

Bio-medical Waste Management Rules, 2016- A review

Unregulated biomedical waste management (BMWM) is a public health problem. This has posed a grave threat to not only human health and safety but also to the environment for the current and future generations. Safe and reliable methods for handling of biomedical waste (BMW) are of paramount importance. Effective BMWM is not only a legal necessity but also a social responsibility. This article reviews the current perspectives on BMWM and rules, conventions and the treatment technologies used worldwide. BMWM should ideally be the subject of a national strategy with dedicated infrastructure, cradle-to-grave legislation, competent regulatory authority and trained personnel. Improving the management of biomedical waste begins with waste minimization. These standards, norms and rules on BMWM in a country regulate the disposal of various categories of BMW to ensure the safety of the health-care workers, patients, public and environment. Furthermore, developing models for the monitoring of hospital health-care waste practices and research into non-burn eco-friendly sustainable technologies, recycling and polyvinyl chloride-free devices will go in long way for safe carbon environment. Globally, greater research in BMWM is warranted to understand its growing field of public health importance.

INTRODUCTION

Expansion of health-care facilities as well as the recent trends of using plastic disposables and increase in medical and surgical interventions has led to unprecedented burden of biomedical waste (BMW). Unregulated BMW management (BMWM) has posed a grave threat not only to human health and safety but also to environment for the current and future generations.

A prior study estimated that about half of world's population is at risk from hazards of improper BMWM either through impact at work in the environment or impact on public health. The public health threat due to improper BMWM has been reported worldwide.¹ Of note are the incidence of hepatitis B virus (HBV) outbreak (240 infected) at Gujarat, India, in 2009 and infectious injuries to scavengers due to BMW generated in mass vaccinations (1.6 million) in Afghanistan.

A nationwide survey performed by International Clinical Epidemiology Network in 25 districts across 20 states highlighted that only two big cities in India, Chennai and Mumbai, had comparatively better system for BMWM. Improper pretreatment of BMW at source and improper terminal disposal was the major challenges observed. It was observed that around 82% of primary, 60% of secondary and 54% of tertiary care health facilities were in the red category, i.e., the absence of a credible BMWM in place or ones requiring major improvement. According to the studies conducted by the World Health Organization (WHO) in 22 developing countries showed that the proportion of health-care facility (HCF) that do not use proper waste disposal methods range from 18% to 64%. In India, annually about 0.33 million tons of BMW is generated and rate ranges from 0.5 to 2.0 kg per bed per day. The poor BMWM practices are attributed to lack of awareness and training as was concluded in a recent study.

India was one of the first countries to implement BMWM rules in 1998 (amended as draft in 2003, 2011) under Environment Protection Act (EPA), 1986. India was signatory to an international legally binding and environmental treaty, Stockholm Convention, 2004, on persistent organic pollutants (POPs) that aims to eliminate or restrict production of POPs.

The Ministry of Environment Forests and Climate Change, Government of India, notified the BMWM rules, 2016 on 28th March 2016, under the provisions of EPA, 1986. These rules fill up the gaps in the old rules to regulate the disposal of various categories of BMW.

Safe and reliable methods for handling of BMW are of paramount importance. Effective BMWM is not only a legal necessity but also a social responsibility. This article reviews the current perspectives on BMWM in the national and the international scenario and rules, conventions and the treatment technologies used worldwide.

DEFINITION

BMW is any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research or in the use of biological or in health camps. It involves all persons who generate, collect, receive, store, transport, treat, dispose or handle biomedical waste in any form. Of the total BMW about 75% and 90% of the waste is non-hazardous or general health-care waste. The remaining 10%–25% of BMW is regarded as hazardous and can lead to a variety of environmental and health risks.

CLASSIFICATION

Hazardous health-care waste includes sharp waste, infectious waste, pathological waste, pharmaceutical waste, cytotoxic waste, chemical waste, liquid infectious waste, radioactive waste, and general health-care waste.

Biomedical Waste Management Rules, 2016 (Ministry of Environment Forests and Climate Change)

The ambit of the rules has been expanded to include vaccination camps, blood donation camps, first aid rooms of schools, forensic laboratories, medical colleges, research laboratories, household BMWs and other such camps/programmers, any other health-care activity related to any system of medicine, apart from HCF. Duties of occupier, common biomedical waste (CBMW) management disposal facility and authorities are delineated better.

The occupier ensures the pretreatment of the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilization on-site in the manner as prescribed. Occupier provides training, immunization, health check-up and occupational safety to all its health-care workers (HCWs). The major accidents are also reported to the prescribed authority and in the annual report. The occupier establishes a system to review and monitor the activities related to BMWM a committee. The occupier and CBMWTF are liable for damages caused to environment or public due to improper handling BMW under section 5 and section 15 of Act.

In BMWM rules, 2016, emission standards and other standards of equipment, effluent, pits are delineated. For traceability of the BMW, bar coding and GPS are introduced. Emphasis has been laid on accident reporting, records and website related to BMW. In the final disposal technologies, sustainable, eco-friendly (plasma paralysis), green technologies, newer technology, waste to energy options and recycling (authorized recyclers) are mentioned.

The salient differences between BMWM rules 2016 and BMW rules 1998 are depicted below

The biomedical waste not documented in the current rules of the country should have a company buy back policy or should be treated as per recommended international guidelines.

Points	Biomedical waste management rules, 2016	Biomedical waste, 1998
Duties of Occupier	Duties of occupier are delineated better There is pretreatment by: disinfection and sterilisation on-site of infectious lab waste blood bags as per WHO guidelines Occupier ensures non-chlorinated plastic bags, gloves, blood bags within 2y of notification Occupier ensures liquid waste is segregated at source by pretreatment and Effluent treatment plant (ETP) is mandatory Occupier ensures to maintain BMWW register daily and on website monthly Annual report should be made available on web-site within 2 years The occupier (≥ 30 bedded) establishes BMWW committee Records of equipments, training, health checkup, immunization compulsory	Duties of occupier not delineated better No pretreatment of waste on site Chlorinated plastic bags, gloves, blood bags were recommended ETP not mandatory The details of records not mandatory The annual report need not to be posted on website BMWW committee not compulsory Records not compulsory to maintain
Duties of CBMWTF	Duties are delineated better Occupier has to establish Bar coding and GPS by first year and ensure occupational safety of all its HCWs by TT and HBV vaccination Reporting of accidents and maintenance of records of equipments, training, healthcheckup	Duties are not delineated better Barcoding and GPS not documented and vaccinations for HCWs not documented. Records not documented
Accident Reporting	Major accidents are reported to authorities and in annual report	No specific reporting of accidents
Schedule I	Yellow	Yellow
Deep burial	Deep burial is an option for remote and rural areas	Deep burial allowed in villages and towns with less than 5 lakhs population
Chemical treatment	Chemicals treatment using 10% hypochlorite solution	Chemical treatment : 1% hypochlorite
Fetus	Fetus less than the age of viability is to be treated as human anatomical waste	No demarcation of fetus mentioned
Drugs	Antibiotics and other drugs and solid chemical waste suggested for incineration Cytotoxic drugs: incineration upto 1200 C and return back to supplier	All drugs to be discarded in black bag For cytotoxic drugs destruction and drugs disposal in secured landfills
Liquid infected waste	Effluent treatment plant is mandatory and effluent to conform to standards mentioned	For liquid waste chemical treatment and discharge into drains to conform to effluent standards mentioned
Microbiology and biotechnology waste	Pretreatment of infectious waste is as per WHO guidelines: log ₆ and log 4 reduction	Pretreatment not mandatory
Infected plastics, sharps, glass	The infected plastics and sharps after mutilation go in for red bag and white container respectively and are sent to authorized recyclers. The glass articles are discarded in cardboard box with blue marking	Infected plastics, metal sharps, glass go in blue container with disinfectant and local autoclaving/ microwaving/incineration is recommended
Recycling	A focus on recycling of plastic, sharps, glass to authorized recyclers	Recycling of plastics, glass to authorized recyclers not mentioned

Risks Associated With Biomedical Waste

The main groups of individuals at risk are HCWs, scavengers and the public. The microbial infections caused by exposure to BMW and samples include systemic and local infections. Mercury, disinfectants and pesticides affect multisystem. Improper handling of sharps can lead to needle stick injuries thereby leading to infections with blood-borne pathogens such as HBV, HIV and HCV, etc. The hazards of cytotoxic and radioactive waste include headache, dizziness, vomiting, tissue destruction, genotoxicity, death and ecological disturbances. It can cause malignancies, foetal malformation, cardiac and respiratory disorders.

Steps in Management of Biomedical Waste: Segregation, Package and Transport

Segregation

The mainstay of waste-segregation system is to separate all hazardous waste from the larger quantity of non-hazardous general waste. The waste is segregated into different fractions based on their potential hazard and disposal route and separate containers should be available for each segregated waste fraction.

Special category of waste disposal

Mutilation of plastics and sharps

To prevent reuse of plastics and sharps, mutilation is required on-site before transportation to CBMWTF. A needle destroyer or hub-cutter is used to destroy/mutilate the needles, and then, the later are put into the tamper proof, leak proof, puncture proof container. All the plastic items, intravenous (IV) bottles, urobags, drains and gloves are given a nick or clipped immediately after use, wherever applicable, by the dedicated pair of scissors placed in the area to prevent reuse, and then, they should be disposed in a red bag. Each bag is labeled and securely tied when three-fourth full and then handed over to CBMWTF for recycling.

From the novel technique of encapsulation, the recycled sharps can be used for benches, hangers, bricks, etc.

Discarded medicines (cytotoxic drugs and antibiotics)

Cytotoxic wastes including all items contaminated with cytotoxic drugs are put in a non-chlorinated yellow container, sealed and labelled as cytotoxic. Expired cytotoxic drugs to be returned to the manufacturer or supplier for incineration at temperature > 1200°C. The antibiotic and other drugs are discarded in yellow bag with biohazard label. Dilution in water and discharge into a sewer for solutions containing vitamins, cough syrups, IV solutions and eye drops, salts, amino acids is recommended.

Mercury and lead waste

The mercury and lead waste generated are contained and then handed over to authorised vendors and covered under the respective rules. The WHO guidelines on mercury lays stress on safe mercury clean-up, handling and storage procedures, replacing mercury-containing products with mercury-free alternatives in the long term.

Disposal of radioactive waste

The treatment and disposal of radioactive waste are under national nuclear regulatory agency and under its respective rule. For isotopes with long half-life, long-time storage at an authorised waste disposal site is recommended. Infectious radioactive waste to be decontaminated after containment by decay time (ten times the half-life) in an isolated, identified and designated room site before final disposal as BMW. Low-level radioactive waste can be discharged in sewers.

Liquid chemical waste

Liquid waste generated due to the use of chemicals in production of biologicals, used or discarded disinfectants, infected secretions, aspirated body fluids liquid from laboratory, labour room, operation theatre, floor washings, cleaning, housekeeping and disinfecting activities should be collected separately and directed to effluent treatment plant (ETP). The infected body secretions such as blood and faeces should be pre-treated and then disposed of in ETP. Silver X-ray film developing liquid, after resource recovery, the chemical liquid waste needs to be pre-treated before mixing with waste water.

Laboratories

The blood sample glass vials or broken or discarded and infected glass need to be disinfected/autoclaved, (pretreatment), wherever applicable and then packed in cardboard boxes with plastic liner with blue-coloured marking and sent to CBMWTF for autoclaving or microwaving for final recycling. The non-infected glass does not need on-site pretreatment.

Microbiology, biotechnology waste and infectious waste

Laboratory waste including microbiology laboratory cultures, stocks or specimens of microorganisms and infectious waste of patients in isolation have to be pre-treated on site by autoclaving in an autoclave safe plastic bags or containers as per the WHO guidelines there after sent for final disposal of autoclaved hazardous waste in yellow bag to CBMWTF for incineration.

Blood bank

The discarded blood bags are to be counted, sealed, weighed and all the records to be made then packed in autoclave-safe plastic bags or containers to be autoclaved on site and then these are sent for incineration.

Packaging, labelling and transport to common waste site

All the biomedical wastes are labelled as waste type, site of generation, date of generation before transportation from the generation site. BMW is transported through designated route, on dedicated, colour coded, covered and leak proof trolleys on fixed and at reliable time and stored in a common waste site. From common waste site, it is then transported to CBMWTF for the final treatment and disposal. No untreated BMW is kept stored beyond a period of 48 h.

Each patient care area has been provided with the waste receipt book to record the quantity/number of yellow, blue, red, white (translucent) bags handed over to HCW. All the staff are required to duly fill in the waste book colour code wise mentioning the number and size of bags handed over and sign the slip for further record.

Transport staff should wear adequate personal protective equipment. The central storage site is cleaned once a week. It should have an impermeable, hardstanding floor with good drainage, include the facility to keep general waste separated from BMW, have an exhaust and water supply as per the WHO guidelines.

Transportation to common biomedical waste treatment facility

The operator of CBMWTF shall transport the BMW from the premises of HCF to any off-site CBMWTF only in the vehicles complying as per the existing rules of the country or as per the United Nation norms.^[17] The body of the vehicle should be of a suitable size to carry secured load and it should have BMW articles, PPE and cleaning equipment. It should be marked with the name and address of the waste carrier, hazard sign.

Minimal Approach to Biomedical Waste Management

Minimal approach in BMWM includes reducing, reusing and recycling, arrangements for waste storage and transport, expenses in the annual budgeting; separate chemical and pharmaceutical waste segregation and storage management, separate storage zones and documentation related to BMWM

Waste Treatment Technologies

The waste treatment technologies include thermal, chemical processes, irradiation technologies, biological processes, disinfection and sterilization.

Thermal: Autoclaves: Steam treatment technologies

Autoclaves sterilize a range of infectious waste (cultures, stocks, sharps, materials contaminated with blood and fluids), laboratory waste and linen waste, medical instruments and for the treatment of BMW. Unlike instrument sterilization autoclaves, waste-treatment autoclaves (prevacuum autoclaves) must treat the air that is removed at the start of the process to prevent the release of pathogenic aerosols through a high-efficiency particulate air filter before it is released and therefore require less time for action and have greater efficiency.

The autoclaves should be able to withstand the repeated build-up and release of steam pressures and should have construction materials, engineering design, fabrication, accuracy of pressure and temperature sensors, and testing must meet basic requirements to operate safely as per the international standards related to pressure vessels including EN 13445, EN 285 and ASME. The operation of autoclave requires a minimum of recommended temperature–exposure time criterion of 121°C for 30 min, pressure of 205 kPa or 2.05 bar (15 psig or 30 psia).

After the initial tests, regular validation tests using biological indicators (weekly), Bowie-Dick test (for prevacuum autoclaves with every batch) and thermochromics strips should be performed at periodic intervals.

Autoclaves for medical devices often use trays or stainless steel baskets, while waste autoclaves use autoclavable carts or bucket-shaped open containers into which the plastic waste bags are stacked. Depending on the type of plastic bags used, some bags may melt and stick to the surfaces of the cart or container. Use of autoclavable plastic bags or liners that prevent sticking is an option.

A post-treatment shredder or grinder could be used if the waste is to be rendered unrecognisable and if reduction of waste volume is desired. Advanced single- or multiple-shaft shredders specially made for medical waste can reduce waste volume by about 80%. The advanced shredders are typically low-speed, high-torque, single-pass shredders with easily replaceable cutters and with discharge screens to control the size of shredded waste.

Microwave treatment technologies

Microwave technology is a steam-based process where the treatment occurs through the action of moist heat and

steam generated by microwave energy with a cycle of 30 min to 1 h. The types of waste treated are cultures and stocks, sharps, materials contaminated with blood and body fluids, other infected waste, laboratory waste and soft waste (e.g., gauze, bandages, gowns and bedding). Microwave treatment should not be used for cytotoxic, volatile compounds, hazardous or radioactive wastes, contaminated animal carcasses, body parts and large metal items. Biological indicators for microwave are *Bacillus atrophaeus* spores using vials or spore strips with at least 10^4 spores.

Dry heat treatment technologies

Hot air ovens have been used to sterilise glassware and other reusable instruments and infectious health waste. The waste is heated by conduction, natural or forced convection or thermal radiation at higher temperatures (up to 185°C) and longer exposure times (90–150 min) than steam-based processes. It should completely and consistently kill the biological indicator *Geobacillus stearothermophilus* **SP** hilus or *B. atrophaeus* spores using vials with at least $\log 10^6$ spores per ml or by a chemical indicator strip.

Sodium hypochlorite (NaOCl, 1-12%)

Chemical disinfection is most suitable for treating liquid waste. Recently, commercial, self-contained and fully automatic systems have been introduced which are more reliable than the manual autoclave.

Chemical disinfectants: The disinfectants used are chlorine compounds, aldehydes, lime-based powders or solutions, ozone gas, ammonium salts and phenolic compounds.

Sodium hypochlorite (NaOCl, 2%–12%): It is active against bacteria, viruses and spores, not effective for disinfection of liquids with high organic content, (blood or stool) and is widely used owing to relatively mild health hazards. Unused solutions should be reduced with sodium bisulphite or sodium thiosulphate and neutralised with acids before discharge into sewers. PPEs should be worn to protect HCWs. Chlorine dioxide is an alternative to hypochlorite. It is a toxic but soluble and stable in water and can be generated onsite.

Lime-based chemical treatment systems use dry powder or calcium hydroxide solutions. Glutaraldehyde and peracetic acid are used to disinfect instruments.

Incineration

Incineration is an increased temperature, dry oxidation process that reduces organic and combustible waste to inorganic, incombustible matter and results in a significant reduction of waste volume and weight, at temperatures from 600°C to more than 1000°C through combustion, pyrolysis or gasification under standard conditions. Its disadvantages include release of combustion by-products (dioxins and furans) and residual ash. The incinerator emissions should comply with national standards and in accordance with the Stockholm Convention BAT and BEP.

The waste types which are not included for incineration are pressurised gas containers; reactive chemical waste; silver salts and photographic or radiographic wastes, PVC plastics, heavy metals, batteries, sealed ampoules or vials, radioactive materials, unstable pharmaceuticals.

Encapsulation and inertisation

Encapsulation involves filling containers (polyethylene/metallic) with waste, adding an immobilising material (plastic foam, bituminous sand, cement mortar, or clay) and sealing the containers. It is used for pharmaceuticals and for incineration ashes with a high metal content. Following filling, the containers are sealed and placed into landfill sites to prevent scavengers gaining access to it and prevention of percolation into groundwater.^[1]

Emerging technologies

Emerging technologies include plasma pyrolysis, alkaline hydrolysis, superheated steam, ozone and promession.

Plasma pyrolysis makes use of an ionised gas in the plasma state to convert electrical energy to temperatures of several thousand degrees using plasma torches or electrodes with minimal or no air. It is used to break down pathological waste, infectious, plastic, hazardous chemical or pharmaceutical wastes. It is safe, eco-friendly, has energy recovery and has negligible harmful emissions of dioxins and furans. Production of clean alloyed slag which could be used in construction material and value added products such as metals. Its disadvantages include large initial investment costs, carbon dioxide pollution, large electrical energy input, highly corrosive plasma flame leading to frequent maintenance.

Ozone (O_3) can be used for especially pharmaceutical waste, water and air treatment. It is a strong oxidizer and

breaks down to a more stable form (O₂). Ozone systems require shredders and mixers to expose the waste to the bactericidal agent. Regular tests should be conducted to ensure that the microbial inactivation standard is met

Promession

It includes freeze-drying using liquid nitrogen and mechanical vibration to disintegrate cadavers into powder before burial. The process speeds up decomposition, reduces both mass and volume and allows the recovery of metal parts.

Alkaline hydrolysis

It is a process that converts body parts, specimens and cadavers into a decontaminated aqueous solution and destroys fixatives, hazardous chemicals and waste contaminated by prion. After the waste is loaded in the basket and into the hermetically sealed tank, alkali is added along with water at temperature of 127°C or higher and stirred. After digestion time of 6–8 h, by-products include mineral constituents of bones and teeth, solution of amino acids, sugars, soaps and salts. It can also destroy chemotherapeutic or cytotoxic agents and aldehydes (such as formaldehyde and glutaraldehyde) commonly used in hospitals.

Nanotechnology

It is used to cleanse environmental air to improve indoor quality air and includes a photo catalyst with wide spectrum of light and is bactericidal and fungicidal. It utilises the energy from light to generate hydroxyl species and superoxide anion (O₂⁻) which decompose and oxidise toxic pollutants to carbon dioxide and water.

Photocatalysis

It is a novel technology for disinfection and decontamination of hospital waste water which utilises solar energy or ultraviolet rays to disinfect microbes and decontaminate antibiotic from waste water at the point of origin. It is efficient and affordable technology.

Membrane bioreactors

It combines the biological-activated sludge process with a membrane filtration step for sludge water separation. Various types of membrane bioreactor (MBRs) are available such as aerobic MBR, anaerobic MBR, organic pollutant MBR.

Other emerging technologies for destruction of BMW include gas-phase chemical reduction, base-catalysed decomposition, supercritical water oxidation, sodium reduction, verification, superheated steam reforming, Fe-TAML/peroxide treatment (pharmaceutical waste), biodegradation (using mealworm or bacteria to eat plastics), mechanochemical treatment, sonic technology, electrochemical technologies, solvated electron technology and phytotechnology. These emerging technologies are not ready for routine application to health-care waste.

Biomedical Waste Management International Scenario

At the global level, 18%–64% of HCFs have unsatisfactory BMW facilities; predictors include lack of awareness, insufficient resources and poor disposal mechanisms. In South-East Asian region countries, 56% of facilities lack adequate waste disposal and treatment.

Similar situation existed in several other developing countries such as Iran, Nigeria, Senegal and Pakistan and the authors reported poor infrastructure, state of collection, transportation, disposal, training, capacity building, PPEs and resource constraints in BMW.

In India, it was observed in many studies the gap in knowledge and practice in relation to availability of resources and processes in place was found as was the need for organised training and structured supervision to bridge this gap. A study on tertiary care hospitals in India found that people with higher education such as consultants, residents and scientists had good knowledge of biomedical rules but was not reflected in their practices. Prior studies from geographically diverse states of India revealed that awareness among hospital staffs regarding segregation of BMW was slightly higher in urban areas compared to rural areas and that employee training and awareness can be a major determinant of establishing optimal BMW. A multistate study revealed that surveillance and monitoring of BMW were consistently deficient; BMW was alarming both at macro- and micro-levels across different parts of country. It was observed that the process of BMW were poor and unacceptable across levels of HCFs and were poorest in primary care settings as compared to secondary and tertiary care settings.

Conclusions

BMWM should ideally be the subject of a national strategy with dedicated infrastructure, cradle-to-grave legislation, competent regulatory authority and trained personnel. Improving the management of biomedical waste begins with waste minimization. These standards, norms and rules on BMWM in a country regulate the disposal of various categories of BMW are envisaged therein, so as to ensure the safety of the staff, patients, public and the environment, in furtherance to its vehement commitment, to ensure the fundamental right to live in clean and safe environment. The novel waste which is generated but not documented in rules should have a company buy back policy or should be treated as per recommended guidelines of Centers for Disease Control and Prevention or WHO. Furthermore, developing models for the monitoring of hospital health-care waste practices and research into non-burn eco-friendly sustainable technologies, recycling and PVC-free devices will go in long way for safe carbon environment. Globally, greater research in BMWM is warranted to understand its growing field of public health importance