OHRDP

ontario harm reduction distribution program

Policy Brief #2: Sterile Water Products

(Revised and updated from Policy Brief of November 16, 2006)

POLICY ISSUE

Ontario Needle Exchange Best Practice Recommendations advise the distribution of single-use 2ml sterile water ampoules to prevent the transmission of HIV and HCV and other blood borne pathogens and to prevent the acquisition of bacterial infections from the use of non-sterile water among injection drug users (IDUs). The current debate centers around delineating the harm/risks of using single-use (1.4 – 3 ml) sterile water for inhalation, for injection purposes, compared to sterile water for injection currently available only in 10ml ampoules.

RECOMMENDATION

Ontario Harm Reduction Distribution Program strongly recommends that Needle Exchange Programs (NEPs) make sterile water for inhalation in 3 ml ampoules available to their clients based on the following considerations.

BACKGROUND

- Ontario Needle Exchange Programs: Best Practice Recommendations document was published in March 2006 offering best practice standards for Needle Exchange Programs.
- The Ontario Harm Reduction Distribution Program provides harm reduction materials, as well as knowledge and support, to Ontario's needle exchange and harm reduction programs. The OHRDP is funded by the Hepatitis C Secretariat, Ministry of Health and Long-term Care. The OHRDP is located in Kingston and is managed through the Street Health Centre, a part of Kingston Community Health Centres.
- OHRDP has researched various suppliers (e.g. Bayer, Baxter Healthcare, Astrazeneca and Draxus Pharma) in Canada and there are none distributing water for injection in ampoules less than 10ml at this time.
- OHRDP began distributing 10 ml ampoules of sterile water for injection in early summer 2006.

- OHRDP is negotiating with a Quebec based company to develop and distribute 1.4 ml ampoules of sterile water for injection – the earliest this might be available is June 2007.

CONSIDERATIONS

- Sterile water for injection is currently only available in 10ml ampoules in Canada.
- Pharmacologist out of Queen's University has indicated that in his opinion sharing the 10ml ampoule of sterile water for injection creates a greater risk than using the 3ml ampoules of sterile water for inhalation (for injection use)
- Further research indicates that tap water is 40 to 1000 times the level of endotoxins than sterile water for inhalation has. (Centre for Water and the Environment, Queen's University, Kingston, On, Canada)

	Sterile water for injection USP	**Sterile water for inhalation USP**	**Municipal "Tap" Water**
USP assigned bacterial endotoxin limit	0.25 EU/ml	0.50 EU/ml	Research has shown for municipal supplies levels of 20 to 500 EU/ml

- Sterile water for inhalation is being distributed for the purpose of harm reduction for persons injecting drugs across North America including British Columbia, Nova Scotia, Quebec, Saskatchewan, Alberta, and throughout the United States (as distributed by, for example, Safety Works out of New York).
- British Columbia has been distributing sterile water for inhalation (for the purposes of injection) for three years. " (Telephone discussion with J. Seto, Pharmacist, BC CDC, November 25, 2006)
- A literature search revealed no indication of harm to people when injecting with sterile water for inhalation however, the same search was unable to document support of injection with sterile water for inhalation.
- If Ontario was to use sterile water at the same rate as B.C., Ontario would distribute 8,725,000 ampoules (3 ml) of sterile water for inhalation

	Volume of Water	Units of Water / year	General Population	Ratio Water/population
British Columbia	3 ml	3,000,000	4,300,000	.698
Ontario	10 ml	800,000	12,500,000	.064
Estimate: If Ontario follows BC	3 ml	8,725,000	12,500,000	.698

- 21 Needle Exchange Programs and associated satellites recently responded to a survey on the use of 10ml ampoules of sterile water for injection. The results reveal that:
  - 73.3% report using the 10ml. sterile water ampoule more than once themselves
  - Almost 54% report sharing the 10ml. ampoule with others
  - 57% report damaged needles using the 10ml. ampoules
- Front line workers report that the current 10 ml sterile water for injection ampoules being distributed through OHRDP dull and bend the needle when drawing water up into the syringe because the rubber stopper on the ampoule is non-pliable; increasing the risk of vein damage and bacterial infection.
- Several studies demonstrate the prevalence of transmission of blood borne pathogens through the sharing of other injection equipment (e.g. sterile water, tourniquets, cookers). (Hagan, Thiede and Des Jarlais 2005)
- Sterile water for inhalation packaging indicates “not for injection” and is being distributed ‘off label’.
- Sterile water for inhalation is approximately 15% the cost of 10 ml ampoules of sterile water for injection ($0.14 compared to $0.95 per ampoule).
- OHRDP continues to attempt to access, for distribution to NEPs, sterile water for injection in single-use ampoules.

ANALYSIS

- Best Practice Recommendations indicate that while there have been no investigations of the role that ampoule size may have in sharing water, frontline workers report, both through the survey results and anecdotally, that clients are sharing 10 ml ampoules and therefore dramatically increasing the risk of transmitting HCV, HIV and other blood borne pathogens.
- Because survey results indicate that clients are sharing the 10ml ampoules of sterile water for injection, smaller ampoules are recommended.
- Sterile water for inhalation is being widely distributed across Canada and the United States. A telephone poll and literature review show no indication of harm to people injecting drugs through its use. (National Survey of Sterile Water Use – OHRDP, October 2006)
- Best Practice Recommendations do not indicate that the grade of sterile water distributed must be for injection use.
- Sterile water for injection is intended for intravenous administration after addition of a suitable solute in an institutional environment where hygienic sterile conditions can be monitored and kept constant. The environment where drugs are being injected is rarely constant or sterile. The risks introduced through the user's environment can significantly outweigh the incremental risks associated with the switch from the 10 ml sterile water for injection to the 3 ml sterile water for inhalation USP “off label”. In addition, the 3 ml sterile water for inhalation USP vial provides a potential risk reduction in that the possibility of sharing and reuse of the water is reduced considerably. It is therefore quite possible that the cumulative user risk associated with the

distribution of 3 ml sterile water for inhalation USP is less than that associated with the distribution of 10 ml sterile water for injection, given the environment in which the water is used.

- Even small amounts of blood in rinse water can be enough to infect another user with HCV.

CONCLUSION

NEPS should make 3ml ampoules of sterile water for inhalation, for injection use, available to their clients and provide the clients with the above noted information to ensure clients are well educated as to the risks of transmitting HCV, HIV and other blood borne pathogens through the sharing of 10ml ampoules of sterile water for injection.

SOURCES

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2. Hagan, Holly, Hanne Thiede and Don C. Des Jarlais. HIV/hepatitis C virus co-infection in drug users: risk behavior and prevention. AIDS 2005 19 (suppl 3) S199-S207.
3. Ontario Needle Exchange Programs: Best Practice Recommendations. March 2006
4. National Survey of Sterile Water Use – October 2006. Ontario Harm Reduction Distribution Program
5. US FDA Office of Regulatory Affairs: www.fda.gov
6. Anderson, William B>, Robin M. Slawson and Colin I. Mayfield. A review or drinking-water-associated endotoxins, including potential routes of human exposure. Canadian Journal of Microbiology, 48: 567-587. 2002.