Characterization and Determination of Antimicrobial Susceptibility of Microorganisms Contaminating Ultrasound Probes in Kenyatta National Hospital

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DECLARATION

This is my original work, and to the best of my knowledge, it has not been presented anywhere else

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LIST OF ACRONYMS

AAGBI - Anesthesia of Great Britain and Ireland

AIUM - American Institute of Ultrasound in Medicine

ANOVA - Analysis of variant

CFU - Colon forming units

ED - Emergency Department

HLD - High-level disinfection

KNH - Kenyatta National Hospital

LLD - Low level disinfection

MHz - Megahertz

MIFU – Manufacturer's instructions for use

MRSA - Methicillin resistant Staphylococcus Aureus

SPSS – Statistical Package for the Social Sciences

TA - Transabdominal

TE - Transesophageal

TR - Transrectal

TV - Transvaginal

UK - United Kingdom

UNITID-University of Nairobi Institute of Tropical and Infectious Diseases

UON - University of Nairobi

US - Ultrasound

WHO - World Health Organisation

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ABSTRACT

Background

Patients subjected to ultrasound probes are at risk of microbial contamination including *Staphylococcus aureus* strains resistant to methicillin. This has been linked to cross-contamination from one patient to another which has been greatly attributed to the disinfection and sterilization techniques applied to these probes. Identification, characterization and antimicrobial susceptibility determination of microorganism isolated from probes will inform about the risk of transmission of potentially pathogenic bacteria with the use of ultrasound probes, which is becoming common in clinical practice. The information can contribute to the design of evidence-based comprehensive strategies for prevention of hospital-acquired infections.

Broad Objective

To characterize and determine the antimicrobial susceptibility of microorganisms contaminating ultrasound probes used at Kenyatta National Hospital radiology department between August and October 2019.

Methodology

This was a cross-sectional study carried out at Kenyatta National Hospital Radiology Department. A total of 271 swabs were consecutively collected before and after an ultrasound session over a period of three months. Growth on Blood agar and MacConkey agar was evaluated for colonial morphology and gram stain. Species identification and antimicrobial susceptibility was done using VITEK - 2 System according to Clinical and Laboratory Standards Institute M100 guideline. Percentages of the total organisms isolated and percentages of select organisms that were resistant to the individual drugs was computed using IBM SPSS Statistics version 21.

Results

A total of 271 swabs were collected from ultrasound probes before and after patient had received clinical services. Among these, 58% had bacterial growth. *Staphylococcus epidermidis* (67%, 105/156) and *S. saprophyticus* (19%, 19/156) were the most predominant species isolated. *Burkholderia cepacia* (4) and *Sphingomonas paucimobilis* (1) were the only gram negative bacteria isolated. Low resistance levels (0-40%) to piperacillin, amikacin, ceftriaxone, ceftazidime and ciprofloxacin was observed. Additionally we observed high resistance rate (75-100%) to aminoglycosides, cephalosporin and penicillin tested.

Conclusion

The ultrasound probes were contaminated with bacteria however much of the bacteria isolated are known skin colonizers. There is therefore the need for adequate disinfection procedures to be carried before and after every scanning session.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background information

Ultrasound diagnostic equipment provides information about the organ systems hence helping in management. The modality is one of the most commonly used in radiological diagnostics (S. T. Odonkor, Sackey and Mahami, 2015).

Although the diagnostic equipment is helpful in diagnosis, the ultrasound probes are used on different patients on the skin surface or endocavitary posing a high risk of cross-contamination. Among the main causes of mortality in the America, associated health infections cause an estimate of 1.7million infections and 99,000 associated deaths in 2002. There are established guidelines for sterilization and disinfection of these probes, but if not followed can lead to numerous outbreaks of infections. Misinformation about disinfection levels can also lead to many outbreaks. Hospitals are required to have policies and procedures to be strictly followed to identify the gaps and improve on them where need arises (Chu *et al.*, 2014).

In North America, there is increased use of the ultrasound equipment in emergency room unit resulting from the increased role of ultrasonography worldwide. Sterilization techniques are not well defined, and some facilities lack standard protocols that adhere to the standard universal sterilization levels, most equipment cleaning techniques are dependent on individual clinician's knowledge and practices. This has qualified ultrasound probes to be possible vectors of microbes including *Staphylococcus aureus* strains which are resistant to methicillin. Ultrasound probes are not exempted from bacterial colonization like other non-invasive medical equipment such as, portable x-ray equipment, electrocardiogram machines and stethoscopes (Sanz *et al.*, 2011).

Nosocomial infections which are diseases that occur 48hours after a patient has been admitted to the hospital affect both developed and developing countries. A WHO survey that featured 55 hospitals in 14 countries captured an estimated 9% nosocomial infected patients. In the US, the prevalence of contamination after getting in contact with patients' skin is as high as 95%, and the frequently isolated pathogen is *Staphylococcus aureus*. Normal flora colonizes the ultrasound probes in up to 33% of cases if cultured (Kıran *et al.*, 2018).

Medical equipment's surfaces are significant contamination sources of normal skin flora and other multidrug-resistant bacteria. Lack of proper sterilization of this equipment in between each usage can lead to the transfer of microbes from one patient to another leading to nosocomial cross infections. The use of ultrasound probes daily has increased because of the variety of medical diseases and conditions which are on the rise ranging from mild cases to critical cases (Sartoretti *et al.*, 2017).

Staphylococcus aureus outbreak had earlier been reported as a result of ultrasound examinations, Weist et al. 2014 made a report on a breakout of *staphylococcus aureus* skin infection in neonates following ultrasound examination (Weist *et al.*, 2014) also Gaillot et al. demonstrated a breakout of *Klebsiella pneumonia* in expectant women and also in neonates (Leroy, 2013).

Increased utilization of portable ultrasound in numerous departments in medicine and deficiency in knowledge on matters concerning standard cleaning procedure has raised worries on ultrasound probes facilitating the transmission of microbes to patients. This worry has been confirmed the increasing prevalence MRSA and other pathogens which are resistant to drugs. MRSA has proved to be infectious even when present in inanimate objects (Lawrence *et al.*, 2014). This study will identify and determine antimicrobial susceptibility of microorganisms contaminating ultrasound probes in KNH radiology department.

1.2 Rationale

Among the many imaging technologies in medicine, ultrasound is one of the most widely used equipment. However infections brought about by ultrasound probes due to cross contamination are on the rise, patients subjected to these probes are at risk of contamination especially the critically ill patients in intensive care units. Research has shown that contaminated diagnostic equipment can infect patients (S. T. Odonkor, Sackey and Mahami, 2015).

There is no specific protocol set for the general cleaning of these probes, this depends on the user of the equipment, primarily the Radiographer to ensure that the equipment is thoroughly disinfected before and after being used on a patient. Without any doubts, this kind of situation displays variability in terms of technique and frequency of cleaning the ultrasound probes making them a possible vector for several microbes including Methicillin-Resistant *Staphylococcus Aureus* (MRSA). There was no given cleaning protocol at the study location and

therefore MRSA was hypothesized to be found in plenty after the ultrasound probes being cultured (Sanz *et al.*, 2011). This is a baseline study done in Kenya; it may be used in the formulation of infection control policies.

1.3 Questions

1. What is the distribution of bacteria isolated before and after sterilization of the ultrasound probes?
2. What is the antimicrobial susceptibility pattern of bacteria isolated?
3. What is the effectiveness of the cleaning of ultrasound probes?

1.4 Main objective

To characterize and determine antimicrobial susceptibility of microorganisms contaminating ultrasound probes used in KNH radiology department between August and October 2019

1.5 Specific objectives

1. To determine microbial contamination status of ultrasound probes
2. To characterize microorganisms isolated from the probes
3. To determine the antimicrobial susceptibility pattern of selected bacterial isolates.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1. Introduction

Ultrasound imaging practice has existed for over half a century among the many imaging technologies in medicine. Ultrasound is one of the most widely used equipment. It is free of radiation risks and in terms of cost it is inexpensive in comparison to other imaging equipment, it is used to investigate organs in the abdomen such as the heart, kidney, liver, and vessels. It can also be used to guide surgeons when carrying out some procedures that include biopsies. However infections brought about by ultrasound probes due to cross contamination is on the rise, patients subjected to these probes are at risk of contamination especially the critically ill patients in intensive care units. Research has shown that contaminated diagnostic equipment can infect patients(S. T. Odonkor, Sackey and Mahami, 2015)

Owing to the increased use of sonography, the ultrasound equipment has been used more often in the emergency departments(ED) worldwide especially in North America. There is no specific protocol set for the general cleaning of these probes, this depends on the user of the equipment, primarily the Radiographer to ensure that the equipment is thoroughly disinfected before and after being used on a patient. Without any doubt, this kind of situation displays variability in terms of technique and frequency of cleaning the ultrasound probes making them a possible vector for several microbes including Methicillin-Resistant *Staphylococcus Aureus* (MRSA). A study done in Canada in 2011 was aimed at identifying the frequency of MRSA colonization of ultrasound probes used in ED. There was no given cleaning protocol at the study location and therefore MRSA was hypothesized to be found in plenty after the ultrasound probes being cultured (Sanz *et al.*, 2011)

There is little clear guidance as to which agent may be the most effective at decontaminating ultrasound equipment. Indeed, the Association of Anesthetists of Great Britain and Ireland (AAGBI) guidelines on infection control do not mention ultrasound equipment, which has become an essential tool in modern unaesthetic practice for vascular access and regional anesthesia. The American Institute of Ultrasound in Medicine (AIUM) produces guidelines for endocavity probes written by a multidisciplinary task force. It recommends initial cleaning of the probe followed by disinfection with a liquid chemical germicide.

2.2 Types of ultrasound probes

Ultrasound probes can be classified into two types:

- Conventional probes which include, phased, linear and curvilinear.
- Specialized probes are the ones that are directed towards specific surgical procedures

Conventional probes are applied in different frequencies depending on the patient's age: Neonates 4-12 MHz, Pediatric 2-12 MHz and adults at 1-5 MHz and also used mostly on body surfaces with intact skin (Abdominal and pelvic ultrasound), and mucous membranes(TV,TE,TR probes)in semi-critical conditions (Luca *et al.*, 2018; Skin, 2016).

Specialized probes are usually developed to aid in operations done inside the body; they are manually manipulated for better viewing of internal organs and spaces found inside the body. Transesophageal, intra-cardiac arrays and laparoscopic arrays are examples of specialized probes (Szabo and Lewin, 2013).

2.3 Epidemiology of bacteria isolated from probes

In Sydney Australia, a study was conducted in 2016 at a public hospital and a private facility aiming at the description of the prevalence of bacterial contamination on ultrasound probes, codes, gel, and machine keyboard. Transabdominal (TA) probes had contamination of 60% while Trans-vaginal (TV) probes have contamination of 14% after an ultrasound examination. The pathogens found were: *Acinetobacter lwoffii* and *Pseudomonas stutzeri*. *Enterococcus faecium* was isolated from the keyboard. It was therefore concluded that both TA and TV probes have contamination and that included potential pathogens which pose an infection risk during the use of these probes(Westerway *et al.*, 2016b)

A study done in Accra Ghana in 2015 in two ultrasound area aimed at evaluation of the presence of pathogens on ultrasound equipment. Samples were obtained from ultrasound probes after scanning period then cultured. The study showed Trans-abdominal ultrasound probes were contaminated, the most frequent microorganism isolated was *Staphylococcus aureus* (27%), *Staphylococcus epidermidis* and *Candida albicans* followed with 15.4% each. Enterococcus faecalis had 7.7% and were the least isolated. Therefore a conclusion was made stating that it was possible for ultrasound probes to be vectors of nosocomial infections and they need to be thoroughly cleaned to avoid cross infections (S. T. Odonkor, Sackey and Mahami, 2015)

According to a 2014 UK study, 57% of probes that were initially considered to be sterile were heavily contaminated with bacteria. Majority of the bacteria found were *Bacillus, Micrococcus, Diphtheroids*, *Flavobacterium,* and coagulase-negative *Staphylococcus* also were isolated(Shukla *et al.*, 2014)

In a study aimed at investigating the hygienic condition of ultrasound probes done in Basel Switzerland, it was proved by a median of 53 colon forming units (CFU) that ultrasound probes were highly contaminated. The contamination was caused by an inadequate routine decontamination and disinfection procedure after use (Sartoretti *et al.*, 2017).

2.4 Sterilization and Disinfection of Ultrasound Probes

All probes should be cleaned before and after being used for diagnostic according to manufacturer's instructions for use (MIFU) to avoid damage of the device and compromise patient safety, it also reduces the levels of contamination. The operative ends of the Probes are immersed with sufficient water but the electrical head is protected. The cleaning solution is properly diluted according to MIFU standards and it is used to clean the electrical head and cord after using a soft lint-free cloth (Skin, 2016)

There are two levels of disinfection of ultrasound probes depending on the procedure. Low-level disinfection (LLD) and high-level disinfection (HLD). HLD involves the complete killing of pathogens except for a few bacterial spores; it is done after the probes have been subjected to the semi-critical procedure. Probe covers used on these probes can fail leading to contamination(Rutala *et al.*, 2008). Specialized probes also should undergo HLD because they disrupt the barrier sheath hence become potential vectors for infection transmission. LLD is the destruction of the majority of bacteria, a few viruses, and some fungi. LLD will not necessarily render *Mycobacterium tuberculosis* inactivate or bacterial spores(Sweitzer, Suite and Laurel, 2018)hence used in noninvasive, non-critical procedures(Skin, 2016)

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study design

Cross-sectional study

3.2 Study site

The study was carried out at Kenyatta National Hospital (KNH) located along Hospital Road, Upper Hill in Nairobi. It's the main teaching hospital for the University of Nairobi, College of Health Sciences. With 50 wards, 22 out-patient clinics, 24 theatres (16 specialized), an Accident and Emergency department and a bed capacity of 1800, the hospital is the largest referral hospital in East and Central Africa. The study was conducted in the KNH Radiology department. On average, 50 patients seeking ultrasound services are attended to at the department per week. The KNH Radiology department is managed by consultants, physicians, graduate resident doctors and radiographers.

3.3 Study population

All ultrasound probes in use at KNH radiology department

3.3.1 Inclusion criteria

All ultrasound probes used on patients undergoing ultrasonography at KNH radiology department

3.3.2 Exclusion criteria

Probes not in use

3.4 Sample size

To determine the sample size, Cochran's formula was used (Israel, 2002). The prevalence of microbes among probes in KNH is unknown. An assumed prevalence of 50% was used to estimate the appropriate sample size. As per KNH records, approximately 10 patients seeking ultrasound probes are attended to in KNH radiology department every day. The total number of patients attended during the three-month study period was approximately 900. A representative sample was calculated using the finite population correction for proportions.

$$n_0 = Z^2pq/d^2$$

$$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$$

Where:
n_0 = initial estimated sample study size
Z = standard normal deviate at 95% confidence interval (1.96)

p = estimated prevalence of microbes among ultrasound probes in KNH.

q = 1-p

d = degree of freedom (0.05)

N= Total population of patients seeking ultrasound probes that will be attended to in KNH radiology department for three months (900)

$$n_0 = \frac{1.96^2 * 0.50\ (1-0.50)}{0.05^2}$$

$$= 384$$

$$n = \frac{384}{1 + \frac{(384 - 1)}{900}}$$

= 270

3.5 Sampling technique

Convenient sampling was used.

3.6 Variables

The study variables included isolated microorganism, antimicrobial susceptibility pattern, location (department unit) of the probe,

3.7 Study procedures

A sample was obtained using a sterile swab from the probe immediately a patient had been cleared from the ultrasound procedure; more swabs were obtained after cleaning/disinfecting the probes until the required sample size was obtained. The samples were transported within 2 hours to the microbiology laboratory, UON for microbiological analysis. Inoculated by streaking using

a sterile wire loop on blood agar and MaCconkey, incubated at 38º C for 18-24 hours. After which gram stain was performed followed by specific biochemical test to confirm the isolated bacteria. Further identification and antimicrobial susceptibility testing was determined using the VITEK 2 system (GP and GN 83; AST) (Appendix 1).

3.8 Data management

Data generated was keyed in Microsoft Excel and imported to SPSS Statistics version 21 for analysis. Univariate analysis using frequencies/proportions or measures of central tendency and bivariate analysis to tests associations using a t-test, ANOVA, chi-square or Fisher's exact test. Data was presented in tables and graphs.

3.9 Ethical consideration

This proposal was approved by KNH-UON Ethics and Research Committee (P477/06/2019). Permission to conduct the study was sought from the Head, KNH Radiology Department and the Director UNITID.

Informed and signed consent was obtained from each participant. The principle investigator explained to them what the study entails, the benefits, the risks, the voluntary participation and the confidentiality of the information collected. Patients benefited from microbiological analysis of collected swabs at no cost.

3.10 Study limitations

This study only focused on bacteria although parasites, fungi and viruses are potential contaminants. Only transducers of the ultrasound probes were swabbed because of their regular contacts with patient’s skin. Patients rarely get into contact with other potentially contaminated surfaces like the keyboard, ultrasound surface, mouse and coupling gel.

CHAPTER FOUR
4.0 RESULTS

4.1 Distribution of bacteriological cultures

The study analyzed a total of 271 samples collected from two ultrasound probes before and after patient had received clinical services. Among the 271 samples, 156 (58%) had bacterial growth before and after scanning and cleaning. Forty two percent of the samples did not shown any growth as shown in figure 1.

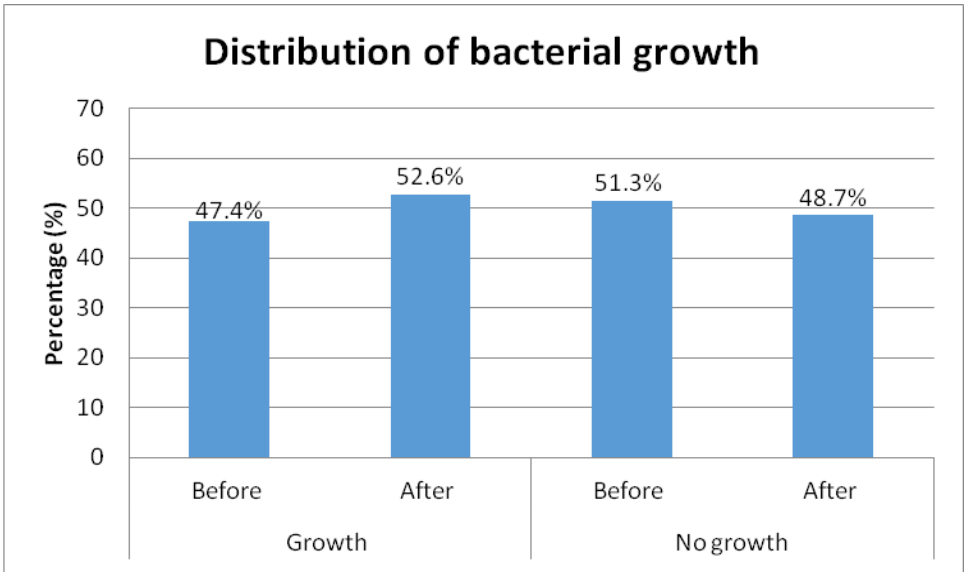

Figure 1: Percentage distribution of bacterial growth following culture cultures of swabs from ultrasound probes before and after scanning and cleaning

4.2 Bacterial isolation

Table 1 shows the bacteria isolated from the ultrasound probes. Eleven species of bacteria were isolated with 5 samples showing mixed bacterial growth. Majority of the bacterial isolates were *Staphylococcus epidermidis* 105 (39%) and *Staphylococcus saprophyticus* 29 (11%). The least bacteria isolated were *Staphylococcus capitis, S. haemolyticus* and *Micrococcus futeus* (1, 0.4%). Less than 2% of the isolates had mixed culture as shown in Table 1.

Table 1: List of Bacteria isolated from the ultrasound probes

Bacterial species isolated	n (%)	Before cleaning	After cleaning
Staphylococcus aureus	3 (1.1)	1	2
Burkholderia cepacia	3 (1.1)	2	1
Staphylococcus capitis	1 (0.4)	1	0
Enterococcus faecalis	2 (0.7)	1	1
Staphylococcus epidermidis	105(38.7)	48	57
Dermacoccus nishinomiyensis	2 (0.7)	1	1
Staphylococcus haemolyticus	1 (0.4)	1	0
Kocuria virians	2 (0.7)	1	1
Staphylococcus lugdunensis	2 (0.7)	2	0
Micrococcus futeus	1 (0.4)	0	1
Staphylococcus saprophyticus	29 (10.7)	9	20
Staphylococcus aureus/ Staphylococcus epidermidis	1 (0.4)	0	1
Burkholderia cepacia/ Staphylococcus aureus	1 (0.4)	0	1
Staphylococcus epidermidis/ Staphylococcus saprophyticus	1 (0.4)	1	0
Kocuria virians/Sphingomonas paucimobilis	1 (0.4)	1	0
Staphylococcus saprophyticus/S. epidermidis	1 (0.4)	0	1
No growth obtained	115(42.4)	69	46
Total	**271**	**138**	**133**

*n represents the number of isolates

Bacterial growth was present in 74 samples (47.4%) before the start of the examination and in 82 (52.6%) out of the 156 positive samples after scanning. Fifty one percent and 48.7% of the samples collected before and after scanning/cleaning showed no growth. The difference was not significant (*0.529*) (Table 2).

Table 2: The results of bacteriological cultures from ultrasound probes before and after scanning and cleaning

Bacteriological culture	n	Scanning		P-value
		Before	After	
Positive	156	74 (47.4%)	82 (52.6%)	*0.529*
Negative	115	59 (51.3%)	56 (48.7%)	

*n represents the number of swabs

Nearly all (97%) bacteria isolated from the ultrasound probe were gram positive cocci or bacilli. Only 2 isolates were gram negative cocci or bacilli. I.e. *Sphingomonas paucimo* and *Burkholderia cepacia*

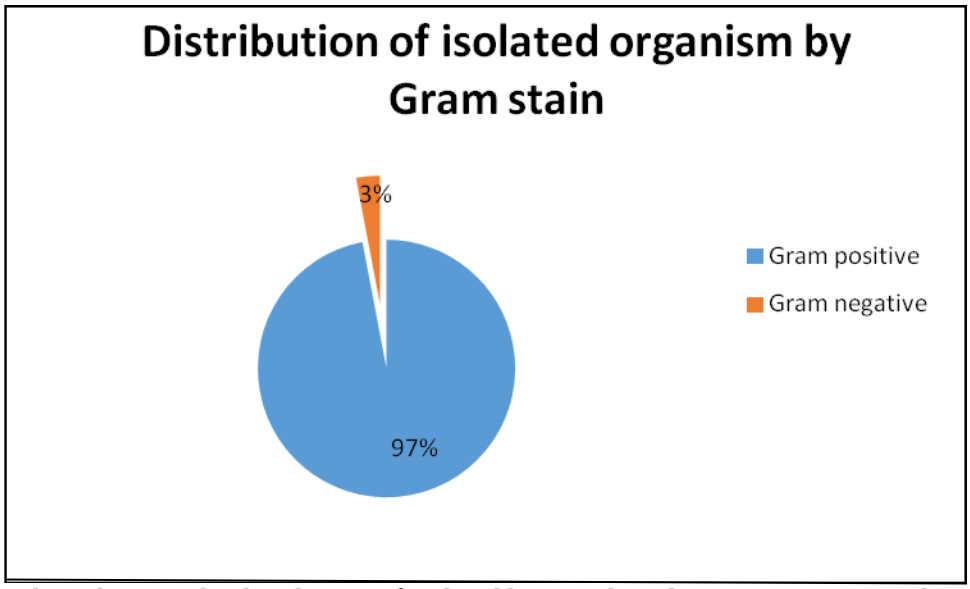

Figure 2: Pie chart showing the distribution of isolated bacteria based on gram staining technique

4.3 Antimicrobial Susceptibility Testing

Antimicrobial susceptibility testing was performed on selected organisms which are naturally resistant to many common antibiotics. *Burkholderia cepacia* (n=4), *Staphylococcus epidermidis* (n=5) and *Staphylococcus haemolyticus* (n=1). Both *Staphylococcus epidermidis* and *Staphylococcus haemolyticus* had high susceptibility to linezolid (100%), teicoplanin (80-100%), vancomycin (80-100%), tobramycin (60-100%) and ciprofloxacin (100%). Low susceptibility of 0-40% to penicillins, erythromycin, clindamycin, gentamicin, tobramycin, levofloxacin and moxifloxacin was observed. *Bulkhoderia cepacia* showed high resistance rate to piperacillin, ceftriaxone, cefepime, aztreonam, meropenem, amikacin, ciprofloxacin and cefoxime (75-100%) as illustrated in table 3 below.

Table 3: Antibiotic Susceptibility profile of selected bacterial organisms isolated

Antibiotic	***B. cepacia* (n=4)**		***S.epidermidis* (n=5)**		***S.haemolyticus* (n=1)**	
	% R	% S	% R	% S	% R	% S
Benzylpenicilin	-	-	80	20	100	0
Oxacillin	-	-	60	40	100	0
Gentamycin	-	-	0	100	100	0
Tobramycin	-	-	20	80	100	0
Levofloxacin	-	-	20	80	100	0
Moxifloxacin	-	-	20	80	100	0
Erythromycin	-	-	80	20	100	0
Clindamycin	-	-	60	40	100	0
Linezolid	-	-	0	100	0	100
Teicoplanin	-	-	20	80	0	100
Vancomycin	-	-	20	80	0	100
Tetracyclin	-	-	40	60	0	100
Tigecyclin	-	-	0	100	0	100
Nitrofurantoin	-	-	0	100	0	100
Fusidic acid	-	-	0	100	100	0
Rifampicin	-	-	0	100	100	0
Trimethoprim-Sulphamethoxazole	43	57	60	40	0	100
Piperacillin	100	0	0	10	0	100
Cefazolin	100	0	0	100	0	100
Ceftazidime	0	100	100	0	100	0
Ceftriaxone	100	0	0	100	0	100
Cefepime	100	0	0	100	0	100
Aztreonam	100	0	0	100	0	100
Meropenem	100	0	100	0	0	100
Amikacin	100	0	0	100	0	100
Ciproflixacin	100	0	0	100	0	100
Cefotaxime	100	0	0	83	0	100

*n represents the number of isolates tested for antibiotic susceptibility

CHAPTER FIVE
5.0 DISCUSSION

This study presents a survey of bacteriological contamination of ultrasound probes used for patients attending Kenyatta National Hospital for radiological and clinical services. The aim of this study was to determine the prevalence and antimicrobial susceptibility profile of bacteria isolated from ultrasound probes.

The prevalence of bacteria isolated from the ultrasound probes in this study was 58% comparable to prevalence reported in Australia and Canada (50-60%) (Westerway *et al.*, 2016a; Muradil *et al.*, 1995). Isolation rates as low as 6-43% of bacteria contaminating ultrasound probes have been reported in United States of America, Canada and Turkey (Chu *et al.*, 2014; Lawrence *et al.*, 2014; Kıran *et al.*, 2018). We observed predominance of *Staphylococcus epidermidis* (39%) and *S. saprophyticus* (11%). Other species isolated were low in numbers and included *Staphylococcus aureus, Burkholderia cepacia, Staphylococcus capitis, Enterococcus faecalis, Dermacoccus nishinomiyensis, Staphylococcus haemolyticus, Kocuria virions, Staphylococcus lugdunensis,* and *Micrococcus futeus.* A similar observation was noted in studies done in Canada (Chu *et al.*, 2014; Muradil *et al.*, 1995) and Ghana (S. Odonkor, Sackey and Mahami, 2015) where *Staphylococcus aureus, Enterococcus faecalis* and *Staphylococcus epidermidis* were the predominant bacteria isolated. The predominance of these bacteria specifically *Staphylococcus aureus* and *Staphylococcus epidermidis* may be due to the fact that these bacteria form part of the normal skin flora. *Staphylococcus aureus* has been reported in at least 40% of healthy people (Fey and Olson, 2011). However it is associated with minor skin infection such as cellulitis, scalded skin syndrome, impetigo, furuncles and life threatening diseases such as pelvic inflammatory disease, pneumonia and meningitis. *Staphylococcus epidermidis* has been associated with hospital acquired infections such as endocarditis in patients with defective heart valves and patients with indwelling biomaterials (e.g. intravenous catheters and medical prostheses) (Fey and Olson, 2011; Otto, 2010). *Staphylococcus saprophyticus* was the second most isolated bacteria in this present study. Globally it is the second most common cause of community acquired urinary tract infection after *E. coli* causing 10-20% of the urinary tract infections (Hur *et al.*, 2016; Pailhoriès *et al.*, 2017).

Our findings on *Staphylococcus epidermidis* and *Staphylococcus haemolyticus* susceptibility to the commonly prescribed antimicrobial agents are consistent with results from studies done in Brazil, Switzerland and Japan reported susceptibility rate of 60-100% to linezolid, vancomycin and teicoplanin (Brescó et al., 2017; Nwibo et al., 2019; Pinheiro et al., 2018). However, due to the current alarming rates of antibiotic resistance of *Staphylococcus* species to the commoly used antibiotics, majority of the studies in Poland, Portugal, Ireland and India have reported resistance rates ranging from50-93% to vancomycin, oxacillin, gentamicin and cotrimoxazole (Gaio and Cerca, 2019; Bora et al., 2018; Czekaj, Ciszewski and Szewczyk, 2015; Hogan et al., 2015). Resistance to penicillin, oxacillin and methicillin which are β-lactam antibiotics may be attributed to *mecA* encoding gene which is carried on the mobile genetic element and staphylococcal cassette chromosome mec (*SCCmec*) (Özdemir et al., 2011). Additionally, resistance to other antimicrobial agents tested such as ciprofloxacin, clindamycin and aminoglycosides may also be due to *aacA/aphD* encoded genes (Hsueh et al., 1998).*Sphingomonas paucimobilis* is a gram negative bacilli, mostly isolated in community or hospital settings. Although it's a bacterium of low pathogenicity, it has been associated with severe infections and septic shock, particularly in immunocompromised patients (Sirmatel et al., 2019). Our study observed high resistance rate to aztreonam and high susceptibility to piperacillin/tazobactam, ceftazidime, cefazolin, ceftriaxone, cefotaxime, meropenem, amikacin, gentamicin, ciprofloxacin and trimethoprim/sulfamethoxazole in Sphingomonas paucimobilis. This observation is comparable to what has been documented in other studies in Taiwan, Turkey Romania and Iran which reported susceptibility to cefazolin, piperacillin/tazobactam, ceftriaxone, cefepime, ceftazidime, meropenem, amikacin, gentamicin, ciprofloxacin and trimethoprim/sulfamethoxazole (Özdemir et al., 2011; Hsueh et al., 1998; Sirmatel et al., 2019; Matros et al., 2014). Contrary to our findings is what was observed in Colombia, Indonesia, Turkey and Pakistan where they observed high resistance rates to cephalosporin, carbapenem, fluoroquinolones and aminoglycosides (Pratama, Lugito and Kurniawan, 2016; Devrim, Apa and Gunay, 2013; Saboor, Amin and Nadeem, 2018). The low virulence may be attributed to the presence of sphingoglycolipid cell wall and the lack of the lipopolysacchride along with its endotoxin activity. Resistance to penicillins and first generation cephalosporins in Sphingomonas paucimobilis noted in our study and other studies may be due to production of B-lactamase encoded on the chromosome (Pratama, Lugito and Kurniawan, 2016).

In this present study, *Bulkhoderia cepacia* isolated showed high resistance rate to piperacillin, ceftriaxone, cefepime, aztreonam, meropenem, amikacin, ciprofloxacin and cefoxime (75-100%). Resistance has also been reported in other countries including the United States of America, Switzerland, Romania and Nigeria with rates of 65 to 100% to piperacillin/tazobactam, meropenem, tobramycin, aztreonam, ceftazidime, amikacin and ciprofloxacin (Obasi, Ugoji and Nwachukwu, 2019; Matros *et al.*, 2014; Zhou *et al.*, 2007; Roy *et al.*, 2014; Lupo *et al.*, 2015). In contrast, studies done in Brussels, United States of America and Latin America noted high susceptibility rates (60-100%) to meropenem, imipenem, ceftazidime, cefepime, trimethoprim/sulfamethoxazole and levofloxacin (Herpol *et al.*, 2017; BSCAC, 2018); Zhou *et al.*, 2007; Gales *et al.*, 2005). The *Bulkhoderia cepacia* resistance to antibiotics tested in our study and other similar studies may be attributed to the genomovar associated with *Bulkhoderia cepacia* complex(BSCAC, 2018). Four new members of the *Bulkhoderia cepacia* complex have been identified presenting with different antimicrobial susceptibility profile. This could also be due to lack of binding sites on the bacterial lipopolysacchride which leads to intrinsic resistance to the polymixin and aminoglycosides. In addition, B-lactam resistance may be due to a combination of impermeability and inducible chromosomal beta-lactamases. Efflux pump confers intrinsic resistance to tetracycline, ciprofloxacin and chloramphenicol (BSCAC, 2018).

The main limitation was that our study focused on isolation and characterization of bacteria contaminating ultrasound probes, however, the probes could be contaminated with other microorganisms. The second limitation is that we only conducted antibiotic susceptibility testing on select bacteria due to scarcity of resources.

5.1 CONCLUSION

The study highlights bacterial contamination of ultrasound probes however majority of whom are known colonizers of the skin. Additionally, we noted that the gram negative bacteria isolated were resistant to meropenem, piperacillin, ceftazidime, cefepime, trimethoprim/sulfamethoxazole, amikacin and ciprofloxacin agents that were tested.

5.2 RECOMMENDATION

We recommend disinfection of ultrasound probes between ultrasound scans to minimize the transfer of pathogenic bacteria and resistance genes from one patient to another, thus reducing

their spread in the hospital setting. Future studies should increase the spectrum of the organisms to cover fungi, parasites and viruses, it should also classify patients into gender and age and their role in pathogenic contamination of ultrasound probes. Additionally, future studies should be designed with approaches that will only allow detection of pathogenic bacteria.

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APPENDICES

1a. Information and Consent form - English version

b. Information and Consent form - Swahili version

2. VITEK 2 (Biomerieux Diagnostics)

3. Ethical clearance

Appendix 1a: Information and Consent Form - ENGLISH

INFORMATION AND CONSENT FORM

STUDY TITLE: Characterization and Determination of Antimicrobial Susceptibility of Microorganisms Contaminating Ultrasound Probes in Kenyatta National Hospital

Kenyatta National Hospital, Nairobi, Kenya

Principal Investigator: Dr. Wycliffe Isaboke Moracha (MSc student, University of Nairobi)

Co-Investigators: Prof. Julius Oyugi (University of Nairobi), Dr. Aywak Angeline (University of Nairobi), Miss Winnie Mutai (University of Nairobi), Dr. Mbuvi Leonida (Kenyatta National Hospital)

Introduction:

I would like to tell you about a study being conducted by the above-listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent.' Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

WHAT IS THIS STUDY ABOUT?

The researchers listed above are conducting a research on microbial contamination of ultrasound probes. The aim of the research is to identify the bacteria present in the ultrasound probes and if it is spread from one patient to another and also the effectiveness of cleaning agents used on these probes in Kenyatta National Hospital. Approximately 270 probes will be selected+ randomly. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen:
You will be informed about the study and immediately after receiving the ultrasound service the probe will be swabbed to collect any microbe present

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is the loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.
Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may not benefit directly as an individual, but the study will aid in development and enhancement of infection control policy. This information is a contribution to science and aid in curbing the burden of antimicrobial resistance. There will be no direct compensation for participating in this study.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

Participation is free and voluntary.

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

There is no expense involved in participating in this study. You will not be compensated.

CONTACTS: WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the Principal Investigator, Dr. Wycliffe Moracha +254 703895129.
For more information about your rights as a research participant, you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.
The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study, and you can withdraw from the study at any time without suffering any negative consequences. You will continue to receive the care and treatment needed even if you do not wish to participate in this study.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.
I understand that all efforts will be made to keep information regarding my identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study:	Yes	No
I agree to have any isolates from my swab preserved for up to 20 years:	Yes	No
I agree that the candida isolates from the swabs be stored (-80ºC) and used for teaching and any other research in future	Yes	No

Participant printed name: _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: **_____ Date**: **_____**

Signature _____

Role in the study: **_____**

Witness (*If witness is necessary, A witness is a person mutually acceptable to both the researcher and participant*)

Name _____ Contact information _____

Signature /Thumb stamp: _____ Date: **_____**

Appendix 1b: Information and Consent Form – SWAHILI

MAELEZO KUHUSU UTAFITI/WARAKA WA IDHINI

Characterization and Determination of Antimicrobial Susceptibility of Microorganisms Contaminating Ultrasound Probes in Kenyatta National Hospital Hospitali ya Taifa ya Kenyatta, Nairobi, Kenya

Mtafiti mkuu: Dkt Wycliffe Moracha (Chuo Kikuu cha Nairobi)

Watafiti weza: Prof. Julius Oyugi Otieno (Chuo Kikuu cha Nairobi), Dkt. Aywak Angeline (Chuo Kikuu cha Nairobi), Miss Winnie Mutai (Chuo Kikuu cha Nairobi), Dkt. Mbuvi Leonida(Hospital Kuu ya Kenyatta)

UTANGULIZI

Ningependa kukueleza juu ya utafiti unaofanywa na watafiti waliotajwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa maelezo unayohitaji ili kukusaidia uamuzi ikiwa Utahusishwa kwa utafiti huu au la. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, kinachotokea ikiwa unashiriki katika utafiti, hatari na faida iwezekanavyo, haki zako kama kujitolea, na kitu kingine chochote kuhusu utafiti au fomu hii ambayo haijulikani. Tunapojibu maswali yako yote kwa kuridhika kwako, unaweza kuamua kuwa katika utafiti au la. Utaratibu huu unaitwa 'kibali cha habari'. Mara unapoelewa na kukubali kuwa katika utafiti, nitakuomba kusaini jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla ambazo zinatumika kwa washiriki wote katika utafiti wa matibabu: i) Uamuzi wako wa kushiriki ni kikamilifu kwa hiari ii) Unaweza kujiondoa kwenye utafiti wakati wowote bila ya kutoa sababu ya uondoaji wako iii) Kukataa kushiriki katika utafiti hauathiri huduma unazostahili kwenye kituo hiki cha afya au vifaa vingine. Tutakupa nakala ya fomu hii kwa rekodi zako.

Naweza kuendelea? NDIO/LA

UTAFITI HUU UNAHUSU NINI?

Mtafiti aliotajwa hapo juu atawaoji watu ambao wanafanyiwa uchunguzi wa ultasound. Lengo la utafiti ni kutambua aina za bacteria ambazo zinapatikana kwenye hichi kidude cha ultrasound probe na kuangalia ubora wa usafushaji unaotumika ili kuhakikisha kwamba bacteria haiambukizwi kati ya wagonjwa wanaohuthuriwa kwa hichi kidude katika Hospitali ya Taifa ya Kenyatta. Karibu vidude 270 vya ultasound vitashiriki katika utafiti huu. Tunaomba ridhaa yako kufikiria kushiriki katika utafiti huu.

NI NINI KITAKACHO FANYIKA UKIAMUA KUHUSIKA KWA UTAFITI HUU?

Ikiwa unakubali kushiriki katika utafiti huu, mambo yafuatayo yatatokea:
Utashughulikiwa na mhojiwaji mwenye mafunzo katika eneo la kibinafsi ambako unajisikia kujibu maswali. Mahojiano itaendelea dakika takriban tano. Mahojiano itafikia mada kama vile aina ya ugonjwa wa kisukari, umri, hali nyingine yoyote ile,

KUNA MADHARA YOYOTE YANAYOTOKANA NA UTAFITI HUU?

Utafiti wa matibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihisia na kimwili. Jitihada zinapaswa kuwekwa daima ili kupunguza hatari. Hatari moja ya kuwa katika utafiti ni kupoteza faragha. Tutaweka kila kitu unachotuambia kama siri iwezekanavyo. Tutatumia namba ya nambari ili kukutambua kwenye darasani ya kompyuta iliyohifadhiwa na nenosiri na tutahifadhi rekodi zote za karatasi kwenye baraza la mawaziri lililofungwa. Hata hivyo, hakuna mfumo wa kulinda siri yako inaweza kuwa salama kabisa, kwa hiyo bado inawezekana kwamba mtu anaweza kujua wewe ulikuwa katika utafiti huu na anaweza kupata habari kukuhusu.
Pia, kujibu maswali katika mahojiano inaweza kuwa na wasiwasi kwako. Ikiwa kuna maswali yoyote utaki kujibu, unaweza kuruka. Una haki ya kukataa mahojiano au maswali yoyote yaliyoulizwa wakati wa mahojiano.
Inaweza kuwa aibu kwa wewe kutoa maelezo ya kibinafsi. Tutafanya kila kitu tunaweza kuhakikisha kuwa hii imefanywa kwa faragha. Zaidi ya hayo, wafanyakazi wote wa utafiti ni wataalamu wenye mafunzo maalum katika mitihani/mahojiano haya.
Unaweza kujisikia wasiwasi wakati wa kukusanya tamba la kina la tishu na huenda ukawa na kuvuta au kuvimba kwenye sehemu yako ya chini. Ikiwa kuna jeraha, ugonjwa au matatizo yanayohusiana na utafiti huu, wasiliana na wafanyakazi wa kujifunza mara moja kwa namba iliyotolewa mwishoni mwa hati hii. Wafanyakazi wa utafiti watawafanyia kwa hali ndogo au kukutaja wakati unahitajika

KUNA MANUFAA YOYOTE KWA KUHUSIKA KWA UTAFITI HUU?

Huwezi kufaidika moja kwa moja kama mtu binafsi, lakini utafiti huu utasaidia katika uteuzi utaratibu na mpangilio wa kusafush vivude hivi vya ultrasound ili kuhepukana na maambukizi ya maginjwawa. Taarifa hii ni mchango kwa sayansi na msaada katika kuzuia mzigo wa upinzani wa antimicrobial. Hutakuwa na fidia moja kwa moja ya kushiriki katika utafiti huu.

KUHUSIKA KWA UTAFITI HUU KUTAGHARIMIA CHOCGOTE?

Hakuna malipo ila tutachukua muda wa dakika kumi

UTAPATA MALIPO YOYOTE AU FIDIA

Hakuna malipo au fidia ili kuhusika kwa utafitu huu

UKITAKA KUULIZA SWALI BAADAYE KUHUSU UTAFITI HUU?

Wasiliana na Mtafiti mkuu, daktari Wycliffe Moracha kwa nambari ya simu: +254 703895129. Ama mwenyekiti au katibu msimamizi, utafiti, Hospitali ya Kitaifa ya Kenyatta na Chuo kikuu cha Nairob kupitia nambari 2726300/44102; au kwa anuani uonknh_erc@uonbi.ac.ke. Watafiti watakurejeshea pesa zilizotumika kwa mawasiliano kuhusu utafiti huu

VITEK-2 Identification and Antimicrobial Susceptibility Testing System (Biomerieux Diagnostics)

The system was used for identification of the organism and determine the antimicrobial susceptibility.

Procedure

Suspension preparation

1. Specific reagent card was selected (GP and GN 83; AST)

2. Suspensions was prepared by transferring a sufficient number of colonies of pure culture using a sterile swab in 3.0 ml sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to7.0) in a plastic polystyrene test tube

3. The turbidity was adjusted to 0.50 -0.63 McFarland turbidity range for yeast card reagent and measured using a turbidity meter called DensiChek™.

Inoculation

1. Identification cards was inoculated with micro-organism suspensions test and controls using an integrated vacuum apparatus

2. The test tube containing the micro-organism was placed into a special rack (cassette) and identification card was placed in the neighboring slot while inserting the transfer tube into the corresponding suspension tube

3. It was barcoded for data entry.

4. The filled cassette was then be transported automatically into a vacuum chamber station for test well filling.

Incubation

1. Automatically, inoculated cards were passed and loaded into the carousel incubator

2. The cards were incubated at 35.5 + 1.0ºC.

3. Every card was removed from the carousel incubator once every 15 minutes, transported to the optical system for reaction readings and then returned to the incubator until the next read time.

4. Data was collected at 15-minute intervals during the entire incubation period

Antimicrobial Susceptibility testing (AMS)

1. Antimicrobial susceptibility cards was inoculated with identified micro-organism suspension and controls using the integrated vacuum apparatus

2. The test tube containing the micro-organism was placed into a special rack (cassette) and antimicrobial susceptibility card was placed in the neighboring slot while inserting the transfer tube into the corresponding suspension tube

3. It was barcoded for data entry.

4. The filled cassette was then transported automatically into a vacuum chamber station for test well filling.

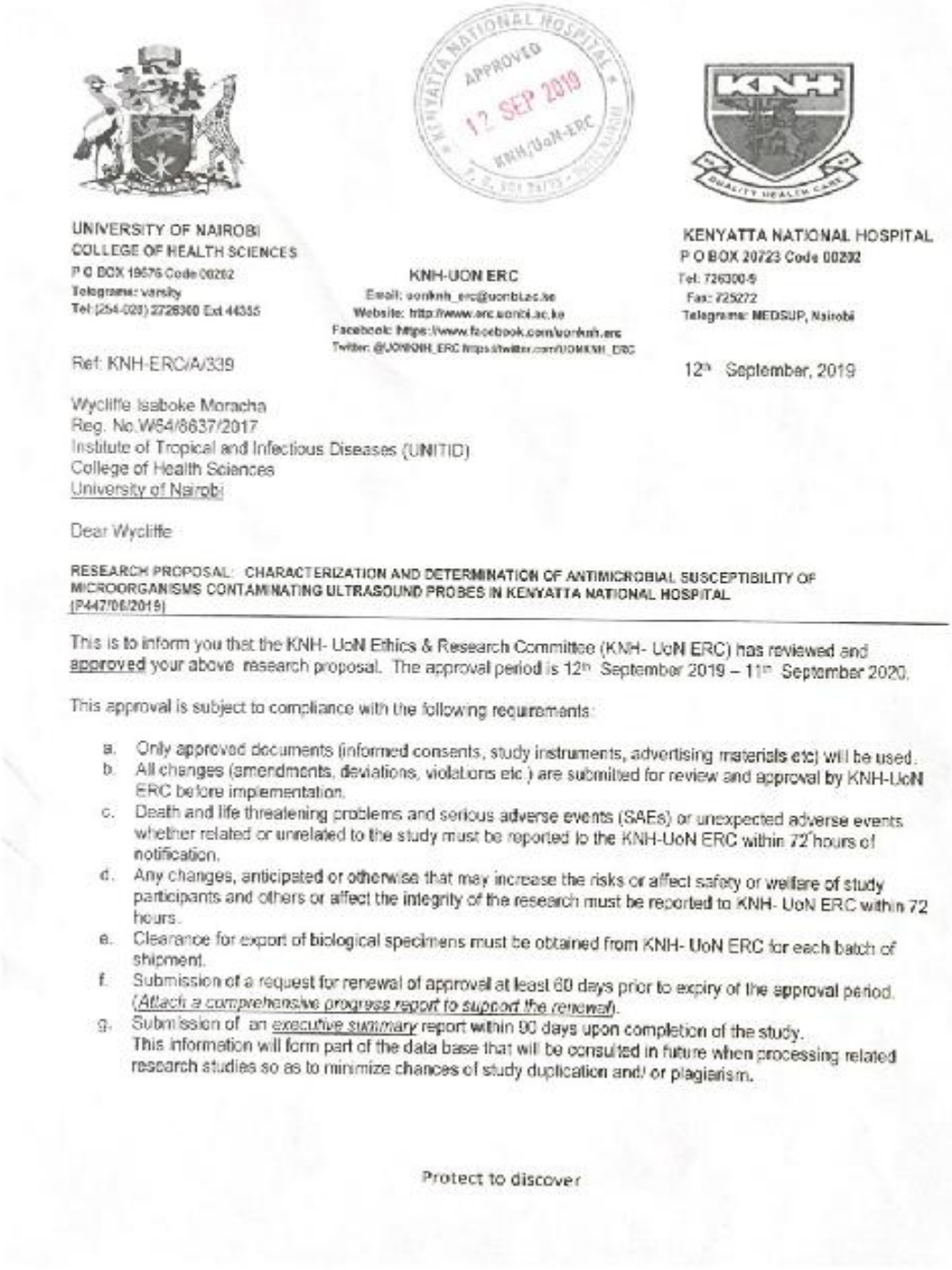
5. Data was collected at 15-30 minute interval during the entire incubation period

Results

1. Identification: The results were interpreted by the ID-yeast database, and the final results obtained automatically

2. Antimicrobial Susceptibility testing: The Minimum Inhibitory Concentration (MIC) of the microbial susceptibility was determined and identified as susceptible, intermediate or resistant according to the National Committee for Clinical Laboratory Standards (NCCLS). The results was obtained automatically from the VITEK 2 system

3. Ethical clearance



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Ref: KNH-ERC/A/339

12th September, 2019

Wycliffe Isaboke Moracha
Reg. No.W64/8637/2017
Institute of Tropical and Infectious Diseases (UNITID)
College of Health Sciences
University of Nairobi

Dear Wycliffe

RESEARCH PROPOSAL: CHARACTERIZATION AND DETERMINATION OF ANTIMICROBIAL SUSCEPTIBILITY OF MICROORGANISMS CONTAMINATING ULTRASOUND PROBES IN KENYATTA NATIONAL HOSPITAL (P447/06/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 12th September 2019 – 11th September 2020.

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 serious 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. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. 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*).
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.

Protect to discover

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

Yours sincerely,

PROF.M.L. CHINDIA
SECRETARY, KNH-UoN ERC

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The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Director, UNITID, UoN
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Dr.Mbuvi Leonida Mutinda(KNH)