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## Major Article

## An economic analysis of the benefits of sterilizing medical instruments in low-temperature systems instead of steam

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## Key Words:

Low-temperature sterilization  
Steam sterilization  
Economic analysis  
Endoscopes

**Background:** Hydrogen peroxide-based, low-temperature sterilization has been shown to do less damage to medical instruments than steam autoclaves. However, low-temperature systems are more expensive to run. Higher costs need to be balanced against savings from reduced repair costs to determine value for money when choosing how to sterilize certain instruments, which are able to be reprocessed in either system.

**Methods:** This analysis examines the economic effects of using low-temperature sterilization systems to reprocess rigid and semi-rigid endoscopes, which are sensitive to heat and moisture, but still able to be sterilized using steam. It examines the changes to costs and frequency of repairs expected over 10 years, resulting from a choice to sterilize these instruments in a low-temperature system instead of steam.

**Results:** Overall, the results showed that increased sterilization costs are outweighed by the savings associated with less frequent repairs. Over a 10-year period, in large health care facilities, the probability of achieving an internal rate of return of at least 6% is 0.81.

**Conclusions:** Our model shows it is likely to be a good decision for large health care facilities to invest in low-temperature sterilization systems.

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## BACKGROUND

With increasing attention focused on the risks of transferring infection between patients when reusing medical instruments, there has been a move toward sterilization, rather than only high-level disinfection, of instruments such as endoscopes. Under the Spaulding classification system, endoscopes are semi-critical, coming into contact with mucus membranes or nonintact skin, but not sterile tissue; as such, they only need to be subjected to high-level disinfection.<sup>1</sup> However, guidelines now recommend that such instruments be sterilized where possible.<sup>2</sup> It is important for health care facilities to understand fully the costs and effects associated with different sterilization systems.

This article is an economic evaluation comparing sterilization of heat-sensitive equipment, primarily endoscopes, using a low-temperature hydrogen peroxide gas plasma system instead of steam

autoclaves. Other low-temperature sterilization techniques, such as ethylene oxide, are not considered, and references to low-temperature sterilization mean hydrogen peroxide systems.

## METHODS

## Model overview

The analysis is designed for facilities currently using steam autoclaves only and considering investment in low-temperature sterilization technology to reprocess heat- and moisture-sensitive instruments. Relevant instruments are therefore those which are sensitive to high temperature and moisture but are able to be sterilized either using steam or a low-temperature system, not those which can only be sterilized at low temperature.

The model is designed to show the internal rate of return on investment in low-temperature sterilization equipment. The Sterrad 100NX (Advanced Sterilization Products, Division of Ethicon US, LLC, Irvine, CA) was used as an example of a low-temperature sterilization system. It is valued at approximately \$130,000, with annual maintenance costs of \$19,000. The model captures all uncertainty within the estimate, and a probabilistic sensitivity analysis is presented.

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By definition, sterilization is the elimination of all forms of microbial life, including bacterial spores and viruses<sup>1</sup>; therefore, there will be no difference in infection risk and associated health outcomes between steam or low-temperature systems.

### Model structure

The model structure was developed and parameters defined after a review of the literature and consultation with industry and health care experts. Costs are separated into those related to the sterilization process and those associated with instrument repairs (Fig 1). Sterilization costs include electricity, water, steam, and sterilant, whereas instrument repair costs are a function of the average cost and expected frequency of repairs (Fig 1).

### Assumptions

The model relies on a number of assumptions to reduce unnecessary complexity and uncertainty. Instruments relevant to the model are those suitable for sterilization in both steam and low-temperature systems, but which are sensitive to the high-temperature, high-moisture environment of steam autoclaves. The model assumes that only instruments that are costly to purchase and repair will be moved to low-temperature sterilization; all other instruments will continue to be sterilized using steam.

Because the model examines incremental costs, it excludes costs that are assumed to be the same or approximately equal in both systems. It is assumed that costs associated with preparing instruments for sterilization, including presterilization cleaning processes, instrument wraps and trays, and biologic indicators are approximately equal for both systems. This assumption is based on consultation with industry experts.

Further, the model assumes that health care facilities will bear the costs associated with repairing damaged instruments. Although many instruments come with a warranty, research by Landman et al<sup>3</sup> found that most repairs are not covered by the warranty. On this basis, we felt it was fair to assume that, in general, individual health care facilities would be responsible for repair costs.

A generally accepted discount rate of 3% was used for future costs and savings to account for the time value of money.<sup>4</sup>

### Model parameters

The values used for each of the parameters in the model and sources of information are described in full in Appendix Table A1. Parameters have been estimated from published literature, including publicly available information such as technical data and, where no published data were available, from expert opinion.

### Number of instruments sterilized

The model scenario is a large health care facility with 300 endoscopes used for 85 procedures per week. This corresponds with the research conducted by Skogas and Marvik<sup>5</sup> in a large university hospital in Norway.

### Capacity of sterilizers

Steam sterilizers tend to be much larger than low-temperature systems, and there is a wide variety on the market. For the purposes of this model, a range of leading-brand medium-sized sterilizers, with a standard configuration of 3 shelves, have been used to estimate average capacity. The chamber dimensions and shelf configuration (2 shelves only) of the low-temperature system have been taken from the technical information.<sup>14</sup> Steam sterilizers with a similar capacity to the low-temperature system have not been included in the model because relevant health care facilities tend to have larger steam autoclaves.

### Size of instruments, once packaged for sterilization

Because endoscopic equipment is packaged in trays for sterilization, the dimensions of leading-brand instrument trays were used to calculate a range of sizes of instruments when packaged for sterilization in each system. Such trays come in standard sizes; therefore, regardless of brand, the dimensions used in the model provide a good estimate of the range of sizes of instruments when packaged for sterilization. An allowance of 10 mm either side was made to account for wrapping.

### Sterilization costs per instrument

It was assumed that in most cases sterilizer cycles would be run at or close to maximum capacity. Therefore, the cost of sterilizing one instrument was determined by dividing the cost of one sterilization cycle by the maximum number of trays able to be sterilized

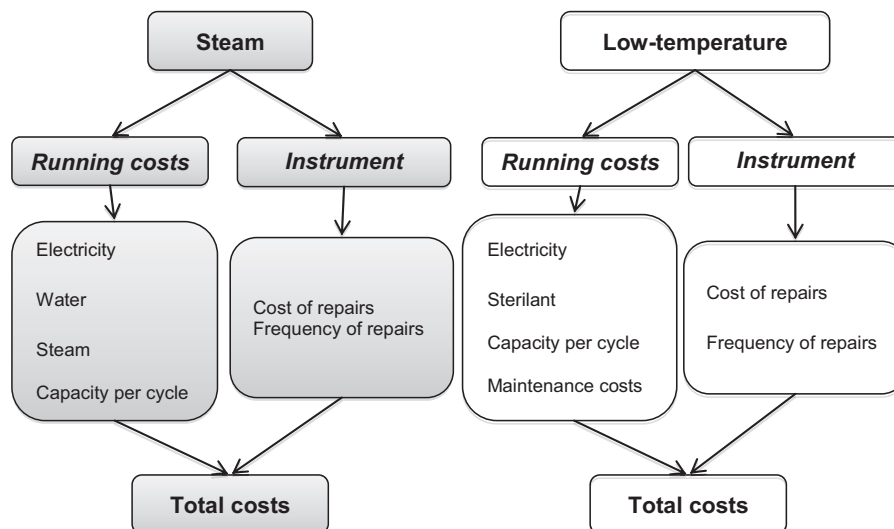


Fig 1. Model structure.

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