SUMMARY

Centers for Disease Control and Prevention
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Medical Waste Management in the Bioterrorism Era

CDC/ATSDR

***Please note:** Data and analysis discussed in these presentations were current when presented. Data collection and analysis are ongoing in many cases; therefore updates may be forthcoming elsewhere on this website, through publications such as CDC's Morbidity and Mortality Weekly Report or other venues. Presentations themselves will not be updated. Please bear this in mind when citing data from these presentations.*

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Learning objectives:

- Know the general categories of regulated medical waste
- Be aware of regulations in their state that address medical waste management
- See how the recent influenza A (H2N2) episode revealed weaknesses in current waste management strategies and
- Understand the importance of on-site treatment in a bioterrorism era

Part I: CDC Guidance on Regulated Medical Waste

- CDC Guidelines for Environmental Infection Control in Healthcare Facilities
  - Full text version December 2003: http://www.cdc.gov/ncidod/hip/enviro/guide.htm
  - Topics include categories of medical waste, treatment, disposal, discharge of blood to sanitary sewers, CJD issues, and issues relating to on-site decontamination

- Epidemiology of Medical Waste
  - Syringes on the beach and the AIDS era…
    - There were many media reports of "panic in the streets" because syringes were washing up on the beaches in Northeast states like New Jersey and New York! It heightened people's awareness of medical waste and shortly thereafter the demand for medical waste segregation and treatment arose due to the public's perception of the potential hazards of this portion of the waste stream. Congress got into the act with the Medical Waste Tracking Act, addressing the public's concerns.
  - However, there is no evidence that traditional medical waste treatment and management processes have contributed to increased levels of disease in the community and/or healthcare workers.
  - We are aware of injuries and infections in health care from needlesticks and

sharps-associated incidents. However, occupational injuries sustained during care delivery (i.e., needlesticks) are excluded from consideration unless the item is already discarded.

General Categories of Medical Waste

- Wastes that represent a sufficient potential risk of infection during handling and disposal and for which some precautions appear prudent
    - Microbiology laboratory waste; pathology and anatomy waste; blood, blood products, and other body substances; sharps
- States may designate additional categories (e.g., animal wastes)

    - These are broad categories of wastes encountered in health care, and it follows there are a number of fine-tuned subcategories. For example, with sharps, we traditionally think of syringes and needles. We might see included in this category broken glass; any sharp, protruding object regardless of material (e.g., a broken pipette); or any sharp-edged item contaminated with blood, blood products, or body substances. OSHA has weighed in on the issue in this regard too, in their bloodborne pathogen standards. State medical waste regulatory programs will determine what waste items are included in each of their major categories of medical waste, and there may be some categories of waste (e.g., wastes from animals intentionally exposed to pathogens) that are not associated with hospitals or healthcare facilities.

Basic Components of Medical Waste Management

- Discard at point-of-use
- Collection and consolidation within the facility
- (Containment and packaging)
- (Transport to treatment location)
- Treatment or decontamination
- Transport to disposal site
- Discharge to solid waste landfill

    - Basically, the whole process starts off where an item that fits the definition or the categories of medical waste is discarded at the point of use.
    - The next step is to put the item in some form of first line containment. The discarded material is collected and consolidated within the facility. At some point, there may be a choice whether this material goes off-site for further processing or it may remain within the healthcare facility. So, that's the purpose of the parentheses: it could go either way – either the waste is managed within the facility for the rest of its processing up until the point of final discharge, or it is packaged and shipped to an off-site location for treatment.
    - If the waste is being sent for off-site reprocessing or further treatment and disposal, then these second, third, and fourth steps will be carried out by another entity. Regardless of whether the waste remains in the facility or is removed for off-site treatment, it is generally put in some form of containment or packaging before being moved to a treatment location.
    - Treatment or decontamination of the waste is performed, the purpose of which is to reduce the potential infectivity of the waste. After treatment, the waste is transported to its site for final disposal.

- Usually this site of final disposal is a solid waste landfill in the state. These landfills are subject to the U.S. Environmental Protection Agency (EPA) RCRA (Resource Conservation and Recovery Act) Rules. And since most, if not all of the treated medical waste is solid (not liquid), all of this treated material coming from a healthcare facility is going to a solid waste landfill.

Medical Waste Management is Heavily Regulated

- Federal government agencies:
  - OSHA
  - DoT
  - EPA
  - CDC (guidance but not regulatory)
- State government agencies:
  - Health department
  - Environmental protection department

  - The medical waste management process is heavily regulated. At the federal government level, there are several agencies involved. OSHA's interest in the process is focused on the healthcare worker's contact with waste. So, OSHA is primarily looking at the ways and manner in which the waste is handled by workers at the point of generation, all the way through the point of final disposal. They are looking for the safety aspect for this whole process. The Department of Transportation (DoT) is interested in how the waste is moving from point A to point B, usually on public highways and city streets and roads. EPA is involved primarily through the regulation of the solid waste landfills, and so local municipalities will be looking to abide by their regulations for the landfills.

  - How does CDC figure in all this? Basically CDC is a guidance organization. Our agency weighs in on the public health impact and epidemiology of medical waste management.

State Medical Waste Regulations

- State medical waste regulations address:
  - Categories of medical waste
  - Treatment or decontamination of these wastes
  - Consolidation, packaging, and storage on-site
  - Transport and disposal
  - Treatment centers vs. on-site

  - The real regulatory entity in this entire process is the state government agencies. Where the regulatory authority is located varies from one state to the next. In some states, the state health department will have the primary responsibility for the regulation of medical waste. In others, it will be something that is similar to an environmental protection agency or department. In other states, it will be a combination of the two agencies, where they have a memorandum of understanding outlining operations and how one agency's rules will affect the other.

  - An example of this shared regulatory authority is this: a health department may designate the state's medical waste categories and the accepted

methods of treatment, and an environmental protection department would probably be interested in how the waste is packaged, transported from a facility to a landfill or treatment facility, and how the waste is finally discarded in the landfill.

Where Can I Find My State's Medical Waste Regulations?

- EPA has a link to all the state regulatory web pages: http://www.epa.gov/epaoswer/osw/stateweb.htm

- EPA also links to other Federal government agencies' web pages: http://www.epa.gov/epaoswer/other/medical/#state

Treatment of Medical Waste

- Method of treatment
  - Traditional – autoclaving, incineration
  - Chemical immersion
  - Alternative treatment technologies
  - Use conditions
- Treatment site
  - On-site vs. off-site
  - Off-site locations necessitate transport of untreated waste

- General methods of treatment are commonly recommended by the different states. Traditional methods are: steam autoclaving, or incineration, and many hospitals used to have pathology incinerators on-site. More recently, there have been interests in a technique known as chemical immersion, where waste items are immersed in disinfecting chemicals. State regulations will list what chemicals are approved in their state for this use. The chemical immersion process were helpful, especially for small volume generators (i.e., healthcare entities producing small amounts of medical waste), individual physician offices, or small healthcare practices. Having this method available is very helpful if a healthcare facility lacks the capacity for autoclaving or incineration.

- Within the last ten years, there's been a great deal of interest on the part of manufacturers, inventors, and entrepreneurs to develop "alternative treatment technologies." Basically, these are physical and/or chemical technologies which are designed specifically for medical waste treatment.

- They handle large volumes of waste, and they do so using a wide variety of physical and chemical processes. All of these are affected by the volume of waste, the amount of surface area of the waste, how much organic material is present in the waste. The basic characteristics of the medical waste will affect the "use conditions" (i.e., parameters of treatment) and these must be considered when attempting to determine the best treatment method for the wastes we generate.

- Treatment off-site will necessitate the transport of untreated medical waste across highways, city streets. So, this is one concern that needs to be taken into account when determining what strategy for treatment your facility should be using.

What Happened?!?

- Over the last 10 - 20 years, many hospitals determined that outsourcing medical waste treatment to a third party (consolidating wastes, packaging them, transporting them to a regional treatment center), would save a great deal of money.

- As a result of moving the waste treatment from in-house to off-site, many hospitals decommissioned their decontamination autoclaves (typically located in or near laboratories).

- Another factor that facilitated the removal of the autoclaves from the laboratory was the fact that hospital labs were moving towards prepackaged, pre-sterilized supplies and reagents, and so, there was no longer any benefit, as it were, to prepare reagents and supplies and working devices, sterilize them in-house in a clean autoclave. So, the need for the autoclaves in the labs was greatly reduced.

- The other thing that happened over the last 15 to 20 years, with the Clean Air Act, is that the EPA developed and enforced strict quality standards for emissions from the incinerators at the hospitals. As a result, various hospital incinerators were decommissioned or deactivated. Efforts to retrofit the incinerators to meet the emissions requirements would have been prohibitively costly. So, most of the hospitals decided to shut them down.

Cluster of Mycobacterial Infections Associated with Medical Waste Treatment

- May – September 1997: 3 cases of TB among workers at a regional medical waste treatment facility in Washington state
- Grinding/shedding, “electrothermal deactivation” (radio frequency oven)
- Workers who became infected worked with the waste prior to the electrothermal deactivation step

    - Basically, what happened in 1997 is a small cluster of tuberculosis cases was identified among workers at a regional medical waste treatment facility in Washington State. Now, the method of waste treatment used at this facility was a multi-stage treatment consisting of a grinding and shredding process (effectively increasing the surface area of the waste stream) and then the treatment method, which was electro-thermal or radio frequency process to the deactivation of the waste. The workers who became infected were working with the waste in this assembly line process before the waste got to the deactivation step.

    - It turns out, when investigators did an environmental and occupational investigation of the situation, they found numerous containment inadequacies contributing to poor air quality in the area where this grinding and shredding process took place. They found thhe equipment was missing some safety devices to keep aerosols created during the grinding and shredding contained within the equipment, so there was release of infectious aerosols.

    - The respiratory protection for the workers was deemed inadequate, and there was some worker confusion about some of the safety measures and personal protective equipment. So, there were a number of deficiencies in occupational safety noted for the operation as well.

- Finally, when they did a laboratory analysis of the isolates, the mycobacterial isolate from one of the infected workers was compared that from some of the patients from hospitals that released their untreated waste to this regional processor. Investigators found a match between these isolates by using pulse field gel electrophoresis (PFGE). The banding pattern from one isolate matched that of the patient, even though the waste treatment facility was located miles away from the patient's place of residence. As per that state's regulations, active cultures of bacteria and viruses (in this case *Mycobacterium tuberculosis*) did not have to be decontaminated before this medical waste left the laboratory. So, off-site reprocessing was perfectly legitimate, perfectly acceptable from that state's medical waste rules. This would have been true in a number of states, so it's not unique to Washington State.

Influenza A (H2N2) in 2005

- CDC advises hospitals to destroy virus via autoclaving or incineration
- Many hospitals attempt to use the clean autoclaves in central sterile prep. room
- Labs attempt chemical decontamination
- Incorrect assumptions at work:
  - Pandemic strain must be more difficult to inactivate
  - Any sterilizer is suitable to use

- As early as November 2004, certainly through March 2005, a set of proficiency samples was distributed to hospital laboratories and diagnostic laboratories that perform diagnostic testing of viral cultures, among other things. Part of the proficiency panel required the labs to demonstrate the ability to identify influenza A and B samples correctly. In order to provide a suitable challenge for the laboratories, the group distributing the proficiency samples wanted to diversify the panel material, and so they selected from their archives what they thought was a perfectly innocuous influenza A virus with a subtype not presently circulating.

- Unfortunately the virus selected turned out to be a strain within subtype H2N2, which just so happened to be the pandemic strain from 1957 for the influenza A Asian flu. When the group distributing the panel materials realized what had happened, they immediately advised the hospitals to either send the material back or to destroy that particular virus sample via autoclaving or incineration. Now, the problem with that recommendation, while it's perfectly fine in terms of the appropriateness of either of those methods to inactivate this virus, the vast majority of hospitals no longer had the capacity to do either on-site. Many of the hospitals had decommissioned their autoclaves in their laboratories, and virtually, I would say, 95% of the hospitals, maybe even as high as 98% of the hospitals, no longer had access on-site to incineration.

- So the staff in many of the hospitals decided to take the material to the central sterile preparation department and use their clean autoclaves. It is not considered to be good practice to use clean autoclaves (i.e., autoclaves used to provide terminal sterilization of patient-care instruments, devices, and other materials) for decontamination purposes.

- There was another erroneous assumption at work as well when strategies to manage the situation were discussed. One was the fact that this is a pandemic strain of influenza virus. Therefore, the assumption is the pandemic strain must be more difficult to inactivate, compared to a non-pandemic influenza virus, and that's clearly

not the case. Severity of the resulting infection is independent of the virus' sensitivity to chemical disinfection or inactivation via a physical process. The two viruses, either the pandemic strain or the strains we see currently, really do not differ tremendously in terms of the biophysical and biochemical properties as virus particles. So autoclaving or any of the medical waste treatment methods are appropriate to use for inactivating this agent.

- This episode highlighted a number of things. Certainly one of those is that the hospitals need to look to their state regulatory processes to see what decontamination/medical waste treatment/disposal options are available for a microbiological agent and circumstances that are clearly of great concern (e.g., influenza A (H2N2) virus, pathogens that would be considered as "select agents," transport, and "chain of custody" issues).

Weaknesses in Medical Waste Management Processes

- Labs lack the capacity to do decon on-site
- Lack of awareness of key information:
    - State regulatory process and recommended decon methods
    - Transport and chain of custody issues
    - EPA registered chemicals for medical waste treatment (List G) http://www.epa.gov/oppad001/chemregindex.htm
    - Autoclave operations
    - Infectious waste is not hazardous waste

- The definitions within the medical waste topic are very important to keep in mind, because infectious waste is generally not hazardous waste from the perspective of solid waste regulatory definitions. Landfills for hazardous waste are few and disposal fees are very expensive, whereas treated medical waste can go to any Class II, solid waste landfill (municipal landfill) in your vicinity.

- If chemical treatment for medical waste on-site is an option, one other thing to look is the EPA List G. These are registered chemicals for medical waste treatment, and that certainly would have been an option during the influenza A (H2N2) episode as well.

Disposal of Agents of Bioterrorism

- The influenza episode from this past April also heightens awareness of what to do when a facility is faced with the management and decontamination of a bioterrorism agent. For example, the bacterium that causes anthrax is a select agent. If a healthcare facility lacks the capacity to decontaminate these materials on-site, they need to be aware if their state has unique regulations or guidance for the management of these items as medical waste, as they move down the medical waste stream.

- For example, does each state have a plan to treat and dispose of bioterrorism agents? Does each state have a plan for the management of discarded bioterrorism agents after they are identified in culture? A good resource for information on this issue is the CDC "Laboratory Response Network," or LRN. This group works closely with state health departments and larger hospitals' laboratories to develop a rational response approach in the event of a bioterrorism attack or event.

- Certainly the hospitals need to look to their state regulatory processes to see what options are available for an agent that is clearly of a great concern. With an issue like the influenza A (H2N2) virus, or for items or pathogens that would be considered as select agents, transport and chain of custody issues has to be well thought-out.

Restore the Capacity of In-Laboratory Decontamination of Stocks and Cultures

- AIA construction guideline, 2001 (7.12.G)
- CDC's EIC guideline (Category II), 2003
- CDC's Select Agent Rule, 2003
    - Addressed the issue, simply because there is chain of custody concern, and by virtue of this regulation, people need to know who has what and under what conditions.
- ASM / American Academy of Microbiology endorsement, 2001
    - The American Society for Microbiology through their American Academy of Microbiology had a consensus meeting on a number of issues as they relate to bioterrorism, and they endorse the concept of in-house management of agents for bioterrorism and emerging diseases in a statement that can be picked up from the ASM Web site. It was released in 2001.
- Bioterrorism concerns

Part II: Q & A with speakers

Question:

For those of us who are located in smaller population areas or are responsible for smaller budget hospitals and other healthcare facilities, do you think it's prudent to have a small autoclave that's basically just kept in reserve and not used on a daily basis for that capacity?

Answer:

This situation was one of the questions we had to address when Texas was developing its rules – treatment and disposal strategies for the small volume generator versus the mega-hospitals that generate tons of this material over the course of a year. I think that question is probably best answered by working with your state regulators, because they may have a variety of options built into their rules that would assist the small volume generator. For example, are there options for a partnering with other small practices in your community so that you can consolidate the waste and maximize your cost effectiveness by working with a waste management firm that may offer better rates for larger amounts of waste? That might be one possibility, if this approach is allowable under state rules.

Your state rules will have some discussion about waste treatment methods that can be used for small volumes. These will in all likelihood be chemical immersion techniques. There are also some small autoclaves that might be used for medical waste treatment for smalll practices. But, I think it prudent to consider designating a small autoclave for medical waste treatment and using a second autoclave unit for sterile supply preparation and medical/dental instrument reprocessing. If your practice is inspected or surveyed (e.g., an accrediting or a standards organization) and your office practices are reviewed, the surveyor will probably raise an eyebrow if you do both waste decontamination and the preparation of

sterile supplies in the same unit. So, that's one thing to consider.

If you have questions of how your state might deal with that issue, certainly contacting your colleagues in the hospitals in the area is helpful, as they can give you some insight as to what works in your location.

Question:
One of the things that was mentioned was not using infectious waste and hazardous waste terminology interchangeably. What other recommendations would you have for folks who are providing public information on labs?

Answer:

I think you would benefit your audience and your community greatly if you educate them as to the differences in the definition of the terms. I'm trying to think of the best way to do that, and I'm trying to also think of the evolution of that thinking. Medical waste is very often described as hazardous waste, and I want to say it probably grew out of the use of the biohazard symbol from OSHA, in terms of labeling and color coding waste receptacles and items that have had some contact with blood and body fluids, or other potentially infectious materials. If you are doing a presentation to a group that may not be aware of the differences (e.g., healthcare administrators, and others who are not familiar with solid waste terminology), you could definitely do them a big service by educating them as to the distinctions between the two wastes. I would say your state, bureau, or division of solid waste management would be more than happy to give you their current definitions of hazardous waste and medical waste and provide you with the information tools to carry the message forward.

Alternatively, you could get a sense of that definition from the EPA Web site, looking at their Resource Conservation and Recovery Act (RCRA) page. That would be in the Office of Solid Waste Management within EPA.

Basically, it boils down to this problem – hazardous waste disposal is so much more costly than treated medical waste disposal. When you have treated medical waste, you have made the waste much safer to handle, and therefore, it is suitable to be deposited in a Class II landfill. Hazardous waste does have treatment concerns that are very, very different from medical waste. We're primarily talking about hazardous chemicals. For example, we all grew up with red bags, and in the manufacturing process of a red bag, you will find the chemical cadmium. Cadmium is central to that red color, and cadmium is a hazardous chemical. Over the years, we've moved away from using only red bags and explored using other colors, like orange or even white and brown. But, cadmium is a hazardous chemical, and disposal of cadmium goes to hazardous landfills.

So, that's an attempt at your question, but clearly, if you can educate your audience about the differences between the two categories of solid waste, you will save them a great deal of money.

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