ADHERENCE TO WORLD HEALTH ORGANIZATION GUIDELINES ON THE PRACTICE OF SURGICAL ANTIMICROBIAL PROPHYLAXIS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA.

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This thesis research is submitted in partial fulfillment of the requirements for the award of the degree of Master of Medicine in General Surgery at Moi University School of Medicine

MOI UNIVERSITY

SCHOOL OF MEDICINE

DECLARATION

Declaration by the student

This research is my original work and to the best of my knowledge, has not been submitted for an award of academic credit in any other university or research institution.

KIBOS K. EZEKIEL

SM/PGGS/05/17

Signature…… Date……

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This work has been submitted with our approval as university supervisors

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DEDICATION

This work is dedicated to all persons and organizations that put their efforts, time and other resources in provision and improvement of surgical services and antimicrobial stewardship.

DISCLOSURE

The investigator did not receive any funding or grants in support for this study. Neither he nor a member of his immediate family received payments or other benefits thereof or commitment or agreement to provide such benefits from a commercial entity.

Signature…… Date……

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ACRONYMS AND ABBREVIATIONS

AMR	Antimicrobial resistance
AMS	Antimicrobial stewardship
ASA	American Society of Anesthesiologists
ASHSP	American Society of Health-System Pharmacists
HCPs	Healthcare Providers
IDSA	Infectious Diseases Society of America
IPC	Infection prevention & Control
IREC	Institutional Research and Ethics Committee
KMTC	Kenya Medical Training College
LMICs	Low and middle income countries
MTRH	Moi Teaching and Referral Hospital
NICE	National Institute for Health and Care Excellence.
NNIS	National Nosocomial Infections Surveillance System
SAP	Surgical Antimicrobial Prophylaxis.

SHEA	Society for Healthcare Epidemiology of America
SIGN	Scottish Intercollegiate Guidelines Network.
SSI	Surgical Site Infection
WHO	World Health Organization

OPERATIONAL DEFINITIONS OF KEY CONCEPTS

ADHERENCE; Conformity in fulfilling or following official, recognized, or institutional requirements, guidelines, recommendations, protocols, pathways, or other standards. In our case, conformity or following the WHO recommendations on the use of surgical antimicrobial prophylaxis. Adherence is in the following aspects; indication, choice of antimicrobial, timing of first dose, and duration of prophylaxis.

PROPHYLAXIS; Prophylaxis refers to the prevention of an infection and can be characterized as primary prophylaxis or secondary prophylaxis.

Primary prophylaxis; this refers to the prevention of an initial infection before it occurs like in this study.

Secondary prophylaxis; refers to the prevention of recurrence or reactivation of a preexisting infection.

GUIDELINES; are systematically developed evidence-based statements (**in this case WHO guidelines**) which assist providers and other stakeholders ***(in this case the surgical team*)** to make informed decisions about appropriate health interventions ***(in this case surgical antimicrobial prophylaxis use)***

SURGICAL ANTIMICROBIAL PROPHYLAXIS; is the use of antimicrobials to prevent postoperative infectious complications including infection at the surgical site.

ABSTRACT

Background: Surgical antimicrobial prophylaxis (SAP) is important in prevention of postoperative infections which would otherwise cause morbidity and mortality. However, there are concerns about its inappropriate use globally which may account for emergence of drug-resistant pathogens. Guidelines have been developed but adherence is suboptimal.

Objective: To determine the level of adherence to World Health Organization (WHO) guidelines on the practice of SAP at Moi Teaching and Referral Hospital (MTRH) and identify reasons for non-adherence.

Methods: The study was done in two stages. In stage one, an audit was conducted between March 2019 and March 2020 using observational study design. In this stage a total of 224 patients who underwent elective surgical procedures were recruited using stratified sampling based on the operating specialty. By reviewing patients' treatment sheets, discharge summaries, nursing and anesthetic charts, and by direct observations at the operating theatres, the practice of SAP was compared with WHO recommendations on timing of the 1st dose, the choice of antimicrobial, indication and duration of prophylaxis to determine adherence. In this stage, means and standard deviations were used to summarize continuous variables while categorical data were summarized using percentages and frequencies. Fisher's exact test was used to assess association between variables and adherence. In stage 2, a crossectional study was done to obtain quantitative data that could explain reasons for non-adherence. A total of 86 healthcare providers (surgeons, anesthesiologist, nurses and pharmacists) filled self-administered closed-ended questionnaires. The tool used was formulated using information obtained from the guideline and published literature. Data was then summarized using frequencies and corresponding percentages.

Results: Adherence to optimal timing of 1st dose, antimicrobial selection, indication and duration of prophylaxis were 100%, 39.7%, 85.7% and 39.7% respectively. The overall adherence to the four aspects of SAP guideline is 12.5%. Greatest discordance was observed in the duration of prophylaxis which was prolonged in 60.3%. Wound class (P=0.028) and presence of comorbidity (P= 0.003) were significantly associated with appropriate SAP use. Only 73% of the healthcare providers are aware of the WHO recommendations. The main reason for non-adherence are perceived increased risk of infection at the theatres and post-operative care rooms and lack of local hospital protocols adopting WHO recommendations cited by 81% and 47% of the healthcare providers respectively.

Conclusion: Adherence to WHO guideline is low mainly due to inappropriate antimicrobial selection and their prolonged use. Lack of hospital protocols and perceived increased risk for postsurgical infection are some of the reasons for noncompliance.

Recommendations: There is urgent need for intervention programs targeting the surgical team regarding SAP to create awareness and improve adherence to the guidelines. The hospital should prioritize development of local policies on the use of antimicrobials for prophylaxis in surgery. There is need to objectively assess the actual risk of postsurgical infection in the hospital to guide decision making regarding SAP use.

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background Information

Antimicrobial prophylaxis in surgery has become a routine practice in preventing complications from bacterial infections that would otherwise increase morbidity and mortality following surgical interventions. There are however, concerns about the excessive, inappropriate or suboptimal use of antimicrobial prophylaxis in both developing and developed countries (Aiken et al., 2013; Ierano et al., 2019). This may be contributing to antimicrobial resistance that has now become a global issue (Prestinaci et al., 2015; Usha et al., 2010; WHO, 2014). As a result, WHO has raised concerns about injudicious use of antimicrobials.

There is adequate published evidence that a single dose of antimicrobial prophylaxis, given within appropriate time to ensure adequate tissue concentration at the time of incision, and with an antimicrobial spectrum that is effective against the pathogens likely to contaminate the procedure, is enough to prevent surgical site infection(SSI) (ASHP; SIGN, 2008; WHO, 2018) for as long as other multimodal measures of SSI prevention are adequately implemented. At the same time, prolonged use of antibiotic prophylaxis postoperatively does not confer any additional benefits (ASHP; WHO, 2018). Surgeons are well aware of this evidence but there is fear of infectious postoperative complications and a belief that longer duration of postoperative antibiotic prophylaxis will reduce SSI (Aiken et al., 2013; Saied et al., 2015; Schmitt et al., 2017). Most guidelines do not recommend the use of antibiotic prophylaxis for clean surgeries for example clean neck surgeries (thyroid and parathyroid) which form the bulk of elective procedures in general surgery (ASHP; SIGN, 2008; WHO, 2016, 2018). There is supporting evidence from both cohort studies and clinical trials

that the use of antimicrobial prophylaxis in some clean surgeries does not change the risk of surgical site infection and are therefore not recommended (Li et al., 2018).

Globally, efforts have been put to develop Surgical Antimicrobial Prophylaxis Guidelines to assist surgeons use antimicrobials appropriately, but policies adapted to the local environment in Kenyan hospitals are limited. Practitioners in Kenya mostly rely on the WHO guidelines which were developed in 2016 and are continually being updated based on available evidence on best practice. The WHO 2016 and 2018 global guidelines for the prevention of surgical site infection contains a range of preventive measures before, during and after surgery that needs to be intergraded to prevent infection. One of the key preventive measure outlined in the guideline is the use of antimicrobial for prophylaxis and the recommendations are summarized in table 1. The specific agents to be used for each specific surgical procedures and indications are contained in their proposal on EML (Essential Medical List) of 2019(WHO).

Table 1: Aspects of Surgical Antimicrobial prophylaxis and WHO recommendations

Key aspects of adherence	Strong Recommendations Level of evidence* moderate
1. Indication for use of surgical antimicrobial for prophylaxis	✓ Only when risk for SSI is high ✓ Or If SSI will have serious consequence. ✓ Not recommended in clean neck surgeries
2. Selection of appropriate antimicrobial	✓ 1st line SAP should be Narrow spectrum antimicrobial. ✓ Inexpensive antimicrobial ✓ Effective against the pathogen expected to contaminate specific surgical fields
3. Timing of 1st dose of SAP before incision	✓ First dose should be given within 120 minutes before incision, (while considering the half-life of the antimicrobial)
4. Duration of prophylaxis	✓ Only a single dose before surgical incision ✓ Additional intraoperative doses if 1. surgery take >2 half-life of the SAP used 2. Excessive blood loss.

Adherence to these guidelines has been reported to be suboptimal even in developed countries and thus likely to be worse in developing countries (Ierano et al., 2019; Murri et al., 2016) A few studies describing the level of adherence to guidelines and the factors determining uptake of such guidelines have been carried out in Africa. Saied et al., (2015) in Egypt reported a low level of adherence ranging from 0.0 to 6.7 % while one study in a Kenyan county hospital reported that prophylactic antimicrobials were exclusively used postoperatively (Aiken et al., 2013), a practice that is not recommended by any existing guidelines.

Adherence to guidelines would promote judicious use of prophylactic antibiotics, optimize protection of patients from postoperative infections, reduce wasteful use of antibiotics, prevent the emergence drug resistant pathogens that has become a global concern, and reduce the cost associated with the use of antibiotics (Aiken et al., 2013; WHO, 2018).

As it appears, evidence- based medicine is poorly applied in day-to-day clinical practice especially in surgical prophylaxis. Even with the awareness of existing guidelines, published evidence, and educational programs that have been used routinely as a means of improving adherence to SAP guidelines, change of practice has been minimal (Saied et al., 2015). Therefore, there is need to assess the level of adherence locally and explore barriers that hinder adoption of guidelines or the translation of knowledge to clinical practice.

1.2 Problem statement

The level of adherence to existing national and international guidelines on the use of surgical antimicrobial prophylaxis is reported to be low both in developed and developing countries (Brink et al., 2017; Ierano et al., 2019; Saied et al., 2015; Schmitt et al., 2017). In 2016, WHO developed a global guideline for prevention of SSI, SAP being one of the preventive measures (WHO, 2016). The recommendations contained in the guideline were to be adapted into locally appropriate policy documents that are able to meet the specific needs of each country. However, the level of adherence to the recommendations on SAP use remain unknown in our set up. In one study done in Egypt, compliance to other SAP guideline regarding optimal timing of the first dose of prophylaxis ranged between 0 - 6.7% at the beginning of an antimicrobial stewardship program to promote prudent use of antimicrobials (Saied et

al., 2015). In Kenya, one study available in literature documented an outdated practice of exclusive postoperative use of antimicrobial prophylaxis in one of the county hospital (Aiken et al., 2013). This suggests there is a problem of inappropriate use of SAP in Africa.

In a recent study done in MTRH, it was documented that over 50% of the bacteria causing SSI are resistant to the antibiotics commonly used in the hospital (Onyango et al, 2018). It is therefore a possibility that the existence of drug-resistant pathogens in MTRH is as a result of failure to adhere to the recommended guidelines on the use of antimicrobials in surgery. There is evidence that the driving force for the emergence of drug resistant-pathogen is the abuse and misuse of antimicrobials (Morrison & Zembower, 2020; Roca et al., 2015). It is therefore a necessity for a National Referral Hospital like MTRH to examine its practices with reference to evidence-based international guidelines developed to promote judicious use of antimicrobials.

On the other hand, it is identified that surgeons are aware of the problems of drug resistance as a result of inappropriate use of antimicrobials. They are also aware of evidence-based practices regarding antimicrobial use in surgery but adherence to SAP guidelines has generally been very poor (Giusti et al., 2016). This suggests that there are barrier to successful change of practice or translation of scientific evidence to clinical practice.

1.3 Justification

Because inappropriate or suboptimal use of surgical antibiotic prophylaxis is recognized as a problem both locally and globally and it is linked to the emergence of drug resistance pathogens, there is need to assess the level of adherence to SAP guidelines in our set up to highlight the problem of misuse of antimicrobials. It is hoped that this would draw the attention of surgical team who should take part at the center stage in tackling antimicrobial resistance threat.

To initiate any antimicrobial stewardship program aimed at improving judicious use of antimicrobials in the hospital, it would be very important to document the baseline level of adherence and this study aims at evaluating SAP practice in comparison to what is recommended by WHO.

At the same time, for Antimicrobial stewardship program (AMP) to design a suitable intervention program to promote the use of SAP guidelines in our set up, there is need to understand the reasons for non- adherence in MTRH. These barriers may not be unique to the institution but may be applicable to other hospitals in the region and it would help focus interventional program to address inappropriate use of antimicrobial that has become a global issue.

Judicious use of antimicrobials in surgery is our ultimate goal and this study could serve as a starting point of processes that are aimed at changing the practice of SAP at MTRH. And given that MTRH is a teaching hospital, greater effect can be realized through the students that graduate from the college of health science each year.

1.4 Research question

1. What is the level of adherence to WHO guidelines on the use of surgical antimicrobial prophylaxis in MTRH?
2. What are the reasons for non-adherence to WHO guidelines on the use of surgical antimicrobial prophylaxis in MTRH?

1.5 Objectives

1.5.1 Broad objective

To determine the level of adherence to WHO guidelines on the use of surgical antimicrobial prophylaxis in MTRH and to identify the reasons for non-adherence.

1.5.2 Specific objectives

1. To determine the level of adherence to WHO guidelines on the use of surgical antimicrobial prophylaxis at MTRH.
2. To identify reasons for non-adherence to WHO guidelines on the use of surgical antimicrobial prophylaxis at MTRH.

1.6 Conceptual framework.

This framework illustrates the key aspects of adherence to be measured; the indication for use of surgical antimicrobial prophylaxis, the choice of antimicrobial appropriate as per WHO criteria, the timing of the initial dose of SAP and the duration of SAP use as outlined in the guideline. Adherence to each of these recommendations will yield the overall adherence to the guideline. The framework also outlines specific category of determinants that affect the SAP prescription behaviors in the hospital that will eventually affect overall adherence to the guidelines.

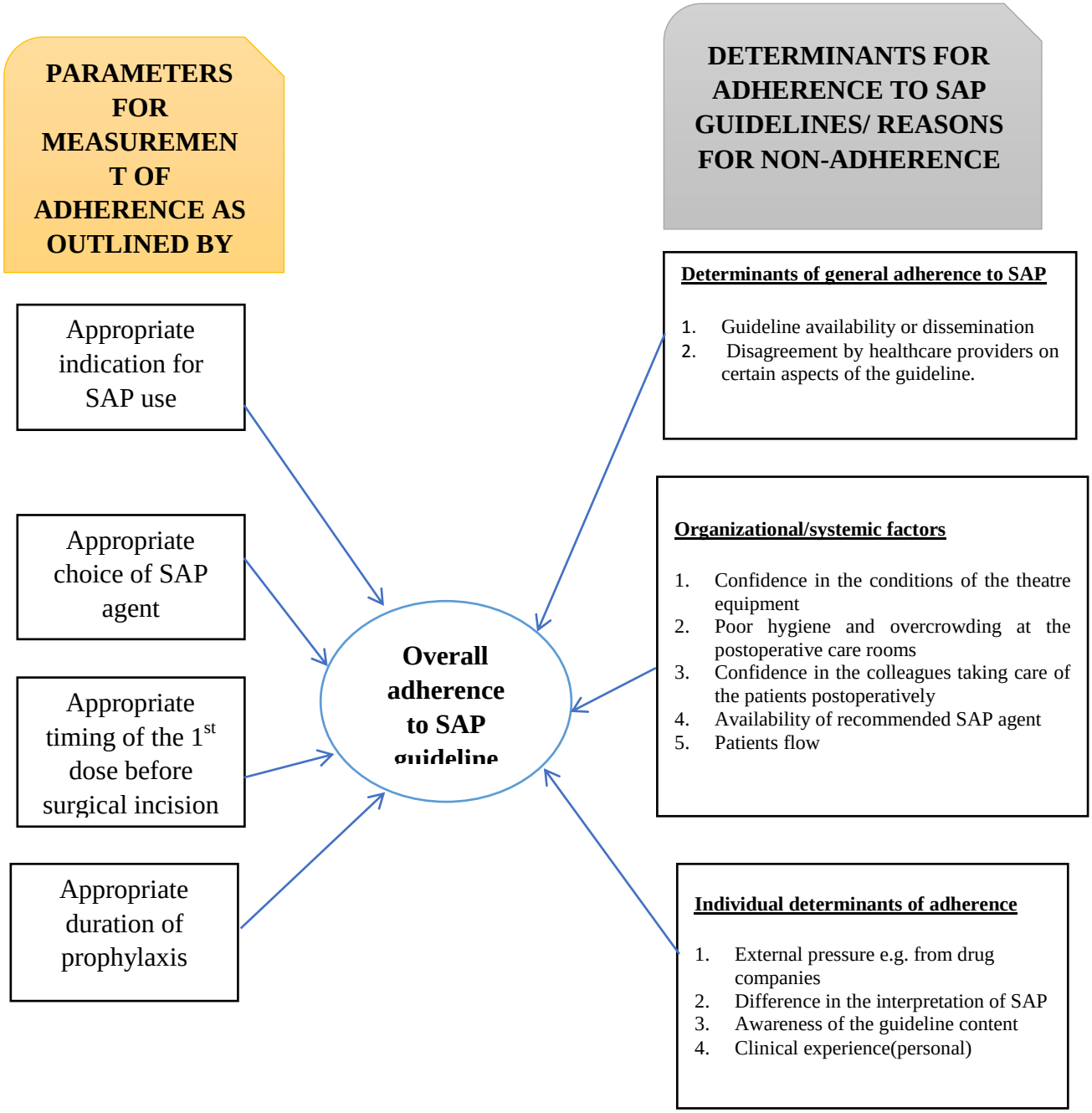

Figure 1: Conceptual framework. (Adopted from Giusti et al. (2016) 16:203 but modified to incorporate measurements of adherence to SAP guideline).

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

The concept of preoperative use of antimicrobials to prevent postoperative infection in surgical patients was introduced before the modern era of antibiotics but its evidence base was firmly established in the 1960s by H.R. Bernard and W.R. Cole (HR & WR, 1964)**.** Currently surgical antimicrobial prophylaxis is the standard of care in every institution interested in good surgical outcomes.

The use of antimicrobial prophylaxis has undeniably reduced the rate of surgical site infection and its associated morbidity and mortality (Westerman, 1984). However, the concern has been its inappropriate use. There are many reports of inappropriate use of antibiotic prophylaxis globally both in developed and developing countries though the problem could be much worse in developing countries (Brink et al., 2017; Gouvêa et al., 2015; Ierano et al., 2019; Schmitt et al., 2017). Inappropriate use of antimicrobial prophylaxis could be linked to the development of drug resistance (Morrison & Zembower, 2020; Usha et al., 2010; WHO, 2018).

Many guidelines have been developed in an attempt to guide the use of antimicrobial prophylaxis in surgery but there is poor adherence with regards to indication for surgical antibiotic prophylaxis, timing of the initial dose and the duration of prophylaxis which is often longer than recommended (Aiken et al., 2013; Saied et al., 2015; Schmitt et al., 2017). Despite the availability of local and international guidelines with supporting evidence, compliance in the use of antimicrobial prophylaxis guidelines has been very poor (Aiken et al., 2013). Factors responsible for non-compliance to available guidelines appear to be complex and multifactorial

and the reported key issues vary among studies. Some of the factors include lack of awareness of the available guidelines, fear for unfavorable surgical outcomes and misconception (Brink et al., 2017; Saied et al., 2015).

2.2 The routine practice on surgical antimicrobial prophylaxis.

Despite the availability of published evidence that optimal timing and duration of prophylaxis increases efficacy of antimicrobials while at the same time preventing the induction of drug resistant pathogens, the practice of antimicrobial prophylaxis is reported to be inappropriate not only in developing countries but globally (Ierano et al., 2019; Saied et al., 2015; Schmitt et al., 2017). In an antimicrobial stewardship pilot study done in five hospitals in Egypt, Saied et al., (2015) reported that surgical prophylaxis was generally suboptimal especially regarding appropriate timing of first dose and the duration of prophylaxis (Saied et al., 2015). In this interventional study, appropriate timing of the first dose of surgical antimicrobial prophylaxis before surgical incision ranged between 0 to 6.7% among the five hospitals at the pre-intervention stage. After a rigorous intervention program of policy enforcement mainly through training, monitoring and feedbacks to improve prescription habits, the rate increased significantly to 38%, but this was still suboptimal indicating that there are other barriers to change (Saied et al., 2015)

In another study done in Thika level 5 hospital in Kenya involving development and implementation of a Surgical Antibiotic policy as an intervention to change the prescription behavior in this County hospital, the use of Antibiotic prophylaxis was almost exclusively (99%) in the postoperative period. Less than 2% of all antibiotic prophylaxis was administered preoperatively at the pre-intervention phase. The routine practice prior to the intervention was that of intravenous postoperative

antibiotic prophylaxis given for 3 to 5 days followed by an additional course of oral antibiotics (Aiken et al., 2013). This is likely to be the practice in many hospitals in Kenya and other similar settings despite availability of guidelines on antimicrobial prophylaxis.

Of the four key parameters of used widely to assess adherence; indication, choice of antibiotics, timing of first dose, and duration of prophylaxis, the major flaw is in the duration of prophylaxis which is often prolonged than recommended (Aiken et al.,). This is in agreement to most other studies in both developed and developing countries (Quattrocchi et al., 2018; Schmitt et al., 2017). This suggests a potential disagreement of the healthcare providers with the existing guidelines (Schmitt et al., 2017). Published Studies describing the level of adherence to SAP guidelines in African hospitals particularly Kenya are very limited.

Another observation is the routine use of antimicrobial prophylaxis in all surgeries without consideration of the indications. One example is clean neck surgeries including g thyroid and parathyroid which has been extensively studied and there is overwhelming evidence that antimicrobial prophylaxis is of no benefit especially if hollow viscera like trachea and pharynx are not entered (Uruno et al., 2015). Clean surgeries form the bulk of elective surgeries and antibiotic prophylaxis is almost always given in most medical institutions (Uruno et al., 2015).

The appropriate use of surgical antibiotic prophylaxis can improve as it has been demonstrated in the pilot study in Egypt and the Thika study in Kenya following almost similar intervention. The documented improvement in the Egypt study is a change in optimal timing from 6.7% to 38.7% following an intervention focusing on education supported by auditing and feedback (Saied et al., 2015). In Thika, the

demonstrable change is that of a near-exclusive postoperative antibiotic use to a near-exclusive preoperative prophylaxis and associated risk reduction in SSI (Aiken et al., 2013). The unique thing about the Thika intervention was that the antibiotic policy was developed and implemented within the same hospital in collaboration with the surgical team.

2.3 Surgical antimicrobial prophylaxis guidelines

A number of guidelines developed by countries, organizations and institutions on the practice of surgical antimicrobial prophylaxis have been published (Anderson et al., 2014; Berriós-Torres et al., 2017; Bratzler et al., 2013; Ministry of medical services, Kenya,., 2010; SIGN, 2008). However, WHO indicated that there are inconsistencies is some of these guidelines and therefore developed an international guideline with recommendations that can be adopted by any country, irrespective of their level of development and resources (WHO, 2016). The document was updated in 2018 and covers multiple measures of SSI prevention including SAP especially on appropriate timing and duration of prophylaxis (WHO, 2018). A separate document was published in 2019 containing specific indications and proposals of appropriate selection of antimicrobials for use in each surgical procedure that should be included in Essential Medical List(WHO, 2019).

The developers of these guidelines emphasize that surgical antibiotic prophylaxis is not a substitute for good surgical technique but an adjunct to it. Most of the guidelines give recommendations on every component of SSI prevention but in this study one component (antimicrobial prophylaxis) is going to be examined with regards to the following aspects; indication for antibiotic prophylaxis, choice of antibiotic used, timing of the initial dose and the duration of prophylaxis.

2.3.1 The indication for surgical antimicrobial prophylaxis.

Most of the guidelines emphasize that antimicrobial prophylaxis should be considered where there is evidence of benefit, where there is a risk of postoperative infection, or if postoperative infection will have serious consequences (Bratzler et al., 2013; Ministry of medical services, Kenya., 2010; SIGN, 2008; WHO, 2018). And that it should not be considered if there is evidence of lack of benefit.

The Kenyan infection prevention guideline recommends that the benefits of using SAP must be weighed against the risks of toxic and allergic reactions, the emergence of resistant bacteria, drug interactions, super infection, and the cost involved. It further states that antibiotic prophylaxis is recommended only for procedures with high infection rates and those in which the consequences of infection are especially serious (Ministry of Medical services, Kenya., 2010) and this is agreed by other guidelines.

Most guidelines have specified the types of surgeries where SAP is not indicated including most clean elective surgical procedures. But it is emphasized that the ultimate decision rests with the surgeon's assessment of risk and benefit. This means the surgeons can prescribe antimicrobial prophylaxis even when the guideline do not recommend if in their best judgment the patient is at a high risk of developing serious SSI. But in such circumstances the indication should be justified in writing on the patient's records (SIGN, 2008). This is supported by evidence from multiple studies evaluating the need for antibiotic prophylaxis in clean surgeries like thyroid, parathyroid and laparoscopic hernia repairs (Köckerling et al., 2015; Li et al., 2018; Uruno et al., 2015) although most of these studies support routine use of

antimicrobial prophylaxis in all open hernia surgeries and those repaired with prosthesis.

2.3.2 Choice of appropriate surgical antimicrobial

Most guidelines seem to agree about the criteria to be used in deciding the appropriate antibiotics to be selected for prophylaxis. The most important property a SAP agent should possess is effectiveness against the pathogens expected at the specific operative site (Allegranzi et al., 2016; Bratzler et al., 2013; Mininstry of medical services, Kenya., 2010; SIGN, 2008; WHO, 2019). The SAP agent should also be able to achieve adequate tissue concentration by the time surgical incision is made and its' half-life should last the duration of the procedure (Allegranzi et al., 2016; WHO, 2019). SIGN, (2008) recommended that the choice of antibiotic should take into account local antimicrobial resistance patterns and costs of SAP. However, consideration of local antimicrobial resistance profile in deciding specific antimicrobials to be used in a given institution is not uniformly agreed among guidelines because what is considered important is the resistance profile of those pathogens that are known to cause SSI and not all pathogens cultured on surfaces and theatre equipment. In most guidelines (Bratzler et al., 2013; SIGN, 2008; WHO, 2018, 2019), SAP selected as 1st line should be a narrow spectrum and less expensive antimicrobial although the Kenyan guidelines recommend a broad spectrum agent (Ministry of medical services, Kenya., 2010). The main reason for using a narrow spectrum agent is to avoid collateral damage to hosts' normal-flora that usually results in altered immunity with subsequent infections like *Clostridium difficile*-associated colitis (Bratzler et al., 2013; Nasiri et al., 2018).

2.3.3 Optimal timing of the first SAP dose

World health Organization safe surgery guideline 2009 indicates that the appropriate time to administer SAP should be within 0 - 60minutes before incision. This timing is widely accepted by multiple guidelines across the world including SHEA/IDSA (2014), NICE (2013), ASHSP (2013), The Royal College of Physicians of Ireland (2012), USA Institute of Health Improvement: surgical site infection (2012), Health Protection Scotland bundle (2013), UK High impact intervention care bundle (2011) and SAP clinical guidelines of Australia.

However, the Global guideline on prevention of surgical site infection by WHO, 2016 (updated in 2018) has come up with a new recommendation that administration within 120mins is acceptable. This was achieved following rigorous analysis of evidence that showed no difference between 0-30mins, 30-60mins and 60-120mins while there was a significantly high risk of SSI when SAP is given beyond 120mins before surgical incision (WHO, 2016, 2018). It is however emphasized that the drug's half-life must be considered and the time be adjusted within the 120mins, meaning drugs with shorter half-life should be given much closer to the time of incision (WHO, 2016, 2018, 2019). Although the developers of these guidelines indicate there is still debate about the optimum time for administration of 1st dose of SAP, the aim is to achieve adequate concentration by the time incision is made and a maintained tissue level until the wound is closed.

The knowledge of drug half-life is important to consider when planning the timing of SAP in a surgery because there are situation when additional doses should be given intraopperatively in case surgery takes longer or there is significant blood loss (Bratzler et al., 2013; Ministry of Medical services, Kenya., 2010; SIGN, 2008; WHO, 2018). What most guidelines agreed on is that additional intraoperative doses

be given if there is significant bleeding, and when the surgery takes more than 2 half-life of the SAP used or the surgery takes more than 4hours. ASHP 2013 has gone further to recommended re-dosing intervals for each SAP agent listed for use to guide on this issue (Bratzler et al., 2013).

2.3.4 The duration of SAP

All the guidelines recommend against the prolongation of SAP after completion of surgery for the purpose of preventing SSI (Bratzler et al., 2013; Ministry of Medical services, Kenya., 2010; SIGN, 2008; WHO, 2016, 2018). WHO, (2016, 2018) states that prolongation beyond 24hours after surgery is not beneficial and may in fact promote development of antimicrobial resistance or alter the patient's microbiome. It is also linked to the spread of *C. difficile* with a higher risk of a clinical manifestation of infection (Allegranzi et al., 2016; Bratzler et al., 2013; SIGN, 2008). Aiken et al (2013), Brink et al (2017) and Saied et al (2015) have mentioned prolonged use of SAP as a major problem and that it should be avoided because it is wasteful, increase chances of adverse effects to the patient, and is linked to emergence of drug resistance

2.4 Factors associated with inappropriate use of SAP

Barriers to successful change in prescription behavior that have been documented include lack of knowledge about the concepts of antimicrobial resistance that develop as a result of inappropriate antimicrobial use, the resistance to change routine practice by healthcare providers , and a strong belief that hospitals especially in developing countries have a higher risk for bacterial contamination of surgical wound compared to hospitals in high income countries (Aiken et al., 2013; Brink et al., 2017; Saied et al., 2015). Other factors include lack of national or local hospital guidelines on

surgical prophylaxis, lack of coordinated effort by regulatory bodies to promote optimal use of antimicrobials, and misconception on SAP by the clinicians and surgeons (Aiken et al., 2013; Saied et al., 2015).

Negative surgical outcomes following surgical site infections are a great concern amongst surgical teams who are often forced to overuse antimicrobials for protection. Overcrowding and the perception of unclean environment noted in hospitals are thought to increase the risk of a surgical site getting infected in the postoperative periods. There is also the fear of litigation secondary to unfavorable surgical outcomes (Aiken et al., 2013; Brink et al., 2017). All these feed into the general belief by surgeons that prolonged antimicrobial prophylaxis after surgery is protective and will reduce surgical site infection (Aiken et al., 2013; Saied et al., 2015; Schmitt et al., 2017). But the question is; are there any justifications for prolonged use of SAP? Or can these conditions of general hygiene be improved instead?

However, there are those that believe that routine use of antimicrobial prophylaxis in clean surgeries could be justified if an ideal clean surgical environment is not available due to lack of equipment, regional situations or other socioeconomic situations that could increase the risk of infection (Uruno et al., 2015).

Other studies have reported lack of awareness of existing guideline by the clinicians, ineffective distributions of the guidelines to the intended users, lack of audits and feedback regarding rates of SSI as well as the local antimicrobial resistance profile as the main reasons for poor adherence to SAP guideline. Suboptimal adherence to guideline is also linked to logistical and organizational constrains that are unique to different settings and external barriers including pressure from pharmaceutical

companies (Giusti et al., 2016; Kasteren et al., 2003) . Giusti et al., (2016) also mentioned that non-compliance to appropriate SAP selection could be due to the high cost of antimicrobials or disagreement by health care practitioners with the specific recommendation in the guideline. Kasteren et al., (2003) believe that testing the feasibility and the acceptance of guidelines should be done to enhance its effective implementation.

2.5 The benefits of adherence to SAP guideline in surgery.

Antimicrobial resistance is a global public health threat and one of the contributing factors is inappropriate or overuse of antimicrobials (Prestinaci et al., 2015; Roca et al., 2015). In a recent study in MTRH, isolated pathogens from surgical infection sites and blood culture were resistant to most antimicrobials commonly used in the hospital (Onyango, 2018). It is believed that adherence to SAP guidelines would promote judicious use of antimicrobials in surgery and therefore become an important step in preventing further development of drug resistance (WHO, 2018).

A number of studies measuring the impact of adherence to guidelines on antimicrobial prophylaxis, have demonstrated that optimal use of antimicrobial prophylaxis actually reduces the risk of surgical site infection (Aiken et al., 2013; Kilan et al., 2017; LiuJuyuan et al., 2018; Sánchez-Santana et al., 2017). These reports however have varying level of significance for example Kilan et al., (2017) in a quality improvement project that identified and addressed barriers to successful uptake of guidelines reported a reduction of SSI rate from 9% to 5.1%.

Significant cost reduction for both patients and the facility has been demonstrated. One study evaluating the impact of educational intervention in improving compliance with SAP guidelines demonstrated that the total cost of inappropriate antibiotics use

in a hospital in Turkey was US$26,230.20 within a 3-month intervention period (Kilan et al., 2017). In Kenya, Aiken et al., (2013) at Thika level 5 hospital demonstrated a net reduction in the costs of intravenous antibiotics and associated consumables of approximately $2.50 per operation and 70% reduction in nursing time spent preparing and administering antimicrobials. Therefore, adherence to SAP guidelines will not only help achieve optimum prevention of SSI but would also prevent development of resistance and reduce cost of treatment.

CHAPTER THREE

METHODOLOGY

3.1 Study Site

The study was conducted at the pediatric surgical ward in Shoe for Africa (a children's hospital of MTRH), the adult surgical wards (both male and female) and the operating theatres of the MTHR, Eldoret. This is a national teaching and referral hospital in western region of Kenya attending to both rural and urban populations. Eldoret town is located North-West and approximately 311km from the capital city Nairobi. It lies on the geographical latitude of 0^0 31' N and longitude of 35^0 17' E.

The hospital has a bed capacity of about 1000. The facility boasts of highly trained and specialized medical staff from both the hospital and its associated training institution, College of Health Sciences, Moi University. It has a catchment population of 20 million people including Western part of Kenya and even extending to Eastern parts of Uganda. The hospital is also a training ground for students from Moi University, Kenya Medical Training Centre (KMTC), University of East Africa, Baraton, and the MTRH nursing program as well as international students on exchange programs courtesy of Moi University.

The hospital has a busy department of surgery which is serviced by other key departments of the hospital e.g. laboratory, physiotherapy, occupational therapy, nutrition, social work, and well-equipped operating theatres. The department experiences high bed occupancy of between 100% and 150%. The hospital also has a well-stocked pharmacy within the theatre building dedicated to proving medicines required during surgical procedures, well trained pharmacists and an active infection prevention & control team as well as antimicrobial stewardship teams.

3.2 Study design

The study was done in two stages. In stage one, an audit was conducted between March 2019 and March 2020 using observational study design. In stage two, a crossectional study was done to obtain quantitative data that could explain reasons for non-adherence to guidelines

3.3 Study population

The study participants comprised of two different populations involving patients from the department of surgery and the hospital staff.

1. **Patients**; those who were admitted in the pediatric and adult surgical wards and underwent elective surgical procedure in the department of surgery between March and October 2019.
2. **The hospital staff**; this involved the surgical team (both ward and theatre nurses, the anesthetist and the surgeons) who were involved in the elective surgical procedures within the period adherence to surgical antimicrobial prophylaxis guidelines was evaluated. It also involved the pharmacists who play a key role in monitoring antimicrobial use. The pharmacists were also involved in dispensing as well as the procurement processes of antimicrobials used in MRTH. Hospital staff also involved the Infection Prevention &Control nurses.

3.3.1 Inclusion criteria for patients.

- Patients who underwent the planned elective operation under urology, general surgery and pediatric surgical specialties.
- Patients whom antimicrobial prescription was intended for primary prophylaxis.

3.3.2 Exclusion criteria for patients.

- Patients undergoing elective surgery under orthopedics, cardiothoracic and neurosurgery were excluded in this survey because of an additional recommendation by WHO to screen for *S. aureus* and identify carriers who should receive pre-operative treatment with nasal mupirocin ointment. This practice is not routinely done in MTRH. This recommendation is conditional when applied to other surgeries.
- Patient with existing infection requiring to be initiated on antimicrobials as therapy and not prophylaxis.
- Patients already on antimicrobials for other therapeutic purposes.

3.3.3 Inclusion criteria for hospital staff

- The surgical ward nurses, theatre nurses, anesthetists, the surgeons, pharmacists, and Infection Prevention and Control nurses who were active in the period adherence to SAP guideline was being evaluated.

3.3.4 Exclusion criteria for hospital staff

- New staff (staff whose first appointment to work in the areas of interest fall within the 7months period during which adherence was being evaluated)

3.4 Sample size for the patients

The estimated number of patients admitted for the selected surgical procedures through the selected surgical outpatient clinics (pediatric surgical outpatient clinic, general surgical outpatient clinic and urology outpatient clinics) are about 23 patients per week giving us an average of approximately 92 per month. It was therefore, expected that about 644 surgical procedures were going to be audited in the seven

months of the study. The sample size was determined using the following formula by (Cochran, 1963).

$$n = \left(\frac{Z_{1-\alpha/2}}{d}\right)^2 \times P \times (1 - P)$$

$$= \left(\frac{1.96}{0.05}\right)^2 \times 0.38 \times (1 - 0.38)$$

$$= 363$$

Where P (=38.0%) is the proportion of operated patients who had optimal timing for the first dose of the antimicrobial prophylaxis (Saied et al., 2015), d (=5%) is the margin of error, $Z_{1-\alpha/2}$ is the quantile of the standard normal distribution, and α (=5%) is the type 1 error.

The finite population size as given above is approximately 644 in seven months. Correcting for this gives $\frac{363}{1+\frac{363}{644}}$ =233 as the required number for the study.

3.5 The study procedure

The study was done in two stages; it begun with a 7-month audit period where routine practice of surgical antimicrobial use was observed and compared with the WHO recommended guidelines. In the subsequent period, the hospital staffs were issued self-administered closed-ended questionnaires that were formulated to determine barriers that hinder the use of surgical antimicrobial prophylaxis recommended guidelines because our assumption was that the guidelines were not optimally followed.

3.5.1 The initial stage

This was the audit phase where the routine practice on the use of surgical antimicrobial prophylaxis was observed and described. All the patients who met the inclusion criteria were recruited once they were included in the list for elective surgery at their respective surgical wards; they were followed up in theatre where there was direct observation of the administration of antimicrobial prophylaxis and also followed up postoperatively until discharge from the unit. The following information was obtained; patient socio-demographics, their clinical characteristics including ASA(American Society of Anesthesiology) patient classification, wound class, length of preoperative hospital stay, specific surgery done, indication for antimicrobial use, specific antimicrobials used, the timing of the first dose of antimicrobial prophylaxis before surgical incision, duration of surgery, estimated blood loss, intraoperative re-dosing of antimicrobials and the duration of antimicrobial prophylaxis. This data was compared with the recommendations by WHO to determine the level of adherence or divergence.

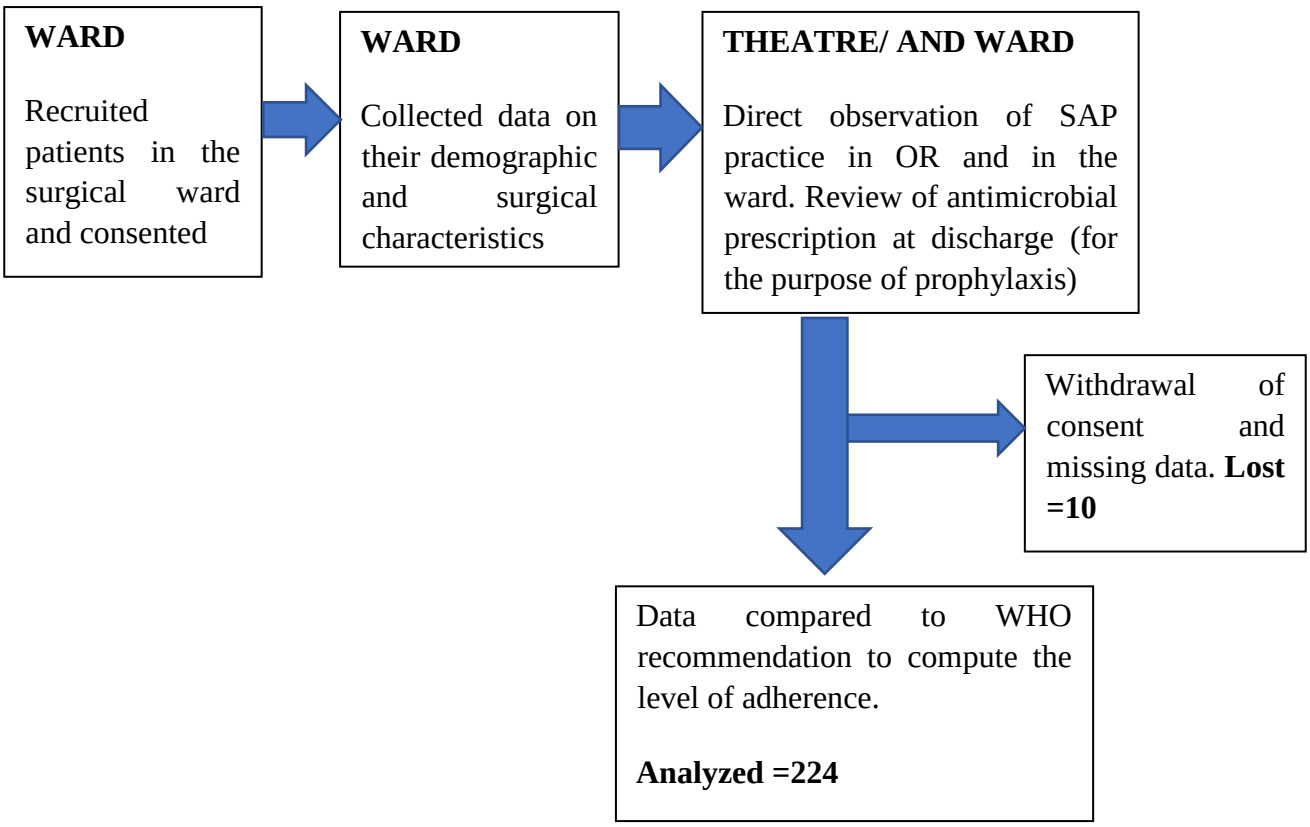

Figure 2: Flow chart describing stage 1 of the study procedure.

3.5.2 The second stage

In this stage, the surgical team (the nurses, anesthetists and the surgeons) who directly took part in the use of antimicrobial prophylaxis, the pharmacists who were directly involved in ordering and dispensing antimicrobials for consumption by the surgical team as well procurement process were issued self-administered closed-ended questionnaires to fill. The aim was to identify both healthcare-provider factors and systemic factors that could explain poor adherence to SAP guidelines in the hospital.

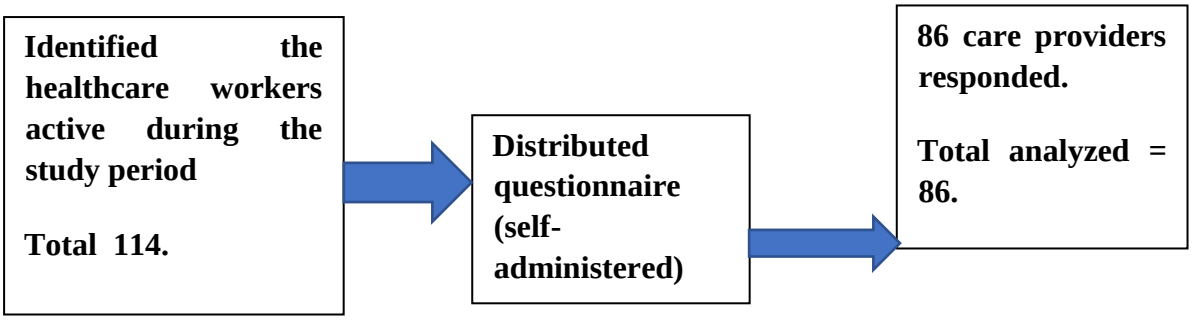

Figure 3: Flow chart describing the second stage of the study.

3.6 Sampling procedure

All the patients admitted for elective procedure in pediatric, urology and general surgery who met the inclusion criteria were selected using stratified systematic random sampling method. Sampling was done proportionate to size and stratification was based on the specialty in which the patient was operated (each specialty is different in terms of patient and surgical teams hence the basis for stratification). These specialties were; the pediatric surgery, general surgery and urology. In each stratum, systematic random sampling was done. This was done as shown in Table 1 below.

Table 2; Proportionate allocation of the sample size for each surgical specialty's planned elective procedures.

Surgical specialty.	Population Size (N) which is also the sample frame.	Proportion	*Number to Sample (n)
Pediatric surgery	187	0.29	68
Urology	97	0.15	35
General surgery	360	0.56	131
TOTAL	644	1.0	234*

*because of rounding of the total number of patients is slightly higher than the sample size.

The sampling interval was determined as k = N/n. So, every K^{th} patient was selected for enrolment in the study where starting point was selected at random from the first elective list for surgery in each of the specialties at the beginning of the study. This was calculated for each stratum as follows;

a) Pediatric surgery k = N/n = 187/68 = 3. So, every 3^{rd} patient on the elective list scheduled for pediatric surgery was selected. Each list of patients scheduled for surgery was patched onto the previous list to create an ordered sequence in which every 3^{rd} patient could be identified.
b) Urology k = N/n = 97/35 = 3. Therefore, every 3^{rd} patient on the elective list scheduled for urology surgery was selected.
c) General surgery k= N/n = 360/131 = 3. Therefore, every 3^{rd} patient on the general surgery elective list scheduled for surgery was selected. The values for each k have been rounded off to a whole number.

Each time a patient is cancelled from the list, the next patient was selected.

The sampling procedure for the healthcare workers (surgeons, anesthesiologists, nurses and pharmacist) was census. This approach was used because the numbers of these personnel active at the time of assessment of compliance with surgical antimicrobial prophylaxis guideline was small.

3.7 Patient recruitment and follow up

Patients were recruited at the pediatric surgical ward, adult surgical male and female wards in which they were admitted for the planned elective procedure. Most of the patients were admitted through their respective outpatient clinics and the decision to operate was made by the respective attending consultant surgeons with their residents. The patients were followed up to make observations of the practice of surgical antimicrobial prophylaxis until discharge. The purpose of follow up was to maximize data collection as it was known that documentation can sometime be poor otherwise their medical records could have be examined only at discharge.

3.8 Data collection method

Two separate data collection tools were used; one for the patients and the other for the hospital staff who directly or indirectly determined surgical antimicrobial prophylaxis used in MTRH. A patient's checklist was used to extract the following information; socio-demographic characteristic, their preoperative characteristics which include diagnosis, type of planned surgery, wound class, presence of comorbidities and ASA class. Indication for prophylaxis, specific antimicrobial used, timing of initial dose before incision, additional intraoperative doses if any, the time of incision, duration of surgery, estimated blood loss and the duration of prophylaxis was recorded on an adherence assessment form attached to each checklist. This data

was obtained from the patients' medical records and by direct observations of the practice of surgical prophylaxis in the operating theatres.

In the second stage, self-administered closed-ended questionnaires were used to obtain quantitative data that could explain the prescription behaviors or the lack of conformity to the WHO recommended guidelines which has been our assumption. The tool used was formulated using information obtained from the guideline and other published literature. The surgical team (nurses, surgeons and anesthesia team), IPC nurses and the pharmacists responded to the questionnaires. Data obtained include their interpretation of SAP meaning (a multiple choice question), awareness of the WHO recommendation on the use of antimicrobial prophylaxis, their attitude towards specific recommendations contained in the guideline (based on 4-point Likert scale questions) and organization/systemic issues in MTRH that could limit adherence to the guideline.

3.9 Quality Control

Development and pre-testing of the questionnaires was carried out at the pediatric surgical wards, Rehema and Kilimanjaro (both adult surgical wards) and the main operating theaters of MTRH. Data was reviewed after collection to check for missing data and unclear entries. Data cleaning and counter checks on data entry was done.

3.10 Data management strategy

Data captured using the questionnaires were entered into an electronic database. The database was encrypted with password to ensure confidentiality. The password was only accessible to the main investigator. To cushion against data loss, the electronic database was backed up using external data drives that were encrypted and kept in separate and safe locations. The forms, once conversion to electronic database was

complete, were kept in a safe cabinet under a lock and key retained by the lead investigator.

3.11 Data analysis

Descriptive statistics such as means and standard deviations were used to summarize continuous variables such as age, duration of the surgery, and duration of prophylaxis use among others if Gaussian assumptions hold. Where Gaussian assumptions failed to hold, then the median and the corresponding inter quartile range (IQR) was used. Gaussian assumptions were assessed using Shapiro Wilks test, and plots such as histograms and normal probability plot.

Categorical variables such as gender, type of surgery done, wound class, and ASA class among others were summarized using percentages and frequencies.

Adherence to the specific aspects of WHO guidelines such as adherence to correct timing of the first dose before incision, appropriate choice of antimicrobials, correct identification of the indication and correct duration of administration of antimicrobials prophylaxis were summarized using frequencies and the corresponding percentages.

The overall level of adherence with the WHO guidelines which is defined as adherence to all four studied parameters (correct timing of the first dose before incision, appropriate choice of antimicrobials, correct identification of the indication and correct duration of administration of antimicrobials prophylaxis) was calculated as the total number of patients who were surgically treated under correct adherence with all four studied parameter of the WHO guidelines divided by the total number of

patients enrolled in the study. The corresponding 95% confidence intervals were calculated.

Fisher's Exact Test was used to assess the association between patient's surgical characteristics and adherence.

The reasons for the failure to adhere to the WHO guidelines were also described using frequencies and their corresponding percentages.

Results are presented using tables.

Data analysis was done using R version 3.6.0.

3.12 Ethical considerations

To carry out this study, permission was sought and obtained from the Institutional Research and Ethics Committee (IREC) of Moi Teaching and Referral Hospital **(FAN: IREC 3249)** and from the hospital administration. Informed written consent was obtained from all eligible patients. For minors, an assent was sought from the minors and additional consent was obtained from their parent/guardian. Approval for use of vulnerable populations was also sought from IREC. Informed consent was obtained from the Healthcare providers who responded to the questionnaires. It was a voluntary participation and every participant was respected and was allowed to withdraw from the study at any stage. Information of the participants was kept with utmost confidentiality.

3.13 Guideline on the dissemination of study findings

At the end of this study, the findings will be disseminated through relevant institution channels to reach all the stakeholders (the department of surgery, the pharmacy, infection control teams, Antimicrobial stewardship team of MTRH and the hospital administration), the findings will also be disseminated through CME meetings held at the College of Health Science. It will also be presented to the faculty, at scientific conferences and it will be published in journals. Bound copies of the thesis will be submitted to the supervisors and Moi University library.

CHAPTER FOUR

4.0 RESULTS

4.1 Patient and operative procedure characteristics

A total of 234 patients were recruited and undergone planned surgery but because of missing data and withdrawal of consent, only 224 surgical procedures were included in the Analysis. Table 2 shows descriptive characteristics of the patients and the operations. The mean age of the patients was 36.2 years (SD=5.7) with a Male; female ratio of 1:1. The mean preoperative hospital stay was 2.5 days (SD=5.5) and majority of the participants were undergoing General surgery 130 (58%) and 67 (30%) pediatric surgery. More than half of the participants 137 (61.2%) had a clean wound and 125 (55.8%) were scored ASA1 by the anesthesiology team. Very few 23(10.3%) had a comorbidity, the median duration of surgery was 75 minutes (IQR: 55,120) and the median blood loss in litres was 0.10(IQR: 0.05, 0.20).

Table 3: Patient and operative procedure characteristics

Variable		**N=224 Freq (%)**
Age (years)	Mean age (SD)	33.3 (23.5)
	Age Range	1.0 - 90.0
Sex	Female	113 (50.4%)
	Male	111 (49.6%)
Preoperative hospital stay (days)	Mean (SD)	2.545 (5.461)
	Range	0.000 - 48.000
Type of surgery	General surgery	130 (58.0%)
	Pediatric	67 (29.9%)
	Urologic	27 (12.1%)
Class of Wound	Clean Wound	138 (61.6%)
	Clean- contaminated Wound	86 (38.4%)
ASA score	ASA: 1	125 (55.8%)
	ASA: 2	85 (37.9%)
	ASA: 3	14 (6.2%)
Comorbidity	No	201 (89.7%)
	Yes	23 (10.3%)
Duration of surgery (mins)	Mean (SD)	89.219 (52.93)
	Range	25.0 - 270.0
Blood loss (litres)	Mean (SD)	0.16 (0.20)
	Range	0.0 – 1.8

4.2 Adherence to the WHO recommended guidelines on the use of surgical antimicrobial prophylaxis

The study found that 192 (85.7%) cases had the appropriate indication for SAP. Procedures in which SAP was given when not indicated included clean neck surgeries 31(13%) and for all the surgical procedures (100%), the timing of the 1st dose before surgical incision was appropriate as indicated in the guideline (within 120min). In our observation, mean duration of time from administration of 1st dose of SAP to incision was 22.79 mins (SD=11.67). In 89 (39.7%) of the procedures, the SAP agent was appropriately selected. In cases where SAP was inappropriately selected, either ceftriaxone was used, or a single agent was used instead of a combination, or, a combination was used when only a single drug is recommended by WHO. Metronidazole recommended in combination with other drugs in specific procedures was regularly omitted. 87 (39.2%) had the appropriate duration of prophylaxis. Inappropriately prolonged postoperative use of antimicrobial was observed in 60% of the surgical procedures as presented in table 3 and 4 below. Intravenous antimicrobials were given to 123 (54.9%) patients postoperatively over mean duration of 3.97 days, whilst 80 (35.7%) patients were discharged home with an additional oral antimicrobial for a mean duration of 4.42 days. Overall adherence to all four parameters assessed was seen in 28 cases giving an overall rate of 12.5%.

Table 4: Frequency of compliance to SAP guideline

Variable	Appropriateness	Freq (%)
Appropriate indication	**Yes**	**192 (85.7%)**
	No	32 (14.3%)
Timing appropriate	**Yes**	**224(100.0%)**
	No	0(0.0%)
Drug Choice appropriate	**Yes**	**89 (39.7%)**
	No	135 (60.3%)
Appropriate Duration of prophylaxis	**Yes**	**89 (39.7%)**
	No	135 (60.3%)
Adherence to All 4 Aspects assessed.	**Yes**	**28 (12.5%)**
	No	196 (87.5%)

4.2.1 Post-operative use of surgical antimicrobial prophylaxis

It was also observed that 151 (67.4%) cases had additional antimicrobial prescribed post operatively while 32.6% (73) had no antimicrobial given after surgery. Of these 151 prescriptions, 16 were considered appropriate in our analysis because they were stopped within 24hours as per the guideline. The commonest intravenous SAP used after surgery was ceftriaxone as a single agent 58 (25.8%) or in combination with parenteral metronidazole 44 (19.6%) while those prescribed at discharge were oral Augmentin 34 (15.2%), oral Flucloxacilin 19 (8.4%) and oral Cefuroxime 12 (5.4%). In 43.3% of postoperative prescription of antimicrobial for the purposes of prophylaxis, we observed multiple drug-class combinations in which the agents used pre-incision is different from those use in the ward and subsequently at discharge. The specific drugs and duration are described in table 3 below.

Table 5 :Post-operative use of SAP

Intravenous antimicrobials used post-op in hospital for the purpose of prophylaxis	Freq (%)	mean duration(days)
Amikacin	1 (0.4%)	5
Augmentin	1 (0.4%)	5
Cefazolin	2 (0.9%)	1
Ceftriaxone	58 (25.8%)	3.5
Ceftriaxone, metronidazole	44 (19.6%)	4.5
Ceftriaxone, meropenem	1 (0.4%)	5
Cefuroxime	4 (1.8%)	2.8
Cefuroxime, metronidazole	1 (0.4%)	5
Ciprofloxacin	1 (0.4%)	7
Metronidazole	2 (0.9%)	7.5
Flucloxacillin	6 (2.6%)	3.3
Levofloxacin, metronidazole	2 (0.9%)	6
Total number of cases with post op IV SAP use	123 (54.9%)	3.97days
Oral antimicrobial prescribed at discharge	**Freq (%).**	Prescribed mean duration of use (days)
Amoxicillin	2 (0.9%)	5
Amoxicillin, metronidazole	1 (0.4%)	5
Ampicillin-cloxacillin	2 (0.8%)	5
Augmentin	34 (15.2%)	5.7
Flucloxacilin	19 (8.4%)	6
Cefuroxime	12 (5.4%)	5.9
Cefuroxime, metronidazole	1 (0.4%)	5
Ciprofloxacin	1 (0.4%)	5
Erythromycin	1 (0.4%)	5
Azithromycin	1 (0.4%)	3
Metronidazole	4 (1.8%)	5.5
Metronidazole, ciprofloxacin	1 (0.4%)	5
Levofloxacin	1 (0.4%)	5
Total number of cases with post op oral SAP use	80 (35.7%)	4.42days

There were 3 (1.3%) participants where the surgery took more than 4 hours when cefuroxime was used for prophylaxis. Of these, only 1 was given an additional

intraoperative dose of SAP while the remaining two, there was no re-dosing as recommended.

In terms of blood loss, 4 (1.8%) had a blood loss greater than 1500ml but none was given any additional intraoperative doses of surgical antimicrobial prophylaxis as recommended by guideline.

The decision to use antimicrobial in the postoperative period was made by the surgeon in all the cases. Decisions on SAP preoperatively was made by the anesthesiology team in 99.6% (n=223) of the procedures while in one case the surgeon made the recommendation based on expected contamination.

4.2.2 Association between variables

Table 6: Bivariate association between factors and Appropriate Indication

	Appropriate Indication		
Variable	**No (N=32) Freq (Row %)**	**Yes (N=192) Freq (Row %)**	**Fishers' exact p value**
Duration of surgery			0.372
<4	31 (14.0%)	190 (86.0%)	
>4	1 (33.3%)	2 (66.7%)	
Class of wound			< 0.001
Clean- contaminated Wound	0 (0.0%)	86 (100.0%)	
Clean Wound	32 (23.2%)	106 (76.8%)	
ASA			0.304
ASA: 1	14 (11.2%)	111 (88.8%)	
ASA: 2	16 (18.8%)	69 (81.2%)	
ASA: 3	2 (14.3%)	12 (85.7%)	
Comorbidity			0.752
No	28 (13.9%)	173 (86.1%)	
Yes	4 (17.4%)	19 (82.6%)	
Blood loss			1.000
<1500ml	32 (14.5%)	188 (85.5%)	
>1500ml	0 (0.0%)	4 (100.0%)	

Class of wound was significantly associated with correct indication for SAP use

Table 7: Appropriate duration prophylaxis and factors

Variable	Appropriate duration of SAP		Fishers' exact p value
	No (N=135) Freq (Row %)	Yes (N=87) Freq (Row %)	
Duration of surgery			1.000
<4	133 (60.7%)	86 (39.3%)	
>4	2 (66.7%)	1 (33.3%)	
Class of wound			0.028
Clean- contaminated Wound	59 (70.2%)	25 (29.8%)	
Clean Wound	76 (55.0%)	62 (45.0%)	
ASA			0.360
ASA: 1	76 (60.8%)	49 (39.2%)	
ASA: 2	48 (57.8%)	35 (42.2%)	
ASA: 3	11 (78.6%)	3 (21.4%)	
Comorbidity			0.003
No	128 (64.3%)	71 (35.7%)	
Yes	7 (30.4%)	16 (69.6%)	
Blood loss			0.157
<1500	131 (60.1%)	87 (39.9%)	
>1500ml	4 (100.0%)	0 (0.0%)	

Both wound class and presence of comorbidity was significantly associated with appropriate post-operative use of antimicrobials

4.3Barriers responsible for non-adherence to WHO recommended guidelines

To identify barriers to successful uptake of guidelines, we interviewed healthcare workers. A total of 86 HCP responded to the questionnaires, they include 37 doctors (both surgeon/anesthesiologists), 36 nurses and 13 pharmacists. Their median years of work experience was 7 years (IQR: 4, 10), 10 years IQR (7,10) and 8 years IQR (7.5,10) respectively. Only 20 (54.1%) of the doctors (anesthesiologists and surgeons) reported that the guidelines were available to them.

4.3.1 Individual determinants

Interpretation of the meaning of SAP was discordant with the definition stated in the guideline as shown in table 7. A large number of the health care practitioners were neither aware of the WHO SAP recommendations nor the definition of SAP. For example, only 29.7% of surgeons and anesthesiologists correctly defined surgical antimicrobial prophylaxis as stated in the guideline.

Table 8: Interpretation of the meaning of SAP and awareness of WHO recommendation

Category of HCP	Median yrs. of work experience	Freq (%) Correct Definition of SAP	Freq (%) awareness of WHO-Recommendations on SAP
Doctors(37)	7 years (IQR: 4,10),	11 (29.7%)	27(73%)
Nurses (36)	10 years IQR (7,10)	7 (19.4%)	22 (61.1%)
Pharmacists (13)	8 years IQR (7.5,10)	1 (7.7%)	4 (30.8%)

*****Doctors include the surgeons, resident surgeons and the anesthesiologists

4.3.2 General determinants.

The attitudes of doctors towards specific WHO recommendations relating to indications for SAP, the principles guiding SAP choice, timing of first dose, prolonged use and the potential consequence of non-compliance are summarized in table 8.

A. Indication for antimicrobial prophylaxis use

A total of 28 (75.6%) doctors agreed that antimicrobial prophylaxis should NOT be used in ALL surgical procedures but only in specific cases where the risk of infection is high. For those that disagreed with this recommendation, their main reasons was that there is a higher risk infection because of perceived increased contaminations in

the postoperative care rooms and lack of confidence in the sterility of the operating theaters.

B. Timing of the 1st SAP dose before incision

A total of 19(52.8%) doctors (surgeons and anesthesiologist) disagree with 120mins recommended by WHO. They believe SAP should be administered much closer to the time of incision (within 30mins) because there are potential delays in starting surgical procedures due to logistical issues in the hospital.

Table 9; Attitude of the doctors on specific WHO SAP recommendations (based on 4-point Likert scale questions)

Variable(recommendations)				Freq (%) attitude
	Strongly Agree	**agree**	**Disagree**	**Strongly Disagree**
1. SAP should not be used in ALL surgical procedures but only in specific cases where the risk of infection is high.	18(48.6%)	10(27.0%)	4 (10.8%)	5(13.5%)
2. The choice of antimicrobial be one that can adequately protect patient against pathogens expected in the operative site.	11(30.6%)	17(47.2%)	7 (19.4%)	1 (2.8%)
3. Broad spectrum agent is discouraged because it interferes with host defenses	6 (17.6%)	19(55.9%)	8 (23.5%)	1 (2.9%)
4. Timing of the 1st dose should be within 120mins before the first incision.	3 (8.3%)	14(38.9%)	15(41.7%)	4(11.1%)
5. Giving antimicrobial beyond 24hours post-op is not beneficial and therefore not accepted.	11(30.6%)	15(41.7%)	10(27.8%)	0(0.0%)
6. Prolonged use of SAP could induce drug resistance in pathogens	10(27.8%)	22(61.1%)	4 (11.1%)	0(0.0%)

C. Duration of prophylaxis

72.3% the doctors agree that a single dose given before incision is adequate and if additional dose is given should not extend beyond 24hours. For those that disagree with this recommendation, their main reason is a belief that a single dose cannot offer adequate protection due poor conditions of the postoperative care rooms and majority of patient's home environment.

D. Specific SAP choice

The recommendation pertaining appropriate choice of SAP is generally accepted as summarized in table 8 although 26.4 % of the doctors still believe a broad spectrum agent should be used in prophylaxis for better a protection (cover) from SSI. Drug availability in the hospital is mentioned among the hindering factors. 30 (81.1%) of the doctors think decision on SAP before incision should be made by the anesthesiologist and 32 (86.5%) believe the surgeon should then decide after wound closure.

4.3.3 Organizational/structural determinants of adherence to SAP.

Systemic issues that hinder adherence to SAP guidelines include lack of confidence in the conditions of the operating theatres reported by 50% of the health care workers, perceived poor conditions of the post-operative care rooms reported by 81%, delays in availing recommended antimicrobial to the operating theatres(21%), delays in starting operations due to logistic issues that affect proper timing of 1^{st} dose (63%), and lack of guideline/policies (developed locally) by the hospital to guide use of SAP reported by 47.7% of the health care providers. The pharmacist clarified that the availability of specific SAP agents is not a problem in the hospital because procurement of antimicrobials is solely based on prescription patterns by those using it.

CHPTER FIVE

5.0 DISCUSSION

5.1 Adherence to WHO surgical antimicrobial prophylaxis (SAP) guidelines.

Adherence to surgical antimicrobial prophylaxis guidelines is still a bigger problem in low-income countries (Abdel-aziz et al., 2013; Ahmed et al., 2019; Alahmadi et al., 2020) as is the case in the current study. Four key parameters of adherence outlined in the WHO guideline were evaluated in 224 surgical procedures. This included indication for SAP, timing of the 1st dose before incision, correct selection of antimicrobial and duration of prophylaxis. In only 12.5 % of the procedures were the four studied parameters consistently in-line with WHO guidelines similar to other findings documented in other areas of Africa by Allegranzi et al., (2018) but much lower than we expected. The greatest violation was seen in the selection of appropriate antimicrobial 135 (60.3%) and total duration of prophylaxis 135 (60.8%) which was often prolonged beyond 24hours.

5.1.1 Indication for Surgical Antimicrobial prophylaxis

Regarding correct indication, surgical antimicrobial prophylaxis was administered in all the cases although it was only indicated in 192 (85.7%) procedures as per the guidelines. This finding is similar to what is reported by Satti et al., (2019) in Pakistan. Most guidelines recommend the use of antimicrobial prophylaxis when there is a clear benefit, that is in clean-contaminated, contaminated, dirty wounds and in specific clean wounds in which the risk of SSI is high or the consequences of an infection is severe (ASHP; SIGN, 2008; WHO, 2018).

In our study 14.3% of the cases in which antimicrobials were used without appropriate indication include clean neck surgeries that form the bulk of our elective general surgical procedures. Studies have documented no benefits of SAP use in clean neck surgeries (Uruno et al., 2015) but because of perceived increased risk infection due contamination in our set up, surgeons have continued to use antibiotics in almost every surgical procedure. In our study, majority of the cases had relatively low risk of SSI because they were classified as clean procedure in 137 (61.2%) with ASA 1(healthy) and ASA 2(mild systemic disease) in 209 (93.8%) cases and median duration of surgery was 75 minutes (IQR: 55,120). This represents patients with low National Nosocomial Infections Surveillance System (NNIS) risk index hence the 100% use of SAP was not justified.

5.1.2 Timing of the 1st dose of SAP before incision.

Appropriateness of timing of the first dose of SAP was exceptionally good in our study because in all the cases, the initial dose of antimicrobial was given within 120 minutes (recommended by WHO) before incision, an adherence of 100% which is much higher than what is reported in literature elsewhere even in the developed countries (Ierano et al., 2019; So et al., 2015; Van Der Sandt et al., 2019). This finding is similar to what was reported recently by Satti et al., (2019) in Pakistan. The reason for the success in both settings is because the antimicrobial prophylaxis was administered by the anesthesiologist on the operating table before induction of anesthesia, a practice that should be recommended to overcome logistical problems that usually result in delays in starting operations if a patient is administered SAP outside OR.

The other reasons that can explain the variation in compliance could be the use of different guidelines in various published audits. WHO guideline that we used in our audit recommends optimal time frame within 120 minutes but with consideration of drug half-live to accommodate agents like Vancomycin which take longer time of infusion (WHO, 2018). However, other international and local guidelines recommend 60 minutes as optimal time while giving separate recommendation for Vancomycin (ASHP; SIGN, 2008).

Optimal timing of administering SAP is important to achieve adequate tissue and serum concentration by the time incision is made and should be able to last until wounds are closed for adequate protection from infectious complications (ASHP; WHO, 2018). The specific agents proposed by various guidelines have different half-lives e.g., Cefazolin and cefuroxime (ASHP; SIGN, 2008; WHO, 2018) have a short half-live and hence should be given much closer to the time of incision (less than 60 minutes). The issue of optimal timing is still regarded as controversial (Ierano et al., 2019), therefore, it is our hope that optimal time frame be harmonized between guidelines or specific recommendation regarding optimal timing and re-dosing intervals be given for each of the antimicrobials proposed for use as SAP.

5.1.3 Selection of specific antimicrobials.

Although the hospital (MTRH) pharmacy is adequately stocked with the agents included in the Essential Medical List (EML) that are recommended for use in surgical prophylaxis, appropriate drug selection is still a challenge. We recorded an adherence rate of 39.7% for appropriate drug selection. This concurs with 40.6% reported by Satti et al., (2019) of Pakistan and 57% by Abdel-aziz et al., (2013) of

Qatar. This rate is much higher than what was reported earlier elsewhere in the country by Aiken et al.,(2013). It is also higher than adherence rate of 13% reported by Ahmed et al., (2019) in Sudan although this pertained only to gastrointestinal surgeries.

The main challenges seen in these studies is in the use of broad-spectrum agents including 3rd generation cephalosporin. In our study broad spectrum agent ceftriaxone was used in 55.17% of the cases similar to 42.67% reported by Satti et al., (2019) in Pakistan. This is mainly due a belief by the prescribers that broad spectrum agents could provide better cover and hence protection from SSI. WHO and other guidelines have recommended that a suitable agent for use in SAP should be a narrow spectrum agent that target the pathogen likely to contaminate the surgical site with as little collateral damage to the hosts' normal flora as possible (ASHP; WHO, 2018).

When the risk of selection of bacterial resistance is considered, Ceftriaxone should not ideally be used for surgical prophylaxis because it is a 3rd generation cephalosporin that belongs to the antibiotic categories listed in essential medicine WHO *Watch* groups (WHO, 2019b), WHO highest-priority list and critically important antimicrobials (CIA) list (WHO, 2017). Recently, Onyango et al, (2018) evaluated blood samples and pus swabs from patients with SSI in MTRH and reported that MSSA (Methicillin-sensitive *Staphylococcus aureus*) that was commonly cultured was 55.6% resistant to ceftriaxone and o% resistance to cefuroxime which is proposed by WHO as an alternative to Cefazolin (WHO, 2019) although one may find it strange as we would expect similar mechanism of resistance to ceftriaxone and cefuroxime. The inappropriate use of ceftriaxone seen in our study may have been a major contributor to the development of the reported resistance.

A more serious issue noted in the present study is the use of multiple antimicrobials in the course prophylaxis. We observed that 43.3% of all the cases received two or more combination, that is, one set of antimicrobials before incision, a different class of SAP in the ward post-operatively with or without another class of antimicrobial at discharge. Of this, 11.34% patients who had low risk for SSI received three different classes of antimicrobial in the course of prophylaxis for example, cefuroxime before incision, ceftriaxone with metronidazole post-op in the ward and amoxicillin-clavulanic acid at discharge. As we know cefuroxime, ceftriaxone and amoxicillin all fall in the same class of Beta-lactam that work by inhibiting bacterial cell wall biosynthesis therefore using all these in the course of prophylaxis in the same patient does not add any value and therefore irrational. Changing from antimicrobial to another multiple times just for the purpose of prophylaxis for an infection that may not even occur may also have negative impact on antimicrobial resistance and is of concern when it comes to patient safety. Although there are limited studies evaluating adherence to SAP guidelines that have detailed the pattern of misuse, the reason that could explain this prescription behavior is lack of consultation among the surgical team on what should be ideal prophylaxis when the guideline is not applied or unavailable.

In our observation, the decision on appropriate SAP pre-incision was made by the anesthesiologists in 99.5% of the cases. It was only in one case of Low Anterior resection (LAR) of a colorectal cancer in which there was a discussion with the surgeon regarding the best choice of SAP depending on the expected contamination and there was compliance to the WHO recommendation as a result. After wound closure, 100% of the antimicrobial given was decided by the surgeon and more often

an ideal choice that should have been used pre-incision was prescribed postoperatively. This appears to be an attempt to correct what was missed pre-incision. This suggests the need for adequate communication between the surgical team on ideal prophylaxis throughout perioperative period for patient safety and prevention of AMR even as we tackle the issues of unnecessary prolonged use of SAP.

Regarding re-dosing of antimicrobial prophylaxis, seven patients required additional doses intraopperatively due to either significant blood loss or prolonged duration of surgery usually beyond 4hours (estimated 2 half-lives of cefuroxime and Cefazolin recommended as first line by ASHP and WHO, (2018). Only one patient received additional intraoperative doses as per the guideline. Although this aspect was not included in assessing the overall adherence, it is highlighted to reflect lack of awareness concerning appropriate re-dosing of SAP in the hospital. Ideally, Intraoperative re-dosing is needed to ensure adequate serum and tissue concentrations of the antimicrobial if the duration of the surgical procedure exceeds two half-lives of the antimicrobial or there is excessive blood loss (ASHP). The re-dosing interval should only consider time of administration of the 1st dose and not time from the first surgical incision.

5.1.4 Duration of Surgical Antimicrobial Prophylaxis

Prolonged use of SAP was the main problem contributing to poor adherence in our present study similar to reports from other Low and Middle Income countries (Musmar et al., 2014; Ng Ru Shing, 2012). Only 32.6% of our patients received single dose of SAP pre-incision as recommended by WHO, while 60.3% received additional doses beyond 24hour after surgery. This concurs with 31.8% adherence rate reported by Musmar et al., (2014) and 59.3% and 56.4% prolonged use reported

by Abdel-aziz et al., (2013) and Alahmadi et al., (2020) respectively. It differs with rates in South Africa 80.8% (Brink et al., 2017) and other developed countries (Quattrocchi et al., 2018) where antimicrobial stewardship and intervention programs to improve compliance to guidelines is actively being undertaken as opposed to our situation.

In our study, more than half of the patients received intravenous antimicrobials of mainly a 3rd generation cephalosporin with or without metronidazole for an average 3.97days in the ward, while 35.7% received additional oral antimicrobial of mainly amoxicillin-clavulanic acid, Flucloxacilin or cefuroxime for another 4.42days at discharge. (WHO, 2016, 2018) and multiple international guidelines (ASHP, SIGN, 2008) strongly recommend against this practice because prolonged SAP use could promote AMR both in the patient and at the facility and also alters patient's microbiome while adding no additional benefit in protecting the patients from SSI. In addition to multiple antimicrobial agents used, prolonged SAP is a potential risk for developing *Clostridium difficile*-associated colitis (ASHP; SIGN, 2008; WHO, 2018)) although the prevalence was not evaluated in our study and other previous studies in our set up.

Although we did not evaluate the cost implication of prolonged SAP use, it is obvious that our patients incurred cost of additional doses of intravenous antimicrobials while in hospital, medical supplies used to administer the medication and oral antimicrobials at discharge from the hospital. Cost-saving associated with appropriate duration of SAP has been demonstrated elsewhere in the country by Aiken et al., (2013). It is clearly demonstrated that prolonged SAP use after completion of surgery brings more harm than good but because other measures of SSI

prevention are often poorly implemented in LMICs as in our set up, we have continued to rely on antibiotics to prevent infectious complications after surgery.

5.2 Reasons for poor adherence to WHO SAP guidelines

In the present study, we also sought to identify reasons for non-adherence with particular focus on the acceptance by the surgical team of the specific recommendations made in the WHO guidelines and on whether the local interpretations of surgical antimicrobial prophylaxis (SAP) meaning was similar to that published in the guidelines. The level of awareness differed among the health care workers with 73% of surgeons & anesthesiologist, 61.1% of the nurses and 29.7% pharmacist aware of the specific recommendation contained in the guideline. The low levels of awareness compares with 51% reported in Pakistan by Satti et al., (2019) but differs with 12.5 % reported Alahmadi et al., (2020) in Sudan. Poor awareness of guideline content has also been reported widely as the major reason for non-adherence and that is why education has largely been a focus of most intervention programs to improve SAP (Saied et al., 2015).

The other reason that explains the non-adherence seen in our study is the discordance in the interpretation of SAP meaning as only 29.7% of the doctors and 7.7% of the pharmacist could define SAP as explained in the guideline. In their definition, additional doses after completion of surgery should constitute adequate SAP. This concurs with findings by Giusti et al., (2016) in which the definition of surgical antimicrobial prophylaxis was not uniformly agreed. In our case, the observation could be because to the best of our knowledge, there have never been any intervention programs in the hospital targeting uptake of SAP guideline in the form of education or workshops. Availability of guideline in the hospital is another contributing factor,

because only 54.1% of the surgeons have access to the guidelines. This is purely a personal initiative by the surgeons/anesthetists to have this resource because of lack of local guidelines or protocols developed for use in the hospital. This also reflects the ineffective dissemination of the guideline by the developer, ministry of health and health institutions to the intended users that has been mentioned by Ng Ru Shing et al, (2012).

Apart from the optimum timing for administration of 1st SAP dose in which our surgical team prefer to be administered much closer to time of incision as opposed to 120 minutes recommend, all other specific recommendations are fairly accepted with the lowest consensus regarding duration of prophylaxis in which only 72.3% agree. This reflects the willingness by the surgical team to implement the guideline should the conditions of the theatres and post-operative care rooms be improved. The healthcare providers (HCP) strongly mentioned lack of confidence in sterility of the operating theatre due to poor hygiene and suboptimal adherence to theatre disciplines. This response is supported by unpublished reports by a full-time infection prevention control team of MTRH. In a recent survey conducted in the hospital emergency department, radiology, consultant clinics and the operating theatres, Infection Prevention and Control (IPC) team found out that the average compliance by the clinicians to the five moments of hand hygiene and other measures of infection prevention including environmental cleaning and care of peripheral intravenous line was very low at 59%. The post-operative care rooms are also perceived to be different in terms of levels of contamination due to overcrowding by both patients and relatives. This has been the major reason for administration of surgical antimicrobial

in all our surgical procedures and their prolonged use after surgery that compares well with reports by Saied et al., (2015) in Egypt.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1: Conclusion

In conclusion, adherence to WHO SAP guideline in MTRH is very low. Low adherence was observed particularly in the area of antimicrobial selection and duration of prophylaxis which is often more prolonged than recommended. In contrast to WHO guidelines, use of broad spectrum antibiotics as well as inappropriate combination of antimicrobials that could promote AMR are common surgical prophylaxis practices at the hospital.

Although WHO specific recommendations are generally accepted by the surgical team, the main reason for non-adherence include; lack of awareness of existing guidelines, divergent interpretation of SAP meaning, lack of local guidelines developed for use in the hospital, ineffective dissemination of guidelines to the surgical team, lack of active intervention programs to improve surgical antimicrobial prophylaxis and perceived poor conditions of the operating theatres and post-operative care rooms that often force surgeons to overly rely on antibiotics for protection of infectious complications.

6.2: Recommendation

There is urgent need for intervention programs targeting the surgical team regarding SAP to create awareness and improve adherence to the guideline. This can be in the form education such as seminars and workshops targeting the surgeons, anesthesiologist, nurses and the pharmacists on the issue of surgical antimicrobial prophylaxis and adherence to evidence- based guidelines. These interventions can then be followed by post-intervention survey to assess impact and identify other areas

that require improvement. The AMS team of MTRH should be empowered and facilitated to lead such intervention.

There is need for development of a local guideline in the hospital in collaboration with the surgical team, microbiologist, IPC team and the pharmacy to enhance adherence to evidence-based practice in SAP. This can be started by adopting WHO specific recommendation into a hospital protocol to guide surgical antimicrobial prophylaxis.

The hospital should prioritize resource allocation for the operating theatres to enhance sterility, general hygiene, and enforcement of theatre disciplines. It should also innovate ways of decreasing risks of contamination in the post-operative care rooms by decongesting the wards and improving general hygiene. Decongesting the hospital could also be achieved by improving the county hospital within the catchment of MTRH and streamlining referral guidelines by the ministry of health.

Because there is perceived increased risk of postoperative infection at the hospital, there is need to objectively assess the actual risk of infection as well as providing it as feedback to the surgical team. This would be helpful to guide decision making regarding SAP use.

The ministry of Health and health institutions in Kenya should take an active role to ensure effective dissemination of evidence-based guidelines on use of antimicrobials to the intended users as part of antimicrobial stewardship.

6.3 Study Limitation

Patients undergoing elective surgery under orthopedics, cardiothoracic and neurosurgery were excluded in this survey because of an additional recommendation by WHO to screen for *S. aureus* and identify carriers who should receive pre-operative treatment with nasal mupirocin ointment. This practice is not routinely done in MTRH. As a result the calculated adherence level could change slightly should these departments be included in the analysis. However, the results can be generalizable based on the fact that all the surgical procedures in the hospital are done in the same theatres under the same anesthesiology and nursing teams. Therefore the recommendations should apply to all the departments of surgery of MTRH.

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APPENDICES

The following documents are attached as appendices to this research proposal:

- Appendix 1: Introductory letter
- Appendix 2: Consent forms for patients and assent for minors
- Appendix 2; fomu ya idhini ya mgonjwa.
- Appendix 2b: Consent form for hospital staff
- Appendix 3; Criteria for assessing adherence to WHO guideline.
- Appendix 4a: Patients checklist and adherence assessment tool
- Appendix 4b; questionnaire for the surgical team and other stakeholder regarding SAP.

APPENDIX 1: INTRODUCTORY LETTER

INTRODUCTORY LETTER

Dr. Kibos K. Ezekiel

P.O BOX 2499-30100

ELDORET, KENYA

TEL: +254 722220586

Dear respondent.

This communication serves to inform you that I am currently conducting a study on:

"Adherence to WHO guideline on the practice of surgical antimicrobial prophylaxis at Moi teaching and referral hospital, Eldoret, Kenya".

This study is the first step of a mission to promote the use of surgical antimicrobial guidelines to guide our practice. It seeks to describe the current routine practice of surgical antimicrobial prophylaxis use and to determine the factors that influence prescription behavior with the aim of establishing reasons for lack of conformity to specifically WHO guidelines. The result will be helpful in designing appropriate interventional programs for promoting the use of standard guidelines on the use of surgical antimicrobial prophylaxis in an attempt to promote judicious use of antimicrobials in surgery at MTRH. A change in prescription behavior will be a part of the global efforts to prevent emergence of resistant pathogens. This is our ultimate goal.

In this study, the principles of medical ethics will be strictly adhered to.

Yours faithfully

Dr. Kibos K. Ezekiel

APPENDIX 2a: PATIENT CONSENT FORM

Adherence to WHO guideline on the practice of surgical antimicrobial prophylaxis at Moi teaching and referral hospital, Eldoret, Kenya.

INVESTIGATOR – Dr. Kibos K. Ezekiel (KMPDB-Registration Number: A0912)

P O Box 2499-30100,

Eldoret, Kenya

Introduction:

You are being requested give permission for your records to be used in this research study. This information is provided to tell you about this study. Please read this form carefully. You will be given a chance to ask questions. If you decide to be in the study, you will be given a copy of this consent form for your records.

Taking part in this research study is voluntary. You may choose not to take part in the study. Choosing to participate or not participate does not affect the care that you receive. Saying no will not affect your rights to health care or services. You are also free to withdraw from this study at any time after consenting. If after collecting data from your record and you choose to quit, you can request that the information obtained from your records by you be destroyed under supervision- and thus not used in the research study.

Purpose of the study:

The purpose of this study is to determine the level of adhere to WHO guidelines on surgical antimicrobial prophylaxis at MTRH. It is also aimed at determining the reasons for lack of conformity to the recommended guidelines. The result of the study will be useful in designing appropriate intervention program to promote the use of standard SAP guidelines to promote rational use of antibiotics. Rational use of antimicrobials means that a patient is given antimicrobials only when it is indicated

because use of antimicrobials when not needed will amount to wastage, unnecessary spending by both patient and hospital and has been associated with development of resistant disease-causing organisms. Pathogens resistant to the antibiotics we use is now a global problem, and we need to promote judicious use of antibiotics in order to prevent further resistance.

Type of Research Project:

The study involves using information from your medical records and making observations of the treatment you are given without any interference with the aiming of assessing the level of compliance of the surgical team to WHO guidelines on the use of antimicrobial prophylaxis.

Why have I been identified to Participate in this study?

You have been identified to participate in the study, since you have been admitted/operated and the type of care you have been given is what we need to evaluate.

How long will the study last?

You will be a part of the study from the time of admission for surgery to the day of discharge. The research shall be carried out over a period of seven months (2019) and enquiries into it can be directed at us even after the conclusion of study period.

What side effects or risks I can expect from being in the study?

There are no risks involved in this study. This study will be anonymous. You will receive normal treatment as per the diagnosis and the hospital /faculty protocols.

Are there benefits to taking part in the study?

You may not benefit personally from this study.

The possible benefits to society may include improved healthcare service delivery based on the findings of this study.

Reimbursements: There is no cost to the participants, and also no compensation shall be given to patients for participation in this study.

Who do I call if I have questions about the study?

Questions about the study: If you have questions, complaints or concerns about this study, you can contact the investigator from Moi University, School of Medicine, Department of Surgery-

Postgraduate, Dr. Kibos Ezekiel, +254 722220586, e-mail: ezekielkiboss@yahoo.com

Questions about your rights as a research subject: You may contact Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008. IREC is a group of people that reviews studies for safety and to protect the rights of study subjects like yourself.

Will the information I provide be kept private?

All reasonable efforts will be made to keep your protected information (private and confidential). Protected Information is information that is, or has been, collected or maintained and can be linked back to you. Using or sharing ("disclosure") of such information must follow National privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the uses and disclosures of your clinical information. A decision to take part in this research means that you agree to let the research team use and share your Protected Information as described below.

As part of the study, Dr. Kibos K. Ezekiel and his study team which include his supervisors may also share portions of your medical record, with the groups named below:

The National Bioethics Committee, The Institutional Review and Ethics Committee, National privacy regulations may not apply to these groups; however, they have their own policies and guidelines to ensure that all reasonable efforts will be made to keep your personal information private and confidential.

Consent of the Subject (adult patient section):

I have read or have had read to me the description of the research study. The investigator has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I freely give permission for my medical information to be used in this study. _____

_____ _____

Name of Participant Signature of subject/thumbprint Date & Time

(Witness to print if the subject is unable to write)

_____ _____ _____

Name of Representative/Witness Relationship to Subject Date

_____ _____ _____

Printed name of Investigator Signature of Investigator Date

Consent of the Subject (section for under 18yrs to be filled by parent):

I have read or have had read to me the description of the research study. The investigator has explained the study to me and has answered all of the questions I

have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I freely give permission for my child's medical information to be used in the study to be used in this study.

_____ _____ _____

Name of Participant Signature of parent/thumbprint Date & Time

(Witness to print if the subject is unable to write)

_____ _____ _____

Name of Representative/Witness Relationship to Subject Date

_____ _____ _____

Printed name of Investigator Signature of Investigator Date

Assent form for minors.

Project Title: **"*Adherence to WHO guideline on the practice of surgical antimicrobial prophylaxis at Moi teaching and referral hospital, Eldoret, Kenya*".**

Investigator: Dr. Kibos K Ezekiel

We are doing a research study about the use of antimicrobials (drug) to prevent infections during surgical operations. We would like to know to what extend the people working in surgery follow the guidelines provided by WHO. The findings from this research will help us identify areas we need to improve to prevent incorrect use of such drugs. It has been noted that incorrect use of antimicrobial may actually encourage development of disease causing organisms that are resistant to drugs. If you decide that you want to be part of this study, you will be asked to give us permission to use the information written on your file and observe how treatment will be given to you during your surgery, and after your surgery.

There are some things about this study you should know. We are not going ask you other question, there will be no procedures done to you for the purpose of the study. We are only going to sit a observe the treatment your doctors are giving you and document to be analyzed later.

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. We think these benefits might be when we improve services given to patients in future and when we manage to improve practices in order to prevent a resistant disease causing organism from developing. That means that we protect efficacy of the drug available to us if we use them correctly.

If you do not want to be in this research study, it is ok with us. It will not affect any treatment given to you as your doctors are not even we are doing this research.

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that's okay too. Your parents know about the study too.

If you decide you want to be in this study, please sign in the space provided down here.

I, _____, want to be in this research study.

_____ _____

(Sign your name here) (Date)

APPENDIX LA 2: FOMU YA IDHINI YA MGONJWA

Kiwango cha kufuata mwongozo uliopendekezwa juu ya utendaji wa tiba ya kuzuia maradhi ya antimicrobial kwa upasuaji katika hospitali ya mafundisho na uhamisho wa Moi, Eldoret, Kenya.

MCHIMUZI - Dr Kibos K. Ezekiel (Nambari ya Usajili wa KMPDB: A0912)

P O Box 2499-30100,

Eldoret, Kenya **Utangulizi:**

Unatakiwa kutoa idhini kwa rekodi zako zitumiwe katika utafiti huu. Taarifa hii hutolewa ili kukuambia kuhusu utafiti huu. Tafadhali soma fomu hii kwa makini. Utapewa nafasi ya kuuliza maswali. Ikiwa unaamua kuwa katika utafiti, utapewa nakala ya fomu hii ya idhini kwa rekodi zako.

Kushiriki katika utafiti huu ni hiari. Unaweza kuchagua kutoshiriki katika utafiti. Bado utapata matibabu. Kukataa haitaathiri haki zako kwa huduma za afya. Wewe pia yu huru kujiondoa kwenye utafiti huu wakati wowote baada ya kukubaliana. Ikiwa baada ya kukusanya data kutoka rekodi yako na unachagua kuacha, unaweza kuomba kuwa taarifa zilizopatikana kutokankumbukumbu zako zimeharibiwa chini ya usimamizi - na hivyo hazitumiwi katika utafiti huu.

Kusudi la utafiti:

Kusudi la utafiti huu ni kutambua kiwango cha kufuata miongozo ya WHO juu ya utendaji wa tiba ya kuzuia maradhi ya antimicrobial kwa upasuaji katika MTRH. Pia inalenga kugundua baadhi ya sababu za ukosefu wa kuzingatia miongozo iliyopendekezwa.

Matokeo ya utafiti utafaa katika kubuni mpango sahihi wa kuingilia kati ili kukuza matumizi ya miongozo ya SAP ya kawaida ili kukuza matumizi ya busara ya utendaji wa tiba ya kuzuia maradhi ya antimicrobial katika upasuaji. Matumizi ya kimantiki ya

antimicrobial ina maana kwamba mgonjwa hupewa antimicrobials tu wakati inavyofaa kwa sababu matumizi ya antimicrobials wakati hauhitajiki yatapungua matumizi yasiyohitajika kwa wagonjwa wote katika hospitali na imehusishwa na kukuzwa kwa viumbe vinavyosababisha magonjwa. Vimelea vinavyoleta upinzani kwa antibiotics tunayotumia sasa ni tatizo la kimataifa, na tunahitaji kukuza matumizi mazuri ya antibiotics ili kuzuia upinzani zaidi.

Aina ya Mradi wa Utafiti:

Utafiti unahusisha kutumia taarifa kutoka kwa kumbukumbu zako za matibabu na kufanya uchunguzi wa matibabu uliyopewa bila kuingilia kati na lengo la kuchunguza kiwango cha kufuata timu ya upasuaji kwa miongozo ya WHO juu ya matumizi ya kupimia tiba ya kuzuia maradhi ya antimicrobial.

Kwa nini nimejulikana kushiriki katika utafiti huu?

Umejulikana kushiriki katika utafiti huu, kwa kuwa umekubaliwa / uendeshwa na aina ya utunzaji uliyopewa ni kile tunachohitaji kutathmini.

Utafiti utaendelea muda gani?

Utakuwa sehemu ya utafiti kutoka wakati wa kuingia kwa upasuaji hadi siku ya kutokwa. Utafiti utafanyika zaidi ya kipindi cha miezi saba (2019) na maswali ndani yake yanaweza kuelekezwa kwetu hata baada ya mwisho wa kipindi cha kujifunza.

Je, ni madhara gani au hatari ambazo ninaweza kutarajia kutoka kwenye utafiti? Hakuna hatari zinazohusika katika utafiti huu. Utafiti huu haujulikani. Utapokea matibabu ya kawaida kama kwa uchunguzi na itifaki za hospitali / kitivo.

Je, kuna faida ya kushiriki katika utafiti?

Huwezi kufaidika binafsi kutokana na utafiti huu.

Faida iwezekanavyo kwa jamii inaweza kujumuisha utoaji wa huduma za afya kulingana na matokeo ya utafiti huu.

Malipo kwa kushiriki utafiti huu:

Hakuna gharama kwa washiriki, na pia hakuna fidia itapewa kwa wagonjwa kwa kushiriki katika

utafiti huu.

Nitaita nani ikiwa nina maswali juu ya utafiti?

Maswali kuhusu utafiti: Ikiwa una maswali, malalamiko au wasiwasi juu ya utafiti huu, unaweza kuwasiliana na uchunguzi kutoka Chuo Kikuu cha Moi, Shule ya Matibabu, Idara ya Upasuaji- Chuo cha Uzamili, Dr Kibos Ezekiel, +254 722220586, e-mail: ezekielkiboss@yahoo.com. *Maswali kuhusu haki zako kama Mshiriki la utafiti:* Unaweza kuwasiliana na Kamati ya Maadili ya Ukaguzi wa Taasisi (IREC) 053 33471 Ext.3008. IREC ni kikundi cha watu ambao udhibiti masomo kwa usalama na kulinda haki za wahusika wa kujifunza kwao kama wewe mwenyewe.

Je! Habari nitayayoyatoa itawekwa ya faragha?

Jitihada zote za busara zitafanywa ili kuhifadhi maelezo yako ya ulinzi (binafsi na ya siri). Maelezo haya ya siri na ni habari ambayo, au imekuwa, imekusanywa au imehifadhiwa na inaweza kuunganishwa kwako. Kutumia au kugawana ("ufunuo") wa taarifa hiyo lazima ifuate miongozo ya faragha ya Taifa. Kwa kusaini waraka wa hati kwa ajili ya utafiti huu, unatoa idhini ("idhini") kwa matumizi na maelezo ya kliniki yako. Uamuzi wa kushiriki katika utafiti huu una maana kwamba unakubali kuruhusu timu ya utafiti kutumia na kushiriki Habari yako ya faragha kama ilivyoelezwa hapo chini.

Kama sehemu ya utafiti, Dk. Kibos K. Ezekiel na timu yake ya utafiti ambayo ni pamoja na wasimamizi wake wanaweza pia kushiriki sehemu za rekodi yako ya matibabu, na makundi yaliyotajwa hapo chini:

Kamati ya Taifa ya Bioethics, Kamati ya Ukaguzi na Taasisi ya Maadili, Kanuni za faragha za kitaifa haziwezi kutumika kwa makundi haya; hata hivyo, wana sera zao na miongozo ili kuhakikisha kuwa juhudi zote za busara zitafanywa ili kuweka maelezo yako ya kibinafsi na ya

siri.

Idhini ya Mshirika (sehemu ya mgonjwa, watu wazima):

Nimesoma au nimenisoma maelezo ya utafiti. Mpelelezi ameelezea utafiti kwangu na amejibu maswali yote niliyo nayo wakati huu. Nimeambiwa juu ya uwezekano wa hatari, wasiwasi na madhara pamoja na faida iwezekanavyo (kama ipo) ya utafiti. Mimi kwa uhuru kutoa ruhusa kwa maelezo yangu ya matibabu ya kutumika katika utafiti huu.

_____ _____ _____

Jina la Mshiriki, Tarehe Saini na Muri ya kidole gumba

(Shahidi kuchapisha ikiwa mshiriki hawezi kuandika)

_____ _____ _____

Jina la Mwakilishi na tarehe Uhusiano wa Shahidi

_____ _____

_____

Jina la kuchapishwa la Mpelelezi na tarehe Saini ya Mpelelezi

Hati ya Mshiriki (sehemu ya wenye miaka chini ya 18 ya kujazwa na mzazi): Nimesoma au nimenisoma maelezo ya utafiti wa utafiti. Mpelelezi ameelezea utafiti kwangu na amejibu maswali yote niliyo nayo wakati huu. Nimeambiwa juu ya uwezekano wa hatari, wasiwasi na madhara pamoja na faida iwezekanavyo (kama ipo) ya utafiti. Mimi kwa hiari kutoa ruhusa kwa maelezo ya matibabu ya mtoto wangu kutumiwa katika utafiti huu. _____

_____ _____

Jina la Mzazi Msaidizi, Tarehe, saini na Muri ya Kidole gumba

(Shahidi kuchapisha ikiwa

Mshirika haliwezi kuandika)

_____ _____ _____

Jina la Mwakilishi / Tarehe Uhusiano

_____ _____ _____

Jina la kuchapishwa la Mpelelezi na Tarehe Saini ya Mpelelezi

Kiswahili version of assent form for minors.

Mradi: Kiwango cha kufuata mwongozo uliopendekezwa juu ya utendaji wa tiba ya kuzuia maradhi ya antimicrobial kwa upasuaji katika hospitali ya MTRH Eldoret, Kenya **Mtafiti**: Dr Kibos K Ezekiel

Tunafanya utafiti kuhusu matumizi ya antimicrobials (madawa) ili kuzuia maambukizo wakati wa operesheni ya upasuaji. Tungependa kujua ni kiwango gani watu wanaofanya upasuaji ufuata miongozo iliyotolewa na WHO. Matokeo ya utafiti huu itatusaidia kutambua maeneo tunahitaji kuboresha ili kuzuia matumizi yasiyofaa ya madawa hayo. Imebainishwa kuwa matumizi yasiyofaa ya antimicrobial inaweza kweli kuhamasisha uponyaji wa magonjwa yanayosababishwa na viumbe ambavyo

hazijakabili madawa. Ikiwa unaamua kuwa kuwa sehemu ya utafiti huu, utatakiwa kutupa idhini ya kutumia habari iliyoandikwa kwenye faili yako na kuchunguza jinsi utakapopewa matibabu wakati wa upasuaji wako, na baada ya upasuaji. Kuna baadhi ya mambo kuhusu utafiti huu unapaswa kujua. Hatutakuuliza swali lingine, hakutakuwa na michakato itakazofanyika kwako kwa ajili ya utafiti huu. Tunaenda tu kuangalia matibabu madaktari wako wanaokupa na hatimaye kuchambuliwa baadaye.

Si kila mtu anayeshiriki katika utafiti huu atafaidika. Faida ina maana kwamba kitu kizuri kinatokea kwako. Tunatumahi bahadhi ya faida hizi zinaweza kuwa za kuboresha huduma zinazotolewa kwa wagonjwa katika siku zijazo na sisi kusimamia kuboresha utendakazi ili kuzuia ugonjwa sugu kusababisha athari. Hiyo ina maana kwamba tunalinda ufanisi wa madawa yanayotumika kwetu ikiwa tutatumia kwa usahihi.

Ikiwa hutaki kuwa katika utafiti huu, uko huru kukataa. Haitathiri matibabu yoyote uliyopewa na madaktari wako.

Tunapomaliza na utafiti huu, tutaandika ripoti kuhusu kile tulichojifunza. Ripoti hii haitajumuisha jina lako au kwamba ulikuwa katika utafiti.

Huna budi kuwa katika utafiti huu ikiwa hutaki kuwa. Ikiwa unaamua kuacha baada ya kuanza, hiyo pia ni sawa. Wazazi wako wanajua kuhusu utafiti pia.

Ikiwa unaamua unataka kuwa katika utafiti huu, tafadhali tia saini katika nafasi iliyotolewa hapa.

Mimi, _____, ninataka kuwa katika utafiti huu.

_____ _____

(Saini) (Tarehe)

APPENDIX 2b: HEALTHCARE PROVIDER CONSENT FORM.

"**Adherence to WHO guideline on the practice of surgical antimicrobial prophylaxis at Moi teaching and referral hospital, Eldoret, Kenya".**

INVESTIGATOR – Dr. Kibos K. Ezekiel (KMPDB-Registration Number: A0912)

P O Box 2499-30100,

Eldoret, Kenya

Introduction:

You are being requested to take part in this research study. This information is provided to tell you about this study. Please read this form carefully. You will be given a chance to ask questions.

If you decide to be in the study, you will be given a copy of this consent form for your records.

Taking part in this research study is voluntary. You may choose not to take part in the study. Saying NO will have no consequences to you. If after collecting data from you and you choose to quit, you can request that the data you gave be destroyed under your supervision.

Purpose of the study:

The purpose of this study is to determine the level of adherence to WHO guidelines on surgical antimicrobial prophylaxis at MTRH. It is also aimed at determining the reasons for lack of conformity to the recommended guidelines. The result of the study will be useful in designing appropriate intervention program to promote the use of standard SAP guidelines to promote rational use of antibiotics. Rational use of antimicrobials means that a patient is given antimicrobials only when it is indicated because use of antimicrobials when not needed will amount to wastage, unnecessary spending by both patient and hospital and has been associated with development of

resistant disease-causing organisms. Pathogens resistant to the antibiotics we use is now a global problem, and we need to promote judicious use of antibiotics in order to prevent further resistance.

Type of Research Project:

The study involves filling out a questionnaire that you will be provided with.

Why have I been identified to Participate in this study?

You have been identified to participate in the study, since you take part in one way or another (directly or indirectly) in either administering, prescribing, or determining what/how antimicrobial prophylaxis are use in elective surgeries in the hospital.

How long will the study last?

By the time we do this interview, we have already done 6 moths audit of how surgical antimicrobial prophylaxis are used at MTRH and the level of compliance determine. Therefore, this is the conclusion stage of the study just find out why the practice is the way it is.

What side effects or risks I can expect from being in the study?

There are no risks involved in this study. This study will be anonymous.

Are there benefits to taking part in the study?

You may not benefit personally from this study.

The possible benefits to society may include improved healthcare service delivery based on the findings of this study.

Who do I call if I have questions about the study?

Questions about the study: If you have questions, complaints or concerns about this study, you can contact the investigator from Moi University, School of Medicine, Department of Surgery-

Postgraduate, Dr. Kibos Ezekiel, +254 722220586, e-mail: ezekielkiboss@yahoo.com

Questions about your rights as a research subject: You may contact Institutional Review Ethics Committee (IREC) 053 33471 Ext.3008. IREC is a group of people that reviews studies for safety and to protect the rights of study subjects like yourself.

Will the information I provide be kept private?

All reasonable efforts will be made to keep your protected information (private and confidential). Protected Information is information that is, or has been, collected or maintained and can be linked back to you. Using or sharing ("disclosure") of such information must follow National privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the uses and disclosures of your information. A decision to take part in this research means that you agree to let the research team use and share your Protected Information as described below.

As part of the study, Dr. Kibos K. Ezekiel and his study team which include his supervisors may also share portions of your medical record, with the groups named below:

The National Bioethics Committee, The Institutional Review and Ethics Committee, National privacy regulations may not apply to these groups; however, they have their own policies and guidelines to ensure that all reasonable efforts will be made to keep your personal information private and confidential.

Consent of Subject:

I have read or have had read to me the description of the research study. The investigator has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I freely volunteer to take part in this study.

_____ _____ _____

Name of Participant Signature of subject/thumbprint Date & Time

(Witness to print if the subject is unable to write)

_____ _____ _____

Printed name of Investigator Signature of Investigator Date

APPENDIX 3: CRITERIA FOR ASSESSING ADHERENCE TO WHO GUIDELINE.

Table 9; Summary of recommendations by WHO.

ASPECTS OF COMPLIANCE	WHO RECOMMENDATIONS
1. Indication	• Should only be given if there is risk for infection in clean surgeries. (not indicated in clean neck surgeries) • Should be given in the following classes of wounds; clean-contaminated, contaminated and dirty wounds. • Should be given if the consequences of SSI are serious. Specific indications listed in a proposal on EML(Essential Medical list) guidance released by WHO,(2019)
2. Choice of antimicrobial	• SAP agent should be a narrow spectrum • Should be able to adequately cover the pathogens that are expected to contaminate that operative site. • Should be inexpensive Specific agents for each procedure listed in a proposal on EML guidance released by WHO,(2019)
3. Timing of the first dose	**1st dose should be given within 120mins before 1st incision is made. (While considering the half-life of the antimicrobial). Those with shorter half-life are given closer to the time of incision to ensure adequate tissue concentration by the time incision is made and to last the duration of surgery.**
4. Duration of prophylaxis	**Should not be given beyond 24hours of surgery (single dose is adequate).** **Additional intraoperative doses are however recommended if there was excess (>1500ml) blood loss or if duration of surgery lasted more than two half-life of the antimicrobial use.**

NB; There was a clear cut recommendations on timing and appropriate duration of prophylaxis in the (WHO, 2016, 2018) global guideline for prevention of SSI. Framework for drug selection and specific indication were also clearly indicated in

that guideline. However, specific agents for each procedure and those in which SAP in NOT indicated were listed in an EML guidance document proposed by WHO,(2019) pending approval.

Criteria for assessing adherence

Parameter of compliance	Discordant if/ not compliant if
1. Indication for SAP use.	Indication differed from the set criteria by WHO guideline
2. Antibiotic choice	Agent differed from WHO recommendations. Agent cannot adequately cover for pathogens expected to contaminate the operative. If single agent is used when combination of two or more antimicrobials are recommended, or when two SAP agents are used when a single agent is recommended.
3. Timing of first dose within fixed time range	Timing of first dose was given outside the recommended time range which is 0-120 minutes before incision.
4. Duration of prophylaxis	duration differed from WHO recommendations (SAP given beyond 24hour after surgery)
5. Additional doses intra-operatively	No additional doses given intra-operatively in a case where surgery exceeded 2 half-life or there is documented significant blood loss (>1500mls).

NB; adherence is assessed for each of this parameters separately. But the overall adherence is when all these criteria are met in a case.

APPENDIX 4A: PATIENTS CHECKLIST AND ADHERENCE ASSESSMENT TOOL.

Date data collection started for this patient ……

A. PATIENT'S DESCRIPTION

1. Identity (Number)……...
2. Demographic characteristics
    - Age…….
    - Sex ☐Male ☐Female
3. Date of admission……
4. Date of surgery……
5. Type of surgery/specialty ☐gynecological ☐thyroid ☐gastrointestinal ☐anorectal

    ☐hepatobiliary ☐inguinal ☐breast ☐urologic

B. PATIENT CHARACTERISTISTICS

6. The specific diagnosis for which surgery is indicated…….
7. The class of Wound
    (a) Clean wound ☐
    (b) Clean-contaminated wound ☐
    (c) Contaminated wound ☐
    (d) Dirty wound ☐
8. The ASA Physical Status score as indicated by anesthetist
    a. ASA: 1 ☐
    b. ASA: 2 ☐
    c. ASA: 3 ☐
    d. ASA: 4 ☐
    e. ASA: 5 ☐
    f. ASA: 6 ☐

9. Comorbidity present ☐ Yes ☐No. Indicate specific comorbidities if present……
……
……
……

<u>OPERATIVE DETAILS</u> (to be filled by the observer in the main operating theatre)

10. Indicate the exact time of incision ……
11. Duration of surgery (in hour). From time of the first incision to time complete closure of wound. ……....
12. Estimated blood loss (in Liters). If not indicated by the anesthetist/surgeon, please ask them to estimate at the end of operation
……

<u>ASSESSMENT OF ADHERENCE TO WHO GUIDELINES ON THE FOUR ASPECTS; INDICATION, TIMING OF FIRST DOSE, CHOICE OF SAP AND DURATION OF SAP</u>

NB; this tool will be filled with help of the criteria outlined in appendix 3 in page 41 of the proposal.

<u>1). Indication for antimicrobial prophylaxis use</u>

13. Was surgical antibiotic prophylaxis given? ☐Yes ☐ No
    a. Was it indicated according to WHO? ☐Yes ☐ No
    b. if NO, is there any documentation to justify the use of antibiotic in this patient?

       ☐Yes ☐ No

c. specify the reason/justification……
……

……
……

2). Timing of the 1st dose of antimicrobial prophylaxis

d. How many minutes before incision was the 1st dose SAP administered?

…… (in minutes)

e. is it appropriate according to WHO ☐Yes ☐ No.

3). Choice of antimicrobial prophylaxis

f. Specify the antibiotics used

……
……
……

g. Is the choice appropriate according to WHO guideline? ☐ Yes ☐ No

4). Duration of antimicrobial prophylaxis

h. Were there additional doses intraoperatively? ☐Yes ☐ No
i. indicate reason if documented for either answer

……
……
……

j. Was antimicrobials prescribed after the operation? ☐Yes ☐ No.
k. indicate the specific antibiotic as follows. If more than one, list on the space provided bellow each category.

i. Intravenous antibiotics…….……..... for ……. Days

……

ii. Oral antibiotics ……. for ……..…days

……

……...

indicate if appropriate according to the guideline. ☐Yes ☐ No

14. Additional comments at the end of follow up.

1. Who made the decision on SAP at the following stages?
   a. pre-incision. surgeon ☐ anesthetist ☐ both/consultation ☐
   b. After wound closure/post op? surgeon ☐ anesthetist ☐ both/consultation ☐
2. Write down any other comment that may be useful.

……

……

……

……

……

……

……

APPENDIX 4b: QUESTIONNAIRE FOR HCP (SURGICAL TEAM/ PHARMACISTS/ NURSES)

DATE OF

INTERVIEW……

……

STAFF DETALIS (applicable to all)

1. Profession/role ☐NURSE ☐SURGEON ☐ANESTHETIST ☐PHARMACYST

   ☐PROCUREMENT OFFICER ☐DIRECTOR/ADMINISTRATOR/ HOD

2. Years of work experience …….

SECTION 1; TO FILLED BY NURSES, ANESTHETIST, SURGEON AND THE PHARMACIST.

A. <u>ASSESS KNOWLEDGE, AWARENESS OF THE PRINCIPLE OF SAP AND GUIDELINES</u>

3. What is your definition of surgical antimicrobial prophylaxis? Tick only one choice.

   ☐preoperative use of antimicrobial for the purpose of infection prevention

   ☐perioperative use of antimicrobial for the purpose of infection prevention

   ☐postoperative use of antimicrobial for the purpose of infection prevention

☐pre and postoperative use of antimicrobial for the purpose of infection prevention

4. Are you aware of the specific WHO recommendations on surgical prophylaxis? ☐yes ☐NO

B. <u>AVAILABILITY OF GUIDELINES</u>;

5. Do we have a MTRH surgical prophylaxis guideline? ☐yes ☐NO
6. Which guidelines are available or accessible for you to use at MTRH?

   ☐MTRH surgical antimicrobial prophylaxis guideline.

   ☐ WHO surgical prophylaxis guideline.

   ☐ infection prevention control guideline by MOH Kenya.

   ☐ No guideline is available for use at MTRH

SECTION 2; TO BE FILLED BY THE SURGEON AND ANESTHETIST

i. <u>ASSESSMENT OF ADHERENCE</u>

Indication for antimicrobial prophylaxis use

7. WHO guideline and Kenyan guideline state that it is antimicrobial use is not indicated for all surgical procedures. It should only be used in some procedure where risk of infection is high. What is your comment on it?

   ☐strongly agree with it ☐ agree ☐ disagree ☐ strongly disagree

8. If disagreed, what is your reason? (tick at most two choices that can explain your objection to the recommendation)

   ☐ there is higher risk infection because of poor conditions of the theatre.

☐ higher risk infection because of increased risk contaminations postoperative care rooms.

☐ don't trust the people taking care of the patient postoperatively.

☐ don't trust the efficacy of sterilization of equipment's used in theatre.

☐ I give antimicrobial in all surgical procedure for legal protection.

Choice of antimicrobials to use.

9. Who usually decide what to SAP to give during surgery.

   ☐the nurse ☐anesthetist ☐ the surgeon.

   Should that be the case? ☐ yes ☐ No

10. WHO recommend that the choice of antimicrobial be one that can adequately protect patient against pathogens expected in the operative site. most guideline do not recommend a broad spectrum antibiotic. What is your comment on this recommendation?

    ☐strongly agree with it ☐ agree ☐ disagree ☐ strongly disagree

11. If disagree give a reason.

    ……

    ……

    ……

    ……

12. What guides/determines your choice of antimicrobial prophylaxis to use? (Tick at most two choices)

    ☐ My experience with the use of prophylaxis.

    ☐ WHO surgical prophylaxis

    guideline. ☐ availability of the

    drug in the hospital ☐ the cost

    of the drug to the patient.

    ☐ influence from pharmaceutical companies.

13. Do you participate in deciding what antimicrobial are made available for use in surgical prophylaxis?

    ☐YES ☐NO if NO move jump to question 16.

14. If yes in 13 above, when you decide on appropriate drugs, are they procured as requested?

    ☐YES ☐NO

15. If no 14 above, what are the challenges/barriers?

……

……

16. If you do not participate, who makes decisions of appropriate antimicrobials to be used for surgical prophylaxis in MTRH?

    ☐ The pharmacy department

    ☐ Procurement department

    ☐ The hospital management

Timing of first dose

17. What would you recommend as the best time to administer the 1st dose of surgical antimicrobial prophylaxis?

    ☐ Immediately after surgery

    ☐ within 30mins before 1st incision

    ☐ within 60mins before 1st incision

    ☐ Within 120 mins before 1st incision.

    ☐ Intraopperatively

18. WHO 2016, 2018 recommended that antimicrobial prophylaxis be given within 120mins before the first surgical incision. Would you agree with this recommendation?

    ☐strongly agree with it ☐ agree ☐ disagree ☐ strongly disagree

19. disagreed, give a reason ……

    ……

    ……

20. State any challenges that hinder giving patients prophylaxis at the correct timing.

    ☐ delays in starting operations procedures due logistical problems

    ☐ delay in availing the drug to the operating theatre.

    ☐ lack of awareness of the WHO recommendations correct timing.

    ☐ lack of hospital policies recommending appropriate timing for SAP

    ☐ others specify ...……

    …….

Duration of surgical antimicrobial prophylaxis

21. What would consider adequate duration prophylaxis for your elective surgical patient?

    ☐ one dose given preoperatively

    ☐ multiple IV doses given up to 24hrs of surgery and not beyond this time.

    ☐ multiple IV doses given in perioperative period and 2-5days postoperatively

    ☐ multiple IV doses given in perioperative period and 2-5days postoperatively plus oral
    antimicrobial at discharge.

22. WHO recommend that SAP should only be given as a single dose. Additional doses can be added if surgical procedure exceed 4hour or when there is excessive blood loss. Giving antimicrobial beyond hour is not beneficial and therefore not accepted. Do you agree with this recommendation?

    ☐strongly agree with it ☐ agree ☐ disagree ☐ strongly disagree

23. If disagreed, what is your reason? (tick at most two choices that can explain your objection to the recommendation)

    ☐ higher risk infection because of increased risk contaminations postoperative care rooms.

    ☐ higher risk infection because of increased risk contaminations at home.

    ☐ don't trust the people taking care of the patient postoperatively.

    ☐ don't trust the efficacy of sterilization of equipment's used in theatre.

☐ single dose or 24hrs prophylaxis do not adequately give patient protection from

infection.

☐ Fear for litigation in case infection occurs.

☐ the quality of the available for use are poor, therefore makes sense to prolong SAP.

24. Indicate whether or not you agree with the following statements

a. It is reported that prolonged use of SAP could induce drug resistance in pathogens

☐strongly agree with it ☐ agree ☐ disagree ☐ strongly disagree

b. Broad spectrum antibiotic use and its prolonged in surgical prophylaxis is linked to *C. deficile* manifestations and interferes with host defenses and therefore not recommended.

☐strongly agree with it ☐ agree ☐ disagree ☐ strongly disagree

25. Give reason why adherence to SAP guidelines is generally poor.

the WHO guideline is Not meant for use our setup feasibility and acceptance in our set up has not be tested and therefore WHO guidelines cannot be implemented.

☐ the guidelines were not developed locally.

☐ most guidelines during development are influenced politically and by drug companies marketing specific products.

☐ others. Specify …….

SECTION 3; FOR NURSE ONLY

1) What determines the choice of antibiotic/antimicrobial that you administer to a surgical patient for prophylaxis?

   ☐ the prescription/order by the surgeon ☐

   availability of the prescribed drug.

   ☐ recommendations by guidelines.

   ☐ the influence by drug companies.

2) Most guideline recommend a single dose of antimicrobial prophylaxis for elective surgical procedures. If one must use more doses should be stopped after 24hour of surgery. Would you agree with such recommendation?

   ☐strongly agree with it ☐ agree ☐ disagree ☐ strongly disagree

3) If you disagree, give a reason for your rejection. (tick at most two choices)

   ☐ our wards are dirty and therefore require to give more doses

   ☐ our wards are overcrowded and there is increased risk for infection

   ☐ don't trust that sterilization of our theatre equipment is done optimally.

   ☐ we find it difficult to change our routine practice.

4) Do you think WHO guideline on the use of antimicrobial prophylaxis in surgery is useful?

   ☐ Yes ☐ No

5) What are some of the challenges that would make adherence to such guideline difficult?

   ☐ the guideline use is not feasible in our set up.

   ☐ the problem is with the hospital management.

☐ the problem is with the surgeons.

☐ the problem is with the anesthetist.

Briefly expound on your answer above

6) Comment on the general conditions of the theatre and the wards regarding hygiene/sterility clean ☐ dirty/contaminated ☐

Explain your responses above ……

……

SECTION 4; TO BE FILLED BY THE PHARMACISTS

1. WHO guidelines and most other guidelines recommend that the choice of antimicrobial to be used should be able to cover pathogens expected to contaminate the surgical procedure. And a broad spectrum agent is discouraged because of its effects on host defenses. Do you agree with this recommendation?

   ☐strongly agree with it ☐ agree ☐ disagree ☐ strongly disagree

2. If disagreed, give a reason for rejecting such recommendation.

   the guideline use is not feasible in our set up.

   variety of antimicrobial is limited in MTRH so one will use what is available in the formulary.

   ☐ others. specify

   ……I

   f the surgeon requests an appropriate antimicrobial to be for prophylaxis that is not available, do the pharmacy department facilitate acquisition of such drug for the specified use?

   ☐ YES ☐ NO

3. What determines the type of drug to be used for surgical prophylaxis

☐ routine surgeons' prescription

☐ routine requisition from the theatre.

☐ drug availability

☐ hospital management decision on specific antimicrobial

☐ influence by pharmaceutical companies.

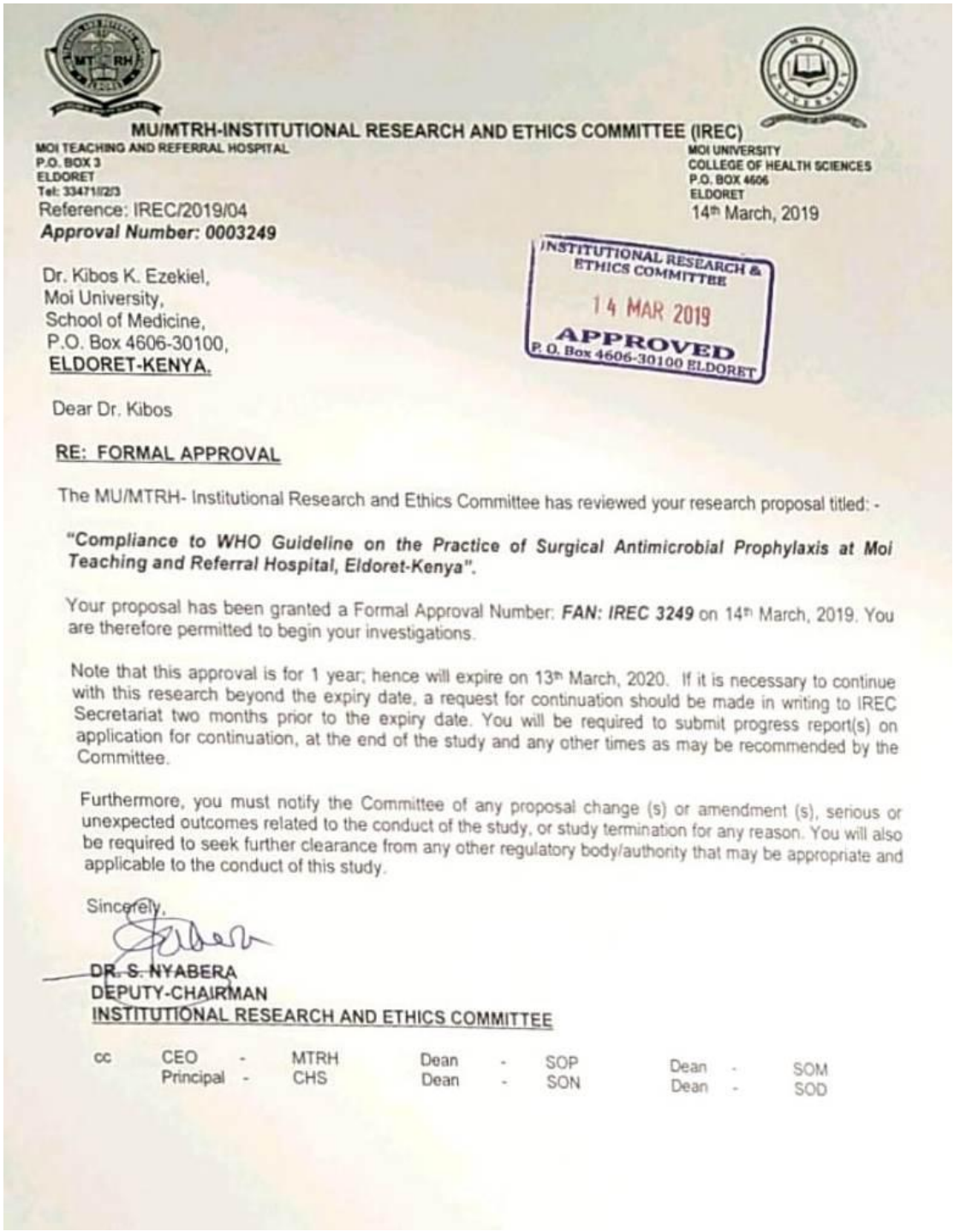
☐ others. Specify ……

4. Any additional comment?

……

……

APPENDIX 6: IREC APPROVAL



MU/MTRH-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET

Reference: IREC/2019/04
Approval Number: 0003249

14th March, 2019

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
14 MAR 2019
APPROVED
P. O. Box 4606-30100 ELDORET

Dr. Kibos K. Ezekiel,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Kibos

RE: FORMAL APPROVAL

The MU/MTRH- Institutional Research and Ethics Committee has reviewed your research proposal titled: -

"Compliance to WHO Guideline on the Practice of Surgical Antimicrobial Prophylaxis at Moi Teaching and Referral Hospital, Eldoret-Kenya".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 3249*** on 14th March, 2019. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; hence will expire on 13th March, 2020. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date. You will be required to submit progress report(s) on application for continuation, at the end of the study and any other times as may be recommended by the Committee.

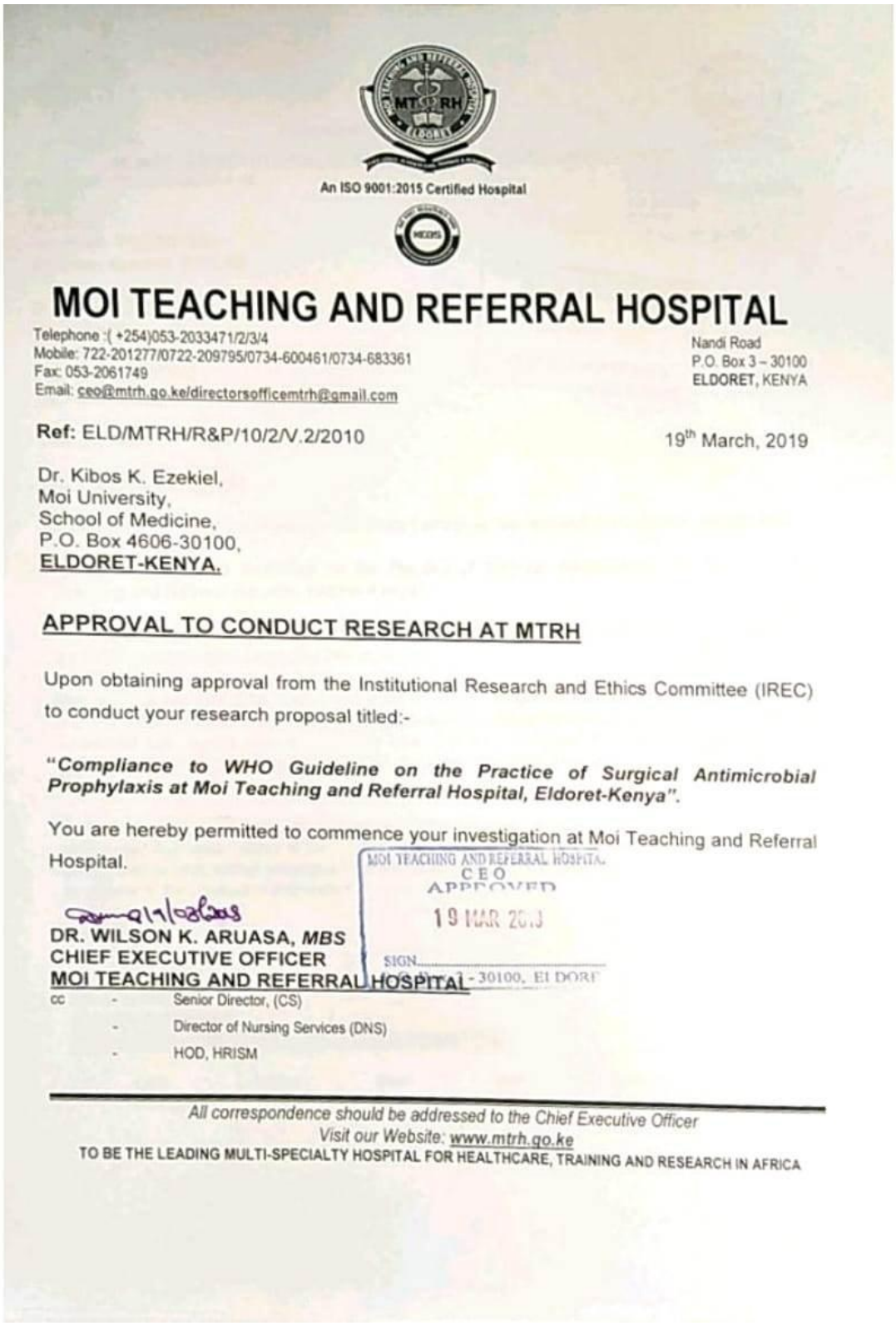
Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. You will also be required to seek further clearance from any other regulatory body/authority that may be appropriate and applicable to the conduct of this study.

Sincerely,

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

APPENDIX 6: HOSPITAL APPROVAL (MTRH)



An ISO 9001:2015 Certified Hospital

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ELDORET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

19th March, 2019

Dr. Kibos K. Ezekiel,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Compliance to WHO Guideline on the Practice of Surgical Antimicrobial Prophylaxis at Moi Teaching and Referral Hospital, Eldoret-Kenya".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

MOI TEACHING AND REFERRAL HOSPITAL
CEO
APPROVED
19 MAR 2019
SIGN.....
P.O. Box 3 - 30100, ELDORET

DR. WILSON K. ARUASA, *MBS*
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

cc - Senior Director, (CS)
- Director of Nursing Services (DNS)
- HOD, HRISM

All correspondence should be addressed to the Chief Executive Officer
Visit our Website: www.mtrh.go.ke
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