ORIGINAL RESEARCH PAPER

Management

KEY WORDS: Biomedical Engineering, Barrier Diagnosis, Infection Control, Medical Gadgets, Electro Cardio Gram – ECG, Bi-level positive airway pressure – Bi PAP, G1 – Group1, ,G2 – Group2, G3 – Group3

BIOMEDICAL EQUIPMENT MAINTENANCE & BARRIER DIAGNOSIS, A SYSTEMATIC INFECTION CONTROL PRACTICE

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ABSTRACT

Biomedical Engineering and Modern Medical Gadgets are key equipment, essential to doctors for providing precession medical care guided by the principle of evidence based treatment. These biomedical equipment are used for diagnosis, continual monitoring and during performing surgical procedure on patient and are unavoidable tools to restore health of patient by all the doctors. Barrier Diagnosis is the term applied to provide safe care to patients by proper sanitation of biomedical equipment used to patients. This study is limited to few types of equipment like Multi Para Monitor, ECG Machine, Defibrillator – these are Biomedical Equipment grouped under G1 – Surface Contact Equipment. Bi PAP Machine, Ventilator – these are Biomedical Equipment grouped under G2 – Airway Contact Equipment. Infusion Pump, Syringe Pump, and Dialysis Machine – these are Biomedical Equipment grouped under G3 – Circulatory System Contact Equipment. The biomedical equipment cleaning study data is collected in two diversified settings, 1. Pre Pandemic Phase (Consisting 3 Months), 2. Pandemic Phase (Consisting 3Months). Observation results in following of Standard Procedure by the cleaning staff for cleaning of Biomedical Equipment at a tertiary care Public Hospital, there is an average improvement of 59% efficiency in Phase I, 83% in Phase II and 98% in Phase III.

INTRODUCTION:

Biomedical Engineering is the field of technology, which has successfully emerged in the recent times with the invention of sophisticated, state of art medical care gadgets, that work to the precision of functional unit level of a human organ, they are designed with the aim of enhancing the quality life of the patients, they are designed to perform highly complicated surgeries and aid in the management of complicated diseases with accurate case management, which otherwise were not possible with human intervention alone[1].

EVOLUTION OF BIOMEDICAL EQUIPMENT:

Medicine is the specialized branch of science with the objective of promoting health and preventing the spread of infections and to help mankind to lead a disease-free life. With the advancement of Biomedical Equipment, the practice of modern medicine has made many milestone achievements and raised the bar of quality life of an individual – what were considered endangered diseases previously got the solution by use of Biomedical Equipment for clinical diagnosis and treatment for patient care[2].

It is learned that about thousands of years ago, ancient Mesopotamian medical healers used alcohol as a sedative agent, there are historical pieces of evidence that Sumerians used to cultivate and harvest Opium poppy as early as 3400 BCE for easing the pain of patients either with chronic ailments or while performing surgical procedures – this is the first recorded use of Anesthetic agents. It is traced in the historical evidence that Ancient Egyptian Surgeons used some surgical instruments, analgesics, and sedatives dating back to 300 BCE. The primitive surgical tools used by Egyptian Surgeons and Chinese Surgeons following them can be considered as Biomedical Equipment of that era, which are adopted to date with refinement and redesigning to carry out various surgical procedures.

Biomedical Equipment ranges from a simple mechanical tool, like a medical thermometer or clinical thermometer used for measurement of the body temperature variation of a sick patient was first constructed by Galileo Galilei Italian Physicist during the circa 1592 – 1593, he is also considered as the father of modern Physics. A stethoscope was invented in the year 1816 by René Laennec a French Doctor for osculation of heart sounds of his patients. In the year 1881, Samuel Siegfried Karl Ritter von Basch an Austrian-Jewish physician invented a Sphygmomanometer for measuring Blood Pressure of a patient. These are the basic biomedical equipment that is widely used by all the doctors across the globe for basic diagnosis of their patients – these types of equipment overtime are developed in their present form with a lot of modifications and precision in the measurement of patient parameters.

A great achievement in the field of Radiation Medicine by safe use of Medical X Rays to capture the hand for studying the skeletal structure was successfully presented by Wilhelm Röntgen's, a German Physicist in the year 1896, this invention further helped for advancement and development of specialized branches of Medicine and Surgery.

Modern Biomedical Equipment adopts digital electronics and computer application – refined knowledge processes as a step further to design combination of Radiology, Medical Physics, Sensors and Probes for understanding the patient condition with various diagnostic procedures at all phases of patient care like Clinical Diagnosis, Laboratory Diagnosis, Image Diagnosis, Surgical Guidance, and Rehabilitation Support. Modern Doctors across the globe provide accurate treatment to their patients by adopting Evidence-Based Medicine – which is possible through extensive use of Diagnostic / Medical / Surgical Care Biomedical Equipment.

Usage of any Diagnostic Tool or Gadget needs safe sterilization or sanitation to control the spread of infections from one patient to another patient. This scientific and prescribed procedure of cleaning and restoring the hygienic conditions of any equipment is called Routine Maintenance.

Maintenance is the process that helps in getting reliable information about the required parameter or accuracy in the use of equipment by running a set of calibration procedures. It is a process that helps in the endurance of life of equipment both in case of an accidental breakdown / preventive scheduled upkeep. Hence in total Maintenance process can be sliced down as routine maintenance to be carried out, regularly immediately after the use of any medical equipment between each patient and can be used only after thorough

cleaning as prescribed by the manufacturer before use of the next patient. Periodic calibrations and maintenance are the processes of ensuring the accuracy of reporting information which can be done by Planned Periodic Maintenance. Accidental breakdowns need immediate restoration by repairing and upkeep this activity is called Breakdown Maintenance, done by removing the equipment from the patient care area to get them back in good working condition post upkeep service.

CONCEPT OF BARRIER DIAGNOSIS:

Routine maintenance is the crucial procedure – which helps in the concept of Barrier Diagnosis, like through cleaning of all Biomedical Equipment using the standard safety procedure. Following are the list of safe and permitted agents for cleaning/disinfecting the Biomedical Equipment, as permitted by the manufacturer standard recommendations[3]: -

Isopropyl alcohol 70%

1. (Range: 48% to 70%, as per manufacturer standards to be used for Disinfect the medical Device internal and external as well as when Bloodstains found in/on a machine)
2. Ethyl alcohol- 99.5%
3. Ethyl alcohol 95 to 96%
4. Ethyl alcohol 90% + methyl alcohol 10%
5. Ethyl alcohol 80%
6. Phenol 2%
7. Purified benzene
8. Chloramines 5%
9. Glutaraldehyde 2%
10. Hospital Detergent solution
11. Distilled water

Biomedical Equipments routine cleaning shall be performed by using the standard procedure for various surfaces sanitization as shown below:-

External surface cleaning: Any Medical device cabinet can be cleaned with soft moist/Damp cloth, then with a dry cloth.

Touch screen display cleaning: can be cleaned with soft moist/Damp cloth which does not drip water drops or soap solution when contacting with the display. Then use dry cloth and clean.

Keypad cleaning: Wipe/clean with a damp cloth with mild detergent, clean keyboard. If blood stains found clean with Isopropyl Alcohol-70% or with keyboard cleaning Spray for disinfection.

Caution while cleaning: Never allow solutions of any kind to collect on the bottom bezel of the display. Never use a brush or device that can cause abrasion (Scratches) to clean the touch display or its bezel; they will cause irreparable damage.

Note while cleaning: Allow the product to dry completely after cleaning before used to patient.

BARRIER DIAGNOSIS AND INFECTION CONTROL:

Three different types of Biomedical Equipment that are connecting to patient by surface contact sensors, internal organs through airway route or circulatory route are identified and measured their usage by simple observation study[4].

1. Multi Para Monitor, ECG Machine, Defibrillator – these are Biomedical Equipment grouped under G1 – Surface Contact Equipment.
2. Bi PAP Machine, Ventilator – these are Biomedical Equipment grouped under G2 – Airway Contact Equipment.
3. Infusion Pump, Syringe Pump, and Dialysis Machine – these are Biomedical Equipment grouped under G3 – Circulatory System Contact Equipment.

In consultation with the hospital infection control specialists and Intensive care specialists, Nursing staff, Patient care providers a well planned observatory study is conducted for seven months at Gandhi Hospital, Secunderabad. Telangana State, India. It is a tertiary care teaching medical college attached hospital – the entire study is divided into three phases

Phase I: - January 2020 to March 2020 Three Months – General Patient Care.

Phase II: - April 2020 to June 2020 Three Months COVID 19 Patient Care.

Phase III: - Post study observation.

Initial one week training on cleaning procedure for G1, G2, G3 types of Biomedical Equipment as named above was given to Patient care providers and Nursing staff – with observation of the procedure adopted by them[5]. The SOP followed for cleaning of each equipment are as follows:

Disinfection Of Multi Para Monitor

1. Switch off the equipment before cleaning.
2. Clean on the surface of monitor with a lint-free cloth moistened with cleaning agent (Ethanol 75%). Do not use strong solvents such as acetone or trichloroethylene.
3. Clean all the accessories with a lint-free cloth moistened with cleaning agent (Ethanol 75%)
4. ETCO2 sensor need to send for ETO/ Plasma sterilization.
5. During Fogging, Equipment should be switched off, disconnect from power source and make sure it is covered.

Disinfection Of ECG Machine

1. Switch off the ECG Machine before cleaning and disconnect from Power Source.
2. Clean the surface area of the ECG front panel with lint-free cloth moistened with cleaning agent (Ethanol 75%).
3. Do not use strong solvents such as acetone or trichloroethylene.
4. Wipe the ECG Cable with lint-free cloth moistened with cleaning agent (Ethanol 75%).
5. Soak the Bulbs and clamps in some lukewarm soap solutions for 5-10minute and wash thoroughly for twice in a week.
6. During Fogging, Equipment should be switched off, disconnect from power source and make sure it is covered.

Disinfection Of Defibrillator

1. Switch off the defibrillator before cleaning and disconnect from Power Source.
2. Clean the surface area of the machine with lint-free cloth moistened with cleaning agent (Ethanol 75%).
3. Do not use strong solvents such as acetone or trichloroethylene.
4. Wipe the ECG Cable with a lint-free cloth moistened with cleaning agent (Ethanol 75%)
5. Clean the paddles after every use.
6. During Fogging, Equipment should be switched off, disconnect from power source and make sure it is covered.

Disinfection Of Bi-PAP Machine

1. Disconnect and discard the disposable circuit immediate after discharge of the patient.
2. Switch off the machine and disconnect power connections.
3. Clean the surface of Bi PAP with a lint-free cloth moistened with cleaning agent (Ethanol 75%).
4. Do not use strong solvents such as acetone or trichloroethylene.
5. During Fogging, Equipment should be switched off,

disconnect from power source and make sure it is covered.

Disinfection Of Ventilator

1. Switch off the ventilator and disconnect from patient.
2. Disconnect and discard the disposable ventilator circuit immediate after discharge of the patient or as per the infection control committee recommendations on long stay patients.
3. Bacterial filter needs to connect at both inspiration and expiratory end of ventilator.
4. Bacterial filter at expiratory end needs to replace for every 48 hrs.
5. HME filter need to be replaced for every 24 hrs.
6. If patient is infected, it is recommended to disinfect the expiratory cassette by ETO / plasma sterilization process.
7. Clean the outer surface of the Ventilator with lint-free cloth moistened with cleaning agent. (Ethanol 75%). Do not use strong solvents such as acetone or trichloroethylene.
8. Clean all the accessories with a lint-free cloth moistened with cleaning agent (Ethanol 75%).
9. Reusable ventilator circuit need to sterile thru ETO/ Plasma sterilization process.
10. During Fogging, Equipment should be switched off, disconnect from power source and make sure it is covered.

Disinfection Of Infusion Pump

1. Switch off the Infusion pump and remove the power cord connections.
2. Clean the outer surface of the pump with a lint-free cloth moistened with cleaning agent (Ethanol 75%). Do not use strong solvents such as acetone or trichloroethylene.
3. Open the door and clean the surface area gently cleaning agent (Ethanol 75%) and close the door properly.
4. During Fogging, Equipment should be switched off, disconnect from power source and make sure it is covered.

Disinfection Of Syringe Pump

1. Switch off the syringe pump and remove the power cord connections.
2. Clean the outer surface of the pump with a lint-free cloth moistened with cleaning agent (Ethanol 75%). Do not use strong solvents such as acetone or trichloroethylene.
3. During Fogging, Equipment should be switched off, disconnect from power source and make sure it is covered.

Disinfection Of Dialysis Machine

1. Need to perform hot disinfection with citrosteril after every case.
2. Switch off the machine and remove the power connections.
3. Clean the outer surface of the machine with a lint-free cloth moistened with cleaning agent (Ethanol 75%).
4. Do not use strong solvents such as acetone or trichloroethylene.
5. During Fogging, Equipment should be switched off, disconnect from power source and make sure it is covered.

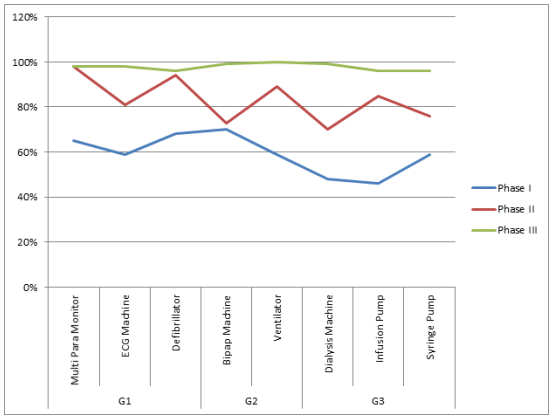
OBSERVATION & REMARKS:

Phase wise biomedical equipment percentage compliance is tabulated below

Group	Biomedical Equipment	Phase I	Phase II	Phase III
G1	Multi Para Monitor	65%	98%	98%
	ECG Machine	59%	81%	98%
	Defibrillator	68%	94%	96%
G2	Bi PAP Machine	70%	73%	99%
	Ventilator	59%	89%	100%
G3	Dialysis Machine	48%	70%	99%
	Infusion Pump	46%	85%	96%
	Syringe Pump	59%	76%	96%

It is a good sign that G1 category biomedical equipment cleaning compliance improved by 27% increase in Phase II and further by 6% added compliance in Phase III.

- G2 category biomedical equipment cleaning compliance improved by 17% increase in Phase II and further by 19% added compliance in Phase III due COVID 19 Instructions for strict compliance for special cleaning of these equipments.
- G3 category biomedical equipment cleaning compliance improved by 26% increase in Phase II and further by 20% added compliance in Phase III due COVID 19 Instructions for strict compliance for special cleaning of these equipments.
- This is a sample observation study and the percentages shown above are collected by convenient random observations and qualitative observation reports collected from the supervising nursing staff.
- There is a substantial improvement in cleaning process and professional skill of patient care providers and nursing staff in the Phase III.



SCOPE FOR FURTHER STUDY:

This study is limited to high usage intensive care ward Biomedical Equipment, there are high value Biomedical Equipment like Radiology and Clinical Laboratory Analyzers which are equally important – present study is limited and does not included them.

This study was focused more on observatory information that includes qualitative data inferences – there is a potential for further study with focused of swab collection from the surfaces and microbial culture study to evaluate the scientific inferences.

REFERENCES:

1. John Denis Enderle, Joseph D. Bronzino (2012), Introduction to Biomedical Engineering. Academic Press.
2. R S Khandpur (2014), Handbook of Biomedical Instrumentation, McGraw-Hill.
3. John B. Durkee (2006), Management of Industrial Cleaning Technology and Processes, Elsevier.
4. Gammon. J (1998), A review of the development of isolation precautions, British Journal of Nursing.
5. Global Guidelines for the prevention of Surgical Site Infection (2016), World Health Organization