TITLE: Denatonium for N95 Respirator Fit Testing: Safety

DATE: 17 February 2011

RESEARCH QUESTION

What is the clinical evidence regarding the safety of denatonium when used as an aerosol to test the fit of N95 respirators?

KEY MESSAGE

Limited evidence is available regarding the safety of denatonium when used as an aerosol to test the fit of N95 respirators.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2011, Issue 2), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. The search was limited to English language documents. No date limits were used and no filters were applied to limit retrieval by publication type. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, and non-randomized studies.
One non-randomized study was identified pertaining to the safety of denatonium when used as an aerosol to test the fit of N95 respirators. No health technology assessments, systematic reviews, meta-analyses, or randomized controlled trials were identified. Additional information which may be of interest can be found in the appendix.

OVERALL SUMMARY OF FINDINGS

Limited evidence was identified regarding the safety of denatonium when used as an aerosol to test the fit of N95 respirators. The identified non-randomized study\(^1\) retrospectively examined eight workers' compensation claims associated with denatonium benzoate fit testing. Most of these claims involved respiratory or dermatological symptoms. The authors concluded that there may be “potentially significant health risks associated with denatonium benzoate-based fit testing at least for a small group of susceptible individuals.” More general material safety information is included in the appendix.
REFERENCES SUMMARIZED

Health technology assessments
No literature identified.

Systematic reviews and meta-analyses
No literature identified.

Randomized controlled trials
No literature identified.

Non-randomized studies


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APPENDIX – FURTHER INFORMATION:

Material Safety Information

   Note: See Material Safety Data Sheet Bitrex Solutions, page 37-40.


Fit Testing Procedures Documents

   Note: See Section 4: Bitrex™ (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol