Reprocessing of single-use medical devices: clinical, economic, and health services impact

CRD summary
This well-conducted review concluded that there was insufficient evidence to establish the safety and efficacy of single-use medical device (SUD) re-use. This conclusion accurately reflected the limited evidence of variable quality that was available and is likely to be reliable.

Authors' objectives
To assess the safety, efficacy, cost-effectiveness and impact on health services of re-use of single use medical devices in Canada.

Searching
BIOSIS Previews, CINAHL, EMBASE, HEED, The Cochrane Library and MEDLINE and related databases were searched without language restrictions from 1966 to July 2007 (details in an online appendix). Search terms were reported. The websites of a large number of institutions and agencies were searched. Bibliographies and abstracts of key papers were checked, conference proceedings were searched and experts and relevant agencies contacted.

Study selection
Studies with a sample size of at least 20 that assessed the use of reprocessed single use devices were eligible for inclusion if they reported the following outcomes: infection of patients; other identifiable adverse events; mortality; device damage or failure; and evidence of device contamination. The acceptable comparator for controlled studies was one-time use of single use devices. Included studies assessed coronary angioplasty catheters, laparoscopic surgery devices, sphincterotomes, external fixation devices for fracture management and phacoemulsification tips.

Two reviewers independently selected the studies for inclusion in the review. Disagreements were resolved through consensus.

Assessment of study quality
The quality of clinical studies was assessed using a previously published approach that awarded up to 5 points for study design and up to 10 points for performance. This examined five broad criteria, which included randomisation, baseline comparability, treatment of withdrawals and dropouts, description of interventions and appropriate statistical analysis. Two reviewers independently assessed studies and resolved disagreements through consensus. Studies were assigned to one of five categories from poor quality to high quality based on the quality scores. Sources of funding were also recorded.

Data extraction
Two reviewers independently performed the data extraction using an a priori designed form. Disagreements were resolved through consensus. Outcomes associated with adverse patient effects and device malfunction were extracted.

Methods of synthesis
The studies were combined in a narrative synthesis grouped by the device assessed. Further differences between the studies were discussed.

Results of the review
Twelve studies of five types of device were included in the review (n=4,348). Sample sizes ranged from 15 to 874. Three studies were randomised controlled trials (RCTs), two were controlled clinical trials (CCTs), three were retrospective comparisons and four were case series. Study quality was mixed: two large RCTs considered high quality, four studies of fair quality and the rest were poor quality.

Coronary angioplasty catheters (five studies, one RCT): The single high-quality RCT (n=377) found no statistically
significant differences between the re-use and single-use groups. The other studies had similar findings of no significant differences between groups and no evidence of harm attributable to re-use of single use devices.

Laparoscopic surgery (three studies, two RCTs): One high-quality RCT (n=125) and one poor to fair quality RCT (n=45) found no significant differences in infection rates between re-use and single-use groups. No evidence of harm attributable to re-use of single use devices and a low infection rate were found by an uncontrolled study.

Sphincteromes (two studies): Two poor-quality uncontrolled studies documented a number of complications, but it was unclear whether these were related to device re-use.

External fixation devices (one study): A fair-quality before-and-after study examined the impact of establishment of a re-use programme and found no significant difference between the patients treated with re-used devices and those treated with single-use devices in pin-tract infection or re-operation rate.

Phacoemulsification tips (one study): One poor-quality uncontrolled study found no intra-operative problems or complications in procedures where single use device re-use was applied.

Cost information
Economic analysis found that eliminating re-use of single use devices would add $17,500 Canadian to the cost of laparoscopic cholecystectomy and $9,200 Canadian to the cost of coronary angioplasty, based on Alberta as the site of analysis. These figures represent less than 0.1% of the total cost of the procedures. The use of several types of reprocessed single use devices saved costs if no adverse effects were assumed. There were insufficient data to establish the cost effectiveness of single use device re-use.

Authors' conclusions
There was insufficient evidence to establish the safety and efficacy of single use device re-use. Those who fund and use reprocessed single use devices needed to consider several legal, ethical and psychosocial issues.

CRD commentary
The review question and inclusion criteria were clear if wide ranging. The authors searched a number of relevant databases and other sources and made attempts to reduce language and publication biases. Rigorous methodology was used at all stages of the review process. An appropriate validity assessment was carried out and was used to inform the synthesis. The decision to adopt a narrative synthesis appeared correct in view of the wide variation in study design. The authors' conclusions reflect the results of the review and are likely to be reliable.

Implications of the review for practice and research
Practice: The authors stated that those who fund and use reprocessed single use devices needed to consider several legal, ethical and psychosocial issues.

Research: Larger studies and systematic monitoring of single use device re-use and associated outcomes would be required to formulate confident conclusions as to the safety, efficacy and effectiveness of the process. Further data would be required for full economic studies.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.