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सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
Government of India
Ministry of Health and Family Welfare
Nirman Bhavan, New Delhi - 110011

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D.O. No. Z.33014/03/2018-IMM-Part(2)
Dated: 23rd December 2020

Dear Sir/Madam,

As you are already aware, India's Universal Immunization Program (UIP) is one of the largest immunization programmes in the world catering to a large cohort of pregnant women and children. To ensure potent and safe vaccine delivery a vast network of Cold Chain Points (CCPs) has been developed across the country.

2. Due to this large and widespread scale of the program, substantial waste is generated at immunization sites (fixed and outreach) and cold chain points. Immunisation activities generate waste that includes both hazardous and non-hazardous waste. Any indiscriminate disposal of the waste generated can have a direct or indirect negative impact on the health of community, health workers and on the environment at large due to its toxic, infectious and other hazardous properties.

3. In this regard, Guidelines on Management of Bio-medical Waste (BMW) under Universal Immunization Programme have been revised to align with the revised Central Pollution Control Board (CPCB) Guidelines and are being shared herewith. I request your supervision and support to institutionalize the revised guidelines and ensure compliance with the revised guidelines by the concerned.

Yours sincerely

Encl: As above

Preeti Pant

(Preeti Pant)

To,

Mission Directors, NHM - All states/UTs

D.O. No. Z.33014/03/2018-IMM-Part(2), Dated: 23rd December 2020

Copy to:

1. SEPIOs - All States/UTs
2. Advisor (RCH)
3. Addl. Commissioner (UIP)
4. Joint Commissioner (Imm.)
5. All partners - WHO, UNICEF, UNDP, JSI, ITSU

Preeti Pant

(Preeti Pant)

Management of Bio-medical Waste (BMW) under Universal Immunization Programme

Health care waste (HCW) is a growing concern across all health areas, including immunisation. Worldwide, an estimated 1600 crore injections are administered every year and India contributes 25% to 30% of the global injection load. According to annual report on BMW by Central Pollution Control Board (CPCB) 2017 (status as on 2nd May 2019), about 559 tons of bio-medical waste is generated per day, with significant contribution from Universal Immunization Programme (UIP) through routine activities and campaigns. UIP of India, one of the largest immunization programmes in the world, with more than 1 crore immunization sessions held annually (source- HMIS), targets close to 2.67 crore new-borns and 2.9 crore pregnant women. To ensure potent and safe vaccines delivery to this enormous cohort, a network of ~27000 Cold Chain Points (CCPs) have been created across the country. The waste generated at immunization sites (fixed and outreach) and cold chain points becomes an integral part of the bio-medical waste generated at health facility.

Immunisation activities generate waste that includes both non-hazardous waste (such as covers for syringes, boxes, papers, etc.) and hazardous ones (syringes including needles, vaccine vials, and cotton/wool for cleaning). Any indiscriminate disposal of the waste generated can cause a direct impact on the health of the community, health workers and on the environment at large due to its toxic, infectious and other hazardous properties. Needles and syringes not disposed safely create a risk of injury and infection and opportunities for reuse. It can lead to health risks like sharp injuries, infections like HIV, Hepatitis B etc. Also, inadequate treatment and disposal of healthcare waste can lead to hazardous environmental impact. If those landfills are not properly constructed, the untreated health care waste can lead to contamination of surface and ground waters. In addition, the treatment of health care wastes with chemical disinfectants can also result in the release of chemical substances into the environment if those substances are not handled, stored and disposed in an environmentally sound manner.[1,2] As we strive towards the goal of reaching full immunization coverage >90% with health system strengthening, it is important to bolster the health care waste management system and coordinate the waste management at all points (streamline the process).

The Bio-Medical Waste (Management and Handling) Rules, 1998, published vide notification number S.O. 630 (E) dated the 20th July, 1998, by the erstwhile Ministry of Environment and Forests, Government of India (GoI), provided a regulatory framework for management of bio-medical waste generated in the country. The said rules were amended by GoI in 2016 and then in 2018. According to Bio-medical Waste Management Rules, 2016 released by Government of India, *'bio-medical waste' 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*. The rules enlist the duties of the occupier[3]; duties of the operator[4] of a

[1] WHO fact sheet: https://www.who.int/news-room/fact-sheets/detail/health-care-waste

[2] Arora NK. Injection practices in India. WHO South East Asia J Public Health. 2012;1(2):189-200. doi:10.4103/2224-3151.206931

[3] occupier means a person having administrative control over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called

common bio-medical waste treatment and disposal facility; duties of the authorities; treatment and disposal of bio-medical waste; segregation, packaging, transportation and storage of waste; formation of advisory committee to oversee the implementation of the rules; and, monitoring of implementation of the rules in health care facilities. The Guidelines for Disposal of Bio-medical Waste generated during Universal Immunization Programme were published in 2004. The Immunization waste management guidelines were re-iterated in the Immunization handbook for Medical officer (2017) and Health Worker (2018). This document has been drafted to bring all the guidelines of Immunization waste management from CPCB, Kayakalp and Routine Immunization guidelines to a symphony.

Potential Bio medical waste generated during the immunization process

S.no	Logistics used in Immunization programme	Type of waste that can be generated during Immunization programme	
		BMW waste	General waste
1	Vaccine	1. Empty vaccine vial 2. Broken vaccine vial 3. Expired vaccine	
2	Diluent	1. Empty Diluent ampoule 2. Broken Diluent ampoule 3. Expired Diluent	
3	AD Syringes with packing	1. Sharp needle 2. Plastic hub of syringe	Packaging Cap of the needle
4	Reconstitution Syringes with packing	1. Sharp needle 2. Plastic hub of syringe	Packaging Cap of the needle
5	Cotton	Cotton contaminated with Blood or body fluid	
6	Syrup Vitamin A	Expired Bottle	
7	Paracetamol	Expired Tab/Syrup	
8	Gloves	Used gloves	
9	Rotasil vaccine administrative parts	1. Rotasil vaccine adaptor 2. Oral syringe	

Steps of Bio Medical Waste Management

Disposal of biomedical waste generated at outreach points/PHCs/CHCs/ district hospitals, etc.

At the Session site

Step 1: At the session site**,** ANMs cut the hub of the AD syringe immediately after administering the injection using the hub cutter, that cuts the plastic hub of the syringe, which along with the needle, will get collected in the puncture-proof container of the hub cutter.

[4] operator of a common bio-medical waste treatment facility" means a person who owns or controls a Common Bio-medical Waste Treatment Facility (CBMWTF) for the collection, reception, storage, transport, treatment, disposal or any other form of handling of bio-medical waste

Step 2: Segregate and store the plastic portion of the cut syringes in the Red bag or container. The containers should bear the biohazard symbol.

Step 3: Store the broken diluent ampoules in a separate Blue container, used cotton swab in Yellow bag.

Step 4: Plastic wrapper and the cap of the needle should be stored as general waste in Black bag.

Step 5: The used, partially used vaccines not under open vial policy and discarded vaccine vials should be returned to the CCP as per existing AEFI guidelines for proper disposal.

Send the Red bag, Yellow bag, Blue bag/container and the hub cutter (White container) to health facility (CCP) for disinfection and disposal by the designated person or handing over to Common Biomedical Waste Treatment Facility Common Bio Medical Waste Treatment Facility (CBWTF).

At the PHC or CCP

Step 6: At the PHC, disinfect the contents of blue box/bag and the vaccine vials by soaking in 1% sodium hypochlorite solution for at least 30 mins or through autoclaving/ microwaving/ hydroclaving and then handover to CBWTF. PHC should send the collected materials of the red bag and white container directly to the CBWTF. Dispose of the black bag as general waste. If the CBWTF doesn't exist, go to Step 7.

Step 7: Treat the collected material of the Red bag, Yellow bag, Blue bag and the hub cutter (White bag) in an autoclave. If unable to autoclave, boil the waste in water for at least 10 minutes or provide chemical treatment using sodium hypochlorite for 30 minutes to ensure that this results in disinfection. However, the district hospital/CHC/PHC will ultimately make the necessary arrangements to autoclave on a regular basis.

Step 8: Dispose the autoclaved (or boiled/chemically disinfected) waste as follows:

- Dispose the needles in a safety pit/tank. In case of the hospitals located in remote in rural or isolated places, dispose the same in captive deep burial pits [WHITE BOX].
- Send the syringes and unbroken vials, diluent ampoules, empty glass bottles for recycling or to a landfill.
- Plastic part of the cut syringes, plastic ampoules should be sent to registered or authorized recyclers or to waste to energy plants or plastics to diesel or fuel oil or for road making [RED BAG]

Step 9: Wash the hub cutters properly with 1% sodium hypochlorite solution before reuse.

Step 10: Maintain a proper record of generation, treatment and disposal of waste at the district hospital/CHC/PHC in order to assess the waste (needles/syringes/vials) generated and disposed. Match the waste by weighing rather than counting to avoid occupational and safety hazards. This

helps to prepare annual reports to be submitted to the prescribed authority by 31st January of every year.

Table: Summary of the segregation guidelines (Changed guidelines have been highlighted)

Logistics used in Immunization programme	Particular	**Previous IWM Guidelines as per MO handbook**	Revised guidelines as per BMW guidelines 2016
AD Syringes with packing	**Cut hub of AD and disposable syringes**	Puncture-proof container	**WHITE** [White coloured translucent, puncture proof, leak proof, tamper- proof containers]
	Plastic hub of the syringe	Red bag	**RED** [Red coloured non-chlorinated plastic bags (having thickness ≥ than 50µ or containers)]
Rotsail vaccine parts	**Rotasil vaccine adaptor**	NA	
	Rotasil oral syringe	NA	
Vaccine	**Expired vaccine**	Red bag	**YELLOW** Yellow coloured non-chlorinated plastic bags (having thickness ≥ 50µ or containers)
	Broken vials	Puncture-proof container	**BLUE** [Cardboard boxes with blue coloured marking or blue coloured puncture proof, temper proof containers]
	Empty unbroken vials	Red bag	
Ampoules	**Ampoules (glass)**	Puncture-proof container	
	Ampoules (plastic)	Puncture-proof container	**RED** [Red coloured non-chlorinated plastic bags (having thickness ≥ 50µ or containers)]
Cotton	**Cotton contaminated with Blood or body fluid**	NA	**YELLOW** [Yellow coloured non-chlorinated plastic bags (having thickness ≥ 50µ or containers)]
Vitamin A	**Expired Bottle**	NA	
PCM	**Expired Tab/Syrup**	NA	
Gloves	**Used gloves**	NA	**RED** [Red coloured non-chlorinated plastic bags (having thickness ≥ than 50µ or containers)]

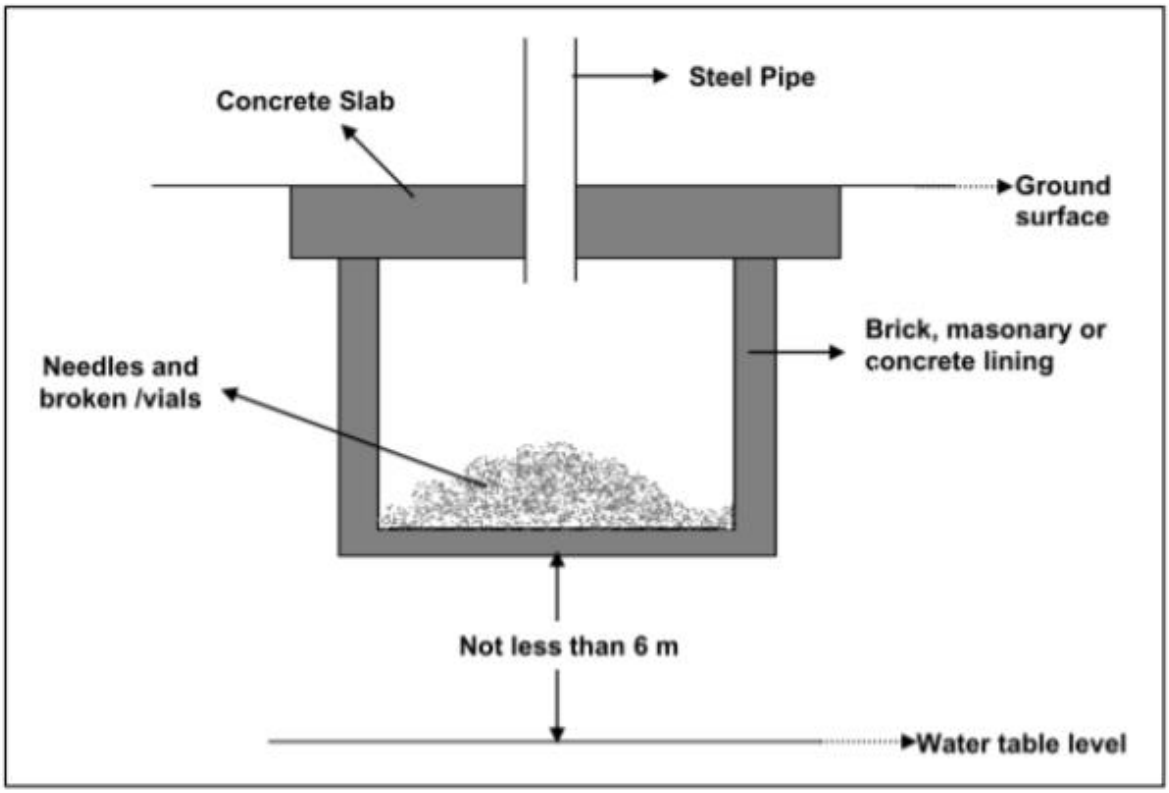
Flow chart for BMW management - Steps of Disinfection

Preparation of Bleaching solutions_- Chlorine solutions gradually lose strength, therefore prepare freshly diluted solutions daily (use within 24 hours). Use clear water, because organic matter destroys chlorine. Since this bleach solution is also caustic, avoid direct contact with skin and eyes. Use plastic containers, as metal containers are corroded rapidly and also affect the bleach.

1. **From Bleaching powder**: To prepare 1% Hypochlorite solution, dissolve 10-15g or 1 tablespoonful of bleaching powder in 1 litre of water, in a well-ventilated area.
2. **From Liquid Bleach solution:**
    a. From commercially available 5% liquid bleaching solution: To prepare 1% Hypochlorite solution, dissolve 200 ml bleaching solution (5% concentration) in 800 ml clean water, in a well-ventilated area.
    b. From commercially available 10% liquid bleaching solution: To prepare 1% Hypochlorite solution, dissolve 100 ml bleaching solution (10% concentration) in 900 ml clean water, in a well-ventilated area.

Standards or specifications of deep burial pits/safety pits

The pit should be constructed within the hospital premises. The treated needles/broken vials should be disposed in a circular or rectangular pit. Such a rectangular or circular pit can be dug and lined with brick, masonry or concrete rings. The pit should be covered with a heavy concrete slab, which is penetrated by a galvanized steel pipe projecting for about 1 meter above the slab, with an internal diameter of up to 50 millimetres or 1.5 times the length of vials, whichever is more. The top opening of the steel pipe shall have a provision of locking after the treated waste sharps has been disposed in. When the pit is ¾ the full it can be sealed completely, after another has been prepared. For high water table regions where water table is less than 6 meters beneath bottom of the pit, a tank with above mentioned arrangements shall be made above the ground.



Additional actions for BMW management

- **Training:** Provide training to all health care workers and all those involved with bio medical waste management handling including AVDs, Group D workers and others at the time of induction and thereafter at least once every year. The details of training programmes conducted, number of personnel trained, and number of personnel not undergone any training shall be provided in the annual report.
- **Record maintenance:** Maintain a proper record of generation, treatment and disposal of waste at the District Hospitals/CHC/PHC/etc.
  - Maintain log of all waste generated from the immunization activity (both fixed and outreach sessions, CCPs)
  - Maintain all records of collection of wastes from CBWTF

- Maintain records of any needle stick injuries
- Maintain all records of incinerator/ hydroclaving /autoclaving for a period of 5 years
- Maintain a log book of each cycle of treatment with all details such as time, date, weight, duration and hours of treatment.
- All records should be supervised (audited) monthly by the Medical officer in charge.

- **Packaging**
  - Bio-medical waste bags and sharps containers should be filled to no more than three quarters full. Once this level is reached, they should be sealed ready for collection.
  - Plastic bags should never be stapled but may be tied or sealed with a plastic tag or tie.
  - Replacement bags or containers should be available at each waste-collection location so that full ones can immediately be replaced.
  - Adequate number of colour coded bins / containers and bags should be available at the point of generation of bio-medical waste
- **Immunize all health care workers** and others involved in handling of bio-medical waste for protection against Hepatitis B and Tetanus, that are likely to be transmitted by handling of bio-medical waste, in the manner as prescribed in the National Immunisation Policy or the guidelines of the Ministry of Health and Family Welfare issued from time to time.
- All the waste generated at the outreach session should be returned to the Cold Chain Point the same day.
- Posters / placards for bio-medical waste segregation should be provided at all the immunization session points as well as in waste storage area.
- All health facilities should have a tie up with CBMWTF. No occupier shall establish on their site a BMW treatment and disposal plant, if, a CBMWTF is available within 75 km of the health care facility (HCF). If no, CBWTF is available, treatment facility should be available within the health facility
- Safety pit is an option in remote rural or remote areas, where there is no other disposal option and no tie up with CBWTF. The groundwater level should be a minimum of 6 meter below the lower level of the deep burial pit.
- Interim storage of bio medical waste is discouraged in the wards / different departments of Health care facility/ Cold chain point. A designated bio-medical waste room should be made for interim storage.
- Bio medical waste can be stored for a maximum of 48 hours at the interim storage site at the health facility.
- **Labelling**
  - All the bags/ containers/ bins used for collection and storage of bio-medical waste, must be labelled with the Symbol of Bio Hazard or Cytotoxic Hazard as the case may be, as per the type of waste in accordance with the BMWM Rules, 2016.
  - Bio-medical waste bags / containers are required to be provided with bar code labels in accordance with CPCB guidelines for “Guidelines for barcode System for Effective Management of Biomedical Waste”.