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Study of Current Practices on Hospital Waste Management and Some of its Effects on Human Health in Kenya

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Abstract: Control of hospital environment is key to success of healthcare quality. Increasing emergence and spread of pathogenic bacteria is of great concern and continues to challenge infection prevention and epidemiology practice. This study aimed at providing information about the management of hospital environment and wastes in selected hospitals in Kenya namely Kenyatta National hospital and Referral (KNH, Public) and Kikuyu Mission Hospital (KMH- Private), the period of March 2020 to June 2020. Both are within similar locality. Simple random sampling was used to distribute a semi structured questionnaire among 246 health workers in each of the hospitals to capture data on management of hospital waste. Results from the study revealed that healthcare facilities whether public or private practiced inappropriate medical wastes management skills. The current practices are inappropriate due to lack of proper facilities and information of the individuals concerned.

Keywords: Hospital Waste, Management, Current Practice, Comparison Study.

Research Paper

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INTRODUCTION

Hospital acquired infections are also called nosocomial infection. It is an infection acquired in hospital by a patient who was admitted for a reason other than that infection (Medubi *et al*., 2006). Nosocomial pathogens are organisms causing diseases that are acquired from the hospital and healthcare environment within few days of admission and are responsible for nosocomial infections (Medubi *et al*., 2006).

Hospital waste means any solid, fluid or liquid waste materials including its container and other product generated during short term healthcare consisting observational, diagnostic, therapeutic and rehabilitative services for a person suffering from diseases or injury and during research testing and immunization of human beings (Jayanthi, 2014). Improper handling and management of the hospital waste is also an important cause of nosocomial infections. Proper management means proper collection, segregation, storage, transportation, treatment and disposal of waste in safer manner to prevent nosocomial or hospital acquired infection (Dwivedi and Pandey, 2008). Research studies shows that in developed countries a system of waste disposal that is able to ensure proper sorting at the source and disposal has been developed. In Africa such facilities lack, medical waste is mixed from collection to disposal (WHO, 2005) in addition to lack of awareness among personnel. In Kenya, mismanagement of hospital waste (HW) or medical waste (MW) is due to insufficient medical equipment's and facilities, hence need to recycle, lack of enforcement of legislation for handling, treatment and disposal. The purpose of the study was to establish the level of knowledge in management of MW and current practices, characterize bacteria present, their susceptibility to antibiotics and detect resistant genes in order to explain the risks associated with poor MW management.

MATERIALS AND METHODS

Study Site

This research study was carried out among eligible healthcare workers working in the two various hospitals within the Nairobi City and surrounding county, Kiambu in the period of March 2020 to June 2020. The hospitals were conveniently classified based on their ownership (public or private) and the diversity of their facilities and services rendered. The research study site included Kenyatta National Hospital (KNH) situated in Nairobi County and PCEA Mission Hospital, Kiambu County. Kenyatta National Hospital was chosen due to the fact that it's the largest public teaching and referral hospital in Kenya. The PCEA Kikuyu Mission Hospital (KMH) represented a private eye referral

hospital serving Kiambu County and surrounding counties. The study participants included health workers who were involved in medical waste management in their service and currently working within the two health facilities.

Inclusion Criteria

All the health care providers' who gave consent to participate, those working in the health-care establishments of KNH and KMH, those directly involved in hospital waste management process and surfaces and sites that were located in selected hospital departments of the study.

Exclusion Criteria

Hospital staff handling wastes and surfaces/sites that were under isolation within the selected hospital departments and surfaces that were not in close contacts with healthcare personnel's in their line of service e.g. roof tops and ceilings.

The sample size was determined based on a prevalence of population estimated to be at risk (0.20) which is the 20% of health workers at risk in Kenya, (WHO, 2002). The sample size was calculated using the Fischer's *et al.,* 1998 formulae.

$n = z^2/p\ (1-p)/d^2$ where,

n = Total sample population,

z = score of confidence interval (1.96 at 95% C.I),

p= Prevalence of population estimated to be at risk (0.20) which is the 20% of health workers at risk in Kenya, (WHO, 2002).

d = tolerable error (5%)

$n = z^2\ /p\ (1-p)/d^2 = 1.96^2$ x0.20 x $(1-0.20)/0.05^2 =$ 246 respondents

Questionnaire on Current Practices of Medical Waste Management

A structured questionnaire (Appendix) was used to collect the data with consent from respondents. Questionnaires had questions on current practices included segregation, color coding, storage and transportation, labeling, treatment and disposal, records of the wastes, final waste disposal among others. About 246 respondents were interviewed from each hospital from the calculated sample size. Observation checklist was used based on Kenya Ministry of Health medical waste management policy and guided by literature.

Data Management and Analysis: Data was presented using tables. Data was entered into a Microsoft® Excel spread sheet.

Ethical Consideration and Recruitment of Participants

Enrollment to the study was on voluntary basis. Scientific approval of the study was obtained from Kenyatta National Hospital Ethics and Review Committee Permit Number P730/12/2014 reference number KNH/UON ERC/A/169 (Appendix C i). Ethical clearance to carry out the study was obtained from KNH and KMH hospitals administration (Appendix C (ii) Approval letters). All procedures were carried out in accordance to the standard biosafety guidelines and waste disposal (WHO, 2014). Informed consent was obtained from the participants and the information collected was in confidence. There were no monetary gains for those who participated in the study and there were no penalties for those who declined participation.

RESULTS

The questionnaire respondents and observation checklist on the current practices on hospital waste management collection, storage, segregation transport, treatment and disposal in both hospitals had the following results (Table 1).

Awareness on practices on medical waste management from generation to disposal scored in most cases was more than 50% which was above average in the questionnaires while from observation during field trip in the hospitals showed that the practices were poorly implemented.

In generation of hospital waste, it was observed that, weighing records for the hospital waste in both hospitals was practiced, and that the records were well maintained however this was not done regularly. KNH recorded over 1000kg daily while KMH had between 90-300kg daily (from hospital data records, unpublished data).

Table 1: Current practices on issues of MW management

Practice	Description	Expected correct answer according to WHO standards	KNH (Yes/positive response)	KMH (Yes/positive response)
Segregation	Place where it takes place (point of generation)	in wards	99(40%)	98(48%)
	Containers marke Biohazard symbol	in both hospitals the containers were health care waste containers, with plastic bags inside	241(98%)	148(60%)
	Correct colour coding of infectious bin	Red	172(70%)	167(68%)
Collection	how often is the collection from the ward	Daily	241 (98%)	226(92%)

	Use of protective clothing's by waste handlers gloves, masks, gumboots	Yes	244(99%)	234(95%)
Storage of MW	Knowledge of location	Yes	near main gate	inside near laundry room away from busy places
		Located inside hospital premises	234(95%)	241(98%)
	Presence of a special equipment for sharp waste and an efficient storage facility		221 (90%)	172 (70%)
Treatment	Does it occur in the hospital premises		Yes212 (86%)	No 236(96%)
Transport	By use of			
	a) open tractors		(192, 78%)	180(73%)
	b) private licensed van		open tractors	private licensed van
Disposal	Incinerator	Yes	177(72%)	197(80%)
Problems faced by waste management staffs in the hospitals	Those who have experienced a hospital waste health related problem in their line of duty	Yes	108(44%)	32(18%)
	Those who have experienced problems like	Respiratory	60(56%)	20(64%)
		eye problems	5(5%)	3(8%)
		skin rashes	27(25%)	8(25%)
		cuts/piercing/bruises	13(12%)	1(3%)
		all of them	3(2%)	0(0%)

Performance according to various steps of hospital waste management current practices as practiced by the various health workers in the two selected hospitals: the steps include segregation, collection, storage, treatment, transport, disposal and problems faced by waste management health workers.

Segregation of hospital waste took place during the time of collection and was done by waste handler/cleaner. Generation of MW according to 99 (40%) KNH response and 98 (39.83%) KMH and was mostly in the wards (Table 4.5). In KNH, MW plastic containers and bags that were used were marked with international biohazard symbols. This hospital was compliant with OSHA standards and plastic containers were labeled but in KMH it was not according to OSHA standards with complete lack of international biohazard sign. The correct color coding (red) of the infectious MW bin was known by most health workers' professionals (KNH, 70% and KMH, 68% (Table 1, Photograph 1).

Collection of hospital waste took place from the wards in both hospitals. The use of protective devices such as gloves, masks and gumboots was recorded as being used and practiced in both hospitals.

In KNH storage area was protected from unauthorized entry with a secured gate, while in KMH there was unrestricted entry. Both storage facilities were not marked with biohazard symbol at the time of study. It was observed that after the container for hospital waste fills it was removed and replaced by another one immediately such that, there were no spill over in both hospitals. In some instances, there were spill overs depending with the quantity of work per day. Storage time of hospital waste in the containers before replacing was about 6 hours in both hospitals (Photograph 2).

Treatment of medical waste was in the hospital premises at least according to KMH majority (96%) of the respondents who knew treatment did not take place in the hospital premises (Table 1). In KNH treatment of MW took place in the storage area located in the hospital premises (86%), where there was an incinerator while at KMH there was no incinerator and hospital waste was collected by a licensed private company. Offsite treatment of medical waste was permitted in both hospitals. In case of offsite treatment, the person responsible for disposal was supposed to obtain a disposal site receipt to ensure it was disposed to the right place however none of these receipts was available at least during the research period.

Photograph 1a: Photographs indicating different stages of the research study

Different color coded containers in KNH clearly marked with the international biohazard symbol.

Photograph 1b: KMH MW containers not labeled with international biohazard symbol

Photograph 2a: MW in a temporally storage area in KNH

Photograph 3a: KNH dumpsite area

Photograph 2b): KMH temporal storage area

Photograph 3b: Dumpsite in a Nairobi area with people selecting some items from hospital waste garbage.

Quality control process for hospital waste management was noted to be once per year in KNH hospital while it was completely absent in KMH hospital. Tracking system for the medical waste from generation to disposal was completely lacking in both health establishments. The person responsible for medical waste management at the time of study was a housekeeper with a diploma in housekeeping at KMH,

while at KNH there was an infection control officer in charge of medical waste management who was a qualified doctor. It was observed that a hand washing facility in every working station was evident in KNH but unavailable in KMH.

Transportation- KNH transported the hospital waste by use of wheeled trolleys from the wards then open tractors to the disposal area. The tractors were not marked with the international biohazard symbols. At the disposal site they possessed a licensed permit with written operating plan for handling and transport of MW. At KMH MW was transported using unlabeled international biohazard symbol wheeled trolley from the ward to the temporal disposal site. In this hospital, the private company responsible for disposal is licensed and used a closed van labeled with international biohazard symbol however it lacked the written operating plan for handling and transport of MW as required in the international standards.

The budgetary allocation of the medical waste management and incinerator at KNH was about Kenya shillings 1-1.5 million each month, while the budgetary allocation at KMH was of about Kenya shillings 100,000 to Kenya shillings 600,000 each month. This cost varied with the amount of MW generated from time to time. In this study, it was observed that there were no properly constructed landfills and ash pits, there was indiscriminate release of toxic pollutants. It was observed that spent syringes, sharps, needles, medicine bottles, bloody bandages etc. were recovered in city garbage though the source of the hospital was unknown as there was no indicator (Photograph 3). The results from this study revealed that healthcare worker faced various problems during their day today activities in line with the process of waste management. Some of the illnesses that the respondents identified during the research study included respiratory problems eye problems, skin rashes, cuts/piercing/bruises and a combination of all the problems (Unconfirmed data from the hospital sources).

DISCUSSION

Poor health care waste (HCW) practices from generation to disposal pose great health risks for the health workers, patients, waste handlers, scavengers and the community (Johannessen *et al.,* 2000). Results from the current study indicated that record keeping and weighing of medical waste took place in both hospitals, however, health workers need to be encouraged to update the records daily and regularly. From the results it was found that KNH recorded over 1000kg daily while KMH had between 90-300kg daily of medical waste. The amount of waste generated in hospitals depended upon various factors; such as number of beds, types of health services provided, economic, social and cultural status of the patients and the general condition of the area where the hospital was situated (Askarian *et al.,* 2004), this could be the reason why KNH had more medical waste.

Segregation reduces the amount of waste and needs special handling and treatment (Sreegri and Babu, 2009). Data from the questionnaire and observation check list from the current study indicated that, segregation of MW took place in the ward with KNH (40%) and KMH 98(39.8%) and that it was done by cleaners. It was further revealed that the hospitals used plastic containers (Appendix E i and ii). Some containers were marked with international biohazard symbol (KNH), while others were not (KMH). Practices of high priority to segregation from source of infectious waste and sharp wastes by use of color coding system were used in KNH and KMH. It was observed that there was no uniformity in color coding of hospital waste in both hospitals. Despite the commendable level of segregation of medical waste currently achieved in the hospitals, media revealed that segregated medical waste are sometimes mixed together by collectors either at the point of collection or at the dumpsites as revealed by the researcher through the media (Appendix E, vi). The whole mixed volume therefore could be considered as being infectious which poses serious risks to the general public as recommended by WHO, 2005. Poor segregation and waste storage if not well managed allows easy access to scavengers hence high infection rates of diseases (Fayez *et al*., 2008). The hospitals basically separate hospital waste from general waste stream at the waste production points Therefore, they are stored and disposed of separately. However, the hospital did not segregate medical waste into different categories. In the wards, doctors and nurses who used sharps were required to drop them into different containers, but this was not diligently followed hence the low level of awareness on segregation point in the current study. KMH hospital did not label infectious waste with a biohazard symbol, no control measures existed for the management of these wastes. Separation of medical waste and general waste was however practiced to a fair extent. WHO rules demand that, hospitals have to provide plastic bags and strong plastic containers for infectious waste such as empty containers of antiseptics used in the hospitals (UNEP, 2000). In relation, bags and containers for infectious waste should be marked with a biohazard symbol (Nwachukwu *et al.,* 2013). Results from this study under practices revealed that infectious wastes bins color red was the type of waste that the study population was most aware according to 172, 70% for KNH and 167, 68% KMH respectively The black color bin waste for general waste scored a low percentage right after the red color at 69, 28% (KNH) and 74, 30% (KMH) while the yellow bin for anatomical waste was the type of color code which was known by the minority i.e. 2% in both hospitals. This could be because the red color was what they would encounter often as opposed to the chemical; genotoxic wastes supposed to be in the yellow color. There was no harmony in the allocation of color codes for the different wastes categories in both hospitals and

this is similar to the findings in a study done in Lagos (Longe and Williams, 2006). Waste segregation is poorly conducted in these facilities, yet rigorous segregation would minimize wastes, pollutant emissions and allow for recycling. It was noted that the only wastes that were properly segregated in both facilities were sharps. These were placed in rigid containers separate from all the other categories of wastes.

It should be noted that with proper segregation of medical waste reduces the cost of treatment and disposal as 80% of a hospital waste is general waste, which does not require special treatment, provided it is not contaminated with other infectious waste.

The collection of medical waste involved use of different types of containers from various sources like operation theatre, wards and kitchen etc. in this study. From the observations made in this study there was also a routine schedule for the collection of medical waste in KNH and it was done daily unlike in KMH where it was not regularly done. Hospital wastes generated in the hospitals was collected daily and transported to a temporary storage area by hospital's staff according to (241, 98%) for KNH and (226, 92%) for KMH. This is in line with a survey done in 2007 by the government of Kenya on hospital waste management in various hospitals, results indicated that the frequency of collection of waste in most hospitals was done once daily (MOH, 2007). In addition, the MOH 2007 survey revealed that hospitals visited were found to have refuse storage areas/rooms. In some of these hospitals, unused rooms, some with leaking roofs were used to store waste. Use of protective clothing by waste handlers during collection scored highly, with (KNH, 244, 99%) and (KMH, 234, 95%). This was not similar to a study in India that revealed that 22.92% of the respondent was aware that the wearing personal protective equipment minimizes sharp injuries (Nwachukwu *et al.,* 2013). It is important to note that the lack of suitable and sufficient protective equipment, incorrect usage of equipment and the lack of pertinent understanding of the personnel regarding the benefits of using protective equipment exposes personnel to serious dangers (MOH, 2007).

The place where the hospital waste was stored before transporting to the final disposal site was termed as a temporary waste storage area. In this study most health personnel knew the exact location of medical waste temporal storage. From the researcher's observation KNH had a well secured but poorly sanitized temporary storage area while KMH had unsecured and not sanitized storage area. This contradicts with the study done by Nwachukwa *et al*., 2013, who revealed that temporal storage place for medical waste must be well sanitized and secured for easy access for staff in charge of handling the waste and secured to prevent access for animals, insects and birds. A similar study done in South Africa at Tygerberg Hospital to assess the hospital waste management practices, results indicated that they had a well secured but poorly sanitized temporary storage area (Leonard, 2004).

In both hospitals the medical waste was emptied after every six to eight hours at KNH and about twenty-four hours of temporal storage. Bins and sharps containers were disposed when three quarters to full capacity in most occasions. This is similar to study conducted in India where a descriptive study was conducted to assess the knowledge on preventive practice regarding needle stick injuries among ninety-six staff nurses at Mangalore (Sristhi, 2000). KNH had its medical waste containers properly labeled with an international biohazard symbol unlike KMH hospital. WHO standards 2007 requires that segregated wastes of different categories need to be collected in identifiable containers, the duration of storage should not exceed for 8-10 hours in big hospitals (more than 250 beds) and 24 hours in nursing homes. It was paramount that container may be clearly labeled to show the ward or room where it was kept. The reason for this labeling was that it may be necessary to trace the waste back to its source (Nwachukwa *et al*., 2013).

During the study, it was observed that KNH used incineration as the main method for the treatment of hospital waste especially infectious and sharp wastes for the hospital, however in a period of one month of this study the incinerator had broken but later repaired. Treatment of medical waste was done within the hospital premises according to 212 (86%). In KMH medical waste was not treated within the hospital according to 236(96%) of the study. When incinerator had broken down and incase of lack of an incinerator in a medical facility altogether this health facility relied on offsite treatment by a private licensed company as was also revealed by a research done by (Nwachukwa *et al*., 2013). Study found that KMH subcontracted waste treatment and disposal to a private company. The company was licensed to handle hospital waste. Incinerator at KNH was located near a residential area and did not have adequate air pollution control devices. Incineration is associated with many negative environmental and health effects (Rao, *et al*., 2004). Autoclaves were better option for treating part of the wastes. The one incinerator that was in good condition during the time of study at KNH had a capacity to hold less than 500kgs of waste. Kenyatta National Hospital had a waste handler who keeps record of the waste generated while KMH had a hospital matron who keeps record of the waste generated (Hospital records). Other waste treatment facilities available in these hospitals included; compost pits for non- hazardous biodegradable waste, and shredders which were found in only KNH but not in KMH. It was recorded that most of the hospitals in Kenya did not have an alternative waste treatment option apart from incineration (MOH Kenya, 2007). Incineration is the best treatment method for HCWs in third world countries because it has the highest volume and weight reduction, requires no prior processing,

renders most of the waste unrecognizable, can be used to treat different waste categories and can also be a source of energy (Manyele, 2004). Private investors should be encouraged to invest in incineration facilities for HCWs, so that hospitals are left to do their core business which is patient management and get only involved in waste segregation.

There was also availability of a hand washing facility in KNH but there were no enough hand washing facilities in KMH. At KNH the availability of a hand washing facility in every work station was a good indicator that there was emphasis on hygiene for the staff. Quality assurance standards should be enhanced in the whole medical waste management (MWM) process to ensure efficiency. Through handwashing with adequacies of water and soap removes more than 90% of the transient, superficial flora including most contaminants, since hands of healthcare workers are the most frequent vehicle of nosocomial infections, handwashing is the primary preventive measure.

It is in order for hospital waste to be transported within the hospital by means of wheeled trolleys, containers, carts or in covered wheelbarrows that are not used for any other purpose as researched by Johannessen *et al*., 2000. It was noted that a truck/lorry was the means of transport used to ferry hospital waste in the KNH hospital, while unlabeled wheeled carts were used to carry waste inside the hospital at KMH. It was recommended that manual loading should be avoided as far as possible. The bags/ containers containing medical waste should be tied before transportation and should be accompanied with a signed document by nurse / doctor mentioning date, shift, quantity and destination. Special vehicles conspicuously marked with an international biohazard symbol must be used to prevent access to and direct contact with the waste by the transportation operators, the scavengers and the public (Nwachukwu *et al*., 2013). The transport containers must be properly enclosed. The vehicles must possess a licensed permit from the government (Nwachukwu *et al*., 2013). All these measures lacked completely in this study.

According to the results, plastic containers are used for disposal as indicated, (Appendix E i, ii) and as recommended by UNEP, 2000 in its research. A storage/disposal facility that is in good condition ought to be well fenced, big enough, well ventilated and that only authorized personnel were allowed in the facilities. This was unlike in KMH which scored averagely low owing to lack of unsecured and non-sanitized facility, unlike KNH. Open damp sites were the commonly used method in the two sites of the study.

According to research done by Abas *et al*., 2018, the committee for medical waste management in a hospital should be properly constituted comprising all representatives of health workers headed by a qualified doctor who is the head of infection control (Abas *et al*., 2018). In the case of KNH, unlike KMH a housekeeper was responsible for hospital waste management. It should set guidelines and policies to be followed in medical waste borrowed from WHO standards (WHO, 2008). Situational analysis of this was contained in a study by Ministry of health, Kenya (MOH, 2005).

Poorly managed MW is reported to have contributed to hazards in healthcare establishments of bacteria resistant to antibiotics. Patients' environment serves as a major reservoir of microorganisms. Plasmids from laboratory strains contained in HCW could be transferred to indigenous bacteria via the waste disposal systems. Reducing bacterial contamination in the environment reduces the risk of acquiring hospital acquired infections (Nwachukwu *et al.,* 2013).

CONCLUSION

Practice of waste generation, segregation up to waste disposal is poor. No appropriate strategy exists for proper management of medical waste in the studied health establishments. Effective implementation of rules, close monitoring of guidelines with regular audit and continuous education can improve medical waste management practice. Clearly there is need for education as to the hazards associated with improper waste management. There was non-compliance of some of the healthcare facility investigated with the existing national regulatory requirements. The practices are inappropriate due to lack of proper facilities and interest of the individual. Poor current practices increase level of surface contamination, a health risk.

No Conflict of Interest- This is part of my thesis objective in my study.

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1. Appendix A: Questionnaire Form

1. **Current practices involved in MW management (segregation, collection, storage, treatment, transport, disposal, effects of MW on human health and environment).**

(Tick in the box where appropriate).

PERSONAL INFORMATION

Name of hospital…….
Type of hospital
i) Public……
ii) Private/ church sponsored……..
iii) Others (specify)……

a) Gender male…… female…….
b) Title of job in your health profession……
c) Level of education ----------

Segregation

1. Where does segregation take place (point of generation of MW)?

Wards…….
During collection……
During disposal…….

2. Are the containers marked with a biohazard symbol?

Yes…….
No…….

3. Which is the correct colour coding of infectious bins

Black……..
Yellow……
Red…….

Collection

➢ How often is the collection of MW from the ward

Daily…….
Twice a week……
Once a week…….

➢ Do waste handlers often use protective clothing (gloves, masks and gumboots)?

Yes……
No……

Storage

a) Do you know the location of MW storage temporal/ permanent in your hospital?

Yes……
No……..
Briefly describe where located…….

b) Is there special equipment for sharp waste handling and an efficient storage facility?

Yes …….
No……..

Treatment

a) Is the MW treated in the hospital premises?

Yes……
No……

Transport

a) What is the means of transport of MW to the final disposal area?

Use of licensed van……
Use of open tractors……

Disposal

a) What means of disposal of MW is used in your hospital

Incinerator…….
Autoclaving……
Burning…….

What are some of the problems or risks that health workers undergo related to hospital waste management?

a) Do you think MW can cause risks and health hazards to human and environment?

Yes……
No……..

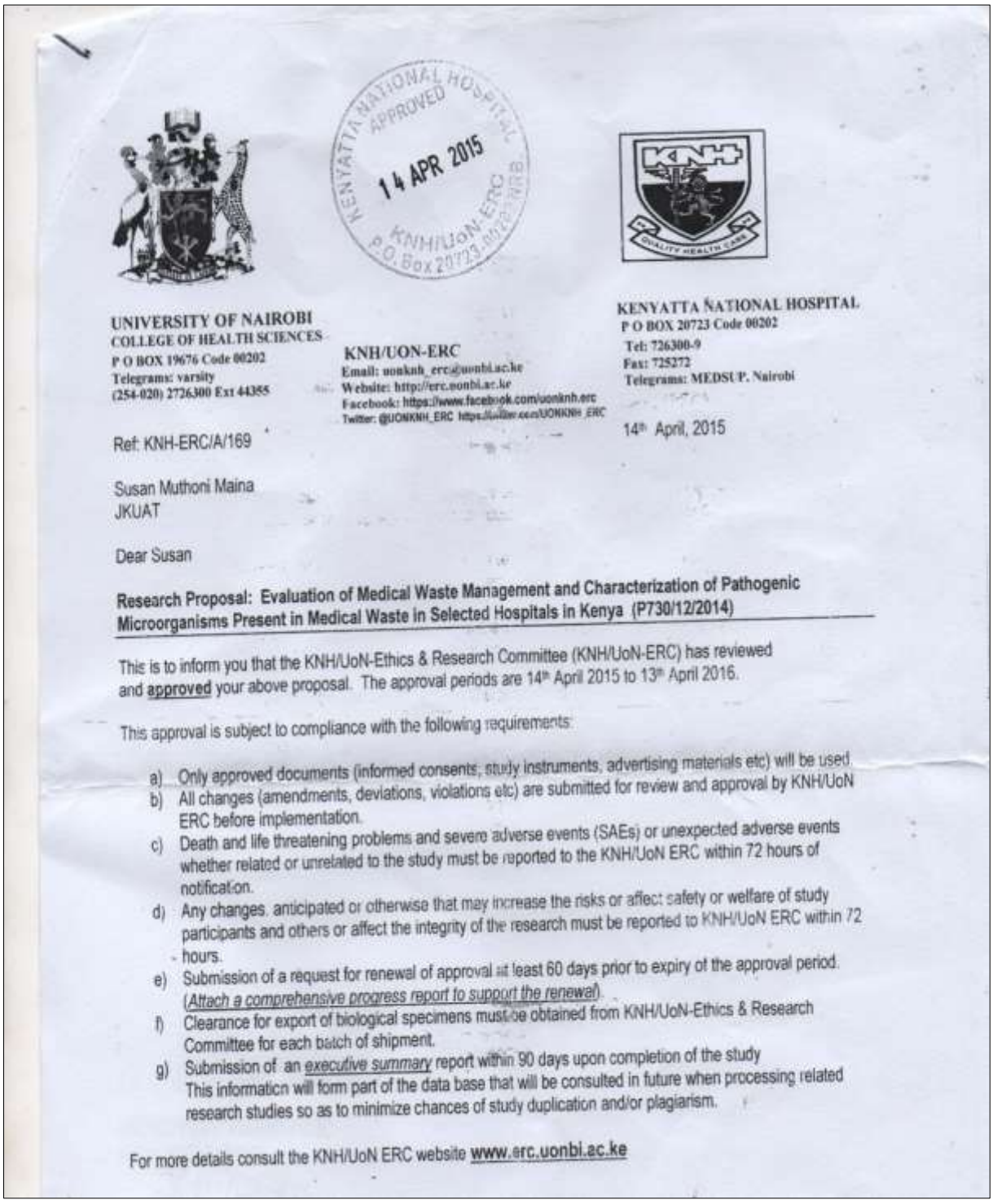
b) Have you ever encountered a health problem in your healthcare duties?

Yes…….
No……

c) For those whose answer is yes in the above question, what type of a problem have you ever experienced among the following

Respiratory problem…….
Eye problems…….
Skin rashes……
Cuts/ piercing…….
All of them…….

Appendix B: Ethical approval Letter KNH



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14th April, 2015

Susan Muthoni Maina
JKUAT

Dear Susan

Research Proposal: Evaluation of Medical Waste Management and Characterization of Pathogenic Microorganisms Present in Medical Waste in Selected Hospitals in Kenya (P730/12/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 14th April 2015 to 13th April 2016.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*)
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.erc.uonbi.ac.ke**