

EMPIRICAL INVESTIGATION ON THE CONTENTS OF THE PATIENTS INFORMED CONSENT FORMS FOR MEDICAL IMAGING SERVICES IN THE GOVERNMENT HOSPITALS IN NAIROBI CITY COUNTY, KENYA

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ABSTRACT

Informed consent is a requirement by the 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 vary across medical procedures. The study therefore seeks to assess the contents of the patients Informed Consent Forms for medical imaging services in the 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. Patients in the imaging departments of the selected hospitals were recruited for 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 SPSS. 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. 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 majority of the domains of the contents of informed consent had a significant statistical association with administration of informed consent among respondents. 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.

Key Words: *Assess, Extent, Informed consent, Imaging, Medical imaging procedures*

INTRODUCTION

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. 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 during information sharing between patient and physician is a core characteristic. According to American Psychological Association, APA., (2002) 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, 2009). 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, in Kenya emphasis is made on pre-operative counseling through written or verbal modes, counseling is important in Kenya to prepare the patient to undergo certain procedures (Gotay, 2011). It ensures that the patient understands the disease that they have and the procedure that they will undergo. It helps the patient understand the disease suffering from and the procedures to be carried out. A signed consent represents the completion of counseling and the full understanding of the disease by the patient. It ensures complete autonomy.

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). However, there are several researches and reports which indicate that the informed consent has not been used in most medical experiments (Bhupathi et al., 2017).

Muthoni (2012) did a cross-sectional study of the practice of obtaining informed consent for elective surgery at the Kenyatta National Hospital. Finding indicated that only 8.8% of the patients interviewed were informed on alternatives to the proposed mode of treatment. Of these patients, 92.2% were not informed on any benefits and possible risks associated with the alternative modes of treatment. Of the patients 83.4% were not informed on any alternative forms of anaesthesia. While, 59.4% of the patients understood the information provided during the pre-operative counseling and 78.4% of the patients interviewed felt satisfied with the current process of obtaining informed consent at the Kenyatta National Hospital. The study concluded that current practice of obtaining informed consent addressed certain aspects of informed consent such as nature and indication for surgery but patients were inadequately informed on complications related to surgery and anaesthesia alternative forms of treatment and their risks and benefits.

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 (Maisel, 1977). 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.

MATERIALS AND METHOD

Study Area

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.

Study 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).

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.

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 drawn from total number of patient within four months. Thus, the formula by Manor et, al. 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).

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

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 using the following formula:

Selected sample size in each hospital = $\frac{\text{Population size in the selected hospital (N)} \times \text{sample size}}{\text{Total population size (N)}}$

For example Kenyatta National Hospital

Selected sample size in each hospital = $(358/1020) \times 307$
= 108

For other hospitals the same was replicated and the sample sizes were as shown below.

Research Instruments

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

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.

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. 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.

RESEARCH RESULTS

Content of the Patients Informed Consent Forms for Medical Imaging Services

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; 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.

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 from majority 189 (85.1%) of the respondents there was a statistical significant association between being explained to why one was referred to the imaging department and administration of informed consent ($\chi^2=26.081$; $df=1$; $p=0.001$). Most, 56 (75.7%) of the respondents showed an association between being told that one had a right to refuse or defer imaging procedures and administration of informed consent ($\chi^2=33.468$; $df= 1$; $p=0.001$).

The results revealed that majority 180 (81.1%) of the respondents showed a 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 ($\chi^2=70.733$; $df= 1$; $p=0.001$). The results showed that 163(73.4%) of the respondents revealed 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 ($\chi^2=13.896$; $df= 1$; $p=0.002$).

Concerning the respondents' unwillingness to hear bad news, 47(63.5%); of the respondents revealed that there was no statistical association between being unwilling to hear bad news especially the risks associated with imaging procedures and administration of informed consent ($\chi^2=0.079$; $df= 1$; $p=0.779$). Majority 183(82.4%) of the respondents showed an association between informed consent helping one to understand the benefits of imaging procedures and being administered with the informed consent ($\chi^2=5.018$; $df= 1$; $p=0.025$).

Majority 186(83.8%) of the respondents showed a significant statistical association between making decisions affecting their well-being easy and administration of informed consent ($\chi^2=5.280$; $df= 1$; $p=0.022$). Regarding physician confirming that he had given adequately informed consent, results from 171(77.0%) of the respondents revealed an association between physician confirming that he or she had given adequate informed consent and being administered with informed consent ($\chi^2=26.181$; $df= 1$; $p=0.001$).

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 ($\chi^2=12.056$; $df=1$; $p=0.001$). Majority 47(63.5%) of the respondents showed no association between the risks that come with imaging being disclosed before the procedure and administration of informed consent ($\chi^2=5.524$; $df= 1$; $p=0.059$). Majority 156(70.3%) of the respondents revealed an association between informed consent

making them understand imaging procedure and being administered with informed consent ($\chi^2=21.006$; $df= 1$; $p=0.021$).

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; 221 (74.7%) of the participants revealed that the legal foundations had helped to examine how the law has evolved over time; 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; 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; 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.

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 showed 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 ($\chi^2=7.648$; $df= 1$; $p=0.006$). Most 49(66.2%) of the respondents revealed no statistical association between the legal foundations helping the respondents examine how the law has evolved over time and administration of informed consent ($\chi^2=3.720$; $df=1$; $p=0.054$).

Majority 176(79.3%) of the respondents revealed a significant statistical association between the legal foundations helping them to meet the needs of an evolving medical system and administration of informed consent ($\chi^2=8.673$; $df=1$; $p=0.003$). Most 199 (89.6%) of the respondents showed that 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 ($\chi^2=22.414$; $df=1$; $p=0.001$).

From the results, 206 (92.8%) of the respondents revealed 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 ($\chi^2=18.156$; $df=1$; $p=0.001$). Most 179(80.6%) of the respondents showed 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 ($\chi^2=4.394$; $df=1$; $p=0.036$).

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; 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; 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; 226 (76.4%) of the respondents said that physical examination was done before other medication; 208 (70.3%) of the respondents reported that practitioners disclosed all information that they considered important when making informed health care decisions.

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 exhibited an association between health practitioners performing a diagnosis from their past medical history and administration of informed consent ($\chi^2=9.788$; $df=1$; $p=0.002$). More than half 133 (59.9%) of the respondents revealed 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 ($\chi^2=4.401$; $df=1$; $p=0.036$).

Majority 157 (70.7%) of the respondents showed the existence of 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 ($\chi^2=14.882$; $df=1$; $p=0.001$). Results showed that 135(60.8%) of the respondents revealed a significant statistical association between health practitioners advising on other alternative treatment options and administration of informed consent ($\chi^2=8.065$; $df=1$; $p=0.005$).

Majority 179(80.6%) of the respondents showed an association between physical examination being done before other medications and administration of informed consent ($\chi^2=9.006$; $df=1$; $p=0.003$). Most 171(77.0%) of the participants revealed a statistical association between disclosure of all information considered important when making informed health care decisions and administration of informed consent ($\chi^2=19.406$; $df=1$; $p=0.001$).

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.

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 showed no statistical association between information explaining what the process should look like being little and administration of informed consent ($\chi^2=0.091$; $df= 1$; $p=0.762$). Most 47(63.5%) of the respondents revealed 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 ($\chi^2=2.845$; $df= 1$; $p=0.092$).

Half 112 (50.5%) of the respondents showed no significant statistical association between having signed some forms prior to initiating treatment and administration of informed consent ($\chi^2=2.822$; $df= 1$; $p=0.093$). Slightly more than half 117 (52.7%) of respondents revealed no association between a having decision aid that provided objective information about all treatment options and administration of informed consent ($\chi^2=2.595$; $df=1$; $p=0.107$). Results showed that 160(72.1%) of the respondents revealed 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 ($\chi^2=0.544$; $df= 1$; $p=0.461$).

160 (72.1%) of the respondents revealed no statistical association between each treatment option helping respondents to understand the likelihood of benefits or harms occurring and administration of informed consent ($\chi^2=0.917$; $df= 1$; $p=0.338$). Most 56(75.7%) of the respondents showed no significant association between awareness on the individual's rights during imaging procedures and administration of informed consent ($\chi^2=2.305$; $df=1$; $p= 0.129$).

DISCUSSION

Regarding the content of general informed consent for medical imaging services among the respondents, the results a statistical association between administration of informed consent and explanation on reasons for medical imaging. 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. The results were in agreement with another study done among musculoskeletal patients seeking medical imaging services (Bourke, 2017).

The results revealed a significant statistical association between understanding the existence of the process and actual administration of informed consent. 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. The results were similar to another study done by Bourke (2017) which revealed that consent for medical imaging has more benefits than 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. 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 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). 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. 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. This contradicts with a research 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. From the findings, informed consent was implemented as a continuous process rather than just a onetime instance. 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.

CONCLUSION AND RECOMMENDATIONS

The results conclude that 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. The study recommends that 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. Further, a comparative study should to compare the process of informed consent for medical imaging between public and private hospitals in Nairobi City County Kenya.

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