MANAGING HIGHLY PATHOGENIC MEDICAL WASTE: FINDING A WAY FORWARD

Report of the April 10, 2017 Workshop at the
University of Maryland, College Park

November, 2019

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Governor

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Executive Summary

On April 10, 2017, representatives from state and federal public health and environmental agencies, health care and waste management industries, employee unions, academic institutions and non-governmental organizations met at the University of Maryland in College Park, Maryland to discuss the challenges of managing highly pathogenic medical waste (HPMW). The approximately 60 participants discussed science and technology, law and regulation, and risk communication. Some of the key needs identified in the workshop include:

- Improvements in risk assessment, including exposure and disease risk for workers and the public at all stages of waste management
- Improved validation methods for both conventional and emerging HPMW treatment technologies
- Better technologies for waste packaging and transportation
- Development of consistent federal regulations that coordinate interagency collaboration and standardize definitions for HPMW
- Public messaging about HPMW management before an emergency occurs, working with the media and social media to transmit culturally competent, targeted, science-based, credible messages about treatment, risk and public health
- Specific training and education for all workers involved in HPMW (not just patient care and environmental services workers), with adequate time for hands-on practical training, using culturally and educationally appropriate materials

The experience of waste management during the response to Ebola Virus Disease (EVD) clearly identified the urgent need to address these issues before a similar event occurs again. Workshop participants stressed the necessity of a collaborative, multi-agency, multi-sector, and multi-level approach. A particular emphasis in the workshop was given to the suggestion to create pilots in individual or groups of states, given that many of these issues involved possible regional solutions or approaches.

Background and Introduction

On April 10, 2017, approximately 60 representatives from state and federal public health and environmental agencies, health care and waste management industries, employee unions, academic institutions, and non-governmental organizations met at the University of Maryland in College Park, Maryland to discuss the challenges of managing highly pathogenic medical waste (HPMW). The Maryland Department of Health and Mental Hygiene (now the Maryland Department of Health, MDH) and the University of Maryland School of Public Health organized the meeting. The stated goal of the meeting was, building on the experience of the response to the Ebola outbreak of 2015 and progress since then, to identify the key gaps, needs, and action items to prepare for the next episode involving Ebola Virus Disease (EVD) or another highly pathogenic medical waste.

The workshop agenda (Appendix A) included presentations and panel discussions from a number of experts in the fields of HPMW and waste management, as well as health care and public health, law, and policy. The participants (Appendix B) spent the morning on some of the key issues related to management of HPMW:

- Interim Federal Planning Guidance on Waste Contaminated with category A Infectious Substances[1]
- Science and Technology
- Law and Regulation
- Risk Management and Risk Communications, including Occupational Issues

In the afternoon, the participants broke into a number of workgroups and discussion sections to explore a series of questions related to the management of HPMW:

- What are the most important scientific and technical gaps to be filled for highly pathogenic medical waste?
- What are the most important legal/regulatory barriers preventing effective management of highly pathogenic medical waste?
- What is needed to address these challenges, and who should address them?

The workgroups individually prioritized their recommendations for each of the discussion questions and then presented them at the closing discussion. These are summarized in the following sections.

[1]The Interim Planning Guidance for the Handling of Solid Waste Contaminated with a Category A Infectious Substance. Washington, DC; (January 19, 2017):81 pp. Accessible at: https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/Interim_Planning_Guidance_for_Handling_Category_A_Solid_Waste.pdf. Since publication of the Interim Planning Guidance, it has been supplanted by a final version: Managing Solid Waste Contaminated with a Category A Infectious Substance. Washington, DC; (August, 2019):111 pp. Accessible at: https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/transporting-infectious-substances/6821/cat-waste-planning-guidance-final-2019-08.pdf.

Science and Technology

The workgroups identified a number of knowledge gaps related to medical waste management generally, particularly in the area of mechanism-based assessment of risk to workers and communities. Participants felt that a tripartite effort by regulatory agencies, the scientific community and industry was crucial to improving understanding of the processes involved. Risk should be assessed from the point of waste generation to wherever the waste is ultimately disposed of in order to determine high risk situations, so that policies and training can be specifically targeted at such points. Additionally, exposure assessment should completely define the contamination risks present for HPMW. Finally, an appropriate categorization of the wastes based on the type, treatment methods, and associated regulations should be developed and adopted.

In addition to addressing the scientific knowledge gaps, there was broad consensus on the need for improvements and updates to the validation of sterilization and/or inactivation processes for medical wastes. There may well be alternative methods and treatment technologies that will be effective for HPMW. Development and validation of these processes, however, requires collaboration between government, industry, and the academic research communities. This will also require a dedicated funding stream for the work. Finally, there is a need for current hospital medical waste management protocols to be validated for specific pathogens and supplemented with appropriate recommendations to establish standardized workflows.

The following scientific and technical needs were identified by workgroup participants:

- *Improved Risk Assessment:* There is a need for mechanism-based risk assessment to:
    1. Define exposure risk for disease transmission for HPMW (important questions include: who makes the decision, and how safe is "safe"); and
    2. Manage the risk to workers and communities during and after the final management of HPMW.
- *Validation of Treatment Technologies:* For sterilization and inactivation process validation, there may be alternative endpoints that could alter treatment technologies to make decontamination easier.
- *Technologies on Waste Packaging:* There is a need for better technologies for waste packaging and transportation, each of which involves a highly complex set of processes, physical infrastructure and equipment, and regulatory requirements.

In no order of priority, the following recommendations were offered:

- Current treatment protocols for HPMW should be validated to establish minimum operating parameters and demonstrate effective treatment for both conventional and alternative treatment technologies, and modified treatment protocols should be established for specific pathogens, waste types (e.g. suction canisters, sharps, pathological wastes), and packaging types (e.g., triple packaging, dense or tightly sealed containers). Consideration should be given to establishing and validating specific recommendations for select pathogens.

- There should be monitoring and validation of the entire HPMW management process on both the front and back ends of the procedures, not just at an institutional level but nationally. This would include development of uniform processes for data collection, performance monitoring (e.g., challenge testing), and process validation and reproducibility (including parametric controls, use of biological indicators, etc.).
- There is a need for more funding (potentially involving cooperative efforts by multiple agencies) for research on comprehensive risk assessment and better alternative treatment methods.
- There is a need for tripartite efforts by industry, the scientific community, and regulatory agencies, to study the processes involved from the point of waste generation to the point of ultimate waste disposal, and a determination of where risks exist between those points, so that people can be trained appropriately to avoid risks.
- There is a need to gather resources to establish baseline protocols and standardization, so that the information can be presented to multiple groups to establish buy-in (for waste management and treatment strategies).
- There is a need to identify a lead agency to establish treatment parameters, personal protective equipment (PPE) requirements, and standardized work flow for waste in the hospital, although this will inevitably also involve multi-agency collaboration and working groups.
- There is both a need for and an opportunity to create centers of excellence utilizing academic centers to generate new ideas and information related to HPMW management.

Law and Regulation

The laws and regulations governing HPMW are highly fragmented, with multiple agencies claiming some jurisdiction over part of the medical waste management and treatment processes. This leads to many unique challenges in efficiently and effectively dealing with HPMW and high levels of variability across jurisdictions on how this issue is addressed.

At the federal level, agencies involved in the management of HPMW include the U.S. Department of Transportation (USDOT), which oversees Category A waste shipments through regulations under the Pipeline and Hazardous Materials Safety Administration (PHMSA).[2] These include requirements for triple packing of Category A wastes in a primary watertight receptacle, a watertight secondary package, and a rigid outer packaging. Special permits are available from PHMSA in the event companies are not able to obtain the required packaging, and HPMW treated on site is not considered Category A and is not subject to USDOT regulations.

In addition to the USDOT, other federal agencies are involved in HPMW. The U.S. Department of Labor Occupational Safety and Health Administration regulates aspects of HPMW

[2] 49 CFR § 178.609. Test Requirements for Packaging of Infectious Substances. See also the U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration at: https://www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-overview.

management pertaining to worker health and safety. The U.S. Environmental Protection Agency (USEPA) has a significant role when it comes to medical waste incineration and treatment technologies through the Clean Air Act, Clean Water Act, Federal Insecticide, Fungicide and Rodenticide Act, and potentially the Toxic Substances Control Act. In addition, USEPA does have some role in landfill requirements through the Resource Conservation and Recovery Act. Finally, though not regulatory, the Centers for Disease Control and Prevention, including the National Institute for Occupational Safety and Health, provides guidance on both hazardous and medical waste management, along with examples of successful state programs.

State regulation and enforcement of medical waste is usually located in either the health department, the environment department, or both. In some states, the health agency plays an important role or is the primary regulatory agency and is typically responsible for on-site management of HPMW while the environmental agency is responsible for transportation and disposal.[3] In Maryland, the Department of the Environment is responsible for regulations related to solid waste and hazardous waste generation, transportation, and disposal,[4] while the Department of Health defines medical waste and whether treatment of medical waste converts that waste to regular (non-infectious) waste.[5]

Additionally, most states have regulations covering packaging, storage, and transportation of medical waste and zoning and permitting of medical waste facilities. Some states require health care facilities to register and/or obtain a permit for handling potentially infectious medical waste (including HPMW) which includes the development of contingency plans, on-site treatment, training, waste tracking, recordkeeping, and reporting. Local agencies may require additional permitting and treatment options and may influence final disposition options.

There are a number of regulatory challenges associated with HPMW governance and control including the fact that federal, state, and local jurisdictions do not have consistent definitions surrounding HPMW:

- There is no uniform definition or guideline for HPMW.
- Most states have no definition of “highly infectious or “highly pathogenic” wastes and don’t define Category A waste in their regulations.
- Most states do not have any treatment or handling regulations governing the medical waste supply chain.
- Most planning for HPMW focuses on emergency preparedness at the health care facility level, not necessarily community response or waste handling.

[3] In Maryland, the Maryland Department of Health establishes the regulations defining medical waste and treated medical waste, but the management of the waste is regulated by the Maryland Department of the Environment.
[4] See “Land Permit Applications and Instructions,” at https://mde.maryland.gov/programs/LAND/Pages/landpermits.aspx.
[5] See https://phpa.health.maryland.gov/OEHFP/EH/Pages/special-medical-waste.aspx.

- Gaps in regulatory requirements for handling of HPMW when discovered outside of a health care facility or waste management facility (i.e., exemptions for household waste, lack of standards for decontamination of public spaces or building materials).
- Some regulations affecting HPMW are based on perceptions of risk that may be exaggerated, compared with what experts consider to be the actual risks.

Workshop participants explored a range of options to improve regulation. Some suggested using examples from other industries and environmental challenges, like radioactive waste, as models. This might include multi-state compacts, or a requirement for local disposal as a condition of licensure. Other suggestions included sponsoring future workshops, focused on the development of regulatory standards that states could use to require or encourage local landfills to accept treated HPMW as a condition of permitting. Some of the key recommendations to emerge included:

- The federal government should develop consistent regulations and standardized approaches for HPMW, including a clear and standardized definition.
- There is a need for model state regulations regarding management of HPMW under specific circumstances; states, in collaboration with non-governmental organizations and the federal government, should be involved in the development of these model regulations.
- There are specific roles that various stakeholders should play in order to create a more uniform, risk-based environment for the successful management of HPMW:
    - *Regulators*: Clearly identify state and federal requirements for HPMW and communicate those requirements to stakeholders;
    - *Generators*: Identify and characterize waste streams; determine how HPMW will be managed internally, and communicate the management plans to local vendors/transporters/treatment facilities as well as government agencies in advance of emergency situations;
    - *Waste management industry*: With state or local officials, determine the applicable handling, transfer, treatment, and disposal requirements; the need for special permitting; and transportation plans to address public safety concerns; and
    - *Policy makers and elected officials*: Assess policy gaps and devise strategies to address those gaps; develop proactive communications plans with government agencies, political leaders, and media, to do more outreach and education about HPMW, risk, and management strategies.

Risk Management and Risk Communication, Including Occupational Issues

Risk communication issues involve the public, key stakeholders, and workers involved in HPMW management at all levels. Panelists emphasized the importance of getting uniform, accurate

information and messages to stakeholders in a single trusted voice. There was wide agreement that this must be done by government agencies, rather than by the private sector. There was also discussion of the need to recognize cultural diversity and customs at the local level. There was considerable discussion about the contents of the message; participants noted that there was a difference in outcome when the message focused on human infection risk, rather than on the need to stop the global spread of live viruses or the specifics about waste management practices and effectiveness, such as incineration of infectious waste into safe waste.

Types of messages and communication needed for workers involved in HPMW management were identified. Communication to workers needs to address all workers (including waste management and laboratory workers), not just staff with direct patient contact. Training must take place before there is a threat of an outbreak, and should cover workers in all sectors (public, private) and levels of employment. There are many different types of training available, but some of the challenges included providing the opportunity, time, and funding for workers to participate in live, "hands-on" practical training (as opposed to online training). Participants noted that awareness training was the most common type of instruction, so that staff would understand what would happen as an infection spread and that their actions and responses would determine if the public felt safe.

Workshop participants felt that some of the most important challenges in risk communication generally were:

- The need for uniform messaging from a credible, authoritative, open source, given the tendency of media sources to focus on the (sometimes exaggerated) risk of HPMW;
- The need for messages to the general public, workers, and specific groups (such as people living near waste management facilities), delivered with both cultural sensitivity and appropriate educational level;
- Changing the messaging from one based on perceptions of exaggerated public risk to one of public health and prevention based on science;
- Offering clear communication about the effectiveness of treatment and the fact that treated waste (including incineration ash) is not infectious; and
- Getting agencies at multiple levels to collaborate and agree on messages ahead of time.

Given these challenges, the workshop participants identified several promising opportunities:

- Agency subject matter experts could work with their public information officers to develop specific key messages and work with the press ahead of any outbreak, to discuss progress in HPMW management and treatment, including developing articles and pieces for social media, and preparing content for public websites. Community-based focus groups could also be used to identify key concerns and messaging opportunities (this might also involve collaboration with academic and research institutions).

- Agencies and institutions should identify key personnel who will be involved in HPMW response and ensure ongoing training and communication, including staff involved in the response (not just patient care and environmental services, but all staff).
- Training and functional drills should include paid and volunteer first responders, such as fire department personnel, paramedics, ambulatory crews, patient transport, and other emergency medical care facilities or services that may encounter a patient prior to admission to a frontline, assessment, or treatment hospital.
- Specific and uniform job aids and checklists should be developed for personnel to use during incidents (not only for donning and doffing of PPE, but specifically for the handling, management, storage, treatment, and disposal of HPMW).

Conclusion

The challenges of effectively managing HPMW continue to require attention, particularly in the interval between Ebola Virus Disease and whatever the next outbreak or incident is that occurs involving a highly pathogenic agent. There are opportunities for federal and state agencies, together with industry, academia, the media, and non-governmental organizations, to address some of the big overarching issues identified in this workshop. Workshop participants were particularly supportive of the idea of developing one or more pilots, possibly involving either individual or groups of states collaborating with federal and industry partners, the waste management and health care industries, academic and research institutions, and non-governmental organizations.

Appendix A: Workshop Agenda

MANAGEMENT OF HIGHLY PATHOGENIC MEDICAL WASTE: FINDING A WAY FORWARD

April 10, 2017

University of Maryland College Park

Marriott Hotel and Conference Center

WORKSHOP AGENDA

8:30	Registration and Refreshments
9:00	Welcome and Introductions *Boris Lushniak, University of Maryland School of Public Health*
9:10	Overview of Workshop *Clifford Mitchell, Maryland Department of Health and Mental Hygiene*
9:30	Overview: Interim Federal Planning Guidance on Waste Contaminated with Category A Infectious Substances *Christopher Brown, U.S. Occupational Safety and Health Administration* *Lynn Slepski, U.S. Department of Transportation*
10:00	Science and Technology *Matthew Arduino, U.S. Centers for Disease Control and Prevention* *Paul Lemieux, U.S. Environmental Protection Agency* *Edward Krisiunas, WNWN International*
10:40	Break
10:50	Law and Regulation *Selin Hoboy, Stericycle* *Douglas Farquhar, National Conference of State Legislatures*
11:25	Risk Management and Risk Communications, including Occupational Issues *Andrea Arredondo, Earth Compliance Solutions* *Rudy Vingris, WM Sustainability Services* *Colleen Cusick, Johns Hopkins Hospital* *Nina Jaitly, National Institute of Environmental Health Sciences* *Travis Parsons, Laborers' Health and Safety Fund of North America*
12:30	Luncheon
1:30	Introduction to Working Breakout Sessions
1:45	Breakout Sessions
3:00	Break
3:20	Breakout Reports and Discussion
3:40	Group Priority-Setting Exercise for Actionable Ideas
4:10	Summary and Closing Discussion
4:30	Adjourn

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Appendix B: Workshop Participants

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