

Safety Standards Compliance in the Successful Operation of Biomedical Equipment: A Study of Port Harcourt Metropolis

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Abstract

This study was carried out to investigate the Safety Standards (sine-qua-non) in the Successful Operation of Biomedical Equipment in Selected Health care facilities in Port Harcourt Metropolis of Rivers State. The study employed a descriptive research design and the instrument for data collection was structured questionnaire which were distributed to the five (5) selected Health care facilities Port Harcourt Metropolis of Rivers State. A total number of 100 respondents were used for the study. The respondent's views/data were collated presented and analyzed using simple percentage statistical method. Findings of the study showed that majority of the respondents (70%) said they do not have safety environment that could guarantee successful operation of some biomedical devices, (75%) said there is no safety standards for operation of some biomedical equipment in their Health care facilities and 90% agreed that there were consequences of poor safety appliance to biomedical equipment. Following the result of the study as indicated above, it could be deduced that safety standards were not observed which resulted in unusable equipment, untreated patients, wrong diagnosis, wrong treatment, electric shock, and infection from contaminated equipment, frustrated medical staff and overloaded repair shops. Hence this study recommended that operation of equipment should be carried under the conditions for which it is appropriate, only staff that are knowledgeable in the operation of the biomedical equipment should be allowed and also ensure that there are routine inspection and maintenance of the biomedical equipment as at when due to avoid the above unpleasant conditions.

Keywords: safety, biomedical equipment, hospitals

INTRODUCTION

The use of biomedical devices in healthcare delivery in Nigeria is faced with many challenges which may lead to shutdown of equipment. It exposes patients, medical staff and visitors to electric hazards. Electric safety is the containment or limitation of hazardous electrical shock, explosion, fire or damage to equipment and buildings. These devices must be properly installed in an environment in which they can give accurate and uninterrupted services such as proper operation, regular care and maintenance of these devices. The consequences of breakdown of biomedical equipment results to unusable equipment, untreated patients, wrong diagnosis, wrong treatment, frustrated medical staff and overload repair shops. The interwoven issues of safety, quality control and maintenance of existing biomedical devices are very important (Oluwadare, 2022; Bamigboye & Bello, 2019).

Safety is the absolute protection from danger or accident. It is also a state of being free and protected from dangers, hazards or accidents arising from the environment or

workplace (laboratory, workshop, house, road, school etc). It is generally concerned with the prevention of accidents, promotion of occupational health, and prevention of environmental pollution and security of entire workforce or equipment. Safety also deals with freedom from hazards or conditions that possess the potentials for causing injury, disease, economic loss or damage to properties and the environment. Thus matter dealing with safety often tends to broaden the concept to include issues of Health, Safety and Security (HSES). Medical instruments are device intended to diagnose, treat or monitor the patient under medical supervision. Regular care, repair and preventive maintenance of these devices are essential (Charles 2009, Health Safety and Environment [HSE], 2023).

MATERIALS AND METHODS

This study adopted descriptive survey design method. The population of this study was centralized on 10 hospitals/health centers in the selected healthcare facilities in the Port Harcourt metropolis. To verify that each unit in the sample was chosen at random, the researcher used probability approaches that involved simple random selection process. Each respondent was given a chance to choose one piece of paper that had been shuffled and written "Yes" or "No." Those who choose the "yes" paper had to respond to the survey. The sample size was 100 staff in 10 healthcare facilities in the study area. Well-structured questionnaire was employed to collect data. While the secondary data were collected from journals, papers, and other literature that explored the availability, use, and significance of life support equipment/devices in healthcare facilities. The data collected were analyzed using statistical parameters i.e. tables, frequency, percentage, bar charts and pie charts. The simple percentage formula is as follows: $Percentage (\%) = \frac{Number}{Total} \times 100$

RESULTS

Analysis of the Results on the PPE’s used and compliance in Radiology Unit

Table 3.1 showed some of the equipment found in radiology unit of the selected hospitals and the level of safety compliance of radiologists. Some equipment found in the radiology was CT scan, mammogram, x-ray machine, fluoroscope, MRI etc. The study showed that 80% of radiologist from the selected hospital complied with safety standards (i.e. outside operation) whereas 20% neglected or did not comply with outside operation. For MRI, 100% of patients with metals in their body notified the MRI staff or complied with safety awareness due to the risk of magnetic force or movement of metal in their body. Not complying with the safety measures could be most severe consequence of potential injury as a result of x-ray penetration or even death of a worker (Safetybank, 2023).

Table 1
Showed the PPEs used in radiology unit

Unit	Equipment	Safety Measures (PPE)	Safety Compliance				Total (%)
			Yes	%	No	%	
Radiology	CT Scan Mammogram X-ray machine Fluoroscope	Outside Operation or Control room	80	80%	20	20%	100(100%)
	MRI	Present of metal on patient	100	100%	-	-	100(100%)

Source: Field Survey, 2023

Result on the Equipment and PPE's Used in Dialysis Unit

Table 3.2 shows some of the equipment and responses of physicians / technicians to PPE in the dialysis unit of the selected hospitals. The study showed that 80% of the respondents made use of surgical mask and disposable shoe, while 20% did not, 70% made use of isolation coat, while 30% did not, 95% made use of disposable plastic apron, while 5% did not and 100% made use of disposable gloves. The major equipment found in the dialysis unit was the dialysis machine. Wearing personal protective equipment (PPE) can prevent accidents from happening. Not complying could lead to exposure to potential hazards and accidents (Opentextbc, 2023).

**Table 2
Showed Equipment and PPE used in Dialysis Unit**

Unit	Equipment	Safety Measures (PPE)	Safety Compliance				Total(%)
			Yes	%	No	%	
Dialysis	Dialysis machine	Surgical mask	80	80%	20	20%	100(100%)
		isolation coat	70	70%	30	30%	100(100%)
		Disposable Plastic Apron	95	95%	5	5%	100(100%)
		Disposal gloves	100	100%	-	-	100(100%)
		Disposable shoe	80	80%	20	20%	100(100%)
			-	-	-	-	-

Source: Field Survey, 2023

Result of the Equipment and PPE used in Special Care Baby Unit (SCBU)/Neonatal Intensive Care Unit (NICU)

Table 3.3 shows some of the equipment used and the responses of physician/technicians to safety measures (PPE) in the pediatric wards of the selected hospitals which are listed below; 70% made use of disposable apron and scrub trouser with top, while 30% did not. 100% made use of disposable gloves and face mask completely, 80% made use of disposable shoe while 20% did not and lastly 90% made use of disposable cap whereas 10% did not. some of the equipment found in SCBU were infant incubator, radiant warmer, autoclave, phototherapy light, suction pump, oxygen mask and nebulizer. Not complying with safety standards in SCBU could result to workplace injuries and accidents which are not only tragic and harmful to workplace morale but are also potentially very expensive (Cleanlink, 2023).

Table 3
Showed Equipment and PPE used in Special Care Baby Unit (SCBU)/Neonatal Intensive Care Unit (NICU)

Unit	Equipment	Safety Measures (PPE)	Safety Compliance				Total(%)
			Yes	%	No	%	
SCBU/ NICU	Infant incubator	Disposable apron	70	70%	30	30%	100(100%)
	Radiant warmer	Disposable glove	100	100%	-	-	100(100%)
	Autoclave	Face Mask	100	100%	-	-	100(100%)
	Phototherapy Light	Eye Google	70	70%	30	30%	100(100%)
	Suction Pump	disposable shoe	80	80%	20	20%	100(100%)
	Oxygen Mask	Disposable Cap	90	90%	10	10%	100(100%)
	Nebulizer	Scrub trouser and Top	70	70%	30	30%	100(100%)

Source: Field Survey, 2023

3.4 Result on the Equipment and PPE's Used in Theatre

Table 3.4 shows some of the equipment used and the level of safety compliance and safety standard (PPE) by physicians (Doctors and nurses) working in theatre of the selected hospitals to prevent or control medical hazards. The equipment found here were suction pump, operating table, microscope, operating lamp/ light, Anesthetic machine, operating bed, sterilization and cleaning equipment. Also the response of technicians to PPE were as follows; 100% made use of surgical hand glove and disposable, 70% made use of disposable plastic apron, filtering face piece respirator and isolation, while 30% did not. 80% made use of disposable fluid resistant gown and disposable shoe, while 20% did not. 90% made use of surgical mask and scrub trouser with top, while 10% did not. Ninety-five percent (95%) made use of protective overall while 5% did not and lastly 60% made use of disposable sleeves while 40% did not. Wearing personal protective equipment (PPE) can prevent accidents from happening while not complying could lead to exposure to potential hazards and infection (Opentextbc, 2023).

Table 4
Showed Equipment and PPE used in Theatre

Unit	Equipment	Safety Measures (PPE)	Safety Compliance				Total (%)	
			Yes	%	No	%		
Theater /Operating Room	Suction Pump,	Surgical hand glove	100	100%	-	-	100(100) %	
	Operating table,	Disposal plastic Apron	70	70%	30	30%	100(100) %	
	Microscope,	Disposable fluid-resistant gown	80	80%	20	20%	100(100) %	
	Operating lamp/light,	Filtering face	70	70%	30	30%	100(100) %	
	Anesthetic machine,	piece respirator	80	80%	20	20%	100(100) %	
		Disposable shoe	100	100%	-	-	100(100) %	
	Operating bed,	Disposal cap						
		Surgical mask	90	90%	10	10%	100(100) %	
	Sterilization and cleaning equipment		Protective overall with hook	95	95%	5	5%	100(100) %
			Isolation Coat	70	70%	30	30%	100(100) %
Scrub trouser and top			90	90%	10	10%	100(100) %	
Disposal sleeves			60	60%	40	40%	100(100) %	

Source: Field Survey, 2023

Result on the Equipment and PPE's used in Laboratory

Table 3.5 shows some equipment used, the level of safety compliance and standard PPE by physicians/ technician working in the laboratory of the selected hospitals to prevent or control health hazards. The equipment found here are water bath, centrifuge machine, autoclave, microscope, glucometer etc. The compliance of medical staff was as follows: 100% made use of lab coat (i.e. Apron, scrubs, coverall etc.) and gloves appropriate to the hazards. Again 80% complied with the usage of safety glasses or splash goggle and fully enclosed foot wear (no sandal, flip-flop or ballet shoes), while 20% donot comply to safety measures. Compliance with safety standards in the laboratory makes the workplace safe. This is done by providing instructions, procedures, training and supervision to encourage people to work safely and responsibly.

Table 5:
Showed Equipment and PPE used in Laboratory

Unit	Equipment	Safety Measures (PPE)	Safety Compliance				Total (%)
			Yes	%	No	%	
Laboratory	Water bath	Lab Coats (i.e. Apron, scrubs, coverall etc.)	100	100%	-	-	100(100%)
	Centrifuge machine	Safety glasses or splash goggles	80	80%	20	20%	100(100%)
	Autoclave	Gloves appropriate to the hazards	100	100%	-	-	100(100%)
		Fully enclosed foot wear (no scandal, flip-flop or ballet shoes)	80	80%	20	20%	100(100%)
	Microscope						
	Glucometer						

Source: Field Survey, 2023

Table 3.6 Results on the Equipment and PPE's used in Intensive Care Unit (ICU)

Table 3.6 portrayed some of the equipment used, the level of safety compliance and standards necessary for ICU workers in the selected hospital to prevent and control the spread of infection, through contaminated devices, chemical hazards etc. The following equipment were found in the ICU, ICU bed, NG tube, ventilator, dialysis machine, nebulizer,

stethoscope, ultrasound machine etc. from the table above, 100% complied with the usage of disposable glove, 85% complied to disposable plastic apron, while 15% did not. 80% complied with filtering face pie respirator, while 20% did not. Seventy percent (70%) complied with disposable fluid resistant gown, eye/face protection and disposable shoe, whereas 30% did not comply with these measures. Not complying could lead to exposure to oxygen-deficient atmospheres, dusts, gases and vapors.

Table 6
Showed Equipment and PPE's used in Intensive Care Unit (ICU)

Unit	Equipment	Safety Measures (PPE)	Safety Compliance				Total (%)
			Yes	%	No	%	
Intensive Care Unit (ICU)	ICU bed	Disposable gloves	100	100%	-	-	100(100%)
	Nasogastric tube (Ng tube)	Disposal plastic Apron	85	85%	15	15%	100(100%)
	Ventilator	Disposable fluid	70	70%	30	30%	100(100%)
	Dialysis machine	Resistant gown					
	Nebulizer	Filtering face piece respirator	80	80%	20	20%	100(100%)
	Stethoscope	Eye & Face Protection					
		Disposable Shoe	70	70%	30	30%	100(100%)
	Ultrasound machine		70	70%	30	30%	100(100%)

Source: Field Survey, 2023

Result on the Equipment and PPE's used in Accident and Emergency Unit (A& E)

Table 3.7 shows some of the equipment found, level of safety compliance and safety standard (PPE) used by physicians in the Accident and Emergency Unit of the selected hospitals to prevent or control health hazards. The following life supporting machines were found and they include dialysis machine, ECG, ventilator, incubator etc. The physicians responded with the following PPE; 80% complied with the use of face mask, air purifying respirator and eye protection, while 20% did not comply. One hundred percent (100%) complied with the use of disposable glove and coveralls. Lastly 70% complied with the usage of half face respirator, while 30% did not comply. Noncompliance in the use of PPE could lead to infection since most of the equipment is prone to be stained with blood and other fluid.

Table 7
Showed Equipment and PPE's used in Accident and Emergency Unit (A& E)

Unit	Equipment	Safety Measures (PPE)	Safety Compliance				Total (%)
			Yes	%	No	%	
Accident and Emergency	All life supporting machines i.e. dialysis machine, ECG, medical ventilator, incubator etc.	Full face or half mask	80	80%	20	20%	100(100%)
		Air purifying respirator	80	80%	20	20%	100(100%)
		Disposable glove	100	100%	-	-	100(100%)
		Hooded chemical resistant clothing (coveralls)	100	100%	-	-	100(100%)
		Eye protection					
		Usually added is a half face respirator worm	80	80%	20	20%	100(100%)
		70	70%	30	30%	100(100%)	

Source: Field Survey, 2023

Result of the Equipment and PPE's used in Anesthesia

Table 3.8 shows some of the equipment and PPE used by Physicians/ Technicians in Anesthesia operation of the selected hospitals to prevent or control health hazards. The

following equipment were found; Anesthetic machine, anesthetic vaporizer, oxygen mask, endotracheal tube, epidural catheter. According to table 7, 100% complied with the use of surgical gloves, coveralls and disposable cap completely. 95% complied with the use of isolation coat, disposable shoe and surgical mask, while 5% donot comply with these standards. Lastly (80%) made use of scrub trousers and tops whereas (20%) donot. Noncompliance in the use of PPE in this unit may lead to infection with communicable diseases.

Table 8
Showed Equipment and PPE's used in Anesthesia

Unit	Equipment	Safety Measures (PPE)	Safety Compliance				Total (%)
			Yes	%	No	%	
Anesthesia	Anesthetic machine	Surgical gloves	100	100%	-	-	100(100%)
	Anesthetic vaporizer	Protective overall with hook	100		-		
	Oxygen Mask	Isolation coat	95	100%	5	-	100(100%)
	Endotracheal tube	Disposal cap	100	95%	-	5%	100(100%)
	Epidural catheter	Scrub trousers and tops	100	100%	-	-	100(100%)
		Disposable shoe	80	80%	20	20%	100(100%)
		Surgical Mask	95	95%	5	5%	100(100%)
			95	95%	5	5%	100(100%)

Source: Field Survey, 2023

Result on the Equipment and PPE's used in Dental

Table 3.9 shows some equipment and PPE used by physician/ Dentist in the dental unit of the selected hospital to prevent or control health hazards. The dental equipment found were suction pump, x-ray machine, dental drill, tonometer, dental syringe, saliva ejector, scaler and mouth mirror, etc. The following level of respondent to safety standards was recorded; 100% made use of surgical gloves, 65% made use of procure mask while 30% did not, 70% made use of surgical disposable shoe and Eye goggle while 30% did not, 70% made use of coverall (protective) while 20% did not, lastly 60% made use of surgical mask while 40% did not. Noncompliance in the use of PPE in this unit may lead to stains; infection and possibly particles from denture could cause injury.

Table 9
Showed Equipment and PPE's used in Dental

Unit	Equipment	Safety Measures (PPE)	Safety Compliance				Total(%)
			Yes	%	No	%	
Dental	Suction pump	Surgical gloves	100	100%	-	-	100(100%)
	X-ray machine	Procure mask	65	65%	35	35%	100(100%)
	Dental drill	Surgical Apron	70	70%	30	30%	100(100%)
	Tonometer	Disposable shoe	70	70%	30	30%	100(100%)
	Dental syringe	Protective coverall	80	80%	20	20%	100(100%)
	Saliva ejector	Surgical mask	60	60%	40	40%	100(100%)
	Scaler	Eye google	70	70%	30	30%	100(100%)
	Mouth mirror						

Source: Field Survey, 2023

Result on the Equipment and PPE’s used in Pharmacy/Pharmaceutical

Table 3.10 shows equipment and PPE used by pharmaceutical staff in the selected hospitals to prevent or control health hazards. The following equipment were found, automatic tablet printing machine, spray coating machine, mechanical shifter, dust extractor, rotary tablet press, industrial stirrer, planetary mixers etc. the level of PPE are listed below; 100% made use of disposable cap and gloves, 95% made use of protective overall while 5% did not, 90% made use of disposable shoe and lab coat while 10% did not, 83% made use of air printing respirator while 15% did not, 80% made use of isolation coat and surgical mask while 20% did not, lastly 70% made use of eye protection while 30% did not. Non-compliance in the use of PPE may lead to chemical burn when equipment is stained with spilled chemical and also inhaling dangerous fumes.

Table 10
Showed Equipment and PPE used in Pharmacy/Pharmaceutical

Unit	Equipment	Safety Measures (PPE)	Safety Compliance				Total(%)
			Yes	%	No	%	
Pharmaceutical	Automatic tablet printing machine	Protective overall with hook	50	50%	50	50%	100(100%)
	Spray coating machine	Disposal cap					
	Mechanical shifter	Disposal gloves	100	100%	-	-	100(100%)
	Dust extractor	Disposal shoe	100	100%	-	-	100(100%)
	Rotary tablet press	Lab coat	90	90%	10	10%	100(100%)
	Industrial stirrer	Isolation coat	90	90%	10	10%	100(100%)
	Planetary mixers	Eye protection	80	80%	20	20%	100(100%)
		Air purifying respirator	70	70%	30	30%	100(100%)
		Surgical mask	85	85%	15	15%	100(100%)
		80	80%	15	15%	100(100%)	

Source: Field Survey, 2023

DISCUSSION

The research showed that, greater percentage of the respondents complied with safety standards with respect to the use of personal protective equipment (PPEs) in the health care facilities visited. The main hazards in the operating room were due to their direct involvement in the surgical operation. Operating room nurses may suffer from cuts, stabs, scratches and stings stemming from the use of syringes and scalpel. Operating room nurses may be exposed to anesthetic gases, drugs and radiation. Another risk here is the leakage of oil from Durable Medical Equipment (DME) like operating table or bed because Hydraulics can leak out oil. A major hazard in the laboratory is the risk presented by the dangerous properties of hazardous chemicals when dangerous chemical is not handled in a safe and compliant manner. They can cause a number of health hazards. These complications include burns, eye injuries, lung disease, asphyxiation and suffocation, the study showed. Most side effects of General anesthesia are minor and temporary such as nausea (vomiting), chills, dry mouth, shivering, itching, muscle aches, sleepiness, confusion for a few days and a sore throat caused by a breathing tube. Exposure to anesthetic gases, drugs and radiation were very common issues here. Another problem encountered was the seizure of flow meter to regulate oxygen during operation and the effect of anesthetic agent.

Finding from Table 9 showed that the dental clinic exposes physicians/dentist to infections (including Human Immunodeficiency virus and viral hepatitis); percutaneous exposure incidents, dental materials, radiation and noise; musculoskeletal disorders,

psychological problems and dermatitis, respiratory disorders and eye insults. General health risks associated with the production of pharmaceutical products include exposure to formaldehyde, repetitive motion disorders, dust and noise, and UV radiation. During manufacturing, dust becomes airborne and becomes a concern for the operators. Additionally, dust from the filling and packing of the final product may present an allergy risk. The product is frequently exposed to formaldehyde and UV light to ensure its sterility. Lung cancer may be triggered by formaldehyde, both prostate cancer and Hodgkin's disease. Acute exposures can result in pneumonia that can be fatal as well as respiratory failure, which causes the lungs to fill with fluid and make breathing difficult. Dermatitis is also brought on by formaldehyde. The use of ultraviolet lamps to maintain sterility is problematic as well. Despite not being ionizing (meaning the radiation does not have an electrical charge and therefore causes less damage to cells). Skin cancer can be brought on by ultraviolet radiation, which is harmful. The first symptom of excessive exposure is wrinkling and dry, inelastic skin. Different localized skin lesions could appear and should be seen as a warning indicator. People with light skin are much more likely to have their skin damaged by UV rays (and to get skin cancer) since their skin lacks pigments that would shield them from excessive exposure (American Cancer Society, 2023).

CONCLUSION AND RECOMMENDATIONS

Conclusion

Safety is the absolute protection from danger or accident. Safety standard in the successful operation of biomedical equipment cannot be overstretched. Biomedical equipment are those machines used to aid treatment, diagnosis and monitoring of diseases and medical conditions. There are different types of biomedical equipment such as diagnostic equipment, durable medical equipment (DME), treatment equipment, life support equipment and medical laboratory equipment. In this study safety standards were observed in the operation of biomedical equipment. But safety of these equipment is sometimes neglected which often results to wrong diagnosis, wrong treatment and frustration to medical care.

Recommendations

From the result of this study, the under listed recommendations were made:

- (1) That hospital management should ensure routine inspection and maintenance of the biomedical equipment.
- (2) That preventative maintenance program be developed to ensure that equipment is kept in good repair.
- (3) That staff operating the biomedical machine be trained and retrained quarterly on the safe use of equipment and PPEs.

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