining conducive environment as she believed that a healthy environment was essential for healing. She recognized the human-being as a recipient of care but places emphasis on the environment (Medeiros et al., 2015; Pirani, 2016).

The environment was also described as being free form pain and other distressing symptoms to guarantee improved quality of life. This resonates with Roy's adaptation model which describes the environment as having four modes of interaction one of which is the *Physiologic–physical mode* (Ursavas et al., 2014). Another view was that the environment had to have the both human and material resources especially drugs to include opioid analgesics to facilitate freedom form pain and other distressing symptoms. This description compares to Betty Neuman's System's Model in which the Environment to her can be fragmented into: internal, external, and created environments, all of which influence the client's adaptation to stressors (Ahmadi, 2017). In this research the created environment can be compared to availability of resources while pain can be considered a stressor.

Health- In the context of this study Health was described in three different ways with majority of the participants describing health as freedom from pain and other distressing symptoms. In the Kenyan legal framework Article 26 of the Constitution which guarantees right to human life is elaborated in the context of palliative care as a right to good quality of life including freedom from pain (Legal aspects in PC, p.

15). Others were of the opinion that health was a state of wellness whereby a patient enjoyed holistic comfort physically, psychologically, spiritually and socially. In that case the patient had achieved a level of acceptance for their condition to include imminent death. This definition resonates with The WHO (1948) definition of health in which Health is defined as "The state of physical, mental, and social well-being, not merely the absence of disease or infirmity" This definition considers a person's health holistically. Additionally, optimum health was described as a state when a patient achieves the desired quality of life meaning that they were free form distressing symptoms or they could perform some manageable tasks. Health is also considered to be "a dynamic state of functioning within the limitations of the person." This resonates with Barbara Artinian's Intersystem Model in which Health is viewed on a multidimensional continuum involving health/ disease (Barbara, west & Conger, 2011, p. 15).

Application of the nursing process- the Model Development process put into cognizance the five steps of the nursing process (Taylor et al., 2011) as follows:

Assessment- this involves assessing pain levels using the appropriate tool based on the patient's age and condition.

Nursing diagnosis- The nurse arrives at the diagnosis of the type and level of pain the patient is experiencing.

Planning- based on the type and level of pain the healthcare provider would then make a conclusion on the best way to improve the patient's well- being.

Implementation- This would depend on the type of pain. It involves consulting the physician for prescription of analgesics and administration of the drugs for physical pain or referring the client for psychotherapy and spiritual intervention in case of emotional, psychological or spiritual pain

Evaluation- Monitoring of treatment outcomes is done by reassessing the patient to ascertain if pain subsided and assessing for side effects of treatment to take necessary action.

5.1.8. Evaluation of the Model

Evaluation of the Model was done to assess the parsimony, usefulness, testability and areas requiring improvement. Following dissemination the users reported that the Model was parsimonious in that it was not complex though it was comprehensive. It was considered useful in practice as well as instructing learners. Concerning testability it was agreed that there was need to allow the users to utilize it for some time so as to identify areas requiring further research. Areas of improvement included considering patient positioning as one of the pain management interventions.

According to Rogers most innovations do require a long time probably years from the time of dissemination to the time they gain full adoption and implementation in the relevant field. It is envisioned that with time the Model will gain full acceptance and attract research to determine its strengths, weaknesses and value in advancing nursing practice.

5.1.9. Generalizability of the study findings

The findings of this research can be generalised to palliative care service provision in Kenya and other parts of the world as follows:

Owing to the fact that the participants were sampled from nurses with varied demographic characteristics e.g. education level showed a good representation of all cadres of nurses in Kenya. The results of knowledge level could be generalized to all nurses practising in Kenya in that their training syllabus is standardized for particular levels. Secondly, pain management being a multidisciplinary practice, the findings could also be generalised to other healthcare providers considering that the education levels for those trained in midlevel colleges are similar. This conclusion can be supported by a study conducted in Moi Teaching and Referral Hospital (Kenya) regarding pain management practices among Doctors, nurses and clinical officers which revealed that the Doctors were knowledgeable while nurses and clinical officers had low knowledge levels (Kituyi et al., 2010). Similarly, studies conducted in other countries for instance a study conducted among healthcare providers

working in seven hospitals in Jordan revealed knowledge deficit on pain management among other healthcare providers (Nuseir et al., 2016).

Another study conducted on physicians and nurses working in Primary healthcare facilities in Jordan revealed that Jordanian healthcare professionals had a low level of knowledge and negative attitudes toward pain management, so educational programmes related to the topic were strongly recommended (Al-khatib et al., 2019).

The findings could also be generalised to other palliative care services as shown in a study conducted in Western Kenya seeking to assess palliative care services which revealed that majority of the healthcare providers lacked any formal training on current palliative care services, including psychological support and pain control (Zubairi et al., 2017).

The study findings can also impact on other sectors e.g. the economic sector. This is owing to the fact that the costs of untreated pain are considerable hence timely, appropriate, and effective pain care is not only morally sound but also economically sounds (Campbell et al., 2012).

5.2. Conclusion and recommendations

5.2.1. Conclusion

Satisfactory pain management is an essential component of palliative care both in the hospital and in home based care settings. Unfortunately, many barriers interfere with the pain and symptom management process, frustrating efforts to assess and control the said symptoms as revealed in this study. The training syllabi for nurses stipulate course content on pharmacology depending on the level of training. However knowledge deficit on general action of opioid drugs proved a challenge for all level of nurses. Despite the initiatives by KEHPCA to ensure integration of Palliative care in the training curricular of healthcare professionals, the study revealed that most of the participants were not aware of the recommended pain management tools/guidelines. Health care providers with insufficient knowledge of pain management may delay/deny the administration of opioids to patients which poses a

hindrance to pain control. This shows that the need for Continued Professional Development (CPD) cannot be over emphasized.

Routine patient monitoring is an essential component of opioid therapy and should be done to assess the need to continue therapy, patient compliance with treatment, and the efficacy of the medication hence patient care should not stop at administering the medications but should include monitoring the outcomes of treatment. The study results revealed that the commonly used pain management tools and guidelines lacked the capacity to assess pain in non- communicating patients as well as to monitor treatment outcomes. Therefore there was a felt need to address the gaps identified in the commonly used pain management tool/guidelines for purposes of providing holistic care to patients with life limiting illnesses. Lack of comprehensive guidelines/ a model to manage pain and symptoms in palliative care particularly by nurses who are most in contact with the patient and in the best position to help and improve the patient healthcare has caused patients to continue hurting. Likewise, it is clear not only from the results of this study but also others that lack of comprehensive pain assessment guidelines is a hindrance to effective pain control. Despite the limitations of this study, it was believed that the study findings represented the current state of pain management by use of opioids in Kenya and that development of a Model plus recommendations from the study would go a long way to improve the practice.

5.2.2 Recommendations

To facilitate sound Palliative care there is need to meet the challenges and remove perceived barriers, including but not limited to, building up knowledge and awareness of health professionals, and developing updated, well-defined, and standard protocols of care e.g. a nursing Model, tailored to palliative care. The following recommendations were also generated from this study:

5.2.2.1. Recommendations on improving general knowledge on opioids- To improve knowledge on opioid pharmacology health facilities should provide professional development opportunities for nurses to improve their knowledge on

opioid drugs. This would not only increase knowledge level but also help dispense myths and misconceptions surrounding opioid use.

5.2.2.2. Recommendations on improving pain management practice-To improve knowledge on pain management nurses needed sensitization on current pain assessment tools. To improve on pain management practices healthcare managers should ensure that the healthcare professionals are given adequate exposure to quality practice in palliative care. There was also need for continued professional development sessions by KEHPCA and Palliative Care experts to update healthcare workers on sound pain management practice in the field of palliative care. It is recommended that the model can act as tool for training nurses on pain management by use of opioids as it gives clear direction from patient assessment to evaluation of outcomes of pain intervention strategies. Adoption of the Model will ensure a seamless approach to pain assessment, management and evaluation. Systems need to be in place to monitor pain management that alerts the healthcare provider when pain is poorly managed.

5.2.2.3. Recommendations to address barriers on pain management - To address other barriers to pain management to include shortage of prescribers and conflicting legislation on handling and use of opioids it was recommended that: the Government needed to employ more physicians to meet the WHO recommended Doctor: patient ratio. Additionally the legislative arm of Government should take initiative to harmonize the three Acts of parliament regulating the trade and use of opioid analgesics to ensure access to pain medication by the patients in need of opioid analgesics. There was also need to ease the stringent legislation governing opioid prescription since the law allowed only physicians to prescribe the opioid analgesics. Changing the legislation would increase the pool of prescribers as it would allow other healthcare professionals with specialized training in palliative care to prescribe opioid to address the challenge posed by shortage of prescribers.

5.2.2.4. Recommendations for improved guidelines on pain management- To address the gaps in the commonly used guidelines in pain management it was recommended the management of health facilities ensure that healthcare workers are

sensitized on the appropriate pain management tools to be able to manage all populations including those with special needs and impaired consciousness.

5.2.2.5. Recommendations regarding the model-

The Model offers a one stop multidisciplinary approach to pain management for enhancing impeccable pain assessment for all patient populations, and monitoring the quality of pain management interventions. It incorporates pain assessment tools for patients with different conditions. It also provides for assessment of breakthrough and emergency pain. Pain intervention measures provide for monitoring and management of other distressing symptoms that can pose hindrance to pain control as well as multidisciplinary approach to management of treatment outcomes.

It is recommended that the Directorate of Nursing in the Ministry of Health recommends the incorporation of the Model into the palliative care policy and its subsequent adoption by healthcare institutions for use in palliative care. This is owing to the fact that it offers a one stop multidisciplinary approach to pain management for enhancing impeccable pain assessment for all patient populations, and monitoring the quality of pain management interventions. It can be used by all healthcare workers involved in provision of palliative care even those without specialized training.

Application of this model in palliative care practice is expected to generate research questions on issues such as its acceptability, parsimony, clarity, consistency, simplicity, generality, accessibility, importance and other qualities that characterize a Model of care. This Model is also recommended for utilization and testing to evaluate its comprehensiveness of content, logical congruence, generation of theory, credibility, and its significant contribution to improvement of patient health outcome and need for further modifications. In addition, some the aspects of the Model and other findings of this research may be used as a source of data for further research in palliative care.

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APPENDICES

APPENDIX I: Modified NKARP questionnaire for phase one

Section A. Questionnaire for nurses' knowledge, guidelines and barriers to pain management in palliative care

Instructions:

The questionnaire has 4 parts. Kindly fill all of them.

Follow instructions on how to respond as given in each section.

Section A: Nurses' socio- demographic factors

For this section circle the appropriate response.

Indicate your gender

- Male
- Female

What is your highest level of educational qualification?

- Certificate
- Diploma
- Higher national diploma in…… (specify).
- Degree
- Masters in ……..(specify)

Indicate the number of years you have served as a nurse since you qualified.

- zero to five years
- Six to ten years
- Eleven to 15 years
- Over 15 years

Section B- Knowledge on pain management

The following items request information about nurses' knowledge of palliative care and the use of opioids in pain management.

For question 1 and 2 circle 0, 1, 2, or 3.

What is your general knowledge of the pharmacodynamics and pharmacokinetics of opioids?

0= Not at all knowledgeable, 1 = slightly knowledgeable, 2= moderately Knowledgeable and 3= extremely knowledgeable.

0 1 2 3

To what extent do you need to increase your knowledge of pharmacodynamics and pharmacokinetics of opioid analgesics?

0= no need, 1= Little need, 2= great need and 3= very great Need

0 1 2 3

Does the use of opioid analgesics improve the quality of life for those with life limiting illnesses? a) Yes b) No

For question 4 and 5 circle the most appropriate response.

How was the content on palliative care or coursework taught in your educational preparation?

- Palliative care was integrated throughout the program(s) of study
- Palliative care was taught in medical surgical nursing
- Palliative care was taught as a common course for all those undertaking clinical oriented courses.
- Palliative care was not taught at all.

Who taught you palliative care nursing?

- Palliative care nursing was taught by nursing faculty
- Palliative care nursing was taught by non-nursing faculty

- I learnt it on the job from colleagues.
- I learnt palliative care as a continuous professional development course while in practice.

What type of pain management techniques have you learnt in school and continuing education programs?

- Assessment……
  ……
- Pain
  management.....
  ...

Section C

<u>Availability of guidelines for administration of opioid analgesics in pain management</u>

1. Does your institution provide guidelines for nursing management of patients on opioid analgesics?

a)Yes b) No

If yes proceed to answer question 2 and 5.

What standard pain assessment tools/ scales does the institution recommend? ……

Who developed the tools/guidelines?

- The hospital/ hospice
- African association for palliative care
- Kenya hospice and palliative care association
- Any other body (specify)……

State the themes addressed in the guidelines…… ……..
……

Do the guidelines provide for

- Patient assessment during medication use Yes No
- Monitoring for side effects of the medication Yes No
- Management of side effects of medication Yes No

If NO how is the assessment done?

.....

Section D: barriers to administration of opioid analgesics

Component 1: knowledge and attitude issues.

For questions 1 to 22 please tick the number that best represents your response.

Strongly disagree 2. disagree 3. Unsure 4. Agree 5. Strongly agree.

Indicate in the spaces provided your attitude towards pain management by use of opioid drugs.

		1	2	3	4	5
1	Pain is a normal experience which the sick should endure					
2	Administration of opioid drugs to patients can create an avenue for abuse by patients and relatives hence the need for alternative drugs.					
3	Opioids decrease the pain threshold hence they should be avoided					
4.	Opioids cause addiction on the chronically ill hence should not be issued					
5	Opioid medication can cause respiratory depression hence it is safe not to use them					
6	Once the patients get used to using strong pain killers they cannot benefit from other analgesics even for little pain					
7	The elderly patients do not strongly perceive pain hence they should not be commenced on opioid analgesics.					
8	Pain killers should be withheld until the cause of the pain is established.					
9	Prior experience with pain creates tolerance in an individual.					
10	The risks posed by use of opioid analgesics outweigh the benefits hence they should be avoided					
12.	Pain without an obvious physical cause, or that is more severe than expected based on findings, is usually psychogenic.					

13	Pain should be treated and not prevented					
14	One can always tell a person is in pain from their behavior					
15	Patients tend to exaggerate their level of pain					
16	Inadequate reporting of pain by patients due to severe illness poses a challenge to pain assessment					
17	Socio-cultural factors affect patients' will to report pain					
18	Inadequate supply of morphine and other opioid drugs has caused a hindrance to pain management					
19	Opioid drugs are unaffordable to most patients hence they should not be prescribed for them					
20	Shortage of prescribers has been a hindrance to administration of opioids for pain management					
20	Lack of clear guidelines on nursing management of patients on opioids can hinder effective pain management					
21	The culture of a health professionals can affect expression of pain which influences their style of managing pain					
22	There is conflict surrounding the decision to commence the patients on opioid analgesics in this health facility.					

Appendix II - Key Informant Interview Guide

Questions directed at administrators

Pain management policies

1. What is your take on pain management policies?

2. Do you support the need for improvement in pain assessment and management guidelines?

3. What is the overall benefit of improved guidelines?

b) Questions for palliative care experts and specialists

Perception of Pain management tools

4. What is your perception on the commonly used pain assessment tools in terms of having the capacity to do total pain assessment?

5. What is your perception on the recommended pain management tool i.e. the WHO ladder as it relates to nursing care?

6. Do we have a standard model for palliative care nursing training and practice?

c) Recommendations for improvement in pain management practice

7. What recommendations would you make concerning improvement in pain assessment?

8. What recommendations would you make concerning pain management?

9. Is there need to have one standard model prepared in the Kenyan context?

If yes specify……..

If No, proceed to question section 2.

SECTION 2

Nursing metaparadigms (for palliative care specialists and experts)

What would you recommend to be included in the model to facilitate improved nursing care?

Whom would you describe as a palliative care client?

What environment would you recommend for sound palliative care?

Who is a nurse in the context of palliative care?

How would you define health in the context of palliative care?

Appendix III: Questionnaire For Testing The Model Of Pain Management By Use Of Opioids In Palliative Care

Parsimony

How would you describe the model in terms of complexity?

Does it require a lot of time to apply?

Can one utilize it without having to refer to the document?

Usefulness

Is the model useful in pain management practice?

If Yes how is it useful?

If no what can be done to improve it?

Can it be useful for clinical instruction?

Does it facilitate team approach to pain management?

Testability

Does the Model have areas that can be researched on?

If Yes specify……

Appendix IV Informed Consent Form

STUDY TITLE

MODEL OF PAIN MANAGEMENT BY USE OF OPIOID ANALGESICS IN PALLIATIVE CARE IN KENYA.

This informed consent form has two parts: Part1- Information sheet (to share information about the study with you) and Part 2- Signature sheet (to indicate whether you agree to participate or not).

Part1: Information sheet

Introductory statement: I am Jostine Mutinda a PhD student at Jomo Kenyatta University of Agriculture and Technology. Currently I am undertaking a research project to develop a Model of pain management by use of opioid analgesics in palliative care in Kenya. The research is in fulfillment of the requirement of the award of a Doctor of Philosophy. The reason for giving you this information is because I want you to participate in the research. If you agree to participate you will be required to sign the signature sheet provided as a sign of your consent. If you prefer not to participate you are free to do so. If there is anything which you do not understand in the questionnaire you are free to seek for clarification from the investigator.

Importance of the research: This study is aimed at determining barriers to effective pain management by use of opioid analgesics among those with life limiting illnesses. The barriers identified from this research will help in developing a model to guide the practice of pain management. Recommendations made from this research will also help in advising the authorities on the importance of policy shift if need be to facilitate better nursing care.

Who can participate? All the nurses working in the identified hospices and palliative care units who will agree to participate and sign the consent forms will be eligible to participate. The participants will be Kenyan citizens employed by the Government or any other organization and deployed to work in the health facilities. Participation is voluntary.

Permission and ethical approval: Permission to conduct this study has been granted by the Jomo Kenyatta University of Agriculture and Technology board of post graduate studies and the ethical approval granted by the University Ethics and research committee. The Nursing officers in charge of the health facilities and other relevant County authorities have also allowed the study to be conducted on the nurses working in these areas. A research permit has been obtained from the National Commission for Science, Technology and Innovation

What the study involves: This study will take one year starting from the day permission to conduct the study was granted. It involves collecting information from nurses working Embu and Machakos county hospitals and hospices. Participants will be recruited through purposive sampling of the nurses working in these areas. If you agree to participate in the study you will be required to sign an informed consent form. You will be issued with a forty item self administered questionnaire requesting you to give information on the barriers you face in your day to day practice, when managing pain by use of opioid analgesics. You will also be required to give the information as adequately as possible.

Confidentiality: Any information collected from you will be confidential, the questionnaire will be coded and you are not required to indicate your name on the questionnaires. The code will only be known to the investigator and no information should be shared among participants. Every information given will be treated with confidence and there will be no victimization.

Handling of the results: The results of the research will be shared with you and other stakeholders upon request. The results will then be published for the benefit of those interested to learn or do further research in the field.

Risks and benefits of participation: There are no direct benefits to you as a participant and you will not be given any compensation. The study may however benefit the policy makers in the Government and the nurse training institutions. The results obtained from phase one of this research will help in developing a model to act as a guideline for Kenyan nurses while managing pain by use of opioids. The results of this study may also aid in making recommendations for shaping of the

syllabus for training of the palliative care nurses on pain management. There are no risks associated with participating in this research and confidentiality is guaranteed. Any issues arising in the process of the study will be appropriately addressed where possible and confidentiality guaranteed.

Rights of the participants: Your participation is voluntary and you may agree or refuse to participate in the research. You are at liberty to withdraw at any stage without any coercion or victimization.

Contact person: For further clarification or if in doubt kindly contact:

My supervisors:

Dr. Mutisya Kyalo on 0721 484869

Dr. Sherry Oluchina on 0724 668425

Part 2: signature sheet

This is to certify that I…… …….. have read and understood the contents and implications of the consent I am required to give and do agree to participate in the research study on barriers experienced by nurses while administering opioids in pain management among patients with life limiting illnesses by Jostine Ndunge Mutinda.

I understand that the research will take one year and will involve filling in of questionnaires. It is voluntary and there will is be no compensation for participating, no risks will be involved in the study and I may withdraw any at any point.

I hereby append my signature as a sign of my agreement to participate in the research titled, Model of pain management by use of opioid analgesics in palliative care in Kenya.

…… ……

Signature of the participant.

Date…….