Using reusable containers for hospital waste

Reusable plastic containers are commonly used to transport health care risk waste. Some regulatory authorities require disinfection, microbiological monitoring or process validation to ensure minimisation of a perceived risk of disease transmission from the containers. The study surveyed scientific literature and relevant guidelines, and as no evidence of risk was found, recommends quality assurance resources be commensurate with these findings. Disinfection, microbiological monitoring and microbiological validation are not indicated. Visual criteria for cleanliness together with written protocols will ensure risk-free use of the containers.

Is there a health risk?

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Health care risk waste (HCRW) is being increasingly transported in reusable waste containers (RWCs) to increase safety of handlers and handling by eliminating sharps injuries and spillages. However, there is a perception that RWCs pose a risk of disease or pathogen transmission to handlers, health care workers, patients, or the hospital environment.

The perception has prompted some authorities to require specific levels of disinfection, microbiological monitoring or process validation in an effort to minimise risk. These requirements have become law, either through incorporation of South African standards into the South African Road Traffic Act, or via provincial government regulations.

Currently in South Africa, reusable HCRW containers are required by law to be disinfected prior to reuse. This requirement is through incorporation of two standards, SANS 10229-1:2005 and SANS 10228:2006 under the National Road Traffic Act of 1996.

Also, one South African province requires daily swabs of RWCs prior to start-up, weekly swabs before dispatch and monthly swabs at delivery for the first four months (and thereafter at half that frequency), cultures for bacteria and fungi by an accredited laboratory, and for the results to be reported quarterly to a government department.

This paper, presented at the June 2009 SA Health Care Waste Summit held in Johannesburg, examines international literature and guidelines to determine the risk of using RWCs and what process validation may be necessary.

Risk

Put simply, risk is the product of probability and consequence, i.e. how frequently does an adverse event occur, and how severe is its outcome? In general terms, risk can be classified as occupational, environmental, legal, political, social or economic. Questions stakeholders legitimately ask regarding RWCs are: Will I get infected? Will antibiotic-resistant pathogens be brought into my hospital? Will use of RWCs impact on the environment? Could staff transfer pathogens from RWCs to patients? Is the monitoring a good use of valuable resources? Clearly, in assessing the use of RWCs, all components need to be addressed.

Decontamination 101

Although HCRW is contained in bags within RWCs, there is the potential for RWCs to be contaminated with pathogens. Decontamination processes must ensure any pathogens are removed to a level that eliminates risk of dissemination to hospital environment, staff or patients.

In discussing processes, a clear understanding of terminology surrounding decontamination is necessary. The following definitions are adapted from Block:

- Decontamination renders an item safe for handling and use.

- Sterilisation is the removal of vegetative (non-sporing) organisms and spores.
- Disinfection is the removal of vegetative pathogens.
- Cleaning is the removal of soil, organic matter and debris.

One can see that sterilisation, disinfection and cleaning are all forms of decontamination.

The literature on these terms is related to hospital surfaces or food – processing surfaces. Care must be taken when extrapolating to other surfaces (such as RWCs).

Prior to the 1970s there was constant questioning of which level of decontamination was necessary for a particular medical instrument on a particular patient when it was just used on a another patient. It was a struggle to weigh up all the risk factors – until Spaulding simplified the decision into just three choices:

- If the instrument enters sterile tissue it needs sterilisation.
- If the instrument touches mucous membranes it needs high-level disinfection.
- If the instrument touches only intact skin it needs intermediate or low level disinfection.

But this classification was for medical devices used on patients. What about environmental surfaces such as hospital floors, walls, tables, beds, etc? This was resolved in 1991 when the US Centre for Disease Control and Prevention (CDC) added three more categories – all environmental:

1. surfaces on mobile medical equipment
2. high-touch environmental surfaces (light switches, door handles, etc.)
3. low-touch environmental surfaces (floors, walls, etc.).

Life for clinical staff and infection prevention personnel became markedly simpler from that point onward with the use of the hierarchy in table 1:

Chain of infection

To be certain of their decision, clinical staff address the chain of infection what–steps need to occur before an individual can become infected:

- pathogen must be present
- pathogen must be in sufficient numbers
- pathogen must be virulent (easily cause disease)
- correct transfer from source to host
- correct entry into host
- susceptible host.

Very importantly, all links in the chain have to occur before infection can take place.

Are RWCs a theoretical risk?

To answer this question, we must address the six risk levels in table 1 and ask the six questions (it is not a patient device so we can skip the first three):

- Is it mobile medical equipment touched by staff who then touch patients? No.
- Is it an environmental surface touched frequently? No.
- Is it an environmental surface touched infrequently? Yes.

This then places RWCs in level 6 – lowest risk.

To confirm our risk assessment, we need also ask: Could RWCs ever fulfil all six links in the chain of infection?

- Could a pathogen be present? Potentially yes.

TABLE 1: DECONTAMINATION LEVELS

Risk	Activity	Decontamination protocol
1. Critical	Enter sterile tissue	Sterilisation
2. Semi-critical	Touch mucous membranes	Sterilisation or high level disinfection
3. Non-critical	Touch intact skin	Intermediate to low level disinfection
4. Low	Medical equip. handles, etc	Clean and disinfect
5. Lower	Environ surfaces – high touch	Clean and disinfect
6. Lowest	Environ surfaces – Low touch	Clean

- Could pathogen be in high numbers? No, average bioburden on RWCs is very low.
- Could pathogen be virulent? Potentially yes, but on inanimate surface – unlikely.
- Can pathogen get from RWCs to a patient? Highly unlikely.
- Can pathogen enter host? Highly unlikely.
- Could the host be susceptible? Potentially yes.

The chain of infection assessment confirms RWCs as low risk.

Combining the two assessments, RWCs:

- pose a nil to negligible risk of disease transmission to patients and environments
- require thorough cleaning for safe reuse (not disinfection).

What is the probability of RWCs causing infection?

To answer this question we need place a probability on each of the six chain of infection links, then we need to multiply all of these together to get the resultant probability of infection.

The probabilities might be estimated to be:

- pathogen present = 1 in 100
- pathogen dense = 1 in 1 000
- pathogen virulent = 1 in 1
- means of transfer to host = 1 in 1 000
- correct entry into host = 1 in 1 000
- susceptible host: 1 in 1.

Multiplying each gives overall probability of infection of: 1 in 100 billion.

What does history show?

If we look at epidemiological evidence from the waste industry and international literature:

1. It can be conservatively estimated that in four countries, USA, Australia, New Zealand and Canada, some 800 million RWCs have been processed in the 20 years HCRW has been under scrutiny.
2. If we assume 10 times more for rest of world, then the total number of RWCs processed would be approximately 8 billion.
3. If the number of reports of disease transmission from RWCs be zero, then incidence of reported disease from RWCs would be <1 in 8 billion.

Having addressed the risk level and estimated the theoretical risk probability, and coupled these with reported incidence, we can confidently deduce that the risk of disease transmission

from RWCs is negligible to nil. For comparison, the annual risk of licensed South African drivers dying in a car accident is approximately 1 in 1 000.

Do we need to microbiologically monitor RWCs?

On the evidence above, the answer is no; it would be a non-judicious use of resources.

To put the decision into perspective we need ask: Do we swab patient crockery and cutlery? The knives, forks, cups, etc. that patients put in their mouths are washed in hospital dishwashers with water and detergent, yet these utensils are not swabbed or microbiologically validated. They are inspected for cleanliness and, if soiled, put back in for a second wash or washed by hand.

If we do not microbiologically monitor level 2: semi-critical items that touch mucous membranes, why would we microbiologically monitor RWCs which are at level 6 – the lowest risk? In the USA where RWCs have been used for more than 20 years:

OSHA state:[5] "Disinfection of these containers is not necessary to ensure their safety for their intended use; it may be possible to achieve their proper decontamination by means of a soap and water wash."

Lynne Sehulster, author of CDC Guidelines states (personal communication): "There is no epidemiological or anecdotal evidence to support decontamination strategies over and beyond simple cleaning. The notion of a microbiological challenge test to confirm decontamination is a scientifically unjustified practice, given that a waste container is, in my assessment, a piece of equipment best described as an environmental surface."

And ASTM Standard 2314 on instrument cleaning states:[6] "Cleaning processes alone can produce up to a 4 log reduction in bioburden."

The evidence from risk assessments and relevant guidelines confirm disinfection, microbiological monitoring and microbiological validation are not indicated for RWCs processing. Thorough cleaning with water and detergent, using visual criteria and written procedures will ensure risk-free use of RWCs.

It is advisable to conduct due diligence to ensure a contractor is elected whose written and observed quality assurance procedures meet the criteria for RWCs cleanliness.

Conclusions

- Scientific risk assessment shows no disease-associated risk with RWCs.
- Clean RWCs thoroughly and use visual and written criteria. Disinfection, microbiologically monitoring, and microbiological validation are not indicated.
- Due diligence, including factory visits, is advised to ensure a contractor is elected whose written and observed QA procedures meet the criteria for RWCs cleanliness.

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Terry Grimmond biography

Terry is a fellow of the Australian Society for Microbiology and a consultant to The Daniels Corporation. He has 40 years' experience in the fields of epidemiology, infection control and medical education and is an international speaker on sharps injury prevention and health care risk waste.

He serves on sharps container standards in five countries, including South Africa, and recently established a foundation to raise funds to reduce South African HCW exposure to bloodborne pathogens. 3S