ADMINISTRATION OF INFORMED CONSENT FOR MEDICAL IMAGING SERVICES AMONG PATIENTS IN GOVERNMENT HOSPITALS IN NAIROBI CITY COUNTY, KENYA

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SEPTEMBER, 2021

DECLARATION

I declare that this thesis is authentic and is my own original work and has not been presented to any other university or institution for purposes of obtaining an academic award.

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We the undersigned, confirm that the candidate under our supervision has submitted this thesis for approval for examination as the University supervisors.

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DEDICATION

This thesis is dedicated to my family members for their support, humble time, prayer and words of motivation.

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ABBREVIATIONS AND ACRONYMS

AMA	American Medical Association
APA	American Psychological Association
APRN	Advanced Practice Registered Nurse
CC	Cardiac Catheterization
COK	Constitution of Kenya
CT	Computed Tomography
ERC	Ethical Review Committee
FBO	Faith Based Organization
GMC	General Medical Council
ICN	International Council of Nurses
KNH	Kenyatta national hospital
MOH	Ministry of Heath
MRI	Magnetic Resonance Imaging
NACOSTI	National Commission for Science, Technology and Innovation
NGO	Non-Governmental Organization
SMOG	Simple Measure of Gobbledygook
SPSS	Statistical Package for Social Sciences
TVS	Trans-vaginal Sonography
UoN	University of Nairobi
USA	United States of America
WHO	World Health Organization
WMA	World Medical Association.

OPERATIONAL DEFINITION OF TERMS

Assess : Evaluate or estimate the quality, ability of nature of a subject at hand or something (Stevenson, 2010).

Extent: The degree to which something has been used; the size or scale of something, the area covered by something (Hornby *et al.,* 1974).

Informed consent: Acquisition of permission from a patient prior to undertaking a healthcare procedure. (Pugh 2020)

Medical imaging: Is the process of providing a representation of the organs of a patient's interior body for clinical diagnosis and prognosis, the representation can also be used to establish the functions of the organs, (Naccache *et al.,* 2013)

Medical imaging procedures: A process that asks for permission to expose internal organs seeks to reveal internal body structures under the skin and bones, as well as to offer a diagnosis and treatment (Sakas, 2002).

Medical imaging services: These are activities which exposes internal organs to reveal internal body structures under the skin and bones to assist in offering diagnostic and treatment which include ultrasound, computed tomography scans, X-rays, MRI among others (Gadeka & Esena, 2020).

ABSTRACT

Informed consent is a requirement by law to allow patients to make decisions with respect to their health and well-being. It is an ethical and legal requirement that patients seeking medical imaging services should give an informed consent prior to seeking treatment with respect from healthcare providers. However, the extent of usage of the informed consent process varies across medical procedures. The study therefore sought to assess informed consent process in medical imaging procedures for patients in government hospitals in Nairobi City County, Kenya. The study adopted a descriptive cross-sectional study design. The study specifically focused on administration of informed consent, contents of the patients Informed Consent Forms and modes of informed consent used among patients for medical imaging services. Imaging departments in Kenyatta National hospital, Mbagathi, Mama Lucy, National spinal injury and National Mathare Hospitals in Nairobi City County were chosen as the area of study. The patients in the imaging departments of the selected hospitals were recruited for the study. The sample size selected was 307 respondents. The respondents were selected using systematic random sampling at a predetermined interval of 3. Collected data was coded for analysis by use of Statistical Package for Social Sciences. Analysis was conducted on descriptive and inferential statistics. Frequency tables, pie-charts and graphs were used to present the quantitative data. Inferential statistics were done using Chi Square tests to determine the association between study variables at 95% confidence interval ($p<0.05$). The ethical considerations were strictly followed during data collection. The study results revealed that majority 222(75.0%) of respondents were administered with informed consent with 79(75.2%) of respondents in Kenyatta National Hospital reporting to have adequately administered with informed consent before a medical imaging procedure. It was established that most 181(61.1%) patients sought for X-ray services compared to other imaging procedures for treatment. Verbal informed consent was the most used mode of informed consent with 123(55.0%) respondents having administered to it. It was further revealed that age ($\chi^2=3.782$; df= 4; p=0.016;), level of education ($\chi^2=3.89$; df= 4; p=0.030), revelation of reason for referral ($\chi^2=26.081$; df=1; p=0.001), provision of right to refuse or defer imaging ($\chi^2=33.468$; df= 1; p=0.001), giving consent for treatment ($\chi^2=70.733$; df=1; p=0.001), decision making for wellbeing ($\chi^2=12.056$; df=1; p=0.001), pre-operative counseling ($\chi^2=9.533$; df=1; p=0.002), cases of negligence from clinicians ($\chi^2=22.414$; df=1; p=0.001), understanding information provided by clinicians ($\chi^2=4.394$; df=1; p=0.036), adaptation of informed consent doctrine meeting physicians and patients ($\chi^2=7.648$; df=1; p=0.006), performance of diagnosis from patients' past medical history ($\chi^2=9.788$; df=1; p=0.002), advice on alternative treatment options available ($\chi^2=8.065$; df=1; p=0.005), disclosure of information by practitioners ($\chi^2=19.406$; df=1; p=0.001) and physical examination done before medication ($\chi^2=9.006$; df=1; p=0.003) were significantly associated with informed consent administration among respondents. The study concludes that informed consent was administered to majority of respondents in Public Hospitals in Nairobi City County. Most of the domains of the contents of informed consent were adhered to. The study further concludes that verbal informed consent was the most prevalent mode administered with most of the respondents utilizing X-ray medical imaging services. These research findings provide a great insights and information to leaders, managers, law makers, governing and oversight authorities in decision making, policy formulation, strategic planning and regulation in a context specific to provide a conducive environment for practicing medical imaging procedures in an ethical and legal manner.

CHAPTER ONE: INTRODUCTION

1.1 Background of the study

Globally, good population health outcomes rely not only on health protection and health improvement, but on the quality and accessibility of healthcare services (Commission, 2012). A health system is more than a mix of facilities and medical examinations. It is a structure where institutions, people and organizations interact to mobilize and allocate resources for quality healthcare delivery (Lazarus and France, 2014). For a healthcare system to function well, it has to rest on certain fundamental concepts which promote efficiency, effectiveness, accountability and monitoring. It is against this backdrop that the World Health Organization (WHO) in 2010 came up with six pillars as broad elements to strengthen health systems. The six pillars are; service delivery, health workforce, health information, access to essential medicines, financing and leadership/governance (WHO, 2010). These pillars are interrelated and have defined characteristics that lead to strengthening of a particular aspect of the health care system.

Leadership and governance in healthcare is being increasingly regarded as a salient feature on the development agenda. This involves ensuring that a strategic policy framework exists and are combined with effective oversight coalition-building, regulation, attention to system design and accountability (WHO, 2010). There is need for greater accountability especially in provision of medical imaging procedures as they are subject to exposing patients to risks which they need to be informed. Management should keep a good oversight role to ensure patients make decisions whenever they seek medical imaging services without being overlooked by physicians. This is because service delivery, according to WHO (2010) is people-centered care focused and organized

around the health needs and expectations of people and communities. Strengthening leadership and government ensures improved service delivery thus access to quality and efficient interventions leading to improved health outcomes especially in medical imaging. Many countries face health systems challenges which in turn affect the quantity and quality of health services. Although, the Kenyan Government is committed to meeting constitutional health requirements and implementing health strategy contained in the country's vision 2030 (GoK, 2012), challenges still persist resulting in poor services delivery.

Dyer (2011) described informed consent as a legal requirement for a patient to take part in decision making of his or her body. According to Alkahatib (2008) informed consent had primary considerations. Promoting understanding of information during sharing between patient and physician is a core characteristic. According to American Psychological Association, APA., (2017) potential patients must understand the information in informed consent and have to make the decision to participate in the medical or research environment without coercion, fraud, duress, undue influence, as advocated by Ethical Principles of Psychologists and Code of Conduct and demanded by the Federal Law (Protection of Human Subjects, 2016).

Acquiring informed consent prior to conducting medical procedures is an ethical and legal requirement of healthcare providers with respect for autonomy that all competent adults have the freedom to decide whether to be part of a medical treatment or not despite the chances of death. Notably, the right of autonomy can be overridden under particular circumstances such as short/long-term mental incapacity, infancy, unconsciousness, and mental illness (Chima, 2013).

However, the extent of usage of the informed consent process may vary across medical procedures, where informed consent comprise of oral and written explanation some of patients to be provided with adequate information on the type and goal of experiment; An elaborate process to be followed, and any drug or tools to be put to use; an explanation of any expected discomforts, risks and benefits, if applicable; a description of alternative treatment and procedures, any tools or drugs to be utilized in the event of complications; a chance to ask questions on the procedure; a declaration that a patient can withdraw from a procedure at will, a photocopy of the original signed and dated informed consent and a time to decide on whether to sign the consent or not without any disturbances (Dalar Shahnazarian, 2008).

Unwarranted radiological tests in the United States of America are estimated to be approximately 10%-50%. A study by Picano (2011), states that almost a third of all radiological tests are either completely or partially inappropriate. Contrary to the studies, emphasis is made on pre-operative counseling through written or verbal modes in Kenya. Counseling is important to prepare the patient to undergo certain procedures (Gotay, 2011). This ensures that the patient understands the disease they are suffering from and the procedure that they will undergo. A signed consent represents the completion of counseling and the full understanding of the disease by the patient. It ensures complete autonomy.

With the existing evidence of the use of informed consent by the imaging departments as per the researches, there is a minimal documentation on the extent of the usage of it especially in Nairobi City County. This then warranted the need to do a study on the process of informed consent and the extent used in Nairobi City County.

1.2 Problem statement

In the new Constitution of Kenya, 2010 under the health bill 2015 on the rights and duties, it is obligated that no specified health service would be provided in government health facilities to a patient without the patient's informed consent and the health care practitioners shall make all the adjustments to ensure acquisition of patients' consent (GoK, 2010). Despite the existence of informed consent as a legal requirement for providing health care, several researches and reports indicate that the informed consent has not been used in most medical experiments (Bhupathi *et al.*, 2017). There are 10-50% unwarranted radiological tests in the United States of America with almost a third of them being either partially or completely inappropriate report (Frizzell, 2014).

There is inadequate or poorly administered informed consent for medical imaging in Kenya and especially in Nairobi. A study done at KNH indicated that only 8.8% of the patients interviewed were informed on alternatives to the proposed mode of treatment (Muthoni, 2012). Patients are inadequately informed on complications related to surgery, anaesthesia, alternative forms of treatment and their risks and benefits (Onderi, 2015).

However, in spite of these formal and several informal reports showing negligence in the use of the informed consent in various medical procedures, there is little reports on the medical imaging procedures. Therefore, there is need for documentation of informed consent process for medical imaging procedures so as to set the findings for corrective action in the government hospitals in Nairobi City County and even in the entire Country.

1.3 Justification of the study

Medical imaging procedures expose the private life of a patient, thus, described to invade the social and cultural lives of people. For example a Trans-vaginal sonography (TVS) invades the private parts of a female. Hence, the feeling of violation may arise among some patients if the procedures are undertaken without their consent. Potential patients should be catered for by making accessibility of information on procedure using modes that are easily understandable. Potential patients should be in a position to understand the information and potential patients must be making the decision to participate in an environment free from force, undue influence, deceit, coercion, or duress which is not always the case as most of the reports show that the patients are not fully explained for the medical process. There are extensive researches and reports that have been paid to negligence of the informed consent but for other medical procedures but not the imaging procedures. There is inadequate documentation on informed consent on medical imaging procedures. Therefore there is need to evaluate informed consent for patients informed consent for imaging services in government hospitals in Nairobi City County.

1.4 Research questions

1. What is the proportion of patients administered with informed consent for medical imaging services in government hospitals in Nairobi City County, Kenya?

2. What is the content of patients' Informed Consent Forms used for medical imaging services among patients in government hospitals in Nairobi City County, Kenya?

3. What are the modes of informed consent used for medical imaging services among patients in government hospitals in Nairobi City County, Kenya?

1.5 Objectives of the study

1.5.1 Broad objective

To assess informed consent for medical imaging services among patients in government hospitals in Nairobi City County, Kenya.

1.5.2 Specific objectives

1. To determine the proportion of patients administered with informed consent for medical imaging services in government hospitals in Nairobi City County, Kenya.
2. To determine the modes of informed consent practices used among patients for medical imaging services in government hospitals in Nairobi City County, Kenya.
3. To identify the contents of the patients Informed Consent Forms used for medical imaging services in the government hospitals in Nairobi City County, Kenya.

1.6 Null hypothesis

H_0: There is no significant relationship between contents of informed consent forms, modes of informed consent practices and administration of informed consent for medical imaging services among patients in government hospitals in Nairobi City County, Kenya.

1.7 Study delimitations and limitations

1.7.1 Delimitations

This study focused on government hospitals in Nairobi City County leaving out hospitals in other counties. Due to the fact that the characteristics of hospitals are the same to some extent, the equipment and general layout of the departments are similar, however, the characteristics of patients might vary in education level, the findings of this study are generalizable though with care. The study was done predominantly in one area.

1.7.2 Limitations

On the process of data collection, some patients were found to have low education level which made it difficult in translating the questionnaire while administering it from English to Swahili. This to some extent might have distorted the intended meaning and thus compromised the objectives projected. However, care was taken to ensure this didn't engulf to be a hindrance.

1.8 Significance of the study

The research would help to create awareness on informed consent and importance to patients and guardians who are about to undergo medical procedure. It would enlighten them on the real function of the informed consent process and clear any misconceptions. Patients would be informed about the holistic nature of informed consent not only in the medical setting but also its legal and ethical implications.

Similarly, the healthcare service providers and practitioners also stand to benefit from the outcomes and suggestions of the study. They would get to understand the shortfalls of the process of informed consent and address short comings to their current standard operating procedures. This would ensure the smooth running of the informed consent process and effective and efficient service delivery. Additionally, it would create a conducive environment that has taken all stakeholders into consideration.

Knowledge gained from the study would contribute great insights and information to leaders, managers, law makers, governing and oversight authorities in decision making, policy formulation, strategic planning and regulation in a context specific. Finally, the findings and recommendations of this research would contribute to academic fields of

healthcare, ethics, law and governance and other related areas of literature by providing to the informed consent process.

1.9 Conceptual Framework

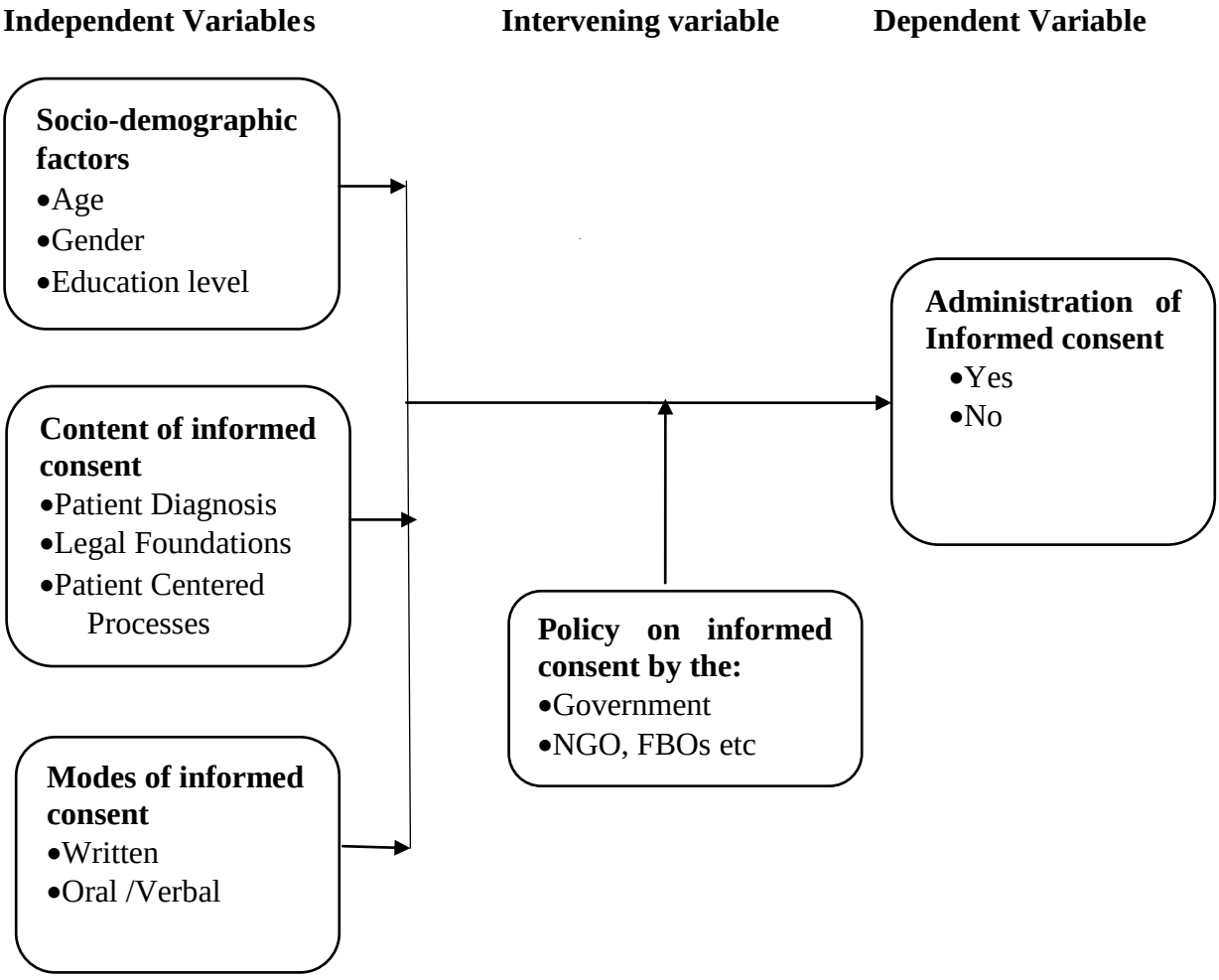

Fig 1.1: Conceptual Framework

Source: Adopted and modified from literature review, (2018)

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

In this chapter, extensive literature review on informed consent. Journals and other publications were used to develop the literature review. Additionally, the chapter covers the theory of informed consent.

2.2 Theoretical framework

2.2.1 A Theory of informed consent

The history of informed consent relates to other subjects of studies such as law, philosophy, social, health, moral and behavioral sciences. Moral and law sciences have been the dominating subjects in the field over the recent years. The two types of informed consent are legal and institutional informed consent. Tom Beauchamp, Ruth Faden, and James Childress refer to effective and informed consent as autonomous authorization/ choice or respect for autonomy (Faden *et al.,* 1986). Thus, informed consent demands for more, other than just compliance, it demands for informed and non-coerced or voluntary consent. The legal approach to informed consent has two components which are competence and disclosure. On the other hand, philosophical approach focuses on voluntariness, understanding, competence, consent, and disclosure (Flory *et al*., 2008). The legal approach to informed consent touches on some philosophical justifications such as bodily integrity and the right to privacy.

2.3 The concept of informed consent

Researchers have attempted to define informed consent. According to Nijhawan, et al, (2013), informed consent involves communicating to participants on all the aspect of a

particular trial. The information includes the type of trial, benefits, and risks associated and the procedure of the trial. This information, in turn, helps the participant make a decision on whether or not to voluntarily participate. Nijhiwan et al, (2013), states that the Nuremberg Code, the Declaration of Helsinki and the Belmont Report are the pillar to which informed consent stands. Informed consent has many definitions in regards to various researchers however, as a whole, it revolves around the meaning, as the process in which a patient or participant acquires knowledge and understanding to help make an independent decision (Bhupathi & Ravi, 2017). Emphasis is made on informed consent to protect patients and participants of research against legal problems.

Ahlin, (2017), in his study, analyzed two articles. The first article resolved the issue of authenticity being part of informed consent. The author disagrees with the reasoning that authenticity should be considered prior to informed consent. Ahlin, (2017), states that authenticity cannot be used in cases involving life and death since death must be justifiable. This means that consent that may lead to death should not be considered regardless of the genuine intentions of the person since death must be justifiable. In the second article, Alhin, (2017) establishes the meaning of voluntary and coercion. The author states that actions are the determinant of either voluntariness or coercion. The actions of a participant are able to elaborate whether their participation was either voluntary or coerced (Ahlin, 2017). A study by Reynolds, (2012) aimed at assessing the extent of understanding informed consent among different people. The study observed two groups of people on their understanding. The first group was taught on informed consent prior to decision making while the second group was not taught. From the results, the group that had information showed a 92.3% level of understanding on the topic. The

other group that was not trained on informed consent scored 78.7%. The large difference indicates the need for the provision of information prior to signing an informed consent (Reynolds, 2012).

2.4 Usage of informed consent process for imaging procedures

Baheti, Thakur, and Jankharia, (2017) explain about the use of informed consent in India, especially in imaging processes. According to the author, India does not have clear guidelines that protect a physician. Thus, the practitioners in India ask for signed consents before conducting an imaging procedure, the reason is that the signed consent protects the practitioners in the case of any unfortunate consequence such as a negative reaction to the imaging by the patient. The use of informed consent on matters imaging is used to shield the practitioners against legal issues (Baheti, Thakur, & Jankharia, 2017). Shieshia (2011) carried out a study to determine the extent of use of informed consent in clinical practice in Kenya. The study concluded that the information offered to patients prior to acquisition of informed consent is insufficient. The study suggested training and development for the practitioners to enhance physician-patient communication. The study recommended that the Ministry of Health should develop education and awareness on matters health and medical rights and design national procedures for informed consent acquisition.

Davis (2009) used semi-structured interviews on 27 nurses involved in clinical research. Participants were asked about the difficulties associated with informed consent in research protocols. Staff interviewed described their role in the consent process as 'undefined' - which led to confusion as to their ethical obligation to the patient. In a retrospective study conducted among connected health systems in various regions in the

United States, found that ultrasound was the most utilized medical imaging procedure between 1996 to 2010 (Smith-Bindman et al., 2013). In another study done in Norway, it was revealed that MRI had the largest frequency as pertains to utilization of medical imaging procedures (Kristin, 2012).

In India, reviewed literature demonstrates that obtaining patient consent prior to taking a particular medical procedure is taken seriously. For example, in his letter to the editor of Indian Radiology Imaging Journal, Sohoni reports that healthcare practitioners routinely take informed consent from patients before taking a CT/MRI due to risks associated with IV contrast administration during medical imaging procedures (Sohoni, 2013). Therefore it is imperative that patients seeking for medical imaging services are legally and ethically consented before proceeding with high risk or invasive clinical procedures (Schenker et al., 2011).

2.5 Content of the informed consent forms for imaging procedures

A study by Tam (2014) was based on determining the understanding of participants on informed consent in clinical trials using meta- analysis and systematic reviews over three decades. This was aimed at identifying the level of understanding of participants about informed consent. The findings indicated that a majority of the participants understood the core elements of informed consent such as the advantages, voluntary participation, freedom to information and the nature of clinical trial. However, the understanding of other components such as placebos and randomization is not understood and has not improved over the last three decades.

The improvement of technical aspect of informed consent would lead to better decision making by patients and participants (Tam et al., (2014). A study by Vučemilo & Borovečki, (2015) assessed 52 consent forms in selected hospitals in Croatia. The study aimed at identifying the type of information provided by consent forms in the hospitals. The study analyzed the secondary information gathered in the form of the 52 consent forms. Qualitative analysis was used for the study by applying the Simple Measure of Gobbledygook (SMOG) formula for the data collected. The findings from the analysis showed 96% of the consent forms described the risks associated with the procedure, 81% covered the benefits to be gained, 78% the description of the procedure to be undertaken, 17% documented the benefits of other alternatives, and 13% covered the advantages and risks of not undertaking the treatment or procedure. The content availed by consent forms is important to help guide a patient on the appropriate decision.

Most patients have little understanding of informed consent used in radiology imaging centers. Hopper, TenHave, and Hartzel, (1995). A cross-sectional study was adopted to contact understanding of clinical and research-based informed consent. The sample population was 549 individuals. The findings concluded that the understanding required to fill most of the informed consents was that of a college education. Bourke, (2017) undertook research to understand patients experience of musculoskeletal imaging. The study used a mixed method of data collection through administering 514 questionnaires and interviewing 33 patients. From the study, it is evident that most arthritis patients believe that the consent for imaging has more benefits than risks. The reason is that the patients take imaging as part of the clinical process for treatment.

The author recommended the need for more information provided by the informed consents to the arthritis patients (Bourke, 2017). Brink, Goske, and Patti, (2012) argue that informed decision-making trumps informed consent in radiation imaging. The trio explains that informed consent relies on communication about the risks following radiation imaging. The authors dispute with the aspect of informed consent since they claim that the risks associated with low ionizing radiations during imaging are unpredictable. Thus, the informed consent provided to patients is not as important as making an informed decision (Brink, Goske, & Patti, 2012).

2.5.1 Patient diagnosis

Klazen, (2007) described medical diagnosis as the process of establishing a condition or disease suffered by a patient to explain the signs and symptoms present. Medical diagnosis is common among all medical practitioners since it is the first step prior to prognosis. The history and physical information about a patient are commonly used to determine the diagnosis. The process of determining a diagnosis often incorporates more than one test such as the diagnostic test. Other times the posthumous diagnosis is considered a kind of medical diagnosis. Informed consent is meant to provide information to the patient about the treatment, procedure, alternatives, risks, and advantages of specific treatments and procedure. Informed consent allows the patient and practitioner to agree on a solution meant to benefit the patients' health. Hassar, (2011) postulates that informed consent is a legal obligation to be executed by the practitioner prior to any form of treatment or procedure to help a patient make an informed decision. Owen (2012) supports the study by Hassar by concluding that it is the responsibility of all

chiropractors to communicate with the patient on the known risks, effects, benefits, side effect, repeat occurrence and procedure of treatment on the diagnosis.

Muramoto (2016) emphasizes on the use of informed consent on brain death circumstances. The author explains that the family of a patient under life support should be provided with informed consent and allowed to make an informed decision. The reason is that, when on life support the chances of getting better are small, thus, the family should be given the right to know their options on what to do next. The study was motivated by the death of a thirteen-year-old, 2 years of being brain dead. Hence informed consent is important in such situations since it may open up opportunities for organ donations to people who are in need and likely to survive (Muramoto, 2016). Jacob, (2014) suggests that informed consent is vital, thus, should be availed to all patients prior to diagnosis. The author stipulates that informed consent must be voluntary and not coerced. A voluntary consent means that the patient is fully away of the risks, benefits, alternatives, period and procedure of treatment involved with the diagnosis (Jacob, 2014).

2.5.2 Legal foundations of informed consent

Informed consent stands on the doctrine of common law that all practitioners are responsible to provide information about treatment, procedures, benefits, risks, and alternatives to patients (Ley, 2010). As the medicine world evolves so has the legal requirements of informed consent. The legal doctrines of informed consent have changed three times in the last century to fit the evolving world of medicine. The first law accommodated to changes in legal action under battery to protect patients who are wrongfully by their practitioners (Fireman, 2013). The second law changed from claims

of battery to unwanted touching to negligence by not providing adequate information to the patient that would facilitate personal informed decision making. The history of the three laws is crucial in helping understand the current informed consent practices and their implementation process and requirements (Shultz, 2010). Worthington (2011) states the government and medical professionals did not advocate for changes in accountability of informed consent. Thus, only a small change was evident after many years. Worthington (2011) continues to explain that there is no definite agreement on the procedure of informed consent according to the law on the issue of liability and accountability. The GMC, (2008) emphasizes that doctors should understand the needs of individual patients to determine the information to share with the patient about the treatment.

The Ethical Research Committee (ERC) is the pillar to which all approvals and informed consent procedures stand. According to Sumathipala et al, (2008) approvals and informed consent of participants taking part in academic research is important. The reason is that informed consent protects respondents of research. Sumathipala *et al*, (2008) undertook a study aimed at determining the level to which approvals and informed consent processes are followed by local and international journals. There were 291 theses analyzed from Sri Lanka and the United Kingdom for the period 1985-2005. From the secondary data, it was established that of the 291 sample 34% documented ERC approvals and 64% had obtained informed consent before the research. A study by Nienabar, (2010) documents the regulations set by the law on informed consent for research participation by mentally ill participants. The study concludes that the law in South Africa stipulates that patient suffering from mental illness if competent should give consent before research trials. The

study established that the law in South Africa only allows participation of patients with mental illness in trials and experiments relating to the mental illness of the patients. From the findings and discussion of Nienabar, (2010) it is clear that the government of South Africa protects the mentally ill against research and trials that do not implement informed consent.

2.5.3 Patient-centered informed consent processes

There are limited data about chiropractors' perceptions of informed consent; however, the research that is available suggests that chiropractors consider informed consent as a single event and not a continuous process (Miller et al, 2011). To most physicians, informed consent represents the permission granted to operate or offer treatment to a patient, while in reality, informed consent represents the whole procedure to be followed by a patient to ensure a full recovery. Researchers who study informed consent in a clinical context advocate for informed consent to be treated as a continuous process of dialogue between a practitioner and a patient throughout the course of a given treatment, rather than a single event such as signing a form (Bakris et al, 2007). Concerns have been raised that simply having patients sign a form prior to initiating treatment may detract from the educational component of informed consent and that this form may be used primarily as a waiver to protect practitioners from litigation rather than an educational tool to enhance patient autonomy (Brenner, 2009).

The approach of patient-centered in medicine provides for the inclusion of informed consent (Sacristán et al, 2016). Informed consent is obtained after the communication of practitioner and patient. However, informed consent is not practiced at all timed in clinical research. Sacristán et al, (2016) observe that clinical procedures are carried out

on patients but without the patient. This means that informed consent is not obtained prior to the procedure, thus going against patient-centered approach of medicine. A research conducted by Miller et al, (2014) Aimed at understanding the involvement of children and adults on informed consent targeted 61 patients from age 7-21. The study wanted to identify the application of a patient-centered approach in informed consent. The findings included that the sharing of information took the major part of informed consent at 73%, 36% indicated physician-patient communication while 3% represented patient-physician communication. The findings conclude that while providing information to patients on informed consent, important aspects of interacting with the patient to help in wholesome treatment may be forgotten (Miller, et al, 2014).

2.5.4 Patients awareness on adequacy of informed consent

Rajesh et al, (2013) in their study aimed at identifying patients' awareness and perception of consent forms concluded that consent forms provided inadequate information. The study used structured interviews to collect primary data from a population sample of 555 patients undergoing surgery. Data collection was carried out from January to June 2011. From the descriptive analysis carried out, the findings showed that 88% of the participants believed that they were not allowed to refuse treatment or a procedure once they have signed the consent forms and 61.6% did not care for the consent forms but trusted their practitioners to make the right surgical and treatment decision. The level of understanding of patients regarding consent forms was satisfactory to 32%. From the results, it is evident that there is a flaw between the perception of patients and actual goal of consent forms (Rajesh et al, 2013). A study by Sulaiman, Ayyuba, Diggol, and Haruna (2015) concluded that patient awareness of consent forms was high in Aminu

Kano Teaching Hospital, Kano State, Nigeria. The study aimed at identifying the level of awareness and attitudes of patients on consent forms in the hospital. Women undergoing surgery in Obstetrics and Gynecology department were the target population. The sample population was 398 women who had undergone surgery who had not been discharged from the hospital. A cross-sectional study was adopted and the data gathered was analyzed using SPSS version 17. The findings established that all participants agreed that consent forms were important, 97% were satisfied with the information provided prior to surgery, 15 % had more questions to the explanations given, while 3 % were dissatisfied by the information provided before surgery.

Frizzle (2014) documented that most patients did not consider informed consent as a medical decision. In his study whose objective was to analyze the attitudes of providers and patients on informed consent for Cardiac catheterization (CC), he adopted mixed research methods. Surveys and interview were undertaken to collect primary data. The sample population was 28 patients. 21 patients were surveyed while 7 were interviewed. From the qualitative analysis, the study concluded that 75% of the patients did not perceive informed consent as a medical decision. The majority of the patients had a negative attitude toward informed consent and relatives and family members had to be used to convince the patients to sign the consent forms (Frizzle, 2014). The study illustrates the inadequate awareness of informed consent by many patients.

Windsor, (2013) argues that nurses need to acknowledge the importance of patients' decisions in determining the fate of their health. The reason is that patients are stakeholders in all the procedures and treatment to be undertaken while under the care of the nurses. Thus, creating awareness to the patients is of at most importance. Cervo et al,

(2013) sought to identify the level of understanding of patients with respect to informed consent. The researchers designed a multisource informed consent procedure for the enrollment of cancer patients in the Cancer Institute Biobank. The sample population for the study was 430 patients. After the first step on testing the level of understanding on informed consent by the patients, only 36.5% had knowledge on informed consent. Later the researchers provided information to the patients and carried out the test to calculate level of understanding of informed consent. From the second test, 95% understood informed consent (Cervo *et al*, 2013).

2.6 Modes of informed consent practices for imaging procedures

The modes of acquiring informed consent from patients help in educating them on the risks, benefit, and alternatives associated with particular procedure. Both written and oral mode of communication can be used to communicate information on informed consent. The law requires that any competent patient be granted the right and freedom to make decisions pertaining to his/her health (American Medical Association (AMA) Code of Medical Ethics 2001).

In medical practice, formal actions such as signing of an informed consent document after an adequate exchange of information between practitioner and patient are only implemented during some instances (Faden *et al.,* 1986). Some of the instances include prior to invasive procedures such as surgeries and radiation imaging. Notably, informed consent is rarely used in another field of medicine such as in pharmacy prescriptions and lab tests. In medical practice, informed consent should only be obtained on the basis that the patient is competent. Research indicates that minimal efforts are put to obtain consent in the current medical practice for routine checkups (Nausbaum *et al.,* 2017).

2.6.1 Audiotaped conversations consents

According to Bottrell *et al* (2000), patients who were informed about informed consent by conversations often omitted important details such as the benefits and risks associated with a procedure while trying to recall. The study was aimed at surrogates undergoing surgery. The surrogates were communicated about the informed consent via audio tapes, interviews, and questionnaires. Thus, the use of audiotapes, not an effective means to communicate informed consent. In some cases, the use of oral conversations is more effective in comparison to written informed consent. According to Gordon, (2000), some patients and participants of research are not able to read written consents. Thus, the use of oral informed consents is more relevant and effective. Oral informed consent works better with patients and participants who cannot read and diabetics who struggle to read small writings (Gordon, 2000). A study by Nusbaum et al, (2017) suggests that the use of oral communication in providing information about informed consent can be used in participants struggling to read. However, the study postulates that as oral communication is used through the use of audio tapes and reading out loud, the written consents should also be provided for the participant or patient of a research or clinical practice respectively to choose.

A study by Bourke (2017), adopted the use of interviews when questioning arthritis patients on their level of understanding of informed consent on musculoskeletal imaging. The interviews were audiotaped and transcribed. The patients were responsive to the form of questions and their response proved that they lacked adequate information about informed consent. Using audio tapes in acquiring information on informed consent proved difficult since most patients preferred the use of pictures to offer reliable answers

(Bourke, 2017). A study by Hall, Prochazka, and Fink (2012) suggest the use of audiovisual technology as informed consent. The trio explains that audiovisual tools are important and effective to gain informed consent. The reason is that the patient is able to learn about the treatment through facts that have been transformed into audiovisual. The audio-visual tool can take the form of videotapes that also accommodate audio tapes. This form of gaining informed consent is most effective on patients who cannot read. However, the use of audiovisual demands a lot of time and money as stated by Hall, Prochazka, and Fink (2012).

2.6.2 Written consents

Any medical or surgical procedure must obtain approval and authorization from the patient, guardian, next of keen, parent, spouse or a representative of the patient in the form of a signature. The attending medical practitioner is in a position to allocate the completion of the form to a medical resident or an advanced practice registered nurse. As noted by Uconn health (2015) all the signatures on the informed consent form must be dated and timed correctly. Written consents are important since they provide evidence. Brink, Goske, and Patti (2017) state that written consents are not only meant to inform the patients about the clinical of research procedures. The written consents help protect physicians and researchers in the case of any unfortunate events. Thus, the trio gives emphasis on the use of written informed consent. The authors argue that in the event of an unfortunate event, patients often try to look for a procedural problem to blame the physicians. However, if the informed consent covers all the liabilities, the physician is protected by the law if the patient had agreed and signed the consent (Brink, Goske, & Patti, 2017). Garapati, (2015) argues that written informed consent forms are normally

difficult to understand for people with little academic experience. The research states that many informed consent forms use technical language that is difficult for people who have not attended higher levels of education or high school to understand. Thus, written consents are not effective to patients and participants with little levels of education

Krogstad *et al*, (2010) in their study argue that written informed consents used in developed countries are not as effective in developing countries. The reason for the conclusion made by the researchers is that in developing countries, most people are illiterate and do not understand western medicine. The researchers establish that the people most affected by diseases in developing countries are mostly illiterate with little experience with western medicine. Thus, the use of written consents may be challenging to use in such countries. Brezis *et al*, (2008) established that the delivery of informed consent information should differ among various patients and participants. The reason is that most patients hardly recall all the information documented or told to them on informed consent. The authors suggest that the patients should be asked to make written summaries to ensure they understood the information shared.

2.7 Summary of literature review and existing gaps

Informed consent is an important aspect of care delivery more especially in medical imaging procedures. Reviewed literature from across the world has revealed that much attention has not been paid on the modalities of provision of informed consent during medical imaging procedures. This is because there is a flaw between understanding of the contents of informed consent by patients and the actual goal of its administration. There is insufficient information provided to patients seeking medical imaging across the globe.

In most cases patients sign informed consent as a formality to get treatment without having to understand the nature of the information contained in those forms. This has led to patients developing a negative attitude to informed consent as they do not regard it as their medical decision. Negligence has been reported on the part of clinicians much as they need to acknowledge the importance of patients' decision in determining the fate of their health. This is attributed to use of informed consent to shield clinicians against legal issues. Informed consent conversations have important information that ought to be availed to patients such as benefits and associated risks with imaging procedures which are rarely given to patients.

Some studies have documented low awareness on informed consent among patients with limited data on informed consent utilization on medical imaging. There is scant data on administration of informed consent in developing countries such as Kenya as much of the literature is from the western countries which are more developed. This study therefore seeks to investigate the informed consent process among patients seeking medical imaging procedures in selected public hospitals in Nairobi City County, Kenya. This study will therefore underpin the administration of informed consent, informed consent contents and informed consent modalities available to patients seeking medical imaging procedures.

CHAPTER THREE: METHODOLOGY

3.1 Introduction

This chapter covers the description study methodologies used in this study. It describes study design, variables, study location, study population, sampling techniques, data collection, data analysis and ethical considerations.

3.2 Research design

The study adopted a descriptive cross-sectional research design. The research design allows for gathering of data from a population at a particular time. The research design was best suited for the research since it allows the collection of qualitative data which are used to measure opinion and habits, which was the goal of the study (Mugenda & Mugenda, 2003).

3.3 Study variables

3.3.1 Dependent variables

The dependent variable in the study was administration of informed consent among patients seeking medical imaging services at public hospitals in Nairobi City County, Kenya. This was measured by using a yes or no answer as reported by patients on whether they were administered with informed consent before undergoing medical imaging services in the facility.

3.3.2 Independent variables

The independent variable included content of the patient's Informed consent (Patient Diagnosis, Legal Foundations, and Patient Centered Processes) and Modes of the informed consent while being administered to the patients (Written informed consent and

Oral Informed consent). They were measured using yes or no answer as reported by respondents.

3.4 Location of the study

This study was conducted in government public hospitals that have imaging department located in Nairobi City County which consisted of both national and county (Kenyatta Hospital, Mbagathi, Mama Lucy, Spinal Injury and Mathare hospitals. Nairobi City County was chosen because most of the government hospitals with the imaging departments are located in Nairobi City County as opposed to other counties.

3.5 Study population

The study population was adult patients seeking medical imaging services and imaging departmental heads in government hospitals in Nairobi City County, Kenya.

3.5.1 Inclusion criteria

All adult patients seeking the medical imaging services (X-rays (including dental X-rays, chest X-rays, spine X-rays); CT or CAT scans; Fluoroscopy, MRI and Ultrasound who agreed to participate.

3.5.2 Exclusion criteria

The study also excluded abnormal or mentally ill patients thus unable to participate in the study.

3.6 Sampling techniques

Nairobi City County was purposively chosen since it is a cosmopolitan county with people from a diverse background. The hospitals selected were stratified into three on the basis of levels of hospital, thus, creating level 6, 5, and 4 hospitals with department responsible for imaging in Nairobi County. The strata were homogenous and mutually

exclusive. Each hospital was assigned to only one stratum. To create a complete list each government hospital was assigned a number. Samples were randomly selected using a set of random numbers. The sampling method allowed for an equal opportunity for all the hospitals to be selected thus, mirroring the characteristics of the entire population (Kothari 2008). To select respondents from each hospital systematic random sampling was used at a predetermined interval of 3 by dividing the total population in the study population by the sample size. The first respondent was selected using simple random sampling using yes/no raffles. Every 3rd subsequent respondent was selected until the sample size from each facility was reached. This was repeated until the required total sample size for this study was reached.

3.7 Sample size determination

Proportionate to size sampling method was used to derive the sample population of the research. The method was appropriate since the population comprised of several subgroups/strata's varying in number. The number of respondents from each stratum was proportionate to the entire population drown from total number of patients within four months. Thus, the formula by Manor, below was used to calculate the appropriate sample size.

$$n = \frac{Nt^2 \cdot p \cdot q}{d^2N + t^2 \cdot p \cdot q}$$

Where;

N=Total population size (1020),

N=Desired sample size,

p =Probability of selecting a respondent from the sample which is 0.5,

Q = (1-p) probability of not selecting a respondent from the sample which is 1-p =0.5,

T =Standard normal deviate usually at 1.96 and d= the degree of accuracy required at 95% confidence interval= 0.05).

$$n = \frac{1020 * 1.96\text{^}2 * 0.5 * 0.5}{0.05\text{^}2 * 1020 + 1.96\text{^}2 * 0.5 * 0.5}$$

n = 279

To cater for non-responses, 10% of respondents were added. Thus 307 respondents were interviewed. The sample size and population size were all proportionally stratified.

Table 3.1: Sample size selected

Levels	**Hospitals**	**Imaging Patient Average for month**	**Sampled size**
Level 6	Kenyatta National Hospital	358	108
Level 5	Mathare Mental Hospital	128	39
Level 5	National Spine Injury Hospital	173	52
Level 5	Mama Lucy Kibaki Hospital	168	50
Level 4	Mbagathi District Hospital	193	58
	Total	**1020**	**307**

3.8 Research instruments

3.8.1 Questionnaires

Semi-structured questionnaires were used to gather primary data. The questionnaire targeted patients who were about to undergo an imaging procedure.

3.9 Pre-testing of research instruments

The pre-test was undertaken in Thika level 5 hospital. The questionnaires were validated by pre-testing them with 10% (31) of the sample size of patients from Thika level 5 hospital. The researcher gained familiarity with the research and procedure of administration by identifying clear instruments and respondents. Through the pre-test, the researcher was able to identify the instruments that required modifications. The outcome

from the pre-test enabled the researcher identify inconsistencies as a result of the instruments and ensure the instruments measured what was intended.

3.9.1 Validity

Brotherton (2008), states that validly indicates whether the items measure what they are expected and designed to measure. Content validity was used to determine whether the instruments answered the research questions. This was gained through using well-structured research tools as per objectives and sampling that ensured randomization and representativeness. Adjustments were made under the direct guidance of supervisors and professionals in the field to determine content validity which is improved by expert judgment. Content validity involves the understanding as to whether the research topic is covered adequately with the instruments.

3.9.2 Reliability

Cooper and Schindler, (2006) described reliability as the degree of measure that a research instrument yield similar outcome after repeated tests. To achieve high data reliability, the researcher was sure to collect most of the data personally and only in relevant few cases, ask for help from qualified well-trained assistants. A pre-test on the questionnaires was undertaken to test reliability. The pre-test was undertaken by administration of questionnaires twice within a one-week interval to respondents.

3.10 Data collection techniques

Self-administered questionnaires were used to collect primary data. Five trained assistants helped administer questionnaires to the selected hospitals in Nairobi County. The research assistants were assigned to the sampled hospitals and the data collection took a period of two months. The data collection exercise was done after the patient has

undergone the medical imaging exercise. All the questionnaires were collected immediately completed to ensure all the questionnaires were filled and returned in time. The research questionnaire collected were kept in locked cabinets and accessed only by the researcher to ensure privacy and confidentiality of the data was maintained.

3.11 Data analysis and presentation

The data was checked for accuracy, cleaned, edited and coded before being entered into Microsoft excel. This was later exported to Statistical Package for Social Sciences (SPSS) version 20.0 for analysis. Descriptive statistics and inferential statistics (cross tabulations) were used in the study. The outcomes from the analysis were presented in frequency tables, graphs, pie-charts and percentages for easy interpretation. Chi-square tests were done to determine the association between the study variables at 95% confidence interval and p-values less than or equal to 0.05 were considered significant.

3.12 Logistical and ethical considerations

Approval to undertake the research was sought and granted from Kenyatta University Graduate School. Authority to carry out the study was obtained from Kenyatta University Ethics and Review Committee (KUERC); and Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH-UoN ERC). Permission from the ministry of Health and the county government of Nairobi was sought. The National Commission for Science Technology and Innovation granted the researcher with a research permit (NACOSTI/P/18/33369/25074). The enrollment of the respondents was on a voluntariness basis. The research was keen to follow the ethical and professional guidelines for conducting a study. The participation of volunteers was made anonymous in the final report to protect the respondents. The questionnaires used were carefully

designed to avoid instances of embarrassment by the participants. The research-maintained confidentiality of the respondents' participation and used the feedback collected for research work. The researcher also has a plan to disseminate the results through publication.

CHAPTER FOUR: RESULTS

4.0 Introduction

The chapter contains the presentation of results on administration of informed consent which are presented thematically based on the research questions and objectives. The specific themes in the study include: demographics, content of informed consent and modes of informed consent.

4.1 Response rate

The study administered 307 questionnaires to respondents in selected hospitals in Nairobi City County. Duly filled and returned questionnaires considered for analysis. After data checking and cleaning, 296 questionnaires were deemed fit for analysis representing a response rate of 96.4%. The results revealed that more than a third 105 (35.5%) of the respondents were from KNH, 57 (19.2%) from Mbagathi, 50 (16.9%) from Mama Lucy Kibaki, 48(16.2%) from National Spine Injury and the rest 36(12.2%) from Mathari Mental Hospital as presented in table 4.1.

Table 4.1: Response rate per facility

Hospital	**Imaging patient per month**	**Sample size**	**Response rate**
Kenyatta National Hospital	358	108	105(97 %)
Mama Lucy Kibaki Hospital	168	51	50 (98 %)
Mathari Mental Hospital	128	38	36 (95 %)
Mbagathi District Hospital	193	58	57 (98%)
National Spine Injury Hospital	173	52	48 (83%)
Total	**1020**	**307**	**296(96.4%)**

Source: Field data, (2018)

4.2 Socio-demographic characteristics

4.2.1 Gender of respondents

The result showed that more than half 159 (54%) of the respondents interviewed were female while the rest 137 (46%) were male. The results were as shown in the table 4.2.

Table 4.2: Gender of respondents (n=296)

Gender	Response	Per cent
Male	137	46%
Female	159	54%

4.2.2 Educational level of respondents

The researcher sought to find out the educational level of the respondents. The results revealed that below a third 87 (29.4%) of the respondents attained secondary education as the highest level of education, followed by 79 (26.7%) who had college/tertiary education. The results were as presented in the figure 4.1.

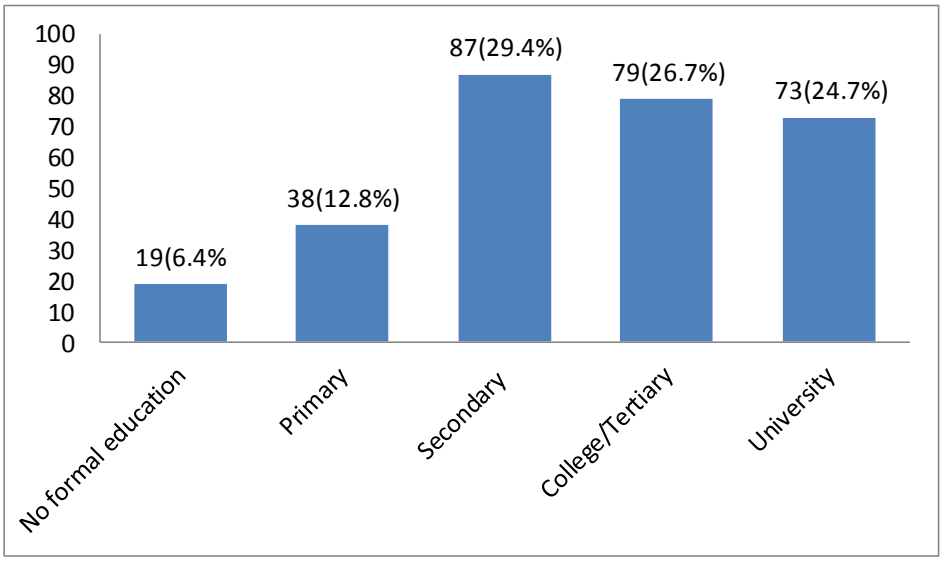

Fig 4.1: Respondents' educational level

4.2.3 Age of respondents

Concerning the respondents age, the results showed that 118 (39.9%) of the respondents were aged between 21-30 years followed by 63 (21.3%) who were aged between 31-40 years of age. The results were as in the figure 4.2.

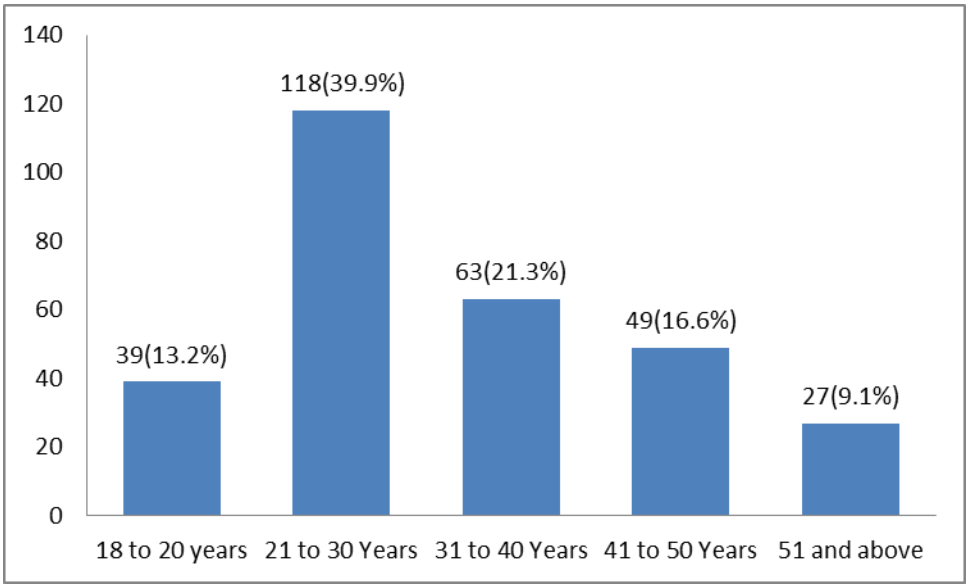

Fig 4.2: Respondents' age

4.2.4 Influence of socio-demographic factors on usage of informed consent

The study sought to find out the influence of socio-demographic factors on administration of informed consent among the respondents. The results showed that less than half 30 (40.5%) of the respondents aged between 21-30 years reported that informed consent was not administered to them. There was a significant statistical association between age and administration of informed consent (χ^2=3.782; df=4; p=0.016). Regarding the respondents' gender, the results found out that more than half 42 (56.7%) of the female respondents reported that informed consent was not administered to them. There was no association between the respondents' gender and having informed consent administered.

Concerning the respondents' highest level of education, the study revealed that less than half 33 (44.6%) of the respondents who had attained secondary level of education had not been administered with informed consent. There was a significant statistical association between highest level of education attained and being administered with informed consent ($\chi 2=3.89$; df=4; p=0.030). The results were as shown in the table 4.3.

Table 4.3: Association between socio-demographic factors and administration of informed consent among respondents (n=296)

Independent variable	Respondent response	Dependent variable (Informed consent administration)		Statistical significance
		No (N=74)	Yes (N=222)	
Age	18-20	10(25.6%)	29(74%)	$\chi^2=3.782$ df= 4 p=0.016
	21-30	30(25%)	88(75%)	
	31-40	15(24%)	48(76%)	
	41-50	13(29%)	36(71%)	
	≥51	6(22%)	21(78%)	
Gender	Male	32(23%)	105(77%)	$\chi^2=0.367$ df= 1 p=0.545
	Female	42(26.4%)	117(74%)	
Highest level of education attained	No formal education	6(32%)	13(68%)	$\chi^2=3.89$ df= 4 p=0.030
	Primary	11(29%)	27(71%)	
	Secondary	33(38%)	54(62%)	
	College/Tertiary	14(18%)	65(82%)	
	University	10(14%)	63(86%)	

4.3 Proportion of patients administered with informed consent

The respondents were asked on whether they were administered with informed consent before embarking on the medical imaging procedures, the results revealed that majority 222 (75%) of the respondents were administered. The results were as shown in the table 4.4.

Table 4.4: Administration of informed consent (n=296)

Administration of informed consent	Response	Per cent
Yes	222	75%
No	74	25%

4.3.1 Administration of informed consent per facility

The study sought to determine the administration of informed consent among the selected facilities. The results showed that Mathari Mental Hospital was the leading with 29 (80.6%) of the respondents reporting to be administered with informed consent while the rest 7 (19.4%) had not been administered with informed consent. This was followed by Mbagathi District Hospital which had 43 (75.4%) of the respondents having been administered with an informed consent while the rest 14 (24.6%) had not been administered with an informed consent.

Kenyatta National hospital had 79 (75.2%) of its respondents having been administered with an informed consent. National Spine Injury Hospital had 35 (72.9%) of the respondents were administered with informed consent and Mama Lucy Kibaki hospital had 36 (72.0%) administered with informed consent. The results were as presented in the figure 4.5.

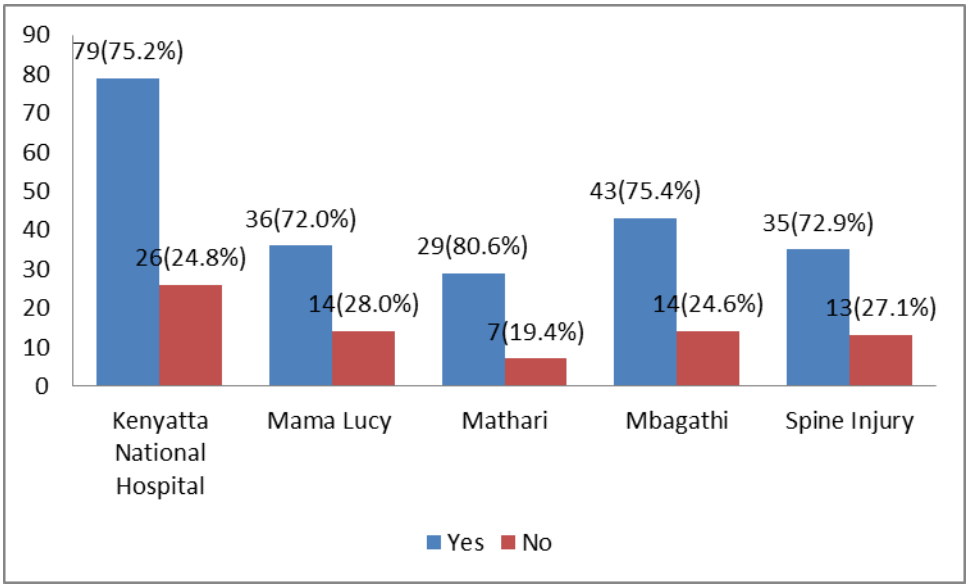

Fig 4.5: Administration of informed consent per facility

4.3.2 Medical imaging procedures among respondents

Regarding the medical imaging procedure sought by the respondents, the results showed that majority 181 (61.1%) had sought X-Ray services followed by 84 (28.4%) who had sought Ultra sound services. The results were as shown in the figure 4.6.

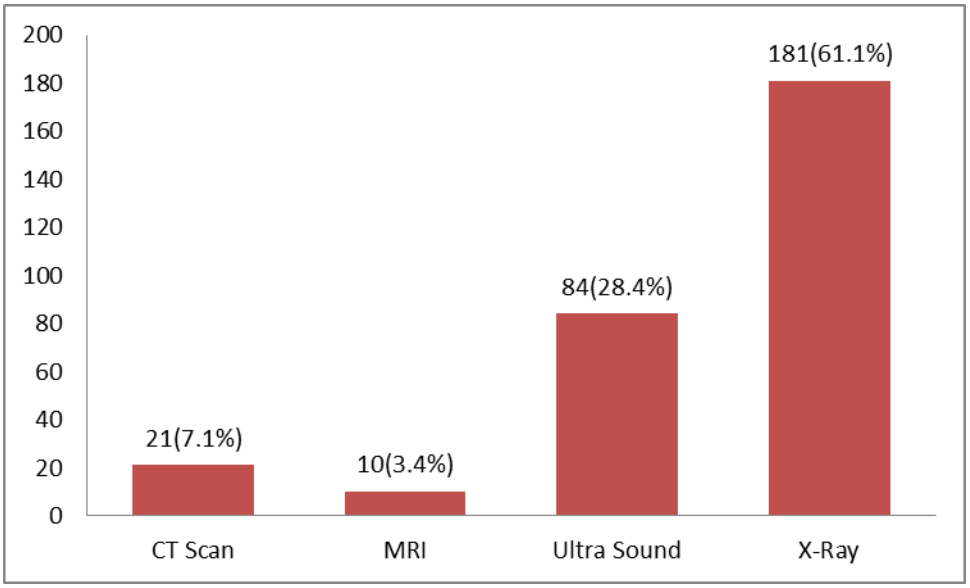

Fig 4.6: Imaging procedures among respondents

4.3.3 Medical imaging procedures per facility

Regarding to the distribution of the medical imaging procedures sought per facility, the study revealed that in KNH majority 72.4% sought for X-ray services, 19.0% CT scan and 8.6% sought for Ultra sound. In Mama Lucy the results revealed that majority 64.0% of the respondents had sought for Ultra sound services with the rest 36.0% of them seeking for X-ray services. Mathari Mental Hospital had 55.6% of its respondents seeking for X-ray services and others 44.4% seeking for Ultra sound.

In Mbagathi majority 66.7% of the respondents sought for X-ray services, 31.6% seeking for Ultra sound services and 1.8% seeking for CT scan services. Most 60.4% of the

respondents in Spine injury hospital sought for X-ray services, 20.8% MRI services and 18.8% seeking for Ultra sound services. The results were as in the figure 4.7.

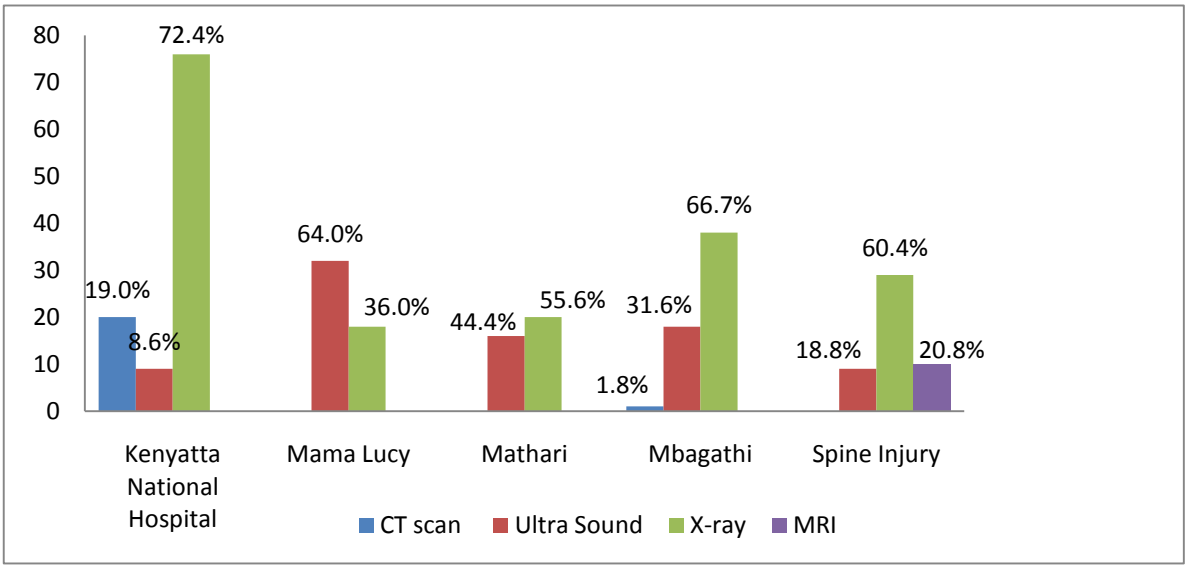

Fig 4.7: Imaging procedures per facility among respondents

4.3.4 Administration of informed consent per imaging procedure

The researcher sought to find out the administration of informed consent per imaging procedure. The results revealed that majority 9 (90.0%) of the respondents who had sought for MRI services reported to have been administered with an informed consent. This was followed by 136 (75.1%) of the respondents who sought for X-ray services and had been administered with informed consent. Most 63 (75.0%) of the respondents who had sought for Ultra sound services had been administered with informed consent. The results also revealed that 14 (60.0%) of the respondents who had sought for CT scan had an informed consent administered to them. The results were as shown in table 4.5.

Table 4.5: Administration of informed consent per imaging procedure

Imaging procedure	Administration of informed consent		Total
	Yes	No	
CT Scan	14(67.0%)	7(33.0%)	21(100.0%)
MRI	9(90.0%)	1(10.0%)	10(100.0%)
Ultrasound	63(75.0%)	21(25.0%)	84(100.0%)
X-Ray	136(75.1%)	45(24.9%)	181(100.0%)
Total	222(75.0%)	74(25.0%)	296 (100.0%)

4.4 Content of the patients Informed Consent Forms for medical imaging services

4.4.1 General informed consent

The study sought to find out the content of general informed consent for medical imaging services among the respondents. The results revealed that majority 231 (78.0%) of the respondents were explained to why they were referred to the imaging department. Slightly more than half 158 (53.4%) of the respondents were informed that they had a right to refuse or defer the imaging procedures. Concerning the respondents being requested to give their consent to treatment so that the procedure developed would concentrate on their prerogative and that of my family, the results showed that most 200 (67.6%) of them agreed.

Majority 200 (67.6%) of the respondents revealed before the imaging they had a poor understanding if the process existed despite being given opportunity to have their questions answered. The study showed that most 192 (64.9%) respondents were unwilling to hear bad news especially the risks associated with imaging procedures. Majority 235 (79.4%) of the participants agreed that informed consent had helped them be able to understand the benefits of imaging procedures. Concerning the ease of making

decisions, the results showed that majority 239 (80.7%) of the respondents felt that making decisions regarding their wellbeing had been easy. Majority 205 (69.3%) of the respondents revealed that the physician confirmed that they had given them informed consent adequately.

The findings revealed that 186 (62.8%) of the respondents felt that informed consent enabled family members assist them in choosing between the imaging procedures options available. Slightly more than half 153 (51.7%) of the study participants reported that the risks that come with imaging were not disclosed to them before the procedure. On whether pre-operative counseling was given before imaging procedure, the results revealed that slightly above half 150 (50.7%) of the respondents were not counseled. Regarding the respondents' being able to understand the imaging procedure they had to undertake an informed consent, the study revealed that indeed majority 186 (62.8%) understood while the rest 110 (37.2%) did not. The results were as presented in the table 4.6.

Table 4.6: Content of general informed consent forms for medical imaging services among respondents (n=296)

Content of general informed consent	Respondents' response	Frequency (N)	Percentage (%)
I was explained to why am referred to the imaging department	Yes	231	78.0
	No	65	22.0
I was told that I have a right to refuse or defer the imaging procedures	Yes	158	53.4
	No	138	46.6
I was requested to give my consent to treatment so that the procedure developed would concentrate on my prerogative and that of my family	Yes	201	67.9
	No	95	32.1
Before the imaging, I had a poor understanding if the process exists despite being given opportunity to have their questions answered	Yes	200	67.6
	No	96	32.4
I had the unwillingness to hear bad news especially the risks associated with imaging procedures	Yes	192	64.9
	No	104	35.1
Informed consent has helped me be able to understand the benefits of imaging procedures	Yes	235	79.4
	No	61	20.6
Making decisions affecting my well-being has been easy	Yes	239	80.7
	No	57	19.3
My physician confirmed that he has given adequately informed consent	Yes	205	69.3
	No	91	30.7
Informed consent enabled my family assist me in choosing between the imaging procedures available	Yes	186	62.8
	No	110	37.2
The risks that come with imaging were disclosed before the procedure	Yes	143	48.3
	No	153	51.7
Pre-operative counseling was also given before imaging procedures	Yes	146	49.3
	No	150	50.7
Through informed consent I was able to understand the imaging procedure that I was to undergo	Yes	186	62.8
	No	110	37.2

4.4.2 Influence of content of general informed consent and administration of informed consent among respondents

The study sought to determine the influence of the content of general informed consent and administration of informed consent among the respondents. The results showed that

majority 189 (85.1%) of the respondents who were explained to why they were referred to the imaging department were administered with the informed consent. There was a statistically significant association between being explained to why one was referred to the imaging department and administration of informed consent (χ^2=26.081; df=1; p=0.001). Most 56 (75.7%) of the respondents who were not administered with informed consent were not told that they had a right to refuse imaging procedures. There was an association between being told that one had a right to refuse or defer imaging procedures and administration of informed consent (χ^2=33.468; df= 1; p=0.001).

The results revealed that majority 180 (81.1%) of the respondents who reported to have been administered with informed consent were requested to give their consent to treatment so that the procedure developed would concentrate on their prerogative and that of my family. There was significant statistical association between requested to give consent to treatment so that the procedure developed would concentrate on their prerogative and that of my family and administration of informed consent (χ^2=70.733; df= 1; p=0.001). Results showed that 163(73.4%) of the respondents who had been administered with informed consent reported that before the imaging they had a poor understanding if the process existed despite being given opportunity to have their questions answered. There was an association between having poor understanding if the process existed before the imaging despite being given opportunity to have questions answered and being administered with informed consent (χ^2=13.896; df= 1; p=0.002).

Concerning the respondents' unwillingness to hear bad news especially the risks associated with imaging procedures, the results revealed that slightly below half 47(63.5%) of the respondents who were unwilling to hear bad news were not

administered with informed consent. There was no statistical association between being unwilling to hear bad news especially the risks associated with imaging procedures and administration of informed consent (χ^2=0.079; df= 1; p=0.779). Majority 183(82.4%) of the respondents who reported that Informed consent had helped them be able to understand the benefits of imaging procedures were administered with the informed consent. There was an association between informed consent helping one to understand the benefits of imaging procedures and being administered with the informed consent (χ^2=5.018; df= 1; p=0.025).

Majority 186(83.8%) of the respondents who were administered with informed consent reported that making decisions affecting their well-being had been easy. There was a significant statistical association between making decisions affecting their well-being easy and administration of informed consent (χ^2=5.280; df= 1; p=0.022). Regarding physician confirming that he had given adequately informed consent, results revealed that 171(77.0%) of the respondents who had been administered with informed consent had their physicians confirming to have given them adequate information. There was an association between physician confirming that he or she had given adequate informed consent and being administered with informed consent (χ^2=26.181; df= 1; p=0.001).

Results revealed that most 152 (68.5%) of the respondents administered with informed consent reported that informed consent enabled their family assist in choosing between the imaging procedures available. There was a significant statistical association between informed consent enabling the family assist in choosing between the imaging procedures available and administration of informed consent (χ^2=12.056; df=1; p=0.001). Majority 47(63.5%) of the respondents who were not administered with informed consent revealed

that the risks that come with imaging were not disclosed before the procedure. There was no association between the risks that come with imaging being disclosed before the procedure and administration of informed consent (χ^2=5.524; df= 1; p=0.059). Majority 156(70.3%) of the respondents who had been administered with informed consent reported that they were able to understand the imaging procedure to undergo. There was an association between informed consent making them understand imaging procedure and being administered with informed consent (χ^2=21.006; df= 1; p=0.021). The results were as presented in table 4.7.

Table 4.7: Association between content of general informed consent and administration of informed consent among respondents (n=296)

Content of general informed consent	respondent's response	Dependent variable (Administration of informed consent)		Statistical significance
		Yes (N=222)	No(N=74)	
I was explained to why am referred to the imaging department	Yes	189(85.1%)	42(56.7%)	χ^2=26.081 df= 1 p=0.001
	No	33(14.9%)	32(43.2%)	
I was told that I have a right to refuse or defer the imaging procedures	Yes	140(63.1%)	18(24.3%)	χ^2=33.468 df= 1 p=0.001
	No	82(36.9%)	56(75.7%)	
I was requested to give my consent to treatment so that the procedure developed would concentrate on my prerogative and that of my family	Yes	180(81.1%)	21(28.4%)	χ^2=70.733 df= 1 p=0.001
	No	42(18.9%)	53(71.6%)	
Before the imaging, I had a poor understanding if the process exists despite being given opportunity to have their questions answered	Yes	163(73.4%)	37(50.0%)	χ^2=13.896 df= 1 p=0.002
	No	59(26.6%)	37(50.0%)	
I had the unwillingness to hear bad news especially the risks associated with imaging procedures	Yes	145(65.3%)	47(63.5%)	χ^2=0.079 df= 1 p=0.779
	No	77(34.7%)	27(36.5%)	
Informed consent has helped me be able to understand the benefits of imaging procedures	Yes	183(82.4%)	52(70.3%)	χ^2=5.018 df= 1 p=0.025
	No	39(17.6%)	22(29.7%)	
Making decisions affecting my well-being has been easy	Yes	186(83.8%)	53(71.6%)	χ^2=5.280 df= 1 p=0.022
	No	36(16.2%)	21(28.4%)	
My physician confirmed that he has given adequately informed consent	Yes	171(77.0%)	34(45.9%)	χ^2=26.181 df= 1 p=0.001
	No	51(23.0%)	40(54.1%)	
Informed consent enabled my family assist me in choosing between the imaging procedures available	Yes	152(68.5%)	34(45.9%)	χ^2=12.056 df= 1 p=0.001
	No	70(31.5%)	40(54.1%)	
The risks that come with imaging were disclosed before the procedure	Yes	116(52.3%)	27(36.5%)	χ^2=5.524 df= 1 p=0.059
	No	106(47.7%)	47(63.5%)	
Pre-operative counseling was also given before imaging procedures	Yes	121(54.5%)	25(33.8%)	χ^2=9.533 df= 1 p=0.002
	No	101(45.5%)	49(66.2%)	
Through informed consent I was able to understand the imaging procedure that I was to undergo	Yes	156(70.3%)	30(40.5%)	χ^2=21.006 df= 1 p=0.021
	No	66(29.7%)	44(59.5%)	

4.4.3 Legal foundations of the informed consent

The study sought to find out the legal foundations of the informed consent, the results showed that majority 220 (74.3%) of the respondents agreed that the legal system had adapted the informed consent doctrine to meet the needs of both physicians and patients. Most 221 (74.7%) of the participants revealed that the legal foundations had helped to examine how the law has evolved over time. Concerning legal foundations helping the respondents meet the needs of an evolving medical system, results showed that three quarters 222 (75.0%) of the respondents felt that indeed legal foundations had helped them meet the needs.

Results further revealed that 248 (83.8%) of the respondents had had no cases of negligence claims from nurses and doctors in the hospital and failure to fulfill a duty to provide the sufficient information to make a personal medical decision. Most 261 (88.2%) of the respondents reported that they had not suffered the failure of doctors and nurses in providing the sufficient information to make a medical decision. The results also showed that 230 (77.7%) of the participants reported that the treating doctor had always ensured that they fully understood all of the information that had been provided. The results were as presented in the table 4.8.

Table 4.8: Legal foundations of informed consent for medical imaging services among respondents (n=296)

Legal foundations of informed consent	respondent's response	Frequency (N)	Percentage (%)
The legal system has adapted the informed consent doctrine to meet the needs of both physicians and patients	Yes	220	74.3
	No	76	25.7
The legal foundations have helped to examine how the law has evolved over time	Yes	221	74.7
	No	75	25.3
Legal foundations have helped to meet the needs of an evolving medical system	Yes	222	75.0
	No	74	25.0
I have had no cases of negligence claims from nurses and doctors in this hospital and failure to fulfill a duty to provide the sufficient information to make a personal medical decision	Yes	248	83.8
	No	48	16.2
I have not suffered the failure of doctors and nurses in providing the sufficient information to make a medical decision	Yes	261	88.2
	No	35	11.8
The treating doctor has always ensured that I fully understand all of the information that has been provided	Yes	230	77.7
	No	66	22.3

4.4.4 Influence of legal foundations on the administration of informed consent for medical imaging services

The study sought to determine the influence of legal foundations on the administration of informed consent for medical imaging services. The results showed that majority 174 (78.4%) of the respondents administered with informed consent reported that the legal system had adapted the informed consent doctrine to meet the needs of both physicians and patients. There was a statistical association between the legal system adapting the informed consent doctrine to meet the needs of both physicians and patients and administration of informed consent (χ^2=7.648; df= 1; p=0.006). Most 49(66.2%) of the respondents who reported that the legal foundations had helped them to examine how the law has evolved over time were not administered with informed consent. There was no

statistical association between the legal foundations helping the respondents examine how the law has evolved over time and administration of informed consent (χ^2=3.720; df=1; p=0.054).

Majority 176(79.3%) of the respondents who reported that the legal foundations had helped them to meet the needs of an evolving medical system were administered with informed consent. There was a significant statistical association between the legal foundations helping them to meet the needs of an evolving medical system and administration of informed consent (χ^2=8.673; df=1; p=0.003). Most 199 (89.6%) of the respondents who had no cases of negligence claims from nurses and doctors in the hospital and failure to fulfill a duty to provide the sufficient information to make a personal medical decision were administered with informed consent. There was association between having had no cases of negligence claims from nurses and doctors in the hospital and failure to fulfill a duty to provide the sufficient information to make a personal medical decision and administration of informed consent (χ^2=22.414; df=1; p=0.001).

Results showed that 206(92.8%) of the respondents who had not suffered the failure of doctors and nurses in providing the sufficient information to make a medical decision had been administered with informed consent. There was a statistical association between having not suffered the failure of doctors and nurses in providing the sufficient information to make a medical decision and administration of informed consent (χ^2=18.156; df=1; p=0.001). Most 179(80.6%) of the respondents who reported that the treating doctor had always ensured that they fully understood all of the information that had been provided had being administered with informed consent. There was an

association between treating doctor always ensuring that the respondents fully understood all of the information that had been provided and administration of informed consent (χ^2=4.394; df=1; p=0.036). The results were as shown in in table 4.9.

Table 4.9: Association between legal foundations for medical imaging services and administration of informed consent among respondents (n=296)

Legal foundations of informed consent	respondent's response	Dependent variable (Administration of informed consent)		Statistical significance
		Yes (N=222)	No (N=74)	
The legal system has adapted the informed consent doctrine to meet the needs of both physicians and patients	Yes	174(78.4%)	46(62.2%)	χ^2=7.648 df= 1 p=0.006
	No	48(21.6%)	28(37.8%)	
The legal foundations have helped to examine how the law has evolved over time	Yes	172(77.5%)	49(66.2%)	χ^2=3.720 df= 1 p=0.054
	No	50(22.5%)	25(33.8%)	
Legal foundations have helped to meet the needs of an evolving medical system	Yes	176(79.3%)	46(62.2%)	χ^2=8.673 df= 1 p=0.003
	No	46(20.7%)	28(37.8%)	
I have had no cases of negligence claims from nurses and doctors in this hospital and failure to fulfill a duty to provide the sufficient information to make a personal medical decision	Yes	199(89.6%)	49(66.2%)	χ^2=22.414 df= 1 p=0.001
	No	23(10.4%)	25(33.8%)	
I have not suffered the failure of doctors and nurses in providing the sufficient information to make a medical decision	Yes	206(92.8%)	55(74.3%)	χ^2=18.156 df= 1 p=0.001
	No	16(7.2%)	19(25.7%)	
The treating doctor has always ensured that I fully understand all of the information that has been provided	Yes	179(80.6%)	51(68.9%)	χ^2=4.394 df= 1 p=0.036
	No	43(19.4%)	23(31.1%)	

4.4.5 Consent on patient diagnosis

The study sought to determine the consent on patient diagnosis for medical imaging services among the respondents. The results revealed that majority 224 (75.7%) of the respondents reported that health practitioners performed a diagnosis from their past medical history. Slightly more than half 167 (56.4%) of the respondents reported that in

the process of diagnosis the health practitioners advised on potential benefits and risks that result due to imaging. Most 191 (64.5%) of the respondents revealed that during diagnosis they were able to communicate about the nature of treatment with the health practitioners.

More than half 166 (56.1%) of the participants revealed that health practitioners advised on other alternative treatment options. Majority 226 (76.4%) of the respondents said that physical examination was done before other medication. The study further revealed that 208 (70.3%) of the respondents reported that practitioners disclosed all information that they considered important when making informed health care decisions. The results were as presented in the table 4.10.

Table 4.10: Consent on patient diagnosis for medical imaging services among respondents (n=296)

Consent on patient diagnosis	**respondent's response**	**Frequency (N)**	**Percentage (%)**
The health practitioners performed a diagnosis from my past medical history	Yes	224	75.7
	No	72	24.3
In the process of diagnosis the health practitioners advised on potential benefits and risks that result due to imaging	Yes	167	56.4
	No	129	43.6
During diagnosis I was able to communicate about the nature of treatment with the health practitioners	Yes	191	64.5
	No	105	35.5
Health practitioners advised on other alternative treatment options	Yes	166	56.1
	No	130	43.9
Physical examination was done before other medication	Yes	226	76.4
	No	70	23.6
Practitioners disclosed all information that I considered important when making informed health care decisions	Yes	208	70.3
	No	88	29.7

4.4.6 Influence of content of patient diagnosis and administration of informed consent

The study sought to determine the association between patient diagnosis for medical imaging services and administration of informed consent among the respondents. The results showed that 178 (80.2%) of the respondents who reported that health practitioners performed a diagnosis from their past medical history were administered with informed consent. There was an association between health practitioners performing a diagnosis from their past medical history and administration of informed consent (χ^2=9.788; df=1; p=0.002). More than half 133 (59.9%) of the respondents who revealed that in the process of diagnosis the health practitioners advised on potential benefits and risks that result due to imaging had been administered with informed consent. There was a statistical association between the health practitioners advising on potential benefits and risks that result due to imaging during the process of diagnosis and administration of informed consent (χ^2=4.401; df=1; p=0. 036).

Majority 157 (70.7%) of the respondents who reported that during diagnosis they were able to communicate about the nature of treatment with the health practitioners had been administered with informed consent. There was an association between reporting that during diagnosis the respondents were able to communicate about the nature of treatment with the health practitioners and administration of informed consent (χ^2=14.882; df=1; p=0.001). Results showed that 135(60.8%) of the respondents who reported that the health practitioners advised on other alternative treatment options had been administered with informed consent. There was a significant statistical association between health practitioners advising on other alternative treatment options and administration of informed consent (χ^2=8.065; df=1; p=0.005).

Majority 179(80.6%) of the respondents reported that physical examination was done before other medication. There was an association between physical examination being done before other medications and administration of informed consent (χ^2=9.006; df=1; p=0.003). Most 171(77.0%) of the participants who reported that practitioners disclosed all information that they considered important when making informed health care decisions had been administered with informed consent. There was a statistical association between disclosure of all information considered important when making informed health care decisions and administration of informed consent (χ^2=19.406; df=1; p=0.001). The results were as reported in table 4.11.

Table 4.11: Association between patient diagnosis for medical imaging services and administration of informed consent among respondents (n=296)

Legal foundations of informed consent	**Respondent's response**	**Dependent variable (Administration of informed consent)**		**Statistical significance**
		Yes (N=222)	**No (N=74)**	
The health practitioners performed a diagnosis from my past medical history	Yes	178(80.2%)	46(62.2%)	χ^2=9.788 df=1 p=0.002
	No	44(19.8%)	28(37.8%)	
In the process of diagnosis, the health practitioners advised on potential benefits and risks that result due to imaging	Yes	133(59.9%)	34(45.9%)	χ^2=4.401 df=1 p=0.036
	No	89(40.1%)	40(54.1%)	
During diagnosis I was able to communicate about the nature of treatment with the health practitioners	Yes	157(70.7%)	34(45.9%)	χ^2=14.882 df=1 p=0.001
	No	65(29.3%)	40(54.1%)	
Health practitioners advised on other alternative treatment options	Yes	135(60.8%)	31(41.9%)	χ^2=8.065 df=1 p=0.005
	No	87(39.2%)	43(58.1%)	
Physical examination was done before other medication	Yes	179(80.6%)	47(63.5%)	χ^2=9.006 df=1 p=0.003
	No	43(19.4%)	27(36.5%)	
Practitioners disclosed all information that I considered important when making informed health care decisions	Yes	171(77.0%)	37(50.0%)	χ^2=19.406 df=1 p=0.001
	No	51(23.0%)	37(50.0%)	

4.4.7 Patient centered informed consent

The researcher sought to find out the Patient centered informed consent for medical imaging services among respondents. The results showed that majority 216 (73.0 %) of the respondents reported that there was very little information available explaining what that process should look like. More than half 163 (55.1%) of the respondents revealed that they were not given forms that were used as a waiver to protect practitioners from litigation to enhance patient autonomy.

Slightly more than half 155 (52.4%) of the participants did not sign some forms prior to initiating treatment. Half 148 (50.0%) of the respondents reported that there was a decision aid that provided objective information about all treatment options. Most 233 (78.7%) of the respondents revealed that the hospital treated informed consent as a continuous process of dialogue as it was done before and after the treatment. Results showed that 209 (70.6%) of the respondents reported that each treatment option in the hospital helped in understanding the likelihood of benefits or harms occurring. Concerning the respondents' awareness on their individual rights during the imaging procedures, results revealed that 203 (68.6%) of them were not aware. The results were as shown in the table 4.12.

Table 4.12: Patient centred informed consent for medical imaging services among respondents (n=296)

Patient centered informed consent	respondent's response	Frequency (N)	Per cent (%)
There is very little information available explaining what that process should look like	Yes	216	73.0
	No	80	27.0
I was given forms that are used as a waiver to protect practitioners from litigation to enhance patient autonomy	Yes	133	44.9
	No	163	55.1
I signed some forms prior to initiating treatment	Yes	141	47.6
	No	155	52.4
There is a decision aid that provides objective information about all treatment options	Yes	148	50.0
	No	148	50.0
The hospital treats informed consent as a continuous process of dialogue as it was done before and after the treatment	Yes	233	78.7
	No	63	21.3
Each treatment option in the hospital helps in understanding the likelihood of benefits or harms occurring	Yes	209	70.6
	No	87	29.4
I am not aware of my individual rights during the imaging procedures	Yes	203	68.6
	No	93	31.4

4.4.8 Influence of content of patient centered informed consent for medical imaging services and administration of informed consent among respondents

The study sought to determine the association between content of patient centered informed consent and administration of informed consent among respondents. The results revealed that majority 55 (74.3%) of the respondents who reported that there was very little information available explaining what that process should look like had not been administered with informed consent. There was no statistical association between information explaining what the process should look like being little and administration of informed consent (χ^2=0.091; df= 1; p=0.762). Most 47(63.5%) of the respondents who reported that they were given forms that were used as a waiver to protect practitioners from litigation to enhance patient autonomy had not been administered with informed

consent. There was no association between being given forms that were used as a waiver to protect practitioners from litigation to enhance patient autonomy and administration of informed consent (χ^2=2.845; df= 1; p=0.092).

Half 112 (50.5%) of the respondents who reported to have signed some forms prior to initiating treatment had been administered with informed consent. There was no significant statistical association between having signed some forms prior to initiating treatment and administration of informed consent (χ^2=2.822; df= 1; p=0.093). Slightly more than half 117 (52.7%) of respondents reported that there was a decision aid that provided objective information about all treatment options and been administered with informed consent. There was no association between a having decision aid that provided objective information about all treatment options and administration of informed consent (χ^2=2.595; df=1; p=0.107). Results showed that 160(72.1%) of the respondents who revealed that the hospital treated informed consent as a continuous process of dialogue as it was done before and after the treatment. There was no significant statistical association between hospital treating informed consent as a continuous process of dialogue as it was done before and after the treatment and administration of informed consent (χ^2=0.544; df= 1; p=0.461).

Regarding each treatment option in the hospital helping the respondents to understand the likelihood of benefits or harms occurring, the results revealed that 160 (72.1%) of the respondents reported that it helped them understand. There was no statistical association between each treatment option helping respondents to understand the likelihood of benefits or harms occurring and administration of informed consent (χ^2=0.917; df= 1;p=0.338). Most 56(75.7%) of the respondents who were not aware of their individual

rights during the imaging procedures had not been administered with informed consent. There was however no significant association between awareness on the individual's rights during imaging procedures and administration of informed consent (χ^2=2.305; df=1; p= 0.129). The results were as presented in table 4.13.

Table 4.13: Association between content of patient centered informed consent and administration of informed consent among respondents (n=296)

Patient centered informed consent	respondent's response	Dependent variable (Administration of informed consent)		Statistical significance
		Yes (N=222)	No (N=74)	
There is very little information available explaining what that process should look like	Yes	161(72.5%)	55(74.3%)	χ^2=0.091 df=1 p=0.762
	No	61(27.5%)	19(25.7%)	
I was given forms that are used as a waiver to protect practitioners from litigation to enhance patient autonomy	Yes	106(47.7%)	27(36.5%)	χ^2=2.845 df=1 p=0.092
	No	116(52.3%)	47(63.5%)	
I signed some forms prior to initiating treatment	Yes	112(50.5%)	29(39.2%)	χ^2=2.822 df=1 p=0.093
	No	110(49.5%)	45(60.8%)	
There is a decision aid that provides objective information about all treatment options	Yes	117(52.7%)	31(41.9%)	χ^2=2.595 df=1 p=0.107
	No	105(47.3%)	43(58.1%)	
The hospital treats informed consent as a continuous process of dialogue as it was done before and after the treatment	Yes	177(79.7%)	56(75.7%)	χ^2=0.544 df=1 p=0.461
	No	45(20.3%)	18(24.3%)	
Each treatment option in the hospital helps in understanding the likelihood of benefits or harms occurring	Yes	160(72.1%)	49(66.2%)	χ^2=0.917 df=1 p=0.338
	No	62(27.9%)	25(33.8%)	
I am not aware of my individual rights during the imaging procedures	Yes	147(66.2%)	56(75.7%)	χ^2=2.305 df=1 p=0.129
	No	75(33.7%)	18(24.3%)	

4.5 Modes of informed

Concerning the mode of informed consent, the results revealed that more than half 123 (55.0%) of the respondents were administered with verbal consent while the rest 99

(45.0%) had been administered with written consent. The results were as shown in table 4.14.

Table 4.4: Mode of informed consent (n=296)

Mode of informed consent	Response	Per cent
Verbal	123	55%
Written	99	45%

4.5.1 Modes of informed consent per facility

The researcher sought to determine the modes of informed consent per facility. The results showed that in KNH more than half 43 (54.4%) of the respondents had been administered with verbal informed consent while the rest 36 (45.6%) had been administered with written consent. In Mama Lucy Kibaki Hospital, the study revealed that 19(52.7%) of the respondent had been administered with a verbal informed consent while the rest 17(47.2%) were administered with written consent. Results from Mathari Hospital showed that 16(55.2%) of the respondents had been administered with verbal consent with the rest 3(44.8%) having been administered with written consent. In Mbagathi results revealed that most 24(55.8%) of the participants were administered with verbal consent while 19(44.2%) were administered with written consent. Majority 21(60.0%) of the respondents had been administered with verbal consent while the rest 14(40.0%) of them reported to have been administered with written consent in the National Spine Injury Hospital. The results were as presented in the table 4.15.

Table 4.15: Modes of informed per facility among respondents

Hospital	Mode of informed consent		
	Verbal	Written	
KNH	43(54.4%)	36(45.6%)	79(100.0%)
Mama Lucy Kibaki Hospital	19(52.7%)	17(47.2%)	36(100.0%)
Mathari Hospital	16(55.2%)	13(44.8%)	29(100.0%)
Mbagathi	24(55.8%)	19(44.2%)	43(100.0%)
National Spine Injury	21(60.0%)	14(40.0%)	35(100.0%)
Total	**123(55.4%)**	**99(44.6%)**	**222(100.0%)**

CHAPTER FIVE: DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter describes the summary of the major findings, the relations to other research studies, suggestions for future research, limitations, conclusion and even recommendations.

5.2 Discussions

5.2.1 Socio-demographic factors

The results revealed that more than half of the respondents who were interviewed were female. However, there was no association between the respondents' gender and administration of informed consent to patients. This may be because there were no significant differences between the male and women who had adequate informed consent administered to them. The results were consistent with a study which was conducted in South Africa which revealed that more women sought for informed consent as compared to their male counterparts (Friedrich-Nel, 2015). This would be attributed to the fact that they tend to be more concerned to their health as well as have better health seeking behavior with regards to radiation risks associated with medical imaging.

The study findings revealed that slightly less than a third of the respondents picked secondary education as the highest level of education attained. There was a significant statistical association between highest level of education attained and administration of informed consent. Education enables people to access more information concerning their healthcare choices. This explains why most individuals with higher education levels

require knowing much concerning their health including the application of informed consent. These results were a true reflection of other studies done in the United Kingdom which revealed that patient awareness and usage of informed consent in seeking healthcare services increased with advances in age and increased educational level (Riordan et al., 2015). Similar results were also reported by a study done in South Africa which showed that the higher the education level the better the perceptions of informed consent process among patients (Tshimanga, 2011).

Concerning the respondents' age, the results showed that less than half of the respondents were aged between 21-30 years. The results further indicated that age of patients played a significant role in predicting the utilization of informed consent among respondents. Age enables people to gain more life experiences thus demanding better services compared to younger individuals. The results were contrary to a study done in Sao Paulo, Brazil which reported that acceptance and use of informed consent forms among patients treated in public hospitals was not influenced by socio-demographic factors such as age, gender and educational level (Souza et al., 2013).

5.2.2 Proportion of patients administered with informed consent

The study sought to determine the proportion of people administered with informed consent prior to seeking medical imaging procedures. The study results showed that majority of respondents were administered with informed before embarking on the medical imaging procedures across the selected hospitals. It was further revealed that majority of the respondents were from Kenyatta National Hospital. This may be due to the fact that KNH is a nation referral hospital hence expected to perform with greater standards of care to patients. The results were similar with a study done in Nigeria on

attitude towards informed consent administration among patients seeking imaging services (Agu et al., 2014).

The results revealed that majority of respondents had sought for X-ray services as compared to other imaging procedures for treatments. This could be attributed to the fact that X-rays are the initial imaging procedures required by physicians before recommending for more advanced subsequent imaging services to reveal finer details of any given medical complications. These findings were contrary to a retrospective study conducted among integrated health systems across different regions in the United States which found that ultrasound was the most utilized medical imaging procedure between 1996 to 2010 (Smith-Bindman et al., 2013). The results were also inconsistent with a study done in Norway, which showed that MRI had the largest frequency as pertains to utilization of medical imaging procedures (Kristin, 2012).

According to the findings of this study, it was revealed that most respondents who were seeking for MRI services, majority of them were administered with informed consent. This may be because those imaging procedures with higher risks are given more priority due to perceived greater impact on the patients. These results were inconsistent with an Indian study which showed healthcare practitioners routinely take informed consent from patients before taking a CT/MRI due to risks associated with IV contrast administration during medical imaging procedures (Sohoni, 2013). This study is consistent with the research by Bourke, (2017) who established that arthritis patients believed imaging was part of the treatment process, thus, did not care for the informed consent forms. Therefore, it is imperative that patients seeking for medical imaging services are legally

and ethically consented before proceeding with high risk or invasive clinical procedures (Schenker et al., 2011).

5.2.3 Content of the patients informed consent forms

Regarding the content of general informed consent for medical imaging services among the respondents, the results revealed that majority of the respondents were explained to why they were referred to the imaging department. There was a significant statistical association between administration of informed consent and explanation on reasons for medical imaging. This means that the respondents had been better informed hence the adequacy of administration of informed consent. The results concurred with a study done in Philadelphia among cancer survivors which showed that there is need for physicians to initiate discussions with patients before referring them for medical imaging services (Thornton et al., 2015).

The results further revealed that a good number of respondents were informed that they had a right to refuse or defer the imaging procedures. This is based on provision of information on the risks and benefits of undertaking of medical imaging examination by consenting. This enables informed decision making thus its significance. The results were in agreement with another study done among musculoskeletal patients seeking medical imaging services (Bourke, 2017). This is because patients are empowered with information under which they can make informed decisions through better choices.

The results revealed that majority of the respondents had a poor understanding if the process existed despite being given opportunity to have their questions answered before undergoing the medical imaging procedure. There was a significant statistical association between understanding the existence of the process and actual administration of informed

consent. This is because through explanation from physicians they were in a position to know the importance of taking the medical imaging procedure to enable the physicians treat them better. The results were contrary to a study done in South Africa which revealed that respondents felt that informed consent did not improve their understanding of the process (Makanjee et al., 2015).

The study showed that most of the respondent were unwilling to hear bad news especially the risks associated with imaging procedures. Explaining to patients the risks and benefits of taking a medical imaging procedure reduces poor perceptions especially those that are associated with radiation during the procedures. The results were similar to another study done by Bourke (2017) which revealed that consent for medical imaging has more benefits that risks. According to Thornton (2015), understanding imaging radiation risks and active participation in decision making is an integral part in the process of informed consent during medical imaging examination. Disclosure of risks associated with medical imaging and benefits enables patients to choose to undergo the procedure since they are aware of the necessary advantages. This is in support of a study by Ley, (2010) that suggests all the information pertaining to a particular procedure should be disclosed to the patient prior acquisition of an informed consent.

On whether pre-operative counseling was given before imaging procedure, the results revealed that most of the respondents were not counseled with before consenting for medical imaging. Counselling of patients improves and prepares patients for undergoing a given procedure through provision of hope and benefits that may arise as a result of using the imaging reports for better treatment of patients. In most cases majority of the patients had a negative attitude toward informed consent and relatives and family

members had to be used to convince the patients to sign the consent forms (Frizzle, 2014).

The study sought to find out the legal foundations of the informed consent, the results showed that majority of the respondents agreed that the legal system had adapted the informed consent doctrine to meet the needs of both physicians and patients. This may be attributed to the fact that legal aspects are the most binding components of informed consent. Informed consent is intended to protect patients from possible harm and ensure good ethical practice (Tshimanga, 2011). Therefore, patients should understand the medico-legal issues associated with medical service provision.

From the study findings, it was revealed that most of the participants revealed that the legal foundations had helped to examine how the law has evolved over time. However, there was no association between administration of informed consent and informed consent helping to examine how the law has evolved over time. This may be attributed to the fact that the patients are only concerned about getting treated for their condition rather than the legal aspects of informed consent. The findings from the study contradict with a study by Worthington (2011) who states that the government and medical practitioners have not implemented laws that clearly explain the process of acquiring informed consent.

The study established that development of a diagnosis mostly relies on a patient's medical history followed by the information provided. Medical history is important in determining a diagnosis. The information provided by the patient to the practitioner is used to develop an appropriate diagnosis to facilitate treatment. From the study, it is

evident that information plays a big role in determining a diagnosis. This contradicts with research findings by Carpeggiani and Picano, (2016) that stipulates that every radiological and nuclear medicine examination confers a definite long-term risk of cancer, but most patients undergoing such examinations receive no or inaccurate information about radiation dose and corresponding risk related to the dose received. Physicians are responsible for providing patients with all the information on risks, benefits, and alternatives useful to the patient to make the decision. Patients need to be informed about a proposed procedure, allowing them to make an educated decision about their own health care (Medical Radiation Working Group, 2015).

Patient-centered care is an approach to medicine that incorporates a patient in decision making. From these findings, informed consent was implemented as a continuous process rather than just a onetime instance. The continuous state of informed consent enhances patient-centered approach to medicine. The findings were aligned with the research by Bakris et al, (2007) that advocated for informed consent as a continuous process. However, the findings contradicted the findings by Miller et al, (2011), who stated that many physicians view informed consent as a single event rather than a continuous process.

5.2.4 Modes of informed consent

Informed consent can either be communicated through writing or oral communication. Verbal communication is often used in informed consent. The reason is that it is easier to understand and fast. The study indicated that the majority of participants reported they had given consent orally without any documentation or signing. The study is supported by research by Gordon, (2000), that states that the use of verbal communication is easier

to many patients in comparison to written informed consents. However, a study by Nusbaum et al (2017) disputes the results and concludes that despite the use of verbal communication, written informed consent should always be availed by the physicians.

5.3 Conclusions

i. The results concludes that majority of the respondents were administered with informed consent for medical imaging procedures. Majority of the respondents were seeking x-Ray services and they were from Kenyatta National Hospital. Most of the patients who were seeking MRI services were administered with informed consent.

ii. Majority of the domains of the contents of informed consent had a significant statistical association with administration of informed consent among respondents. These included general informed consent, legal foundations, patient-centred and patient diagnosis contents of informed consent for medical imaging procedures.

iii. It was further revealed that verbal informed consent was the most common mode of informed consent administered to patients.

5.4Recommendations

5.4.1 Recommendations from the study

i. The Ministry of health in collaboration with the County government of Nairobi City County should scale up health education to increase patient awareness on the importance of informed consent when seeking medical imaging procedures.

ii. The ministry of health and the relevant hospital management should display the contents of informed consent where the patients could be able to read and understand the contents of informed consent.

iii. There should be a standard procedure of administrating both verbal and non-verbal informed consent to all patients attended at the imaging departments.

5.4.2 Recommendation for further study

A comparative study should be done to compare the process of informed consent for medical imaging between public and private hospitals in Nairobi City County Kenya.

REFERENCES

Agoritsas, T., & Perneger, T. V. (2010). Patient-reported conformity of informed consent.

Agu, K. A., Obi, E. I., Eze, B. I., & Okenwa, W. O. (2014). Attitude towards informed consent practice in a developing country: a community-based assessment of the role of educational status. *BMC medical ethics*, *15(1)*, *77*.

Ahlin, J. (2017). *Personal Autonomy and Informed Consent: Conceptual and Normative Analyses* (Doctoral dissertation, Kungliga Tekniska högskolan).

Baheti, A. D., Thakur, M. H., & Jankharia, B. (2017). Informed consent in diagnostic radiology practice: Where do we stand?. *The Indian journal of radiology & imaging*, *27*(4), 517.

Bakris, G., Dickholtz, M., Meyer, P. M., Kravitz, G., Avery, E., Miller, M., ... & Bell, B. (2007). Atlas vertebra realignment and achievement of arterial pressure goal in hypertensive patients: a pilot study. *Journal of human hypertension*, *21*(5), 347-352.

Barit, A. *The doctrine of informed consent in South African medical law* (Doctoral dissertation, University of Pretoria). 2017

Beels, L., Bacher, K., De Wolf, D., Werbrouck, J., & Thierens, H. (2009). γ-H2AX foci as a biomarker for patient Imaging exposure in pediatric cardiac catheterization are we underestimating radiation risks?. *Circulation*, *120*(19), 1903-1909.

Bernat, J. L., & Peterson, L. M. (2008). Patient-centered informed consent in surgical practice. *Archives of Surgery*, *141*(1), 86-92. Paterick Timothy, Fuad Jan, Zachary Paterick, Jamil Tajik, Thomas Gerber (2012). Cardiac Imaging Modalities With Ionizing Radiation: The Role of Informed Consent. *JACC-Cardiovascular Imaging, 5(6):634-640.*

Bhupathi, P. A., & Ravi, G. R. (2017). Comprehensive format of informed consent in research and practice: a tool to uphold the ethical and moral standards. *International journal of clinical pediatric dentistry*, *10*(1), 73.

Bogduk, N. (2009). International Spinal Injection Society Guidelines for the Performance of Spinal Injection Procedures.: Part 1: Zygapophysial Joint Blocks. *The Clinical journal of pain*, *13*(4), 286-292.

Bourke, S. (2017). *The patient experience of musculoskeletal imaging: a mixed methods study* (Doctoral dissertation, University of Otago).

Brenner, J. M. (2009). *A cross-sectional study of the practice of obtaining informed consent for elective surgery at the Kenyatta National Hospital* (Doctoral dissertation, University of Nairobi, Kenya).

Brezis, M., Israel, S., Weinstein-Birenshtock, A., Pogoda, P., Sharon, A., & Tauber, R. (2008). Quality of informed consent for invasive procedures. *International Journal for Quality in Health Care*, *20*(5), 352-357.

Brink, J. A., Goske, M. J., & Patti, J. A. (2012). Informed decision making trumps informed consent for medical imaging with ionizing radiation. *Radiology*, *262*(1), 11-14.

Brotherton, W. (2008). *Business Research Methods* (8th edn) McGrawHill: New York.

Cervo, S., Rovina, J., Talamini, R., Perin, T., Canzonieri, V., De Paoli, P., & Steffan, A. (2013). An effective multisource informed consent procedure for research and clinical practice: an observational study of patient understanding and awareness of their roles as research stakeholders in a cancer biobank. *BMC medical ethics*, *14*(1), 30.

Cervo, S., Rovina, J., Talamini, R., Perin, T., Canzonieri, V., De Paoli, P., & Steffan, A. (2013). An effective multisource informed consent procedure for research and clinical practice: an observational study of patient understanding and awareness of their roles as research stakeholders in a cancer biobank. *BMC medical ethics*, *14*(1), 30.

Christopher Agulanna - (May 2008) Informed Consent in Sub-Saharan African Communal Culture: The "Multi-step" Approach. *Master's Thesis in Applied Ethics - Centre for Applied Ethics Linköpings universitet*

Commission, C. Q. (2012). *The state of health care and adult social care in England in 2011/12* (Vol. 763): The Stationery Office.

Cooper, D and Schindler, P. (2006) *Business Research Methods* (8th edn) McGrawHill: New York

Corbin, C., &Straussf, F. (2010). Patient-centered medicine: a professional evolution. *Jama*, *275*(2), 152-156.

Creswell, J.& Clark, V. (2007). *Designing and conducting mixed methods research.* Thousand Oaks: Sage Governmentations Inc

Davis, A. B. (2009). Informed Consent in Adult Psychiatry. *Oman Medical Journal*, 28(4), 228–231.

Dyer, P. (2011). [Computer-assisted knee arthroplasty: comparison with a conventional procedure. Results of 50 cases in a prospective randomized study]. *Revue de chirurgie orthopedique et reparatrice de l'appareil moteur*, *87*(1), 18-28.

F. (2011). Radiation doses in interventional radiology procedures: the RAD-IR study part I: overall measures of dose. *Journal of vascular and interventional radiology*, *14*(6):711-727.

Fireman, Z., Mahajna, E., Broide, E., Shapiro, M., Fich, L., Sternberg, A., ... & Scapa, E. (2013). Diagnosing small bowel Crohn's disease with wireless capsule endoscopy. *Gut*, *52*(3), 390-392.

Fishbein, M., & Ajzen, I. (1980). Belief, attitude, intention, and behavior: An introduction to theory and research.

Friedrich-Nel, H. (2015). Radiographers' opinion on patients' rights to informed consent: results of an online survey: peer reviewed original article. *South African Radiographer, 53(1), 27-32.*

Frizzell, J. (2014). Patient and Provider Views on Informed Consent for Cardiac Catheterization: A Pilot Study.

Frizzell, J. (2014). *Patient and Provider Views on Informed Consent for Cardiac Catheterization: A Pilot Study* (Doctoral dissertation).

Fry G., & Johnstone, L. (2012). Informed consent: study of quality of information given to participants in a clinical trial. *Bmj*, *303*(6803), 610-613.

Fusako Kitamura,* Atsuko Tomoda,† Kazumi Tsukada,‡ Makoto Tanaka,§ Ikuko Kawakami, i Shuuichi Mishima,§ and Toshinori Kitamura, Method for Assessment of Competency to Consent in the Mentally Ill- Rationale, Development, and Comparison with the Medically Ill, *International Journal of Law and Psychiatry, Vol. 21, No. 3, pp. 223–244, 1998 Copyright © 1998 Elsevier Science Ltd Printed in the USA.*

Garapati, K. (2015). College student understanding of informed consent terminology.

Ginsberg, M. (2014). Informed Consent and The Differential Diagnosis: How the Law Overestimates Patient Autonomy and Compromises Health Care, 60 Wayne L. Rev. 349 (2014).

Githui Donatus, Ethical Issues in Health Care in Kenya. A Critical Analysis of Healthcare Stakeholders; *Research Journal of Finance and Accounting www.iiste.org ISSN 2222-1697 (Paper) ISSN 2222-2847 (Online) Vol 2, No 3, 2011*

Gordon, E. J. (2000). When oral consent will do. *Field Methods*, *12*(3), 235-238.

Gotay, C. C. (2011). Accrual to cancer clinical trials: directions from the research literature. *Social science & medicine*, *33*(5), 569-577.

Hall, D. E., Prochazka, A. V., & Fink, A. S. (2012). Informed consent for clinical treatment. *Canadian Medical Association Journal*, *184*(5), 533-540

Hassar, M., & Weintraub, M. (2011). "Uninformed" consent and the wealthy volunteer: An analysis of patient volunteers in a clinical trial of a new anti- inflammatory drug. *Clinical Pharmacology & Therapeutics*, *20*(4), 379-386.

Helena Länsimies-Antikainen 2009, realization of informed consent in health Research*; kuopio university governmentations e. Social sciences 177*

Hope, N. (2005). Preoperative chemotherapy followed by surgery compared with primary surgery in resectable stage I (except T1N0), II, and IIIa non–small-cell lung cancer. *Journal of Clinical Oncology*, *20*(1), 247-253.

Hopper, K. D., TenHave, T. R., & Hartzel, J. (1995). Informed consent forms for clinical and research imaging procedures: how much do patients understand?. *AJR. American journal of roentgenology*, *164*(2), 493-496.

Hornby, A. S., Cowie, A. P., Gimson, A. C., & Hornby, A. S. (1974). *Oxford advanced learner's dictionary of current English* (Vol. 1428). Oxford: Oxford university press.

Jacob, K. S. (2014). Informed consent and India. *The National medical journal of India*, *27*(1), 35-38

Jallinoja, E., & Ward, P. (2012). Patient participation in decision-making. *Social science & medicine*, *47*(3), 329-339.

Karsli, T., Kalra, M. K., Self, J. L., Rosenfeld, J. A., Butler, S., & Simoneaux, S. (2009). What physicians think about the need for informed consent for communicating the risk of cancer from low-dose radiation. *Pediatric radiology*, *39*(9), 917-925.

Kendrick, D., Fielding, K., Bentley, E., Kerslake, R., Miller, P., & Pringle, M. (2001). Radiography of the lumbar spine in primary care patients with low back pain: randomised controlled trial. *Bmj*, *322*(7283), 400-405.

Kettle, N. M. (2002). Informed consent: its origins, purpose, problems, and limits.

Klazen, C. A. H., Verhaar, H. J. J., Lampmann, L. E. H., Juttmann, J. R., Blonk, M. C., Jansen, F. H., ... & Janssens, X. (2007). VERTOS II: percutaneous vertebroplasty versus conservative therapy in patients with painful osteoporotic vertebral compression fractures; rationale, objectives and design of a multicenter randomized controlled trial. *Trials*, *8*(1), 1.

Kothari, C. (2004). Research Methodology, methods and techniques. New Delhi: New Age international publishers.

Krogstad, D. J., Diop, S., Diallo, A., Mzayek, F., Keating, J., Koita, O. A., & Touré, Y. T. (2010). Informed consent in international research: the rationale for different approaches. *The American journal of tropical medicine and hygiene*, *83*(4), 743-747.

Länsimies-Antikainen, H. E. L. E. N. A. (1999). *Realization of informed consent in health research* (Doctoral dissertation, Doctoral dissertation, Kuopio University Publications E. Social Sciences, Kuopio, Finland).

Lazarus Jeffrey and France Tim (2014). *A new era for the WHO health system building blocks.*

Lee, D. H., Buth, K. J., Martin, B. J., Yip, A. M., & Hirsch, G. M. (2010). Frail patients are at increased risk for mortality and prolonged institutional care after cardiac surgery. *Circulation*, *121*(8), 973-978.

Ley, P. (2010). Satisfaction, compliance and communication. *British Journal of Clinical Psychology*, *21*(4), 241-254.

Makanjee, C. R., Bergh, A. M., & Hoffmann, W. A. (2015). Multiprovider and patient perspectives on conveying diagnostic imaging investigation results in a South African public health care system. *Journal of medical imaging and radiation sciences, 46(2), 197-204.*

Mathur, J.N., Press Manager, ICMR, New Delhi (2006) Ethical guidelines for biomedical research on human participants, *Indian council of medical research New Delhi 2006*

McKeague, M., & Windsor, J. (2003). Patients' perception of the adequacy of informed consent: a pilot study of elective general surgical patients in Auckland. *The New Zealand Medical Journal (Online)*, *116*(1170).

Medical Radiation Working Group (2015). *Towards appropriate use of diagnostic imaging: A guide for medical practitioners and their patients*, Cancer Council, West Australia.

Meredith, P. (1993). Patient participation in decision- making and consent to treatment: the case of general surgery. *Sociology of health & illness*, *15*(3), 315-336.

Michael N. Reynolds (2012), Promoting Understanding of Informed Consent, *Western Michigan University*, michael.reynolds@wmich.edu

Miller, D. L., Balter, S., Cole, P. E., Lu, H. T., Schueler, B. A., Geisinger, M., ... & Cardella, J.

Miller, V. A., Baker, J. N., Leek, A. C., Drotar, D., & Kodish, E. (2014). Patient involvement in informed consent for pediatric phase I cancer research. *Journal of pediatric hematology/oncology*, *36*(8), 635.

Miller, V. A., Baker, J. N., Leek, A. C., Drotar, D., & Kodish, E. (2014). Patient involvement in informed consent for pediatric phase I cancer research. *Journal of pediatric hematology/oncology*, *36*(8), 635.

Mugenda, A. & Mugenda, O. (2003). Research Methods; Qualitative and Quantitative Approaches. Nairobi: Acts.

Mungomba, B. (2011). Factors influencing patients' demand for imaging examinations in rural Kwa-Zulu Natal.

Muramoto, O. (2016). Informed consent for the diagnosis of brain death: a conceptual argument. *Philosophy, Ethics, and Humanities in Medicine*, *11*(1), 8.

Murray, G. B. (2011). Bowel ultrasound in assessment of Crohn's disease and detection of related small bowel strictures: a prospective comparative study versus x ray and intraoperative findings. *Gut*, *50*(4), 490-495.

Mwanamvua Boga1, Alun Davies1, Dorcas Kamuya1, Samson M. Kinyanjui1,2*, Ester Kivaya1, Francis Kombe1, Trudie Lang1,2, Vicki Marsh1,2, Bibi Mbete1, Albert Mlamba1, Sassy Molyneux1,2, Stephen Mulupi1, Salim Mwalukore1(September 2011)- Strengthening the Informed Consent Process in International Health Research through Community Engagement: The KEMRI-Wellcome Trust Research Programme Experience.

Naccache, R., Chevallier, P., Lagueux, J., Gossuin, Y., Laurent, S., Vander Elst, L., ... & Fortin, M. A. (2013). Imaging: high relaxivities and strong vascular signal enhancement for NaGdF4 nanoparticles designed for dual MR/optical imaging (Adv. Healthcare Mater. 11/2013). *Advanced healthcare materials, 2(11), 1477-1477*.

Nancy M. Kettle (2002), Informed consent: its origins, purpose, problems, and limits, *University of South Florida, nancy.kettle@gmail.com.*

Ngechu, T. (2004) Essentials of Educational and Social Science Research methods:

Nienaber, A. (2010). The regulation of informed consent to participation in clinical research by mentally ill persons in South Africa: An overview. *South African Journal of Psychiatry*, *16*(4).

Nijhawan, L. P., Janodia, M. D., Muddukrishna, B. S., Bhat, K. M., Bairy, K. L., Udupa, N., & Musmade, P. B. (2013). Informed consent: Issues and challenges. *Journal of advanced pharmaceutical technology & research*, *4*(3), 134.

Nusbaum, L., Douglas, B., Damus, K., Paasche-Orlow, M., & Estrella-Luna, N. (2017). Communicating risks and benefits in informed consent for research: a qualitative study. *Global qualitative nursing research*, *4*, 2333393617732017.

Owen, R. J., Ryan, E. A., O'Kelly, K., Lakey, J. R., McCarthy, M. C., Paty, B. W., ... & Shapiro, A. J. (2012). Percutaneous Transhepatic Pancreatic Islet Cell Transplantation in Type 1 Diabetes Mellitus: Radiologic Aspects 1. *Radiology*, *229*(1), 165-170.

Parmar, J. M., Brace, M. M., Bernard, G. R., & Masys, D. R. (2016). Assessment of perceptions of patients towards legal aspects of informed consent in medical practice. *Cell and tissue banking*, *9*(1), 55-65.

Picano, E. (2004). Sustainability of medical imaging. *Bmj*, *328*(7439), 578-580.

Picano, R. A. (2011). How doctors and patients discuss routine clinical decisions: informed decision making in the outpatient setting. *Journal of general internal medicine*, *12*(6), 339-345.

Pope, S. M. (2007). *Personal Assistants and Collaborative Decision Making: Promoting a Better Balance of Autonomy and Well-Being for Adults with Moderate, Mild, and Borderline Mental Retardation* (Doctoral dissertation, University of Pittsburgh).

Price, R. (2007). *Developing practice in radiography and diagnostic imaging* (Doctoral dissertation). procedures and participation in clinical research. *QJM: An International Journal of Medicine*, *104*(2), 151-159.

Pugh, J. (2020), Informed *consent, Autonomy, and beliefs- Autonomy, Rationality and contemporary bioethics*. Oxford University Press.

Rajesh, D. R., Abhishek, S., Mukul, C., Gaurav, S. P., Venkteshan, M., & Anu, B. (2013). Patient's awareness, attitude, understanding and perceptions towards legal nature of informed consent. *J Indian Acad Forensic Med*, *35*(1), 40-3.

Reynolds, M. N. (2012). Promoting Understanding of Informed Consent.

Riordan Fiona, Chrysanthi Papoutsi, Julie E. Reed, Cicely Marston, Derek Bell and Azeem Majeed (2015). Patient and public attitudes towards informed consent models and levels of awareness of Electronic Health Records in the UK. *Int J Med Inform. 84(4): 237–247.*

Sacristán, J. A., Aguarón, A., Avendaño-Solá, C., Garrido, P., Carrión, J., Gutiérrez, A., ... & Flores, A. (2016). Patient involvement in clinical research: why, when, and how. *Patient preference and adherence*, *10*, 631.

Sacristán, J. A., Aguarón, A., Avendaño-Solá, C., Garrido, P., Carrión, J., Gutiérrez, A., ... & Flores, A. (2016). Patient involvement in clinical research: why, when, and how. *Patient preference and adherence*, *10*, 631.

Sakas, G. (2002). Trends in medical imaging: from 2D to 3D. *Computers & Graphics*, *26*(4), 577-587.

Schenker Yael, Fernandez Alicia, Sudore Rebecca, Schillinger Dean.(2011). Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: A Systematic Review. *Med Decis Making. 2011(31):151–173.*

Sekaran, D. (2005). *A general guide to writing research proposal and report*: A handbook for beginning research: Kisumu: Options Printers and Publishers.

Shultz, M. M. (2010). From informed consent to patient choice: a new protected interest. *The Yale law journal*, *95*(2), 219-299.

Smith-Bindman R, Miglioretti DL, Johnson E, et al. Use of Diagnostic Imaging Studies and Associated Radiation Exposure for Patients Enrolled in Large Integrated Health Care Systems, 1996-2010. *JAMA.*2012; 307(22):2400–2409. doi:10.1001/jama.2012.5960.

Sohoni CA (2013). Medical negligence: A difficult challenge for radiology. *Indian J Radiol Imaging. 23(1):110-2.*

Souza Miriam, Carlos Jacob, Gama-Rodrigues Joaquim Zilberstein Bruno; Cecconello Ivan and Habr-Gama Angelita. (2013). The written informed consent form (WICF): factors that interfere with acceptance. *ABCD, arq. bras. cir. dig. vol.26 no.3 São Paulo July/Sept. 2013.*

Stecker, M. S., Balter, S., Towbin, R. B., Miller, D. L., Vañó, E., Bartal, G., ... & Gross, K. (2009). Guidelines for patient radiation dose management. *Journal of Vascular and Interventional Radiology*, *20*(7), S263-S273.

Stevenson, A. (Ed.). (2010). *Oxford dictionary of English*. Oxford University Press, USA.

Stewart, L. (2010). Nonsurgical transthoracic epicardial radiofrequency ablation: an alternative in incessant ventricular tachycardia. *Journal of the American College of Cardiology*, *41*(11), 2036-2043.

Sukumar, K. Patra, A., & Das, S. (2013). The Importance of Informed Consent in Medicine. *Sch. J. App. Med. Sci*., 2013; 1(5):455-463

Sulaiman, A. I., Ayyuba, R., Diggol, I. G., & Haruna, I. U. (2015). Knowledge, attitude and perception of patients towards informed consent in obstetric surgical procedures at Aminu Kano Teaching Hospital. *Nigerian Journal of Basic and Clinical Sciences*, *12*(1), 45.

Sumathipala, A., Siribaddana, S., Hewege, S., Lekamwattage, M., Athukorale, M., Siriwardhana, C., ... & Prince, M. (2008). Ethics Review Committee approval and informed consent: an analysis of biomedical publications originating from Sri Lanka. *BMC Medical Ethics*, *9*(1), 3.

Tam, N.T., Huy, N.T., Thoa, L.T.B., Long, N.P., Trang, N.T.H., Hirayama, K. & Karbwang, J. (2014). *Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis.*

Tavakoli, E. (2012). Informed consent and communication of risk from radiological and nuclear medicine examinations: how to escape from a communication inferno. *Lung*,*50*(500), 1000.

Thornton, R. H., Dauer, L. T., Shuk, E., Bylund, C. L., Banerjee, S. C., Maloney, E., ... & Hay, J. (2015). Patient perspectives and preferences for communication of medical imaging risks in a cancer care setting. *Radiology, 275(2), 545-552.*

Tshimanga Kalala (2011). *Patients' perceptions and understanding of Informed consent for surgical procedures.* University of Witwatersrand, Johannesburg.

Vučemilo, L., & Borovečki, A. (2015). Readability and content assessment of informed consent forms for medical procedures in Croatia. *PloS one, 10*(9), e0138017.

Weinstein, J. N., Clay, K., & Morgan, T. S. (2007). Informed patient choice: patient-centered valuing of surgical risks and benefits. *Health Affairs*, *26*(3), 726-730.

White, C. S., Mason, A. C., Feehan, M., & Templeton, P. A. (2010). Informed consent for percutaneous lung biopsy: comparison of two consent protocols based on patient recall after the procedure. *AJR. American journal of roentgenology*, *165*(5), 1139-1142.

WHO. (2010). *Monitoring the building blocks of health systems: A handbook of indicators and their measurement strategies.* World Health Organization: Geneva, Switzerland.

Windsor, J. (2013). Patients' perception of the adequacy of informed consent: a pilot study of elective general surgical patients in Auckland. *The New Zealand Medical Journal (Online)*, *116*(1170).

Worthington, L. O. (2011). Informed consent, cultural sensitivity, and respect for persons. *JAMA*, *274*(10), 844-845.

Yamamoto, H., Sekine, Y., Sato, Y., Higashizawa, T., Miyata, T., Iino, S., ... & Sugano, K. (2001). Total enteroscopy with a nonsurgical steerable double-balloon method. *Gastrointestinal endoscopy*, *53*(2), 216-220.

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APPENDICES

Appendix I: Consent explanation

Informed consent process for patients seeking medical imaging services in Public hospitals in Nairobi City County, Kenya

Dear Respondent

My name is Victoria Otysula Koi, a Lecturer at the Kenya Medical Training College, undertaking a master of health management, in the school of public health, department of health management and informatics, Kenyatta University. I am carrying out a study on informed consent process for patients seeking medical imaging services in government hospitals in Nairobi city county, Kenya

Purpose: The researcher is interested in patients seeking medical imaging services in order to determine the extent of usage of the Informed Consent process among patients, the Content of the patients Informed Consent Forms and the various modes of informed consent practices used among patients for medical imaging services in government hospitals.

Procedure: Kindly answer all the questions without consulting others. There is no right or wrong answers and your honesty is of great value to the researcher. If there are any questions about the study, such as how to fill the questionnaires or complains on the research project, please do not hesitate to call the researcher on 0722385997.

Risk/discomforts: There are no risks associated with participating in this research; your responses will only be available to the researcher. Your participation is completely voluntary and you have a right to withdraw from participation at any level of filling the questionnaire.

Confidentiality: Do not write any personal identification on the questionnaire. The responses you give to the questions will remain confidential and anonymous. All respondents' forms are coded and your responses will not be used to identify you. The information provided even if published will not be used to identify you in any way and hence anonymity is assured.

Researcher:

Victoria Otysula Koi (0722385997)

Master of health management student

School of public health, department of health management and informatics,

Kenyatta University

Supervisors:

1.Dr. Andrea Yitambe

Department of Health Management and Informatics

2.Dr. Peterson Warutere

Department of Environmental and Occupational Health

Reviewed by: KNH-UoN Ethics and Research Committee

TEL: 2726300 EXT 44102.

E-MAIL: uonknh erc@uonbi.ac.ke

Consent certificate

I do understand that there are no risks associated with participating in this research. I voluntarily give my consent to participate in this study.

Respondent Signature……. date……...

Researcher signature…… date……...

Thank you for taking the time to participate in this study.

Appendix II: Questionnaire

S/NO……...

IDENTIFICATION

Instructions: Please tick or fill Gaps where appropriate

Serial number …….Name of Hospital…….

Imaging procedure -

X-ray[ ]Ultrasound [ ]

CT scan [ ]MRI [ ] Other (specify) ……

SECTION A: DEMOGRAPHIC INFORMATION

1.Gender

Male [ ] female [ ]

2.Please indicate the highest level of education attained? (Tick as applicable)

No formal education[ ] Primary[ ]

Secondary[ ] College/ Tertiary[ ]

University[ ]

3.What is your age bracket? *(Tick where appropriate)*

18-20 years [ ] 21 – 30 years [ ]

31– 40 years [ ]41-50 years [ ] 51 and above [ ]

SECTION B:

4.To what extent do you agree with the following statements on informed consent? Use a scale of 1-5, where (1= strongly disagree, 2= disagree, 3= moderately agree, 4= Agree and 5= strongly Agree)

Informed consent	**1**	**2**	**3**	**4**	**5**
I was explained to why am referred to the imaging department					
I was told that I have a right to refuse or defer the imaging procedures					
I was requested to give my consent to treatment so that the procedure developed would concentrate on my prerogative and that of my family					
I acknowledged that informed consent that was taken from me before going for the imaging procedures					
Before the imaging, I had a poor understanding if the process exists despite being given opportunity to have their questions answered					
I had the unwillingness to hear bad news especially when it came to the risks associated with imaging procedures					
Informed consent has helped me be able to understand the benefits of imaging procedures					
Making decisions affecting my well-being has been easy					
My physician confirmed that he has given adequately informed consent					
Informed consent has enabled my family assist me in choosing between imaging procedure and other options					
The risks that come with imaging were disclosed before the procedure					
Pre-operative counseling was also given before imaging procedures					
Through informed consent i was able to understand the imaging procedure that I was to undergo					

5.To what extent do you agree with the following statements on patient diagnosis? Use a scale of 1-5, where (1= strongly disagree, 2= disagree, 3= moderately agree, 4= Agree and 5= strongly Agree)

Patient Diagnosis	**1**	**2**	**3**	**4**	**5**
a) The health practitioners performed a diagnosis from my past medical history					
b) In the process of diagnosis the health practitioners advised on potential benefits and risks that result due to imaging					
c) During diagnosis I was able to communicate about the nature of treatment with the health practitioners					
d) Health practitioners advised on other alternative treatment options					
e) Physical examination was done before other medication					

f)Practitioners disclosed all information that i considered important when making informed health care decisions					

6.To what extent do you agree with the following statements on legal foundations of informed consent? Use a scale of 1-5, where (1= strongly disagree, 2= disagree, 3= moderately agree, 4= Agree and 5= strongly Agree)

Legal Foundations	**1**	**2**	**3**	**4**	**5**
a)The legal system has adapted the informed consent doctrine to meet the needs of both physicians and patients					
b)The legal foundations has helped to examine how the law has evolved over time					
c)Legal foundations have helped to meet the needs of an evolving medical system					
d)I have had no cases of negligence claims from nurses and doctors in this hospital and failure to fulfill a duty to provide the sufficient information to make a personal medical decision					
e)I have not suffered the failure of doctors and nurses in providing the sufficient information to make a medical decision					
f)The treating doctor has always ensured that I fully understand all of the information that has been provided					

7.To what extent do you agree with the following statements on patient-centered informed consent processes? Use a scale of 1-5, where (1= strongly disagree, 2= disagree, 3= moderately agree, 4= Agree and 5= strongly Agree)

Patient-Centered Processes	**1**	**2**	**3**	**4**	**5**
a. There is very little information available explaining what that process should look like					
b. I was given forms that are used as a waiver to protect practitioners from litigation to enhance patient autonomy					
c. I signed some forms prior to initiating treatment					
d. There is a decision aid that provides objective information about all treatment options					
e. The hospital treats informed consent as a continuous process of dialogue as it was done before and after the					

treatment					
f. Each treatment option in the hospital helps in understanding the likelihood of benefits or harms occurring					
g. I am not aware of my individual rights during the imaging procedures					

COMMENTS

……

……

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……

……

END

Appendix III: Checklist

Content on the informed consent checklist		
Informed consent	**Yes**	**No**
a. Explanation to why patients are referred to the imaging department		
b. Option of having the right to refuse or defer the imaging procedures		
c. Requested to give consent to treatment so that the procedure developed would concentrate on my prerogative and that of my family		
d. Informed consent that was taken before going for the imaging procedures		
e. The risks that come with imaging disclosed before the procedure		
f. Pre-operative counseling was also given before imaging procedures		
Patient Diagnosis		
a) The health practitioners performed a diagnosis from past medical history		
b) Health practitioners advise on other alternative treatment options		
c) Physical examination was done before other medication		
Legal Foundations		
a) The legal system has adapted the informed consent doctrine to meet the needs of both physicians and patients		
b) The legal foundations examine how the law has evolved over time		
c) Legal foundations meet the needs of an evolving medical system		
Patient-Centered Processes		
a. Information available explaining what that process should look like		
b. Signing some forms prior to initiating treatment		

Appendix IV: Key Informant Interview Schedule

Identification

Instructions: Please tick or fill Gaps where appropriate

Name of Hospital…….

Position in the Hospital…….

Imaging procedure -

X-ray[ ]Ultrasound [ ]CT scan [ ]MRI [ ]

SECTION B:

1.Which of the following informed consent processes are being undertaken in the hospital when attending to the patients in the hospital

[ ]Entire informed consent

[ ]Patient diagnosis

[ ]Legal foundations

[ ]Patient centered processes

(Based on the responses above, you will move to the next questions)

2.What are some of the informed consent procedures do you go through with your patients?

[ ]Explaining to why the patients is referred to the imaging department

[ ]Requesting patients to give consent to treatment so that the procedure developed would concentrate on the prerogative and that of the patients' family

[ ]Informing them that patients have a right to refuse or defer the imaging procedures

[ ]Informed consent is taken from the patients before going for the imaging procedures

[ ]Others (Specify).....

3.What are some of the patient diagnosis procedures do you go through with your patients?

[ ]Performing a diagnosis from patients past medical history

[ ]In the process of diagnosis the patients are advised on potential benefits and risks that result due to imaging

[ ]Advising on other alternative treatment options

[ ]Conduct physical examination before other medication

[ ]Disclosing all information that the patients considers important when making informed health care decisions

[ ]Others (Specify)

……

……

……

4.What are some of the legal foundations of informed consent do you go through with your patients?

[ ]Disclosing all the legal aspects in place with regards to imaging procedures

[ ]Legal system adapted the informed consent doctrine to meet the needs of both physicians and patients

[ ]Others (Specify)

……

……

……

5.What are some of the patient-centered processes do you go through with your patients?

[ ]Giving forms that are used as a waiver to protect practitioners from litigation to enhance patient autonomy

[ ]Signing some forms prior to initiating treatment

[ ]Others (Specify)

……

……

……

_____END_____

Appendix V: Research authorization from Kenyatta University Graduate School

KENYATTA UNIVERSITY
GRADUATE SCHOOL

E-mail: dean-graduate@ku.ac.ke
Website: www.ku.ac.ke

P.O. Box 43844, 00100
NAIROBI, KENYA
Tel. 020-8704150

Our Ref: Q140/CE/28034/13 **DATE:** 18th October, 2017

Director General,
National Commission for Science, Technology
and Innovation
P.O. Box 30623-00100
NAIROBI

Dear Sir/Madam,

RE: RESEARCH AUTHORIZATION FOR MS. VICTORIA OTYSULA KOI – REG. NO. Q140/CE/28034/13

I write to introduce Ms. Victoria Otysula Koi who is a Postgraduate Student of this University. She is registered for M.HM. degree programme in the **Department of Health Management & Informatics.**

Ms. Koi intends to conduct research for a M.HM. thesis Proposal entitled, **"Investigation into Informed Consent in Medical Imaging in Selected Hospitals in Nairobi City County, Kenya."**

Any assistance given will be highly appreciated.

KENYATTA UNIVERSITY * OFFICE OF DEAN * GRADUATE SCHOOL * P.O. BOX 43844 00100 NAIROBI * 23 OCT 2017

Yours faithfully,

For **MRS. LUCY N. MBAABU**
FOR: DEAN, GRADUATE SCHOOL

EM/cww

Appendix VI: Ethical clearance from KU Ethics and Review Committee

KENYATTA UNIVERSITY
GRADUATE SCHOOL

E-mail: dean-graduate@ku.ac.ke
Website: www.ku.ac.ke

P.O. Box 43844, 00100
NAIROBI, KENYA
Tel. 020-8704150

Internal Memo

FROM: Dean, Graduate School **DATE:** 18th October, 2017

TO: Victoria Otysula Koi
C/o Department of Health Management & Informatics
REF: Q140/CE/28034/13

SUBJECT: APPROVAL OF RESEARCH PROPOSAL

We acknowledge receipt of your Research Proposal after fulfilling recommendations raised by the Graduate School Board of **6th September, 2017.**

You may now proceed with your Data collection, subject to clearance with the Director General, National Commission for Science, Technology & Innovation.

As you embark on your data collection, please note that you will be required to submit to Graduate School completed Supervision Tracking Forms per semester. The form has been developed to replace the Progress Report Forms. The Supervision Tracking Forms are available at the University's Website under Graduate School webpage downloads.

Thank you.

KENYATTA UNIVERSITY OFFICE OF DEAN 23 OCT 2017 GRADUATE SCHOOL P.O. Box 43844-00100 NAIROBI

ELIJAH MUTUA
FOR: DEAN, GRADUATE SCHOOL

CC. Chairman, Department of Health Management & Informatics

Supervisors:

1. Dr. Andre Yitambe
   C/o Department of Health Management & Informatics
   Kenyatta University
2. Dr. Peterson Warutere
   C/o Department of Environmental and Occupational Health
   Kenyatta University

EM/cww

Appendix VII: Research authorization from NACOSTI

NATIONAL COMMISSION FOR SCIENCE,
TECHNOLOGY AND INNOVATION

Telephone:+254-20-2213471,
2241349,3310571,2219420
Fax:+254-20-318245,318249
Email: dg@nacosti.go.ke
Website : www.nacosti.go.ke
When replying please quote

NACOSTI, Upper Kabete
Off Waiyaki Way
P.O. Box 30623-00100
NAIROBI-KENYA

Ref: No. **NACOSTI/P/18/33369/25074**

Date: **15th September, 2018**

Victoria Otsyula Koi
Kenyatta University
P.O. Box 43844-00100
NAIROBI

RE: RESEARCH AUTHORIZATION

Following your application for authority to carry out research on ***"Investigation into informed consent in medical imaging in government hospitals in Nairobi City County, Nairobi, Kenya"*** I am pleased to inform you that you have been authorized to undertake research in **Nairobi County** for the period ending **13th September, 2019.**

You are advised to report to **the County Commissioner and the County Director of Education, Nairobi County** before embarking on the research project.

Kindly note that, as an applicant who has been licensed under the Science, Technology and Innovation Act, 2013 to conduct research in Kenya, you shall deposit **a copy** of the final research report to the Commission within **one year** of completion. The soft copy of the same should be submitted through the Online Research Information System.

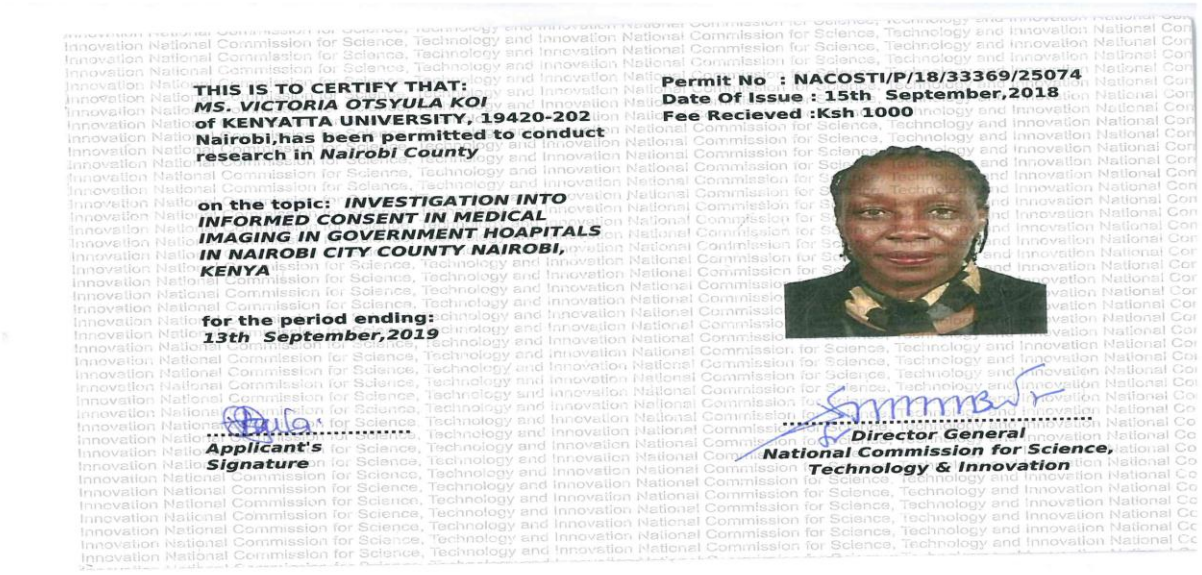
BONIFACE WANYAMA
FOR: DIRECTOR-GENERAL/CEO

Copy to:

The County Commissioner
Nairobi County.

The County Director of Education
Nairobi County.

Appendix VIII: Research permit from National Council for Science, Technology and Innovation



THIS IS TO CERTIFY THAT:
MS. VICTORIA OTSYULA KOI
of KENYATTA UNIVERSITY, 19420-202
Nairobi,has been permitted to conduct
research in *Nairobi County*

on the topic: *INVESTIGATION INTO INFORMED CONSENT IN MEDICAL IMAGING IN GOVERNMENT HOAPITALS IN NAIROBI CITY COUNTY NAIROBI, KENYA*

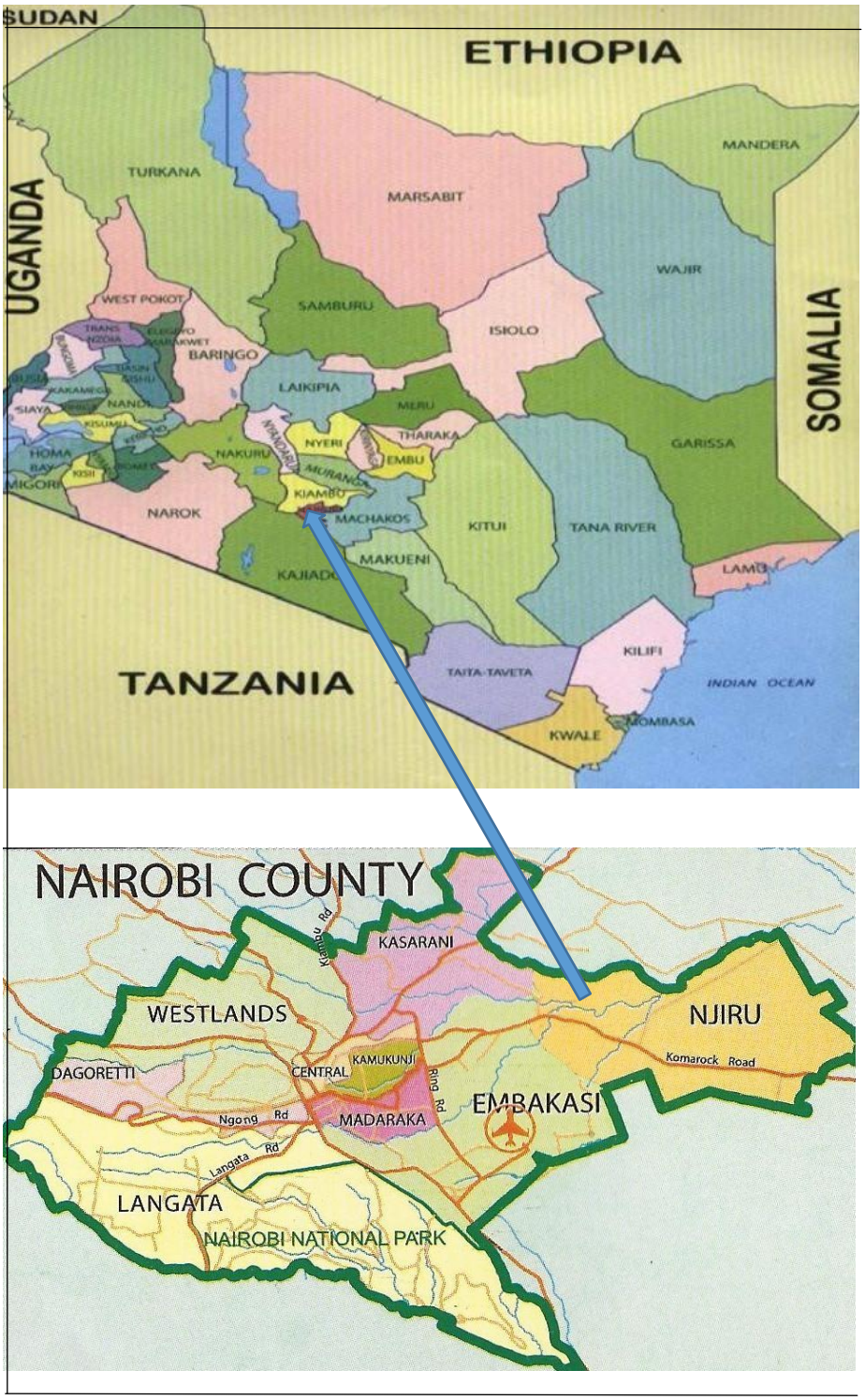
for the period ending:
13th September,2019

Permit No : NACOSTI/P/18/33369/25074
Date Of Issue : 15th September,2018
Fee Recieved :Ksh 1000

.....
Applicant's Signature

.....
Director General
National Commission for Science, Technology & Innovation

Appendix IX: A map of Kenya showing Nairobi City County



Source: https://www.googlemaps.com