International Journal of General Medicine and Pharmacy (IJGMP)
Vol.1, Issue 1 Aug 2012 53-62

BIOMEDICAL WASTE MANAGEMENT USING FAILURE MODE EFFECT ANALYSIS

CALAMUS EMERALD, D SHREEDEVI & HABEEB GHATALA

[1]MHM Final year student, Apollo Institute of Hospital Administration (AIHA), Hyderabad, India
[2]Associate Professor, AIHA, Jubilee Hills, Hyderabad, India
[3]Dean, Apollo Hospitals Educational & Research Foundation, Apollo Health City, Jubilee Hills, Hyderabad, India

ABSTRACT

Proper handling, treatment and disposal of biomedical wastes are important elements of health care infection control programme. Correct procedure will help protect health care workers, patients and the local community. In the present study, Failure Mode Effect Analysis tool is used to the processes of biomedical waste management. Accordingly potential failure modes are identified and their cause and effect are detected. In the brainstorming sessions the persons who were involved in the processes have accordingly given the scores for calculating the risk priority numbers for drawing the inference about the possible action to be taken by the hospital management and also for suggesting the action plan for biomedical waste management.

KEYWORDS: Autoclaving, Clinical Wastes, Incineration, Risk Priority Numbers, Shredding.

INTRODUCTION

Waste is anything discarded by an individual, household or organization. As a result, waste is a complex mixture of different substances, some of which are hazardous to health. As per WHO norms, the health care waste includes all the waste generated by health care establishments, research facilities and laboratories. As per Biomedical Waste (Management and Handling) Rules, 1998, any waste which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining thereto is the biomedical waste.

Hospital waste management is an imperative environmental and public safety issue due to the waste's infectious and hazardous character. Clinical wastes are potentially dangerous and polluting and their safe management and disposal is a matter of continuing public and professional concern. Failures in waste management continue to occur at every point of the disposal chain. However, the implications of infections and environmental impact mandate great care in the handling, packaging, storage, and processing of wastes.

Managing of waste has two vital parts: Firstly, management of hazardous waste of different types generated from different sources, which involves careful segregation, collection, transportation and final disposal. Secondly, effective training and supervision of various categories of personnel involved in the waste management system. In this process, Failure Mode Effect Analysis (FMEA) can be used for managing biomedical waste.

Failure Mode Effect Analysis methodology is designed to identify potential failure modes for a product or process. It assesses the risk associated with those failure modes, to rank the issues in terms of importance and to identify and carry out corrective actions to address the most serious concerns. FMEA can contribute to improved designs for products and processes resulting in higher reliability, better quality, increased safety, enhanced customer satisfaction and reduced costs.

REVIEW OF LITERATURE

Veda Hegde, RD Kulkarni, GS Ajantha[1] examined the various types of waste, its management and the hazards of indiscriminate disposal of hospital waste and particularly about dental waste management. They identified the causes like lack of concern, motivation, awareness and cost factor as some of the problems in the proper hospital waste management. They stressed upon the need for education to increase the awareness level among different categories of staff regarding biomedical waste management.

Rao et al[2] conducted a study of various hospitals to assess the infrastructural requirements for biomedical waste management. They compared the costs of those hospitals where the entire infrastructure as per Biomedical Waste Rules have been implemented with those which made compromises on each stage of biomedical waste management and supported the need to standardize the infrastructural requirements.

Hem Chandra[3] on the occasion of the World Environment Day identified the types of hospital waste and the rationale of hospital waste management. He urged the need for the coordination between hospital and outside agencies like Municipal Authority and Pollution Control Boards in implementing eco-friendly technology for treatment of biomedical and hazardous waste.

J.G. Reiling, B.L. Knutzen and M. Stoecklein [4] analysed the utility of FMEA as a valuable tool in health care facility design. They studied the implementation of FMEA at St. Joseph's Community Hospital in West Bend, Wisconsin, USA. The hospital had used FMEA to create a replacement facility aimed at reducing errors and promoting patient safety and satisfaction through FMEA design. The results proved that a focus on patient safety through design will create facilities that will increase efficiency while promoting a healing environment.

J.S. Krouwer[5] reviewed the Failure Mode Effect Analysis process and recommended fault trees and a list of quality system essentials as additions to the FMEA process to help identify failure mode effects and causes. He suggested a modified Pareto Analysis, when there are quantitatively different failure mode effects with different severities.

OBJECTIVES OF THE STUDY

The main objectives of the study are:

1. To study the process of categorization and classification, segregation, collection, storage, transport, treatment and final disposal of the biomedical waste.
2. To analyse the process of biomedical waste management using FMEA.

RESEARCH METHODOLOGY

The study is purely an analytical study and is based on observations on the process and procedures of waste management on a daily basis and interviewing the people who are directly involved in handling the waste. The study primarily aims at identifying the failure modes in the waste management process by using FMEA tool. Some of the important processes of biomedical waste management are taken for the study and the FMEA tool has been implemented. The analysis and interpretation of the data are on the basis of scores of severity, frequency of occurance, and likelihood of detection. These scores are assigned in the series of brainstorming sessions conducted by the hospital with the people involved in those processes. The supervisor who is responsible for a specific process along with his team members will assign the scores for failure, detection and severity on the basis of the consequences. Based on these three scores, the Risk Priority Numbers (RPNs) are calculated. These calculated RPNs which in turn will suggest the course of action to be adopted by the hospital. These score codes are taken from Clinical and Laboratory Standards Institute.

ANALYSIS AND INTERPRETATION

The wastes generated from health care units are generally classified as infectious and non-infectious. The infectious health care wastes are termed as ‘biomedical wastes’ and are considered to be potentially hazardous in nature. Sources of generation of biomedical wastes are hospitals, nursing homes, veterinary hospitals, dental clinics, pathological and diagnostic laboratories, and blood bank to mention a few. The disposal of untreated biomedical wastes mixed with non-infectious health care wastes or other general municipal wastes poses an environmental threat and public health risk. Indiscriminate disposal of untreated biomedical waste is often the cause for the spread of a variety of infectious diseases. It is also responsible for the nosocomial diseases i.e., the hospital acquired infections to the health care personnel who handle these wastes at the point of generation.

The amount of infectious waste is around 25% of the total wastes generated from a health care establishment and that of non-infectious wastes constitutes nearly 75%. In the absence of proper segregation, the non-infectious waste becomes infectious and poses environmental threat to the society. According to Indian Society of Hospital Waste Management, the amount and composition of hospital waste generated in different countries, namely in U.K 2.5, U.S.A 4.5, France 2.5, Spain 3.0, India 1.5 Kg/bed/day respectively.

APPROACHES TO HOSPITAL WASTE MANAGEMENT

Biomedical waste should be managed according to its type and characteristics. In order for waste management to be effective, the waste should be managed at every step, from acquisition to disposal. The elements of a comprehensive waste management system are categorization and classification of wastes, segregation, collection, storage, transportation, treatment and disposal of hospital waste.

(A) Classification of Wastes Categorization and Classification of waste is important for the purpose of safe waste disposal. In hospitals, the waste generated has been broadly classified into the following categories as per Schedule I of Biomedical Waste (Management and Handling) Rules, 1998: (1) Category 1 Pathological waste, (2) Category 2 Animal waste, (3) Category 3 Microbiology and Biotechnology waste, (4) Category 4 Sharps, (5) Category 5 Pharmaceuticals, (6) Category 6 Infected waste, (7) Category 7 Infected Plastic waste, (8) Category 8 Liquid waste, (9) Category 9 Incineration waste and (10) Category 10 Chemical waste.

(B) Segregation of Wastes: Segregation or the separation of different types (categories) of waste by sorting at the point of generation is considered as the "key" for the entire process as it allows special attention to be given to the relatively small quantities of infectious and hazardous waste, thus reducing the risks and cost of waste management. Conversely small errors at this stage can create lot of subsequent problems. The biomedical waste should be segregated as per Schedule II given below:

Table 1Schedule II of the Biomedical Waste (Management & Handling) Rules, 1998

Colour Coding	Type of Containers	Waste Category
Yellow	Plastic bag	1,2,3,6
Red	Disinfected Container/ Plastic bag	3,6,7
Blue/ White Translucent	Plastic bag/ puncture proof container	4,7
Black	Plastic bag	5,9,10

Studies have indicated that about 2 Kg. of wastes are generated per bed per day which gives an idea about the high volume of waste generated on a day-to-day basis.

(C) Collection of Waste: Collection of biomedical wastes should be done as per rules in colour coded plastic bags as mentioned in the earlier table. There is a need to be vigilant so that intermixing of different categories of waste is not done inadvertently by the patients, attendants or visitors.

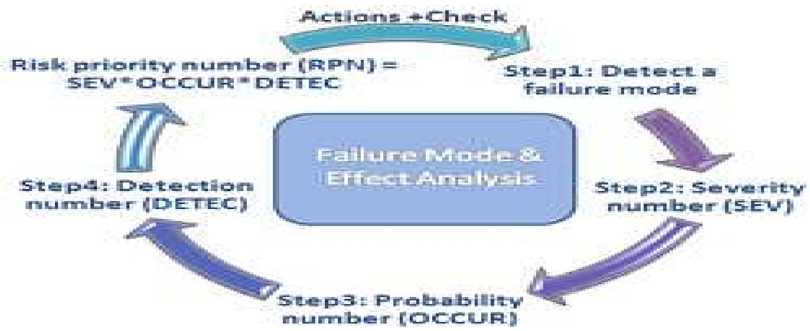
(D) Storage of Waste: Storage refers to the holding of biomedical waste for a certain period of time, after which it is sent for treatment and disposal. In other words, it means the duration of time wastes are kept at the site of generation and transit till the point of treatment and final disposal.

(E) Transportation of Waste: Transportation of biomedical waste can be divided into intramural (internal) and extra mural (external) transportation. The biomedical waste collected in coloured containers shall be transported to common biomedical waste treatment facility in a fully covered vehicle. The waste should not be kept for more than 48 hours.

(F) Treatment and Disposal of Hospital Waste: Treatment and disposal of the biomedical waste shall be done by the following methods, i.e., (1) Incineration (2) Autoclaving (3) Shredding (4) Microwaving depending on the waste category and according to Schedule V of BMW Rules.

Failure Mode Effect Analysis Cycle

In FMEA, failures are prioritized according to how serious their consequences are, how frequently they occur, and how easily they can be detected. The purpose of the FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority ones. The following is the FMEA cycle.



FMEA Cycle

The study covers the steps applied for the selected five processes of biomedical waste management using FMEA, which is as follows:

Step One: Select a Process to Evaluate with FMEA

Evaluation using FMEA works best on processes that do not have too many sub processes. In the present study FMEA is conducted on five processes like segregation into colour bins, segregation at generation, collection, transportation and disposal processes are undertaken in a hospital. Each selected process of biomedical waste management is taken and accordingly FMEA is applied.

Step Two: Recruiting a Multidisciplinary Team

For successful implementation of FMEA, include everyone who is involved at any point in the process. Some people may not need to be part of the team throughout the entire analysis, but they should certainly be included in discussions of those steps in the process in which they are involved. In the study the people who are involved in these five processes are included in the team.

Step Three: The Team Should Meet Together to List all of the Steps in the Process

Number every step of the process, and be as specific as possible. It may take several meetings for the team to complete this part of the FMEA, depending on the number of steps and the complexity of the process. Flowcharting can be a helpful tool for outlining the steps. After process mapping, obtaining consensus from the group is a must. The team should agree that the steps enumerated in the FMEA accurately describe the process. Accordingly, in the study, the selected five processes have been process mapped.

Step Four: The Team Should List Failure Modes and Causes

For each step in the process, list all possible “failure modes” meaning, anything that could go wrong, including minor and rare problems. Then, for each failure mode listed, identify all possible causes. In our study the first process i.e., segregation of the wastes, the failure mode has been identified by the team as lack of awareness and knowledge which in turn the potential cause of failure is lack of proper training and attrition. Like wise, for the other four processes also failure modes and causes are identified by the team, which are shown in the table 6.

Step Five: For Each Failure Mode, the Team Should Assign a Numeric Value for Likelihood of Occurrence, Likelihood of Detection, and Severity

For every failure mode identified, the team should assign the appropriate score, for which the codes and ratings given by the Clinical and Laboratory Standards Institute are used which are presented in the tables 2, 3, and 4 respectively. In our study, the team have given the scores for the first process as severity score of (8), which is classified under very high ineffective service. The probability occurrence score of (8), which is a repeated failure and classified under high occurrence, and detection score of (9), where likelihood of detection of failure is very remote. The team should do this as a group and have consensus on all values assigned. These scores are assigned in the brainstorming sessions of that processes for which FMEA is conducted. Assigning scores helps the team prioritize areas to focus on and can also help in assessing opportunities for improvement.

Table: 2. Frequency of Occurrence Codes

Rating	Classification	Examples of Consequence
10	Very high	Inevitable failure
8	High	Repeated failure
6	Moderate	Occasional failures
3	Low	Few failures
1	Remote	Failure unlikely

Table: 3. Likelihood of Detection Codes

10	Absolute uncertainty
9	Very remote
8	Remote
7	Very low
6	Low
5	Moderate
4	Moderately high
3	High
2	Very high
1	Almost certain

Table: 4.Severity Rating

Rating	Classification	Examples of Consequence
10	Dangerously high	Injury or death
9	Extremely high	Regulatory non-compliance
8	Very high	Ineffective service or treatment
7	High	High customer dissatisfaction
6	Moderate	Potential ineffectiveness
5	Low	Customer complaint
4	Very low	Lowered effectiveness
3	Minor	A nuisance to the customer
2	Very minor	Not apparent; minor
1	None	Not apparent; no effect

Step 6: Calculation of Risk Priority Numbers (RPNs)

For each process of biomedical waste management, which is considered for our present study an detailed failure mode effect analysis sheet is prepared wherein the failure modes and causes and the severity, detection and occurrence scores are shown. Based on these three score the risk priority numbers are calculated. These RPNs are calculated as

Risk Priority Number= Score of Frequency of Occurrence×Score of Likelihood of Detection×Severity Rating

For the study, five processes of biomedical waste management were selected and the team has identified the failure modes, effect of failure and also the reasons for failure and assigned the severity rating and the likelihood of occurance as well as the detection score and presented in table 6. The following is the proforma FMEA analysis sheet for calculating the RPNs.

Table: 5.FMEA Sheet for each Process

Steps in Process(1)	Potential Failure Mode -2	Potential Effect of Failure -3	Severity rating (1–10) (S) (4)	Potential Cause of Failure -5	Frequency of Occurrence (1–10) (O) -6	Detection Code (1-10) (D) -7	Risk Priority Number (RPN) (SxOxD) (8)	Actions to Reduce Occurre nce of Failure (9)
1								
2								
3								

Table: 6.FMEA analysis sheet for the Biomedical Waste Management Process

Process	Potential Failure Mode	Potential Effect of the Failure	Severity Rating (S)	Potential Cause of the Failure	Frequency of occurence (O)	Detection Score (D)	Risk Priority Number (S*O*D)	Recommended Action
Segregation of the biomedical wastes into the color coded bins	Lack of awareness and knowledge of segregation among the staff	Improper segregation	8	Lack of periodic training programmes, Attrition among the staff	8	9	576	Training and testing them periodically, Regular induction programmes, colour coded bins are to be provided
Segregation of the biomedical wastes at the points of generation	Absence of posters on safe disposal at all points of generation	Mixing up of both infectious and non-infectious wastes	8	Lack /less number of posters availability at the required areas	8	3	192	Indenting for more posters, regular/periodical checking of these areas, posters have to be put up
Collection of the wastes from the points of generation at particular times	Lack of assigning a particular team of cleaning staff to handle the wastes	Infection high; waste being transported at all possible times; risk of hospital property being taken out	8	Lack of adequate manpower	6	3	144	Recruitment of house keeping staff with basic qualification and training them periodically
Transportation of the wastes to the central collection area	A pre-defined path is not being followed	Cross-contamination with the general public	8	Delay in the training schedule	7	4	224	Periodic training programmes, trolleys to be provided
Disposal at the central collection area	Absence of Rechecking of the wastes before its disposal to the central collection area	Loss of hospital property; will be fined; mixing up of the wastes.	8	Lack of adequate space for rechecking and segregation	7	3	168	A separate area/place to be demarcated for rechecking, verification at the segregation areas

Source: Primary Data Step Seven: Evaluating the results

After calculating RPNs for each step of the process, the results are evaluated on the basis of priorities which will be between 1 and 1000. Some hospitals define priorities in their procedure as:

(1) Calculated RPNs of less than 201 for each process as acceptable (2) RPNs between 201–500 as undesirable for the hospital (3) RPNs above 500 as unacceptable and requires immediate action.

To calculate the RPN for the entire process, add up all of the individual RPNs for each failure mode. In the present study, RPNs calculated for the above mentioned five processes are shown in the following table.

Table:7.Inference of RPNs calculated

S.No	Process	Potential Failure Mode	Calculated RPNs	Inference
1	Segregation of biomedical wastes into the colour coded bins	Lack of awareness and knowledge of segregation among the hospital staff	576	Unacceptable
2	Segregation of the biomedical wastes at the points of generation	Absence of posters on safe disposal at the points of generation	192	Acceptable
3	Collection of the wastes from the points of generation at particular times	Lack of assigning a particular team of hospital staff to handle the wastes	144	Acceptable
4	Transportation of the wastes to the central collection area	A pre defined path is not being followed	224	Undesirable
5	Disposal at the central collection Area	Absence of Rechecking of the wastes before its disposal to the central collection area	168	Acceptable

Source: Primary Data

Step Eight: Using RPNs to plan improvement efforts

Failure modes with high RPNs are the most important parts of the process on which to focus improvement efforts. Failure modes with very low RPNs are not likely to affect the overall process even if eliminated completely, and they should therefore be at the bottom of the list of priorities.

CONCLUSIONS

Although initially developed by the United States Armed Forces, FMEA methodology is now extensively used in a variety of industries including food processing, plastics, software and health care. It is used extensively in health care to assess risk of failure and harm in processes and to identify the most important areas for process improvements to provide better patient care. In health care, FMEA focuses on the system of care and uses a multidisciplinary team to evaluate a process from a quality improvement perspective.

REFERENCES

1. Veda Hegde, RD Kulkarni, GS Ajantha, "Biomedical Waste Management", Journal of Oral and Maxillofacial Pathology, Year 2007, Volume 11, Issue 1[p. 5-9]
2. Rao,et al, Bio Medical Waste Management: An Infrastructural Survey of Hospitals, MJAFI, Vol.60, No.4, 2004.
3. Hema Chandra, Hospital Waste – An Environmental Hazard and its Management. ISEB Vol. 5. No.3 – July 1999.
4. John G. Reiling and Barbara L. Knutzen, Mike Stoecklein, "FMEA – The Cure for Medical Errors" - Quality Progress – August 2003.
5. Jan.S. Krouwer , An Improved Failure Mode Effects Analysis for Hospitals — Arch Pathol Lab Med – Vol. 128, June 2004.
6. Failure Modes and Effects Analysis (FMEA) – Institute for Health care Improvement, 2004.
7. "Safe Management of Wastes from Health Care Activities- WHO, Geneva, 1999.
8. Hazardous Waste Management at Health Care Facilities – NCDENR – Division of Waste Management.
9. Bekir Onursal, "Health Care Waste Management in India" - The World Bank October, 2003.
10. Eleven Recommendations for Improving Medical Waste Management – Basel Action Net Work (BAN) – April, 1999.
11. Best Management Practices for Hospital Waste, Washington State Department of Ecology, December, 2005.
12. Bio-Medical Waste (Management and Handling) Rules, 1998.
13. Bio Medical Waste Management – Self Learning Document for Doctors, Superintendents and Administrators – WHO, Manual prepared by EPTRI