TITLE: Single-Use Medical Devices Reprocessed by Third Party/Licenced Reprocessors: Patient Benefits and Harms, Cost-Effectiveness, and Guidelines

DATE: 06 February 2014

RESEARCH QUESTIONS

1. What are the patient benefits and harms regarding the use of single use medical devices reprocessed by third party or licenced reprocessors?

2. What is the cost-effectiveness associated with the use of single use medical devices reprocessed by third party or licenced reprocessors?

3. What are the guidelines associated with the use of single use medical devices reprocessed by third party or licenced reprocessors?

KEY MESSAGE

One health technology assessment and one systematic review were identified regarding the use of single use medical devices reprocessed by third party or licenced reprocessors.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 1), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic studies, and guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2004 and January 24, 2014 (with the exception of the focused Internet search- 2009 to January 24, 2014). 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, non-randomized studies, economic evaluations, and evidence-based guidelines.

One health technology assessment and one systematic review were identified regarding the use of single use medical devices reprocessed by third party or licenced reprocessors. No randomized controlled trials, non-randomized studies, economic evaluations, or evidence-based guidelines were identified. Additional references of potential interest are provided in the appendix.

OVERALL SUMMARY OF FINDINGS

One health technology assessment (HTA)\(^1\) commissioned in Quebec, and one systematic review\(^2\) were identified regarding the use of single use medical devices (SUDs) reprocessed by third party or licenced reprocessors; however, the abstract of the systematic review did not provide any in-depth information or guidance on the use of third party reprocessors. The HTA concluded that two options were available for the reuse of critical and semi-critical SUDs: following the highest recognized standards of quality whilst continuing in-house reprocessing, or subcontracting reprocessing to a third party certified by a regulatory authority in order to supply a final product that has met all standards and requirements applicable to all SUD manufacturers.\(^1\) The requirements of health-care institutions that decide to use third party reprocessors included the following:

- formal approval of the board of directors,
- good management principles must be followed and must demonstrate significant cost savings, and
- the highest quality of standards (defined by the United States’ Food and Drug Administration regulatory framework) must be met and contractual conditions and terms must comply with Canada and Quebec’s regulations.\(^1\)

Subsequent recommendations in the HTA indicated that the desired approach to reprocessing critical and semi-critical SUDs would be to subcontract reprocessing to a third party that has met the aforementioned criteria.\(^1\)
REFERENCES SUMMARIZED

Health Technology Assessments


Systematic Reviews and Meta-analyses


Randomized Controlled Trials
No literature identified.

Non-Randomized Studies
No literature identified.

Economic Evaluations
No literature identified.

Guidelines and Recommendations
No literature identified.

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APPENDIX – FURTHER INFORMATION:

Clinical Practice Guidelines – Methodologies Uncertain


Additional References


High-profile hepatitis C outbreaks in 2008 spurred the Centers for Disease Control and Prevention’s attention toward legislative and regulatory action in several states around the practice of reuse of single-use devices. Promulgated in the interest of public safety, some of these new regulations and laws can have a potential impact on hospitals' ability to access third-party reprocessing duly regulated by the Food and Drug Administration.


Economic Articles


Healthcare expenditures in the US are approaching 2 trillion dollars, and hospitals and other healthcare providers are under tremendous pressure to rein in costs. One cost-saving approach which is gaining popularity is the reuse of medical devices which were designed only for a single use. Device makers decry this practice as unsanitary and unsafe, but a growing number of third-party firms are willing to sterilize, refurbish, and/or remanufacture devices and resell them to hospitals at a fraction of the original price. Is this practice safe? Is reliance on single-use devices sustainable? A Markov decision process (MDP) model is formulated to study the trade-offs involved in these decisions. Several key parameters are examined: device costs, device failure probabilities, and failure penalty cost. For each of these parameters, expressions are developed which identify the indifference point between using new and reprocessed devices. The results can be used to inform the debate on the economic, ethical, legal, and environmental dimensions of this complex issue.