

**Piloting an Educational Program to Improve BioMedical Waste Management and  
Disposal System in Hospitals of Pune, Maharashtra, India**

Master of Public Health Integrating Experience Project  
Program Implementation Framework

By

Deepak Ramakrishna Bhale, B.Tech, MPH (candidate)

Advising team:

Vahe Khachadourian, MD, MPH, PhD

Tsovinar Harutyunyan, MPH, PhD

Turpanjian School of Public Health

American University of Armenia

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## **Abbreviations**

AIDS	Acquired Immunodeficiency Syndrome
AUA	American University of Armenia
BMW	Bio-Medical Waste
BMWD	Bio-Medical Waste Treatment and Disposal Facility
BMWMD	Bio-Medical Waste Management and Disposal System
BWMP	Bio-Medical Waste Management Process
HIV	Human Immunodeficiency Viruses
INR	Indian Rupee
WHO	World Health Organization
KAP	Knowledge, attitude and practices

## Abstract

**Background:** BMW is an immense problem across the globe, including India. Fifteen percent of hospital waste contains infectious chemicals, toxins, and radioactive material. Many countries perform the open burning/incineration of biomedical waste causing the emission of hazardous material like dioxins, furans, and particulate matter in the atmosphere. In 2010, Worldwide, new cases of HIV infections, hepatitis B and C were 34,000 and 1,700,000 and 3,15,000 causing many deaths. In 2016, in India, 484 tonnes of BMW is developed on daily bases from 1,68,869 Indian health care system, out of which only 447 tonnes/day is disposed properly and 37 tonnes/day is left untreated. In 2009, the identified cause of 70 died people out of 240 reported cases of hepatitis B was the reuse of un-sterilized and re-use of infected needles and injections in Gujarat, India. The major causes of problems related to BMWMD are inadequate awareness, lack of trained staffs, poor management, or no BMWMD.

**Intervention program:** The current proposal advocates for piloting an educational program to improve BioMedical Waste Management and Disposal system in hospitals of Pune, Maharashtra, India. The BMWMD educational program will be judged for estimating usefulness in increasing knowledge, attitude, and practices of the study participants. The study participants consisted of English-speaking medical staff working in the hospitals and entrusted for biomedical wastes. Random sampling will be done to assign hospitals to the intervention and control groups from the list of government-run and private sector hospitals.

**Aim:** Create awareness and educate medical staff of hospitals regarding proper biomedical waste management and disposal system. The BMWMD educational program will be proven to be successful when there is an improvement in the KAP scores of the study participants.

**Setting:** From the list of hospitals in Pune, Maharashtra, India two government-run hospitals and two private sector hospitals will be selected. One government-run hospital and one

private sector hospital will be in the intervention group. One government-run hospital and one private sector hospital will be in the control group. The eligible participants from the hospitals in the intervention group will receive BMWMD educational program.

**Data collection:** Pre-tested, adopted and adapted questionnaire from the previous successfully done research will act as the study instrument for data collection. Interviewer-administered data collection will be done. At baseline and follow-up, data will be collected on the KAP scores of the study participants.

**Data Analysis:** SPSS statistical software will be used for data analysis. Descriptive analysis for frequency, mean and median will be done to analyze socio-demographic characteristics of participants. The t-test will compare the KAP mean scores of intervention and control groups. Pre-observation and post-observation will be compared with the help of the chi2 test for nominal variables and t-test for the numerical variable. Double data entry and spot check will be done.

**Evaluation project:** Quasi-experimental non-equivalent with the control group: pre and post-assessments with panel design. This design will evaluate the increment in KAP scores and effectiveness of BMWMD educational program. The outcome (KAP score) will be assessed by comparing baseline and follow-up assessment with intervention and control groups.

**Conclusion:** The project proves to be successful if as a result of BMWMD education program KAP scores will increase among medical staff. Then this pilot educational program will be publicized and put up in front of the government agencies suggesting them to implement in all the Indian hospitals.

## INTRODUCTION

### **Background of BioMedical Waste Management and Disposal system**

According to the Indian government's Biomedical Waste (Management and Handling) Rules 2016, "bio-medical waste (BMW) means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including human and animal anatomical waste, expired or discarded medicines, chemical and liquid waste, contaminated waste and metallic body implants."<sup>1,2</sup> All biomedical wastes must be separated and segregated according to their type and placed in dustbins with different colors. In India, all biomedical waste like the living being's waste, outdated or non-usable drugs, contaminated clothes and clothing material soiled with blood or body fluid must be collected in plastic bags or containers which are chlorine free and yellow in color.<sup>1,2</sup> Laboratory wastes must be received in autoclave safe containers.<sup>1,2</sup> Recyclable contaminated waste, must be collected in plastic bags or containers which are chlorine free and red in color.<sup>1,2</sup> Glassware and metallic body implants must be received in blue-colored marking cardboards.<sup>1,2</sup>

"BMWD means any facility wherein treatment, disposal of bio-medical waste or processes incidental to such treatment and disposal is carried out and includes common bio-medical waste treatment facilities".<sup>1,2</sup> Biomedical Waste Management Process (BWMP) involves several steps: a) waste collection, b) segregation c) transportation and storage, d) treatment and disposal, e) transport to the final disposal site, and f) final disposal.<sup>13</sup>

### **Global Burden**

World Health Organization (WHO), 15% of BMW waste contains infectious chemicals, toxins, and radioactive materials.<sup>3</sup> Developing countries like Bangladesh and North Korea are showing a high rate of increment in the generation of medical waste.<sup>18</sup> Without BMWMD,



hazardous medical wastes get mixed with general waste and contaminate total waste generated in medical facilities.<sup>3</sup> In Bangladesh, North Korea, and Middle Eastern countries, the main method is open burning or incineration of biomedical waste, which causes the emission of hazardous materials like dioxins, furans, and particulate matter in the atmosphere.<sup>3,18</sup> Health care workers inflict many injuries such as cuts from an infected sharp object, thermal burns, chemical burns, radiation burns due to the inappropriate management of BMW.<sup>3</sup> In 1987, 12 children of Indiana, USA were playing outside the medical facility and got tainted with AIDS.<sup>18</sup> Improper disposal of needles and syringes are a threat to get infection, injuries and can be reused.<sup>3,10</sup> In 2010, new cases of HIV infection, hepatitis B and C were approximately 34,000, 1,700,000, 3,15,000.<sup>3,10</sup> In lower and middle-income countries, waste handler and scavengers at waste disposal sites pose a risk for needlestick injuries and exposure towards toxicity and various hazardous materials.<sup>3</sup> Among lower and middle-income countries, only 58% of healthcare facilities have biomedical waste management and disposal system.<sup>3</sup> Some countries like the Philippines and Denmark have banned the use and construction of incinerators of biomedical waste.<sup>1</sup> According to WHO survey of 2012, all around the world, the main causes of problems related to BMWMD are inadequate awareness, lack of trained staffs, poor management or no BMWMD, less allocation of fund and low priority towards BMWMD.<sup>3</sup> Many countries do not have a law or do not enforce the law regarding biomedical waste management and disposal system.<sup>3</sup>

### **Impact of BMW on Environment and Health**

The US Environmental Agency declared that the third biggest effusion of harmful gas is from BMW.<sup>5</sup> Untreated landfilling and open incineration of biomedical waste lead to the release of noxious particles into the environment and contaminates water at the surface as well as at the ground level.<sup>3</sup> The residual from the incineration of untreated biomedical waste contains human carcinogens like lead, mercury, cadmium along with toxins and furans.<sup>1</sup> Inapt

destruction of BMW lead to bacterial gastroenteritis infections, hepatitis A, hepatitis B, TB, and HIV.<sup>15</sup> Most of the countries have changed the method of incarnation of biomedical waste to environmentally friendly alternatives.<sup>1</sup>

The biomedical waste management and disposal system expenditure of Balrampur Hospital, Lucknow, India administration is 1700\$/year.<sup>8</sup>

### **BWMD Situation in India**

The BWMD remains a major problem in India.<sup>1</sup> Until the late 90s, biomedical waste was burned in the open environment but after the law on biomedical waste was executed on 20 July 1998, medical facilities stopped the open burning of biomedical waste and the number of machines for the incarnation was increased.<sup>1</sup> “In 2016, 484 tonnes of BMW was collected from 168,869 Indian health care system out of which only 447 tonnes/day were disposed properly and 37 tonnes/day were left untreated”.<sup>1,10</sup> The amputated human body parts were buried within the premises of hospital such as it was practiced in Balrampur Hospital, Lucknow, India or thrown away in the general municipal waste.<sup>8</sup> Specimens of blood, urine, stool and used culture media are drained in swage after sample testing.<sup>8</sup> 150 Goa hospitals discard medical wastes in general bin, which eventually end up into the government garbage collection centers.<sup>19</sup>

In 2009 in Gujarat, India, out of the 240 patients who were infected by hepatitis B because of the reuse of unsterilized and infected needles, 70 died.<sup>7</sup> Eighty-two percent of primary, sixty percent of secondary, and fifty-four percent of tertiary hospitals and health care centers across 20 states of India have no BWMD.<sup>4</sup> Hospital staff are not aware of segregation methods of BMW and need to learn the color coding system for safe BWMD.<sup>12</sup> In Gujarat, 83% of hospitals performed open-air incarnation of biomedical waste and 10% of private hospitals incarnated biomedical waste without pretreatment.<sup>4</sup> Private sector hospitals are not

using needle shredder or separate segregation method for used injections and needles which mix with the common hospital wastes.<sup>4</sup> On the other hand, 11 out of 15 Gujarat government hospitals are using needles shredder and separating them from common hospital waste.<sup>4</sup> A massive volume of medical waste is formed in the Indian healthcare system, which needs to be managed and disposed properly.<sup>10</sup>

In India, the leading cause of hepatitis and AIDS (HIV) is poor biomedical waste management and disposal system or lack of it.<sup>8</sup> Generally, infectious waste is collected and mixed with common hospital wastes and then dumped into general garbage dumping sites in India.<sup>8</sup> Medical staff in Indian hospitals lack training and education to handle bio-medical waste properly.<sup>20</sup> Hospital staff do not practice proper biomedical waste management and safe disposal system.<sup>8</sup> Most of the Indian states do not have treatment and incineration facilities in hospitals.<sup>8</sup>

A study among the population of New Delhi, Mumbai, and Kolkata in 2000 found the alarming level of organochlorine and other dioxins in the human breast milk because of the previous incorrect practice of BMWMD in India.<sup>1</sup>

Doctors lack knowledge about different classifications of BMW in Gujarat, India.<sup>1</sup> The hospital staff, especially doctors in private and NGO-run hospitals have no knowledge of the disinfecting methods of biomedical waste.<sup>4</sup> There is a need for trained and educated hospital staff to ensure patient safety in hospitals.<sup>15</sup> Doctors do not want to take any responsibility for handling medical waste and think open incineration is the best method to get rid of biomedical waste.<sup>4</sup>

It has been suggested by many researchers that the ministry of health (MoH) in India must retain traces of the proper destruction of BMW by Indian hospitals.<sup>5</sup>

## **Rationale for Project**

As the literature proves that the knowledge of BMWMD among Indian hospital staff is low and should be improved. The burden of disease caused due to improper BMWMD is high in India as the medical staff is knowledge deficient regarding BMWMD.<sup>1</sup> The medical staff is the first people to come in contact with biomedical waste.<sup>15</sup> Therefore this proposed BMWMD educational program specifically targets the medical staff. The educational intervention will increase awareness and train the medical staff to practice correct BMWMD and also manage sensitive wastes such as blood spill, and radioactive material.<sup>15,22</sup> Well-educated, aware and fully trained medical staff not only maintains a hygienic environment for patients but also helps in the betterment of the economy of the health care system.<sup>24</sup>

The evidence from the literature suggests that the educational intervention program among medical staff will result in the proper and safe handling, segregation, and disposal of BMW.<sup>15</sup> Urgent attention is required in India for the education and training of medical staff regarding BMWMD.<sup>1,2,4,5,8,11</sup> The earlier educational programs have shown an increase in the KAP regarding BMWMD.<sup>12,15,22,24</sup> As a step forward, the proposed educational programs will also improve the KAP of the staff regarding BMWMD.

## **METHODS**

### **The Implementation Plan of the Educational Program**

#### **Aim**

The main aim of the educational program is to educate the medical staff of hospitals regarding proper biomedical waste management and disposal system.

#### **Objectives**

1. By the end of the educational program, there will be 87% relative increase in knowledge score of the study members about BMWMD.<sup>19</sup>

2. By the end of the educational program, there will be 14% relative increase in attitude score of the study participants regarding biomedical waste management and disposal system.<sup>17</sup>
3. By the end of the educational program, there will be 50% relative increase in practice score of the study participants regarding biomedical waste management and disposal system.<sup>16</sup>

### **Setting**

The piloting of the educational program will be done in Pune, Maharashtra, India. The area covered by the Pune district is 15, 642 km<sup>2</sup> consisting of 1912 Villages.<sup>25</sup> By 2015, the population is 9,426,959, while the density is 600/km<sup>2</sup>.<sup>25</sup> Two large government-run hospitals and two large hospitals from the private sector will be chosen from the list of hospitals in Pune, Maharashtra, India. The selection of hospitals for the educational program will be done by simple random sampling. There are 12 government-run hospitals in Pune district.<sup>26</sup> There are 48 private sector hospitals in Pune district.<sup>27</sup> The separate lists of government-run and the private sector hospitals containing names of the hospitals in Pune will be obtained from the government database. The random selection of hospitals will be done from the list. Using RANDBETWEEN command in Excel. Using this method, 1 government-run and 1 private hospital will be taken for the intervention group. 1 government-run and 1 private hospital will be taken for the control group. All the medical staff, who handle or come in contact with biomedical waste will be eligible for the intervention. The hospitals in the intervention group will receive an educational program and the hospitals in the control group will only participate in the assessments. The eligibility of the participants will be decided on the basis of their documented designation in hospitals, which will be cross-checked through hospital records.

## **Action Plan for Education Program**

The duration of the educational program is 7 months (from March-2020 till September-2020) (*Appendix 1: Timeline*). The project leader will hire the required staff and will keep track of the program. The experts of biomedical waste management and disposal system will be employed for providing intervention to the medical staff. Experts will educate the study participants according to designed study materials. The BMWMD experts will provide training to study participants for 3 hours on every second and fourth Sunday of every month. Each participant has to complete the previous stage of intervention to continue and move to the next stage of intervention. Without completion, they will not be allowed to participate in the next stage of intervention. For the purpose of accountancy, the date, timing, and activities of the participants will be recorded by the program coordinator. The intervention will be organized in hospitals' premises.

## **Materials for Educational Program**

The Biomedical Waste Management and Disposal System (BWMD) experts will design the educational program. All participants enrolled in the intervention group will receive a book and soft copies of all the presentation handouts (slides) on Biomedical waste management and disposal system developed by the experts.

1. Book – The book will contain:
  - a. Definitions of all types of wastes
  - b. Biomedical waste will be described in details with all of its categories
  - c. BMW 1998 laws and BMW 2016 laws by the Indian government for biomedical waste management and disposal system
  - d. Various case studies from the globe on biomedical waste management and disposal system

- e. Proper steps and methods for the safe destruction of BMW
  - f. Safety materials plus types of equipment which must be used for correct BMWMD
  - g. Risk factors related to biomedical waste
  - h. Recommendations for safe and proper biomedical waste management
2. Presentation handouts (slides) - In total 14 sets of lecture slides will be delivered to the participants. These slides will include information about biomedical waste, current situation, categories of biomedical waste, laws by the Indian government for biomedical waste management and disposal system, and many more.

### **The Evaluation Plan of the Project**

#### **Research question**

1. After the implementation of BMWMD educational program (November 2020) will there be 87% relative increase in the mean knowledge score of medical staff after adjusting for the baseline mean knowledge score (January 2020)?<sup>16</sup>
2. After the implementation of BMWMD educational program (November 2020) will there be a 14% relative increase in mean attitude score of medical staff after adjusting for the baseline mean attitude score (January 2020)?<sup>17</sup>
3. After the implementation of BMWMD educational program (November 2020) will there be 90% relative increase in the mean practice score of medical staff after adjusting for the baseline mean practice score (January 2020)?<sup>16</sup>

#### **Study design**

Quasi-experimental non-equivalent control group design (panel) will be utilized.<sup>22</sup> An interviewer-administered survey with both groups. The baseline questionnaire and

follow-up questionnaire will measure the KAP scores of the study participants about BMWMD.

**Campbell & Stanley nomenclature:**

	Baseline assessment	Intervention	Follow-up assessment
Intervention group	O	X	O
Control Group	O		O

**The rationale for the study design**

This study design will allow the evaluation of the educational program by comparing KAP scores from the baseline measurement with the follow-up measurement. The assessment will be done with both groups. As this is a panel design, demographic characteristics such as age, gender of study participants will be only collected at the baseline.

**Study population**

The study population will be the medical staff employed in the selected hospitals of Pune, Maharashtra, India.

- **Inclusion Criteria**

- I. Medical staff handling, managing and coming in contact with hospital wastes
- II. The medical staff who have knowledge of English
- III. Citizen of India and resident of Pune



- **Exclusion Criteria**

- I. Medical staff working in the hospital but not entrusted with hospital wastes
- II. The medical staff who does not have knowledge of English
- III. Non-resident of India (NRI)

### **Study instrument**

The questionnaire will calculate the KAP scores of the study participants. It will include 4 sections focusing on demographic data, knowledge, attitude, and practices. All questions will be in multiple choice format. Trained interviewers will administer the questionnaire. The questionnaire is in the English language. All medical staff in Pune, Maharashtra, India speak English. The questionnaire is developed based on instruments used previously in other studies. The study instrument will be pretested with a similar population and revised accordingly. The questionnaire is included in Appendix 2.

### **Study variables**

*(Appendix 3)*

1. Independent variable: Manipulation of intervention/educational program.
2. Dependent variable: Mean KAP score on Biomedical waste management and disposal system.
3. Intervening variables: Years of experience, age, socio-economic status, designation, exposure to other similar programs.

### **Sample size calculation and sampling**

The random sampling will be done from the list of registered medical staff in hospitals. The sample size is estimated applying the formula for the difference in sample means of two

groups (pre and post). The standard deviation and difference in means of the groups are taken from a similar study done in Maharashtra, India.<sup>20</sup>

The formula for sample size (N)<sup>21</sup>:

$$N = \frac{2(Z_{\alpha} + Z_{\beta})^2 * (1 + (n-1)p)}{n[(\mu_1 - \mu_2)/\sigma]^2}$$

$$Z_{\alpha} = 1.96$$

$$Z_{\beta} = 0.842$$

$$n = \text{Number of time points} = 2 \text{ (pre and post)}$$

$$p = \text{Assumed correlation of the repeated measure} = 0.9 \text{ (90\%)}$$

$$\mu_1 - \mu_2 = 8.96$$

$$\sigma = \text{standard deviation} = 19.5$$

$$N = \text{sample size} = 70.655 = 71$$

The calculated sample size is 71.

### **Data Collection Methods**

Interviewer-administered data collection will be done. At the start of the program (January 2020), the study participants will be examined by the questionnaire to examine their KAP score regarding biomedical wastes management and disposal system, which will be considered as the baseline assessment. At the end of the educational program (December 2020), a follow-up assessment will be conducted to measure the KAP scores. There will be no changes in the study instrument, data collectors, and the study participants from the baseline to the follow-up data collection.

## **Data management and Statistical analysis**

The data entry and analysis will be conducted on SPSS statistical software. For data cleaning, the double data entry will be done.

Descriptive analysis including frequency, mean and median will be done to summarize participant's characteristics. Independent t-test for analyzing the KAP mean scores of the intervention and control groups will be run. The pre-observation and post-observation compare by the paired t-test for the numerical variable. Chi<sup>2</sup> test will be run for analyzing the nominal variables such as demographic characteristics comparing across intervention group and control group.

## **Threats to internal validity**

History can be a threat to internal validity because some other educational interventions such as TV advertisements regarding proper biomedical waste management and disposal system may be going on at the same time. However, history as a threat is reduced due to the presence of the comparison group and both groups will be considered to be exposed to parallelly.

Maturation is a threat to internal validity because this study is a panel design which includes the same medical staff in both baseline assessment and the follow-up assessment but can be reduced by comparing the intervention group and the control group. Testing is a major threat to internal validity because the same questionnaires will be used in both baseline and follow-up measurements but can be reduced by relating two groups. Selection bias is a threat to internal validity but it is lessened by panel design. Attrition is a major threat to internal validity as it is a panel design and study participants can resign from the work or move to a different hospital or die during the program. Compensatory rivalry is a threat to internal validity due to the rivalry between both the groups but the threat is minimized due to panel design. Threat of regression can be a threat to internal validity as there can be participants

with outlying characteristics, such as more knowledgeable participants. *Diffusion* is a threat to internal validity as current study participants may inform other hospitals' staff.

*Instrumentation* is not a threat to internal validity as the interviewers will conduct pre-interviews and post-interviews using the same questionnaires. *Resentful demoralization* could be an problem to internal validity as the intervention group will receive the educational program and the control group might learn that they did not receive the educational program.

### **Threats to External validity**

*Interaction with testing* is a major threat to external validity because the study participants might learn the content from the pre-test which may impact their KAP score at the follow-up data collection. *Selection-treatment interaction* is a major threat to external validity because the findings of this study cannot be generalized for other places as the setting of this research will differ in many aspects. *Multiple treatment interference* is a threat to external validity because the educational program will reproduce different results when implemented in different settings or locations.

### **Project Management**

#### **Team for the evaluation program**

- **Program Leader:** This person will be an expert researcher with medical and public health background. This person will be involved in both administration and development of the program along with the evaluation of the project. The entitled responsibilities of the program leader are:
  1. Selecting hospitals and enrolling participants for the study
  2. Employing required staff members for the project in their respective field of expertise

3. Designing and developing an educational program (Intervention) and a book by the experts of BMWMD
4. Designing and developing of study instrument (Questionnaire) with the experts
5. Keeping records of participants, maintaining and supplying the required materials for the project
6. Administering and ensuring the smooth functioning of the project

The following staff will be employed by the program leader.

- **Experts:** Two experts will work for developing the educational materials and will deliver lectures to the study participants. Experts will be hired by the program leader based on a minimum of 2 years of experience in waste management.
- **Interviewers:** Two interviewers with a minimum of 1-year experience of data collection will be hired. After hiring they will be trained by the experts and program leader in accordance with our project. Their job will be to do interviews and collect data from the study participants. At the end of each interview, they have to check for any unanswered or unfilled question.
- **Data entry staff:** 2 data entry personals will be hired with a minimum of 1-year experience in data entry. After receiving data from the data collector, both will do separate data entry. Double data entry will be done in this project. They will merge the two datasets to review the mistakes and correct them by doing data cleaning.
- **Data analysis staff:** One data analyst with the strong biostatistics background and minimum of 1-year experience will be hired. The data analyst will take merged file from data entry staff and analyze it as per the program requirement.

- **Accountant:** One accountant with a minimum of 1-year clerical experience will be hired. The accountant will keep track of the flow of money.

### **Action plan**

*(Appendix 4)*

“The evaluation project will include the pre-intervention phase, the intervention phase, and post-intervention phase”. In the pre-intervention phase, the study sample will be taken from the large hospitals that have more than 150 beds. After that, a panel of medical staff will be tested for their current KAP score about Biomedical waste management and safe disposal system through the questionnaire. This score will be considered as baseline KAP score. These participants will be selected randomly from every hospital. During the intervention phase, the team of experts will provide an educational program to all the participants. The educational program will include a book, PPT lecture presentations on background information, the situation in India and worldwide, case studies, the demonstration of safe and proper disposal of biomedical wastes and other related topics. Medical staff will also be informed about the rules and regulations made by the Indian government. At the end of the educational program, the follow-up questionnaire will be administered by the same interviewers, who conducted the baseline measurement. All medical staff in the intervention hospitals will receive the education materials. Also in the control hospitals, the medical staff will take part in the pre-assessment and post-assessment via interviews. There will be no selection bias within the groups as this is a panel design. The project leader will hire required staffs and will keep track of the program.

### **BUDGET**

The budget (*Appendix 5*) of this project is estimated with the consideration of employed staff and logistic requirements. This budget includes both the expenditures of the educational

program and the evaluation project. The request for funds will be applied to different funding agencies and non-governmental organizations (NGO) working for biomedical waste management and safe disposal system. Various Indian hospital administrations will also be contacted for funds.

### **LOGISTICAL CONSIDERATIONS**

The collection, analysis and correct interpretation of data will be done by experienced staff appointed by the project leader. The wages of employed staff, purchases of stationaries and transportation cost will be allocated from the project fund. The data collected in the pre-stage and post-stage of the educational program will be done by an interviewer using allocated stationery for this project. All staff members will be given password personal laptops for doing work under ethical considerations such as not sharing data on the internet and other confidential issues. Data entry and data analysis staff will be provided with personal laptops that have SPSS software and other software required for their work. All staff members will be given traveling allowances for doing the project work. At the end of the project, a summarized report will be made public with all the findings and results.

### **ETHICAL CONSIDERATIONS**

Before starting the program, the evaluation study will be approved by the Institutional Review Board(IRB). The study participants will be well informed about the project and treated equally throughout the duration of the project. A written consent form (*Appendix 6*) will be signed by the participants proving their willingness to participate in this program. No personal details will be shared outside the project. Each participant will be given the ID number to keep the anonymity of the collected data. Data contributed by stakeholders will be stringently be used for this program only. The data collected will be analyzed and kept on password protected laptops. As participation in the educational program is voluntary, the

participants possess the liberty and freedom to stop participating in the project at any time. A written permission will be obtained from the hospital's administration before the commencement of the Biomedical waste management and disposal system educational program and evaluation project.

### **Summary**

The proposal utilizes a proof-based methodology from previous research. The educational program is constructed based on Maharashtra government rules and regulations. The six months of intervention consists of educational lectures and study materials regarding BMWMD. The pre-test and the scientifically designed questionnaire will act as an assessment tool for the BMWMD educational program.

The influence of the intervention will be estimated at the end of the program. If the intervention works and shows decisive results, then the final report with successful results will be publicized to demand change in the Indian healthcare system. We are anticipating a notable increment in the awareness and KAP of medical staff via the educational program.

This program will also create BMWMD awareness and train the medical staff. Doctors, nurses and cleaning staff play a vital role in the Indian health care system. If this program demonstrates positive results, then it can also be implemented all over India. Educating medical staff should develop positive maturity in the Indian health care system. Eventually hoping for a healthier population of India.



## References

1. Datta P, Mohi GK, Chander J. Biomedical waste management in India: Critical appraisal. *J Lab Physicians*. 2018;10(1):6-14 doi: 10.4103/JLP.JLP\_89\_17.
2. the Gazette of India, Extraordinary, Part II, Section 3 S (i). *Bio-Medical Waste Management Rules, 2016*. INDIA; 2016. doi:28th March, 2016.
3. World Health Organization. Health-care waste. fact sheet. <https://www.who.int/newsroom/fact-sheets/detail/health-care-waste>. Published 2018. Accessed March 15, 2019.
4. Pandit NB, Mehta HK, Kartha GP, Choudhary SK. Management of bio-medical waste: awareness and practices in a district of Gujarat. *Indian J Public Health*. 49(4):245-247. doi:16, December, 2005.
5. Irin SA. An analytical study on medical waste management in selected hospitals located in Chennai city. *Env Waste Manag Recycl*. 2018;1(1). doi:27, February, 2018
6. Kumar R, Somrongthong R, Ahmed J. Effect Of Medical Waste Management Trainings On Behavior Change Among Doctors Versus Nurses And Paramedical Staff In Pakistan. *J Ayub Med Coll Abbottabad*. 2016;28(3):493-496. doi:September,2016
7. Seetharam S. Hepatitis B outbreak in Gujarat: a wake-up call. *Indian J Med Ethics*. 2009;6(3). doi:10.20529/IJME.2009.042
8. Gupta S, Boojh R. Report: Biomedical waste management practices at Balrampur Hospital, Lucknow, India. *Waste Manag Res*. 2006;24(6):584-591. doi:10.1177/0734242X06068342
9. Kamalakanta Muduli, Akhilesh Barve. (PDF) Challenges to Waste Management Practices in Indian Health Care Sector. *Int Conf Environ Sci Engineering*. 2012;2(1):62-66. doi:September,2012
10. P  pin J, Abou Chakra CN, P  pin E, Nault V, Valiquette L. Evolution of the Global Burden of Viral Infections from Unsafe Medical Injections, 2000–2010. Paraskevis D, ed. *PLoS One*. 2014;9(6):e99677. doi:10.1371/journal.pone.0099677
11. Mathur V, Hassan M, Dwivedi S, Misra R. Knowledge, attitude, and practices about biomedical waste management among healthcare personnel: A cross-sectional study. *Indian J Community Med*. 2011;36(2):143. doi:10.4103/0970-0218.84135
12. Hosny G, Samir S, El-Sharkawy R. An intervention significantly improve medical waste handling and management: A consequence of raising knowledge and practical skills of health care workers. *Int J Health Sci (Qassim)*. 2018;12(4):56. doi:July,2018
13. Radha K V, K.Kalaivani, R.Lavanya. A Case Study of Biomedical Waste Management in Hospitals. *Glob J Health Sci*. 2015;1(1):82-88. doi:April, 2009

14. Himabindu P., H. M, T. U. International Journal of Engineering Research and Technology IJERT. *Int J Eng Res.* 2012;4(03):81-88. doi:03, March, 2015
15. Jadhav J, Thangaraj S, Dsouza L, Rao A. Assessment of educational intervention on biomedical waste management among Government Nursing College students, Bengaluru. *Int J Med Sci Public Health Online.* 2015;1:726. doi:10.5455/ijmsph.2015.07012015150
16. El-Sharkawy R, Hosny G, Samir S. An intervention significantly improve medical waste handling and management: A consequence of raising knowledge and practical skills of health care workers. *Int J Health Sci (Qassim).* 2018;12(4):56. doi:July,2018
17. Mohammed Elnour A, Mohamed Reda Moussa M, Darwish El-Borgy M, Eldin Eltahir Fadelella N, Hanafy Mahmoud A. Impacts of an Educational Intervention Program on the Attitude of Kosti, Rabak, and Eduiem Hospitals' Nursing and Sanitation Staff with regard to Healthcare Waste Management. *Int J Basic Appl Sci IJBAS-IJENS.* 2015;15(5). doi:October 2015
18. Shareefdeen ZM. Medical Waste Management and Control. *J Environ Prot (Irvine, Calif).* 2012;03(12):1625-1628. doi:10.4236/jep.2012.312179.
19. Rao PH. Hospital waste management system - A case study of a south Indian city. *Waste Manag Res.* 2009;27(4):313-321. doi:10.1177/0734242X09104128.
20. Mimi Lalmuanpuii, Tukuram B Zagade, Vaishali Mohite, Mahadeo B Shinde. (PDF) Effectiveness of Video Assisted Teaching Program Regarding Knowledge on Biomedical Waste Management among Staff Nurses. *Int J Sci Res.* 2015;4(3). doi:March 2015
21. Hedeker DR, Gibbons RD. Longitudinal Data Analysis. Wiley-Interscience; 2006.
22. Weiner J. Research Design for HSRE: Part 1. The Johns Hopkins University. [http://ocw.jhsph.edu/courses/HSRE/PDFs/HSRE\\_lect4\\_weiner.pdf](http://ocw.jhsph.edu/courses/HSRE/PDFs/HSRE_lect4_weiner.pdf). Published 2007. Accessed May 3, 2019.
23. Kumar R, Somrongthong R, Shaikh BT. Effectiveness of intensive healthcare waste management training model among health professionals at teaching hospitals of Pakistan : a quasi-experimental study. 2015:1-7. doi:10.1186/s12913-015-0758-7
24. Ozder A, Teker B, Eker H, Altindis S, Kocaakman M, Karabay O. Medical waste management training for healthcare managers - a necessity? *Journal of Environmental Health Science & Engineering* 2013;11(1):20. doi:10.1186/2052-336x-11-20
25. Bhamare P, Gawande S. Bio Medical Waste Disposal System for Pune. *Int J Sci Res ISSN.* 2013;4(6). doi:June 2015
26. GOVERNMENT OF MAHARASHTRA. Government Hospitals | Cultural Capital of Maharashtra. <https://pune.gov.in/public-utility-category/hospitals/>. Published 2019. Accessed May 5, 2019.

27. List of CGHS approved Private Hospitals in Pune as on 29th May 2018 -  
GConnect.in.<https://www.gconnect.in/orders-in-brief/cghs/list-cghs-approved-private-hospitals-pune-29th-may-2018.html>. Accessed May 5, 2019.

## Appendixes

- **Appendix 1: Timeline**

Activities	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Paperwork and Official formalities	✓											
The hiring of experts and staff for the project	✓	✓										
Developing educational materials(Book and PPTs)	✓	✓	✓									
Enrolment of participant			✓									
Developing educational program design, including the evaluation study	✓	✓	✓									
Training of trainers	✓	✓										
Developing and Pre-testing Questionnaire		✓	✓									
Conducting pre-test			✓									
Intervention phases			✓	✓	✓	✓	✓	✓	✓			
Conducting post-test									✓			

Data Entering and Data Cleaning			✓							✓	✓	
Data Analysing											✓	
Preparing and Publishing the final findings in the report											✓	✓

- **Appendix 2: Questionnaire in English**

**Questionnaire to test KAP of the target population** (Read all the response options and mark one stated option for each item)

**Section A: Demographic <sup>1</sup>**

1. Sex: 1.Male 2.Female
2. Age (Years): (\_\_\_\_\_)
3. Educational level
  - a. Primary.      b. Secondary.      c. Tertiary.      d. Others (please specify\_\_\_\_\_)
4. Designation
  - a. Medical doctor.    b.Nurse.    c.Dentist.    d.Paramedic.    e.Laboratory worker
  - f.Ward attendant.      g. Porters.      h. Cleaner
5. Years of experience: (\_\_\_\_\_)

	<b>Section B: Knowledge</b>	<b>ANSWER</b>
Q1	What is the correct procedure which must be applied for handling and collection of waste in the hospitals?	0. Do not Know 1. Segregation 2. Collection in one bin
Q2	The main area for the storage of medical waste before disposal?	0. Do not Know 1. Separate room 2. Storage room
Q3	How biomedical waste should be disposed of?	0 - Do not know 1- Dump directly into general garbage bins    2- Handled by

		Biomedical waste collection agencies
Q4	According to biomedical waste management law, 2016, untreated medical waste should not store beyond?	0 - Do not know 1- 24 hours 2- 48 hours
Q5	What happens to the various categories of waste such as sharps, anatomical waste, pathological waste, and infectious waste, etc?	0. Do not Know 1. Collected together with general waste 2. Collected separately from general waste
Q6	Are different kinds of medical waste collected separately?	1.Yes. 2. No
Q7	What are the various kinds of containers or bags used for the different categories of wastes?	0. Do not Know 1. Red bag, yellow bag, green bag, purple bag 2. Black bag, red bag, yellow bag, green bag, blue bag.
Q8	The biomedical waste is poisonous and toxic in nature?	1.Yes. 2. No 0. Do not Know

Q9	Is it necessary to use proper protective gears such as coat, masks, gloves, and boots by the workers while collecting, segregating, storing and disposing of wastes?	1.Yes. 2. No 0. Do not Know
Q10	Do you need a separate permit to transport biomedical waste?	1.Yes. 2. No 0. Do not Know
Q11	Do the Indian government have biomedical waste management law?	1.Yes. 2. No 0. Do not Know
Q12	Is the medical staff required to be trained for handling biomedical waste?	1.Yes. 2. No 0. Do not Know
Q13	Which type of waste is collected in puncher proof bags?	0. Do not Know 1. All type of medical waste 2. Infectious Waste
Q14	How many categories of medical waste are there in Biomedical waste management according to 2016 rule?	0. Do not Know 1. One 2. Two 3. Three 4. Four



Q15	What is the color codes of bags in Biomedical waste management according to 2016 rule?	0. Do not Know  1. Yellow, red, black and blue.  2. Green, pink, grey and brown
Q16	Biomedical Waste Management Rules, 2016 has been published by?	0. Do not Know  1. Indian government  2. Association of medical waste management
Q17	Where do you dispose of used masks and gloves of medical staff?	0. Do not Know  1. General bin  2. Red bin
Q18	The final treatment for chlorinated objects is done by?	0. Do not Know  1. Autoclave  2. Incarnation
Q19	Where do you discard expired medicines?	0. Do not Know  1. Incarnation  2. Bury deep in the ground
Q20	Used syringes are to be discarded in?	0. Do not Know  1. Red bin  2. Puncher proof bin

	<b>Section C: Attitude</b>	1. Strongly Agree	2. Agree	3. Neither Agree nor Disagree	4. Disagree	5. Strongly Disagree
Q1	Segregation of waste at source increases the risk of injury for the biomedical waste handlers.					
Q2.	Safe biomedical waste management is not an issue at all.					
Q3.	Waste management is teamwork and no single class of people is responsible for safe management.					
Q4.	Reporting of needle-stick injury is an extra burden on the work of medical staff.					
Q5.	Safe management efforts by the hospital increase the financial					

	burden on hospital management.					
Q6	Infectious medical wastes do not cause a health hazard.					
Q7	Do you think that infectious waste should be sterilized by autoclaving before shredding and disposal.					
Q8	Use of color codes for segregation of waste is a must.					
Q9	Post exposer prophylaxis should be initiated as soon as possible.					
Q10	Proper segregation and disposal of BMW part of your responsibility.					
Q11	There is a need for strict implementation of BMW management rules.					
Q12	Biomedical waste management is an institutional problem.					

Q13	Needles must be recapped before disposal.					
Q14	Following biomedical waste management, percussion protocol is necessary.					
Q15	Safe waste management is teamwork.					
Q16	Soil disposal of cotton, gauze piece contaminated with blood is correct.					
Q17	Safe management of medical waste is the responsibility of government, not the medical staff					
Q18	occupational safety of medical waste handlers is a must.					
Q19	Labelling of different dustbins before segregation of medical waste is not necessary.					
Q20	Training and educational interventions are a must for medical staff.					

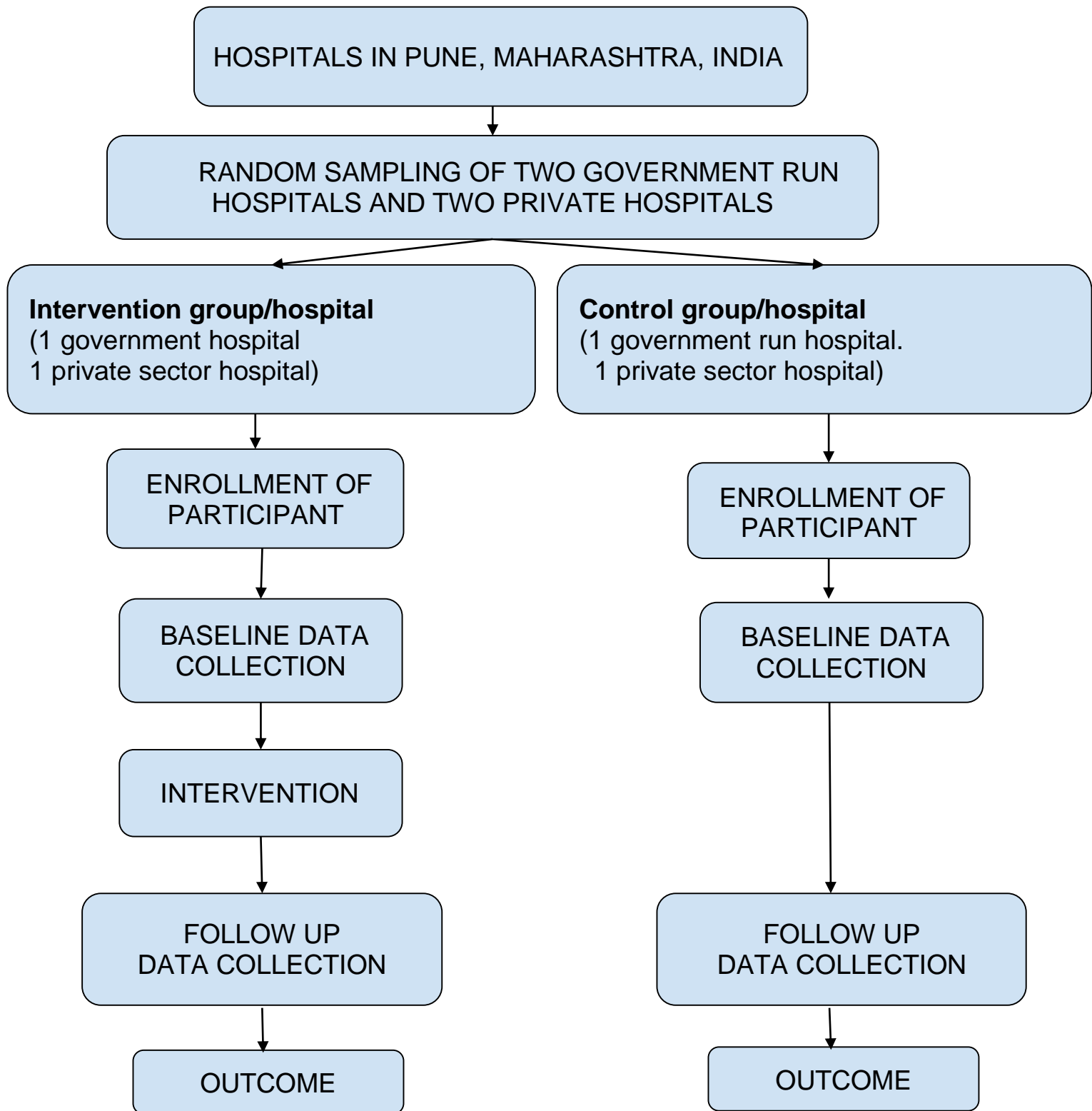
	<b>Section D: Practice</b>	1.Yes	2.No
Q1.	Do you segregate medical waste during collection?		
Q2.	Do you separate sharp waste from blunt waste?		
Q3.	Do you move medical waste using trolleys?		
Q4.	Do you clean the waste trolley directly after each collection?		
Q5.	Do you use personal protection tools (e.g. gloves, safety goggles, face mask) ever or when handling medical waste?		
Q6.	Do you follow the system of recording and reporting of injuries/accidents caused due to poor BMWMD?		
Q7.	Do you collect liquid waste in bags that prevent leakage?		
Q8.	Do you collect blood waste in bags that prevent leakage?		
Q9.	Do you collect human tissue remains in separate bags to prevent leakage?		
Q10.	Do you collect liquid waste together with other waste?		
Q11.	Do you collect blood waste together with other waste in ordinary bags?		

Q12.	Do you collect human tissue remains together with other wastes in ordinary bags?		
Q13.	Do you collect expired medicines together with other wastes?		
Q14.	Do you dispose of liquid waste into the sewage system after processing?		
Q15.	Do you use furnaces in hospital for the destruction of medical waste?		
Q16.	Do you treat sharp objects prior to disposal?		
Q17.	Do you gather medical wastes in open areas within the hospital for temporary storage before being transferred outside the hospital?		
Q18.	Does the hospital have standard stores for the temporary storage of medical wastes?		
Q19.	Do you follow color coding for segregation of medical waste?		
Q20	Do you store the excess of mercury/amalgam in water or fixed solutions?		

- **Appendix 3: Study variables**

<b>Variable</b>	<b>Type</b>	<b>Measure</b>	<b>Source</b>
<b>Independent:</b> educational program	Dichotomous	Baseline measurements	Follow-up measurement
<b>Dependent:</b> KAP score	Continuous	Calculation of KAP score	Interviewer Administered Questioner
<b>Intervening:</b> Years of experience	Continuous	questionnaire	Interviewer Administered Questioner
<b>Intervening:</b> Age	Continuous	questionnaire	Interviewer Administered Questioner
<b>Intervening:</b> Socio-economic status	Continuous	questionnaire	Interviewer Administered Questioner
<b>Intervening:</b> Designation	Continuous	Questionnaire	Interviewer Administered Questioner
<b>Intervening:</b> Another program	Continuous	Interviewee Reply	Interviewer Administered Questioner

- **Appendix 4: Conceptual Framework for Evaluation project**





- **Appendix 5: Budget details**

**The BUDGET**

<b>Personnel</b>	<b>Numbers</b>	<b>Cost</b>	<b>Working months</b>	<b>Budget in INR (Number X Cost X working Hours)</b>	<b>Budget in USD (1 USD =71.04 INR)</b>
Project Leader	1	40,000	12	4,80,000	6757.18
Experts	2	20,000	12	4,80,000	6757.18
Data entry staff	2	15,000	12	3,60,000	5067.89
Accountant	1	10,000	12	1,20,000	3378.59
Data Analyst	1	15,000	12	1,80,000	1689.18
Data collectors	2	10,000	12	2,40,000	3378.59
Computers	10	60,000	1	6,00,000	8446.48
Stationary	9 packets	1,000	12	1,08,000	1520.37
Travels	9	3,000	12	3,24,000	4561.10
<b>TOTAL</b>				<b>28,92,000</b>	<b>40,709.45</b>

- **Appendix 6: Consent Form**

American University of Armenia

Gerald and Patricia Turpanjian School of Public Health

Institutional Review Board

Oral consent form

**TITLE OF RESEARCH PROJECT:** Piloting an educational program to improve Biomedical Waste Management and Disposal system in hospitals of Pune, Maharashtra, India.

Hello, My name is Deepak Bhale and I am a graduate student of the Master of Public Health program at the American University of Armenia (AUA). We are Piloting an educational program to improve Biomedical Waste Management and Disposal system in Indian hospitals. Biomedical Waste Management and Disposal is a very big issue in India causing numerous infectious disease. According to many studies among Indian hospitals, one of the prominent reasons for this is lack of education and awareness among medical staff.

We would like to include you and 70 other medical staff from your hospital into this study. This program and the findings of this study will allow us to evaluate the knowledge, attitude, and practices of all stakeholders in Indian hospitals regarding Biomedical waste management and disposal system. We are conducting a survey via a questionnaire. The survey will take approximately 30-40 minutes. In this questionnaire, there will be some questions about your knowledge, attitude, and

practices followed by you concerning biomedical waste management and disposal system in Indian hospitals.

Your participation is voluntary. If you are willing to take part in the study, we will ask some questions about Biomedical waste management and disposal system. Your willing participation or withdrawing from this study at any time will not cause any harm to your career. There will be no penalties for not completing the questionnaires and you can leave any questions unanswered if you are not willing and/or feeling uncomfortable to answer. We will contact you again in the month of December for the follow-up survey. The information provided by you and the data obtained from this study are fully confidential and will be used only for the study. Your contact information will be destroyed upon the completion of data collection. Your name, contact information and other identifying information will not appear on the questionnaire and final report. By participating in this study you are helping the Indian healthcare system to improve.

If you have any questions about this study you can call to the Dean of The AUA Gerald and Patricia Turpanjian School of Public Health Dr. Varduhi Petrosyan, (37460) 612592. If you feel you have not been treated fairly or think you have been hurt by joining the study you should contact Varduhi Hayrumyan, the Human Participants Protections Administrator, Institutional Review Boards of AUA, Phone:(37460) 60 61 2561 Email: vhayrumyan@aua.am.

Would you agree to participate in this study?

Thank you.

If yes, shall we continue?