Endoscope disinfection by ortho-phthalaldehyde in a clinical setting: an evaluation of reprocessing time and costs compared with glutaraldehyde

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Disinfection of endoscopes using ortho-phthalaldehyde (CIDEX OPA solution 0.55% w/v; Advanced Sterilization Products) was compared with glutaraldehyde.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised endoscopes used in a busy endoscopy unit, which were cleaned between use according to the guidelines of the Society of Gastroenterology Nurses and Associates (SGNA) and using automatic endoscopic reprocessing systems.

Setting
The setting was secondary care. The economic study was carried out in the endoscopy unit of Massachusetts General Hospital, USA.

Dates to which data relate
The years during which the data were collected for the effectiveness analysis, resource use and prices were not stated.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The cost data were obtained from the same setting as the effectiveness study. It was unclear whether the costing was undertaken retrospectively or prospectively.

Study sample
The author did not report any power calculations. The study was conducted over three trial periods (two 14-day periods and one 10-day period) during which all endoscopes were cleaned in a reprocessor containing the OPA solution. During the study, 1,839 endoscopes were processed in 1,201 cycles.
Study design
This was a prospective comparative study with historical controls, which was carried out in a single centre.

Analysis of effectiveness
The analysis of effectiveness was based on the time saved to disinfect the endoscopes using 12-minute cycles with OPA, compared with 20-minute cycles with glutaraldehyde. The biocidal efficacy of the disinfectant solution was measured before every processing cycle using test strips (CIDEX OPA Test Strips) to ensure the solution was maintained above the minimum effective concentration of 0.3%. Samples of the solution were sent for analysis to determine the exact concentration of OPA at the end of its 14-day reuse period. It was not apparent whether the three trial periods reflected normal volumes of endoscope usage, and consequent disinfection requirements, as the study did not record comparable baseline periods when a glutaraldehyde solution was used. The glutaraldehyde disinfectant time was calculated, on the basis of SGNA guidelines, for the resource use observed in the study.

Effectiveness results
The time savings in the three periods were 3,392 minutes (56 hours), 2,984 minutes (50 hours) and 3,232 minutes (54 hours).

The biocidal efficacy of the OPA solution was maintained throughout the 14-day maximum reuse period, during which time an average of 80 cycles were performed in each processor. This compares favourably with glutaraldehyde solution, which only remains effective for an average of 40 cycles.

Clinical conclusions
The author concluded that processing endoscopes using OPA instead of glutaraldehyde saved at least 50 hours of disinfectant time in each study period. The OPA solution remained efficacious throughout the 14-day maximum reuse period, despite heavy use.

Measure of benefits used in the economic analysis
The author did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed.

Direct costs
The direct costs incurred by the hospital were included in the analysis. These were for the disinfecting solution, test strips and the technician's labour. The resource use data were collected during the study, and the reduction in labour was extrapolated from the time saved in the cleaning process. The retail cost of the materials was used in the analysis. The labour costs were derived using the hourly wage rate for a technician, which was presumably obtained from the study hospital. The costs and resource use were reported separately. Discounting was not conducted, but this was appropriate because of the short time during which the study was conducted. The price year was not reported. The total costs were reported.

Statistical analysis of costs
The resource use and cost data were treated deterministically.

Indirect Costs
The author did not give a rationale for including efficiency losses. The study reported the cost incurred when a procedure was delayed because a clean endoscope was not available. Although this was reported as an intangible cost, it would be more correctly defined as an indirect cost. The cost estimate was taken from the room charge component made by the hospital for a similar procedure. The price year was not stated. The average number of procedures delayed each day and the average length of delay were reported. Discounting was not relevant.
Currency
US dollars ($).

Sensitivity analysis
A sensitivity analysis was not undertaken.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total cost of filling the five reprocessors with OPA solution was $930.90 per 14-day period, compared with $396.00 for glutaraldehyde.

The cost of test strips was $74.90 when using OPA solution and $74.32 when using glutaraldehyde.

For the same 2-week period, using OPA solution resulted in savings in technician's wages of $601.55.

The average daily cost of delayed procedures was $820.20.

The use of OPA solution instead of glutaraldehyde resulted in annual savings of $1,536.60.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
Using ortho-phthalaldehyde (OPA) solution cost-effectively increased the availability of endoscopes while maintaining biocidal efficacy. The cost of using OPA was more than twice the cost of using glutaraldehyde, but the author stated that this higher cost was offset by the savings in time and the greater number of cycles for which OPA remained efficacious.

CRD COMMENTARY - Selection of comparators
Although no explicit justification was provided for using glutaraldehyde as the comparator, it did represent current practice in the author's setting. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a prospective comparative study design with historical controls. This is associated with some limitations, given the study question, because it was not apparent whether the study period reflected normal volumes of endoscope usage. The design of the study represents a limitation to its internal validity. The effectiveness of OPA will have been overestimated if the study periods were busier than the normal workload, as the number of hours saved is dependent on the volume of usage. No statistical analysis was undertaken and no power calculations were reported.

Validity of estimate of measure of benefit
The author did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed.

Validity of estimate of costs
The analysis of costs was performed from the perspective of a hospital. Given this perspective, it appears that all the
relevant categories of costs have been included in the analysis. The costs and the quantities were reported separately, thus enhancing the reproducibility of the study in other settings. Since no statistical analysis of the quantities was performed, the reliability of the conclusions is uncertain. The author did not clearly identify the source of the cost data, but it was implicit that it represented costs in the author's setting. The author did not report any measures of variance or the results of any statistical analysis, and this introduces possible uncertainty into the results. The author concluded that increased efficiency due to time savings would offset the higher materials cost of OPA. However, this relies on the capacity to realise these efficiency savings in the practice setting. The savings due to the greater number of cycles for which OPA remained efficacious, compared with glutaraldehyde, is dependent on high volume use. Discounting was not applied, which was appropriate given the short timeframe of the study. Costs, rather than charges, were reported. The price year was not reported.

**Other issues**
The author made appropriate comparisons of her findings with those from other studies. The issue of the generalisability of the results to other settings was briefly discussed. The author does not appear to have presented her results selectively and did not report any limitations to her study. The author acknowledged the support of the manufacturer, Advanced Sterilization Products, in designing and funding the study.

**Implications of the study**
The author reported that there were benefits in using OPA rather than glutaraldehyde. However, it would appear that these are dependent on the volume of usage and the ability to realise efficiency savings, and these factors were not explored in the study.

**Source of funding**
None stated.

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