



Lowering standards of clinical waste management: do the hazardous waste regulations conflict with the CDC's universal/standard precautions?

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Summary Clinical waste is a costly and troublesome commodity. Comprising the detritus of medical care, the foremost hazard is the risk of infection from micro-organisms present in these wastes. Infection commonly occurs through penetrating injury, the so-called 'sharps' or 'needlestick' injury, although contamination of non-intact skin or splashes to the eye may transmit infection. Bloodborne viruses (hepatitis B, hepatitis C, human immunodeficiency virus) are the most serious threat, although respiratory, soft tissue and enteric infections are not unknown. The European Hazardous Waste Directive, that harmonizes the categorization and control of wastes, permits downregulation of clinical wastes where the risk of infection may be low. Although strengthened by the requirement for risk assessment in waste classification, UK regulatory guidance promoting classification of some clinical wastes as non-hazardous completely ignores the Centers for Disease Control and Prevention's Universal Precautions for the prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings, which seek to prevent bloodborne virus infection in healthcare workers and others, and the more extensive Standard Precautions that extend these principles to the prevention of healthcare-associated infections and the environmental spread of nosocomial pathogens. By creating a potent cost driver encouraging downregulation of some clinical wastes, UK legislation based on the European Hazardous Waste Directive conflicts with the CDC's Universal/Standard Precautions.

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Introduction

Clinical wastes predominantly comprise wound dressings and swabs together with infusion and irrigation equipment, catheters, blades, syringes and needles. Also included are tissue and post-mortem wastes, waste from clinical laboratories, sanitary wastes including incontinence pads and nappies etc., and waste pharmaceuticals. Most wastes will be disposed to yellow bags or rigid yellow bins, including sharps bins where appropriate, and removed from clinical areas for destruction by high temperature incineration, or made safe using one of a number of alternate treatment technologies including autoclave, microwave or hot oil auger treatments.

Clinical waste may contain a high proportion, between 20% and 40%, of innocuous wastes including packaging materials and domestic-type refuse. It may contain fewer bacteria than household refuse,¹⁻⁴ although it generally contains more human pathogenic species. Despite this, only around 3% of the total volume of clinical waste may be infectious,⁵ although cross-contamination may render the entire load potentially hazardous. The risk of serious or life-threatening infection through exposure to clinical wastes is foremost among several distinct hazards. Other risks include physical injury and adverse local or systemic effects through contact with potentially hazardous pharmaceuticals.⁶

There has been an underlying disparity across Europe in the approach to the management of clinical wastes, both within hospitals⁷ and in the commercial sector. Differences will be harmonized by the European Hazardous Waste Directive 91/689/EC (HWD), which seeks to provide a precise and uniform European-wide definition of hazardous wastes, including clinical wastes, and to ensure its regulation and correct management. The classification of a waste as hazardous has considerable impact in determining how that waste is regulated, and thereby on the care required at all stages from initial disposal to final destruction. A detailed classification of wastes is set out in the European Waste Catalogue 2000/532/EC (EWC), an essential first step in the implementation of the HWD. EWC classification permits downregulation of some clinical wastes. This introduces potential conflict at the interface between healthcare activities and EWC classification. It is appropriate, therefore, to question the impact of the EWC and to examine the likely impact of this upon the safety of healthcare staff and of those in the waste industries involved in the management of clinical wastes.

European Hazardous Waste Directive

The European HWD, and the Hazardous Waste Regulations 2005 (HWR) which will implement this European Directive in the UK from July 2005, have much to commend them. They seek to identify wastes hazardous to health or to the environment, and to ensure that care is taken in their disposal. The EWC is pivotal to this legislation, enabling classification of wastes based upon composition and hazard (Table I). Non-hazardous wastes escape stringent control in disposal that had previously been applied blanket fashion, permitting correspondingly lower disposal costs.

Classifications are clear and largely unambiguous, although application to clinical wastes may be fraught with difficulty as classification is subjective. Befitting such legislation, several caveats and exceptions require full and detailed risk assessment to ensure correct classification. Notwithstanding, the risk of infection will always be troublesome in interpretation. Guidance available from the Environment Agency⁸ includes schemata for the classification of infection risk of wastes. These may be oversimplified. For example, it is proposed that waste from orthopaedic wards should be classified as non-hazardous since those patients 'are unlikely to be suffering any infectious disease'. Although provision is made for wastes from patients known to suffer from, for example, hepatitis B virus, hepatitis C virus or human immunodeficiency virus (HIV) infection, no provision is made for those with undiagnosed or unrecognized infection. Clearly, we do not know with certainty which patients pose a risk of infection. Thus, to propose a scheme for the further segregation of clinical wastes based on assumptions of the risk of infection, while permitting classification of some wastes, including sharps, as non-hazardous, is to negate totally the US Centers for Disease Control and Prevention's (CDC) Universal Precautions for the prevention of transmission of HIV and other bloodborne infections.⁹ With the implementation of the HWD and the HWR, universality in the protection of patients, healthcare workers and others has become conditional. As the legislation rolls out, an increase in the incidence of serious and potentially life-threatening infections associated with exposure to clinical wastes may become apparent if these are classified as non-hazardous and handled with lesser care. This may arise through simple error or omission in the classification of wastes, through misinterpretation of the EWC and the

Table I European Waste Catalogue (2002) categorization of clinical wastes

18	Wastes from human and animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)	
18 01	Wastes from natal care, diagnosis, treatment or prevention of disease in humans	
18 01 01	Sharps (except 18 01 03)	
18 01 02	Body parts and organs including blood bags and blood preserves (except 18 01 03)	
18 01 03*	Wastes whose collection and disposal is subject to special requirements in order to prevent infection	A
18 01 04	Wastes whose collection and disposal is not subject to special requirements in order to prevent infection (e.g. dressings, plaster casts, linen, disposable clothing, nappies)	
18 01 06*	Chemicals consisting of or containing dangerous substances	M
18 01 07	Chemicals other than those mentioned in 18 01 06	
18 01 08*	Cytotoxic and cytostatic medicines	A
18 01 09	Medicines other than those mentioned in 18 01 08	
18 01 10*	Amalgam waste from dental care	A

Any waste whose six-digit code is marked with an asterisk (*) is a hazardous waste. Classification may be absolute (A), defining waste as hazardous regardless of the concentration of any 'dangerous substance' within it, or a 'mirror entry' (M), covering wastes having the potential to be hazardous or non-hazardous depending on their composition and the concentration of 'dangerous substances' within them. The hazard potential is determined by reference to published threshold limits or, for infection hazards, on risk assessment.

inadequacies in official guidance,⁸ or through failure of risk assessment. The potent cost driver created by downregulation in waste classification may exacerbate these difficulties.

Practical issues arise. Hazardous clinical wastes, as listed in the EWC, require additional care and control in disposal, with constraint on their transfer, transport, storage and terminal destruction. The HWR requires complete separation of hazardous wastes from non-hazardous wastes to ensure correct processing and to avoid cross-contamination or inadvertent and inappropriate co-disposal. Problems occur wherever a choice in disposal exists. Although not subject to detailed epidemiological study, several informal studies have concluded that removing choice in disposal, and thereby eliminating as many waste streams as possible from clinical areas, reduces the hazards from fugitive wastes lost within an inappropriate waste stream.¹⁰ To further segregate sharps and other clinical wastes based on a known or presumed risk of infection, for individual patients or for a cohort of patients, will require two waste containers at every location where currently there is only one. Marking of these containers, for hazardous and non-hazardous wastes, must be clear and unambiguous to ensure that they receive only the intended wastes. Subsequent handling of wastes must ensure complete separation of waste streams. Practical time and space constraints that limit the space available in clinical areas for multiple

additional waste containers^{11,12} become critical, making the additional EWC distinctions impractical and prone to error.

Universal/Standard Precautions

Hepatitis B virus, hepatitis C virus and HIV are the principal infection risks for those handling clinical wastes. The risk of transmission of bloodborne viruses is well documented. Although sharps users are at greatest risk of sharps injury, porters and other ancillary workers involved in the early stages of the disposal chain feature as the next most frequent group reporting needlestick injuries.¹³ Under-reporting is widely assumed, and this may be particularly true among waste industry personnel where occupational health services are unlikely to be co-ordinated and accurate statistical data is impossible to obtain.

The CDC's Universal Precautions are intended to prevent parenteral, mucous membrane and non-intact skin exposures to bloodborne pathogens. These have been broadened to encompass a set of more extensive Standard Precautions intended to afford protection against transmission of the full range of pathogens implicated in healthcare-associated infections. These Standard Precautions, which must be adopted during the care of every patient irrespective of disease status,¹⁴ define framework protocols for handwashing, the use of

personal protective equipment, and the care and safe use of clinical equipment, as well as the more specific blood and body fluid precautions.⁹ The CDC's Standard Precautions apply to blood, all body fluids, secretions and excretions except sweat, regardless of whether or not they contain visible blood, non-intact skin and mucous membranes. They are designed to reduce the risk of transmission of micro-organisms from both recognized and unrecognized sources of infection. Logically, therefore, these Standard Precautions would apply, *inter alia*, to the wound dressings, swabs and other items that comprise clinical wastes. Effective containment and safe handling of these wastes is appropriate to protect those required to handle such wastes, and to protect the clinical and wider environment from local or more extensive contamination; the CDC's Standard Precautions mandate the disposal of infectious clinical waste materials in a manner that will ensure the protection of those who may handle them, and prevent injury or spread of infection to the community. The CDC's Standard Precautions are pivotal to the prevention of infection in healthcare and associated support staff, and central to the success of more general infection control strategies for the prevention of hospital-acquired infection. These are fundamental to the training and protection of healthcare staff, and are practiced worldwide. In the UK, the Department of Health fully supports these guidelines.¹⁵ Although not intended to dictate waste management procedures in healthcare establishments or elsewhere, the CDC's Universal/Standard Precautions inevitably impact upon waste management activities as they provide overarching guidance for the prevention of infection. Hepatitis B virus, hepatitis C virus and HIV all survive outside the body for several weeks.^{16,17} Hepatitis B virus has the highest virus density in untreated individuals and remains viable for the longest periods in needles stored at room temperature.¹⁶ Other, predominantly bacterial, pathogens will be encountered within clinical wastes, often in high numbers. As containment of wastes is not absolute, some local environmental contamination, including contamination of individual waste containers, may be anticipated. Although there are few recorded incidences of bacterial infection acquired by personnel involved in the onward disposal of clinical wastes, these are not unknown. As the risk of transmission does not end abruptly with the primary disposal of potentially contaminated wastes to a bag or bin, it is appropriate that all those involved in the subsequent disposal chain adopt the principles of the CDC's Universal/Standard Precautions at all times and that clinical wastes are handled

accordingly. This will, moreover, strengthen and support overall standards of hospital hygiene, and may be an important supplementary factor in preventing the spread of multidrug-resistant and other nosocomial pathogens.

Health and Safety legislation

Conflict between the HWR and UK Health and Safety legislation is of particular concern. Health and Safety legislation has been used to bring successful prosecution of National Health Service (NHS) trusts in breach of Section 3, sub-section 1, of the Health and Safety at Work etc. Act, 1974. This Act places on employers 'a duty to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected are not thereby exposed to risks to their health or safety'. The UK Health and Safety Executive Public Register of Convictions, accessible at <http://www.hse-databases.co.uk/prosecution/>, records several cases involving failure in the safe and proper management of clinical wastes by NHS trusts. Prosecution has followed storage of clinical wastes in areas of hospitals accessible to the public, prompted in one case by adverse reportage in a national daily newspaper. No mitigation was entertained based on the infectious nature of the waste, or lack of it. Thus, under Health and Safety legislation, clinical wastes are deemed to be a potential hazard to health, and producers must exercise an appropriate duty of care to ensure that wastes are properly managed in such a way as to ensure the safety of its employees and others.

It is questionable if this duty of care will be satisfactorily discharged if some wastes are managed to a lesser standard based upon arbitrary and ill-defined EWC categorization that may be fundamentally flawed through our inability to apply meaningful and precise definitions of infection risk. The infection risk, although possibly small, cannot be dismissed, and relevant Health and Safety legislation may apply; additional civil liability may greatly magnify the costs. Overarching Health and Safety legislation may thus be at odds with the UK HWR. Clarity is provided by the CDC's Universal/Standard Precautions. These are at the heart of the protection of patients and healthcare workers from infection with bloodborne viruses and other pathogens, can apply equally to those involved in the subsequent disposal of clinical wastes, and support the classification of all clinical wastes as hazardous in the context of the EWC.

Conclusion

The prevention of infection among healthcare staff and others, particularly infection caused by blood-borne virus agents including hepatitis B, hepatitis C and HIV, has received considerable attention in recent years, and directly influence the approach to waste management in hospitals. Linked with overall standards of hospital hygiene, this is an issue of considerable public and professional concern. It is particularly important, in order to protect against infection, that blood and tissue wastes and other more general components of clinical wastes, such as used swabs and dressings, should be considered, without exception, as potentially hazardous to health and that these are managed accordingly,¹⁸ although with the recent (July 2005) implementation of the HWR, this is not necessarily so. Some have recommended, on ecological and financial criteria, exclusion of items that may carry only a negligible risk of infection and may be categorized as 18 01 04 (Table I).^{5,18} However, economies of scale, simple logistics and the principles of risk management should prevail since dual waste streams are impractical, and where additional choice exists, the frequency of error and thereby the overall risk of adverse events rise proportionately.

A dichotomous waste classification based upon risk, although superficially sound in principle, may be largely unworkable in acute health care. It may worsen the already poor standards of waste management in hospitals through the introduction of additional complexity and promotion of error, creating serious deficiencies in the safe handling and storage of wastes.^{19,20} Critically, it completely undermines the CDC's Universal/Standard Precautions practiced by healthcare workers worldwide, may increase the risk of infection among portering and ancillary staff and workers in the waste disposal industry, and increase the incidence of environmental spread of nosocomial pathogens.

With few exceptions, an all-embracing site-wide policy for the disposal of clinical wastes to a hazardous waste stream completely avoids the possibility of infectious wastes from hospitals being disposed to a lesser waste stream. Choice in disposal is removed, and the possibility of error in classification is eliminated. The architects of the European HWD, and of the enabling UK legislation, may not have foreseen the difficulties that these distinctions in waste classification may force upon hospitals. More seriously, it seems likely that they have failed to consider that by undermining the CDC's Universal/Standard Precautions, there may

be a significant increase in risk to all those involved in the disposal of clinical wastes. This may require that we apply similarly stringent controls in collection and disposal to wastes categorized as non-hazardous in order to comply with the demands of Health and Safety legislation. This is illogical and the EWC categorization of waste 18 01 01 and 18 01 02 (Table I) should be abandoned. This should effectively remove the conflict between the HWD/HWR and the CDC's Universal/Standard Precautions, promote the highest standards of care in the disposal of clinical wastes, and thereby prevent any possible increase in acquired infections from clinical wastes from their point of initial disposal to final destruction.

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