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SUMMARY WITH CRITICAL APPRAISAL

Disinfection of Multi-Use Ocular Equipment for Ophthalmological Procedures: A Review of Clinical Effectiveness, Cost-Effectiveness, and Guidelines

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Abbreviations

AORN	Association of perioperative Registered Nurses
EKC	Epidemic keratoconjunctivitis
HIV	Human immunodeficiency virus
ICER	Incremental cost-effectiveness ratio
IFU	Instructions for Use
RCT	Randomized controlled trial

Context and Policy Issues

In ophthalmology, there are certain equipment that are used and reused across different patients within a medical practice that resulting in indirect contact between multiple patients.[1] This could pose a risk of cross infection between patients, especially with viruses and bacteria.[1] One example of such equipment would be the tonometer, a device to measure the intraocular pressure in patients to determine risk of glaucoma.[1] The tonometer tip is in direct contact with the patient's eye and studies have demonstrated the transmission of hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV), and Creutzfeldt-Jakob disease can occur between patients.[1] Therefore, equipment cleanliness is critical.

The Canadian Optometrists Association has a general infection control guideline; however, in general, among available guidelines, there is little consistency and guidance in what the best approach would be to reduce transmission of diseases between patients.[2] *In vitro* studies compared various sterilization techniques to determine whether or not viral particles are removed from the ophthalmic equipment but it is important to evaluate the impact of these cleanliness techniques on clinically relevant outcomes, such as infection transmission.[1] Various guidelines and recommendations exist but it is unclear if there is any association between these techniques and disease transmission between patients.

The objective of this review is to evaluate the comparative clinical and cost-effectiveness of various disinfection techniques and/or procedures for multi-use ocular equipment in ophthalmology patients, as well as the guidelines for its use.

Research Questions

1. What is the comparative clinical effectiveness of various disinfection techniques and procedures for multi-use ocular equipment?
2. What is the comparative cost-effectiveness of various disinfection techniques and procedures for multi-use ocular equipment?
3. What are evidence-based guidelines informing the use of disinfection techniques and procedures for multi-use ocular equipment?

Key Findings

One relevant economic analysis and one evidence-based guideline was identified for this review comparing clinical effectiveness of various disinfection techniques for mutli-use ocular equipment in ophthalmology patients.

The identified cost-effective analysis compared alcohol swabs and peroxide bleach as a disinfection technique of tonometers. Using alcohol swabs as a base case, the cost-

effective analysis demonstrated that the incremental cost-effectiveness ratio for peroxide bleach was $12,152 Canadian dollars per epidemic keratoconjunctivitis averted.

The identified guideline recommends that ophthalmic equipment be cleaned immediately as per the manufacturer's written instruction of use based on strong evidence. Additional recommendations were general and with respect to how the cleaning should be done in an adequate manner, such as, ensuring there is a designated cleaning area, enough personnel to ensure thorough cleaning and sterilization, and maintaining records of all cleaning methods.

Although there is evidence regarding disinfection techniques, the clinical comparative effectiveness remains inconclusive as most of these outcomes are *in vitro*, making it difficult to identify the most clinically, cost-effective, and safe technique for the disinfection of multi-use ocular equipment for ophthalmic use.

Methods

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, 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, 2014 and January 20, 2019.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Q1-Q3: People undergoing any diagnostic or therapeutic procedure with multi-use ocular equipment as part of an ophthalmology exam or treatment
Intervention	Q1-Q3: Disinfection techniques or procedures for ocular equipment
Comparator	Q1 & Q2: Other disinfection techniques or procedures Q3: None
Outcomes	Q1: Clinical effectiveness i.e., benefits (e.g. reduced infection rates), harms/safety (e.g., clinical burns to the eye surface, incorrect diagnoses caused by equipment damaged from disinfection techniques/procedures) Q2: Cost-effectiveness Q3: Evidence-based guidelines
Study Designs	HTA, systematic reviews, meta-analyses, RCTs, non-randomized studies, guidelines

HTA = health technology assessments; RCT = randomized controlled trials

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications or were published prior to 2014. Primary clinical studies were excluded if they were not a randomized controlled trial or systematic review. Primary studies that did not provide specific sterilization procedures were also excluded as were guidelines with unclear methodology.

Critical Appraisal of Individual Studies

The included economic study was assessed using the Drummond checklist,[3] and the guideline was assessed with the AGREE II instrument.[4] Summary scores were not calculated for the included studies; rather, a narrative review of the strengths and limitations of each included study were described.

Summary of Evidence

Quantity of Research Available

A total of 372 citations were identified in the literature search. Following screening of titles and abstracts, 354 citations were excluded and 18 potentially relevant reports from the electronic search were retrieved for full-text review. 14 potentially relevant publications were retrieved from the grey literature search for full text review. Of these potentially relevant articles, 30 publications were excluded for various reasons, and two publications met the inclusion criteria and were included in this report. These comprise one economic evaluation and one evidence-based guideline. Appendix 1 presents the PRISMA[5] flowchart of the study selection.

Additional references of potential interest are provided in Appendix 5.

Summary of Study Characteristics

Details of the individual study characteristics are provided in Appendix 2.

Study Design

The included cost-effective analysis, using a decision tree model, evaluated disinfection techniques for multi-use ocular equipment from a Canadian hospital perspective, with a time horizon of one year.[6] One of the main assumptions was that it used *in vitro* studies to determine the clinical rate of epidemic keratoconjunctivitis (EKC).[6]

The relevant evidence-based guideline was developed by the Association of perioperative Registered Nurses (AORN) through a systematic search of databases for meta-analyses, systematic reviews, randomized controlled trials (RCT), non-randomized trials and studies, case reports, letters, reviews and guidelines from January 2008 to June 2013.[7] AORN had its own evidence appraisal tools and evidence-rating model that was used to evaluate the quality of evidence and the strength of recommendation.[7]

Country of Origin

The investigators of the cost-effective analysis were based in Canada.[6] The identified guideline was developed by AORN, which is an association from the United States and is intended for use in the United States.[7]

Patient Population

The economic evaluation modelled cost-effectiveness in a Canadian hospital setting who were patients that would come into contact with a tonometer.[6]

The guideline developed by AORN is intended for perioperative nurses but may be applicable to any user who is involved in operative or other invasive procedures, and there are specific recommendations for ophthalmic equipment.[7]

Interventions and Comparators

The cost-effective analysis compared alcohol swabs and bleach baths.[6] The guideline from AORN considered cleaning techniques that are recommended by the manufacturer's instructions for use.[7]

Outcomes

For the cost-effective analysis, the outcome studied was the cost of the intervention to avert a case of nosocomial EKC.[6]

The guideline from AORN focuses on the cleanliness of a surgical instrument after cleaning and sterilization.[7]

Summary of Critical Appraisal

Additional details regarding the strengths and limitations of included publications are provided in Appendix 3.

Economic Evaluation

The identified economic evaluation was a cost-effective analysis and it clearly described the research question, the economic importance of the question, perspective, time horizon, and chosen alternatives.[6] The data for effectiveness was stated and was from a systematic review that was conducted prior to the economic evaluation; however, the outcomes for effectiveness were derived from studies with *in vitro* outcomes.[6] The investigators did comment that it was extremely difficult to extrapolate the limited available evidence to a clinical outcome but it is unclear how the *in vitro* studies were synthesized.[6] The source of the cost was clearly stated and were from a Canadian facility; therefore, it would be possible to generalize to the Canadian healthcare setting.[6] However, no information on what year the cost was from and whether or not inflation was adjusted for was provided.[6] The model, a decision tree, details were provided and seem appropriate for the question of interest given the nature of infection transmission and progression.[6] Information on discounting, for cost and benefits, was not provided, though may not be necessary as the time horizon was one year.[6] The results were presented in a clear manner, including incremental analysis complete, along with a conclusion that supports the data and analyses.[6]

Guidelines

The included guideline it was developed by AORN for use by perioperative nurses.[7] This was a general guideline for the cleaning of all surgical instruments and a small section was included for ophthalmic equipment.[7] The scope and purpose were clearly stated in the guideline but it was unclear whether or not stakeholders were involved.[7] The methods for guideline development as provided and AORN used its own evidence appraisal tools and rating model to assess the quality of the evidence.[7] The recommendations, however, were

explicitly indicated although rather general without specific recommendations on cleaning techniques as it was considering a broader scope surgical tools.[7] There was no discussion on the applicability of this guideline in a practice setting and no information on funding was providing.[7]

Summary of Findings

Comparative clinical effectiveness

No relevant evidence regarding the clinical effectiveness of various disinfection techniques and procedures for multi-use ocular equipment in ophthalmology patients was identified; therefore, no summary can be provided.

Cost-effectiveness

One cost-effectiveness analysis was identified comparing Canadian patients from the hospital perspective which compared the cost-effectiveness between the use of alcohol swabs and peroxide bleach for cleaning of tonometry trips.[6] Alcohol swabs are more cost-effective compared to peroxide bleach as the incremental cost-effectiveness ratio was $12,152 for each EKC case averted.[6]

Evidence-based guidelines

Recommendations from the guidelines are summarized below and details are presented in Appendix 4.

The recommendations from the AORN guidelines are general and apply to all multi-use ophthalmic equipment in a surgical setting.[7] The guideline indicates there is strong evidence to support the immediate cleaning of ophthalmic equipment according to the manufacturer's instruction for use.[7] There is moderate evidence to ensure the cleaning process is done in an adequate manner, including allowing enough time and personnel to ensure thorough cleaning and sterilization.[7]

Limitations

Since no systematic reviews or primary studies were identified for this report, it is difficult to conclude the comparative clinical effectiveness for various cleaning and sterilization techniques for multi-use ocular equipment in ophthalmic patients. Of note, there were studies that were identified that included *in vitro* outcomes for various cleaning techniques, these are included in Appendix 5. There remains a research gap in identify the most clinically effective cleaning and sterilizing method for reducing transmission of potential diseases between patients in this setting.

One study examining the cost-effectiveness of various cleaning techniques was included and although it was a based on a Canadian population, the effectiveness outcomes were extrapolated from *in vitro* outcomes.[6] This ultimately reduces the validity of these results as it may over or underestimate the magnitude of effect of the cleaning techniques. Additionally, little detail was provided on the exact cleaning procedures within this study, making it difficult for decision makers to determine what the cost-effective disinfection method may be.[6]

One guideline from the United States was identified and the recommendations are non-specific and do not provide much insight for policy makers as it was intended for a broad setting.[6] Although there are a number of guidelines available in this particular area, many of

them do not document rigorous methods or guideline development; therefore, are not included in this report but are listed in Appendix 5.

There remains a paucity of studies with patient relevant outcomes, ultimately making it difficult to inform clinical decisions.

Conclusions and Implications for Decision or Policy Making

One cost-effectiveness study and one guideline were identified regarding cleaning techniques for the disinfection of multi-use ocular equipment.[6,7]

The identified cost-effective study indicated that the use of alcohol swabs was a more cost-effective technique compared to peroxide bleach as a cleaning method of tonometers for reducing epidemic keratoconjunctivitis in a Canadian population.[6] However, no details on the cleaning procedures were provided.

One guideline recommends the importance of following the manufacturer's instructions for use when cleaning and sterilizing ophthalmic equipment.[7] It also stresses the importance of thorough and adequate cleaning and sterilization by ensuring the required conditions.[7]

No systematic reviews or primary studies were identified to answer the comparative clinical effectiveness between various cleaning techniques. Further research addressing various cleaning and sterilization techniques for multi-use ocular equipment, specifically for clinical outcomes in patients undergoing ophthalmology screening or treatment, would help to reduce uncertainty.

References

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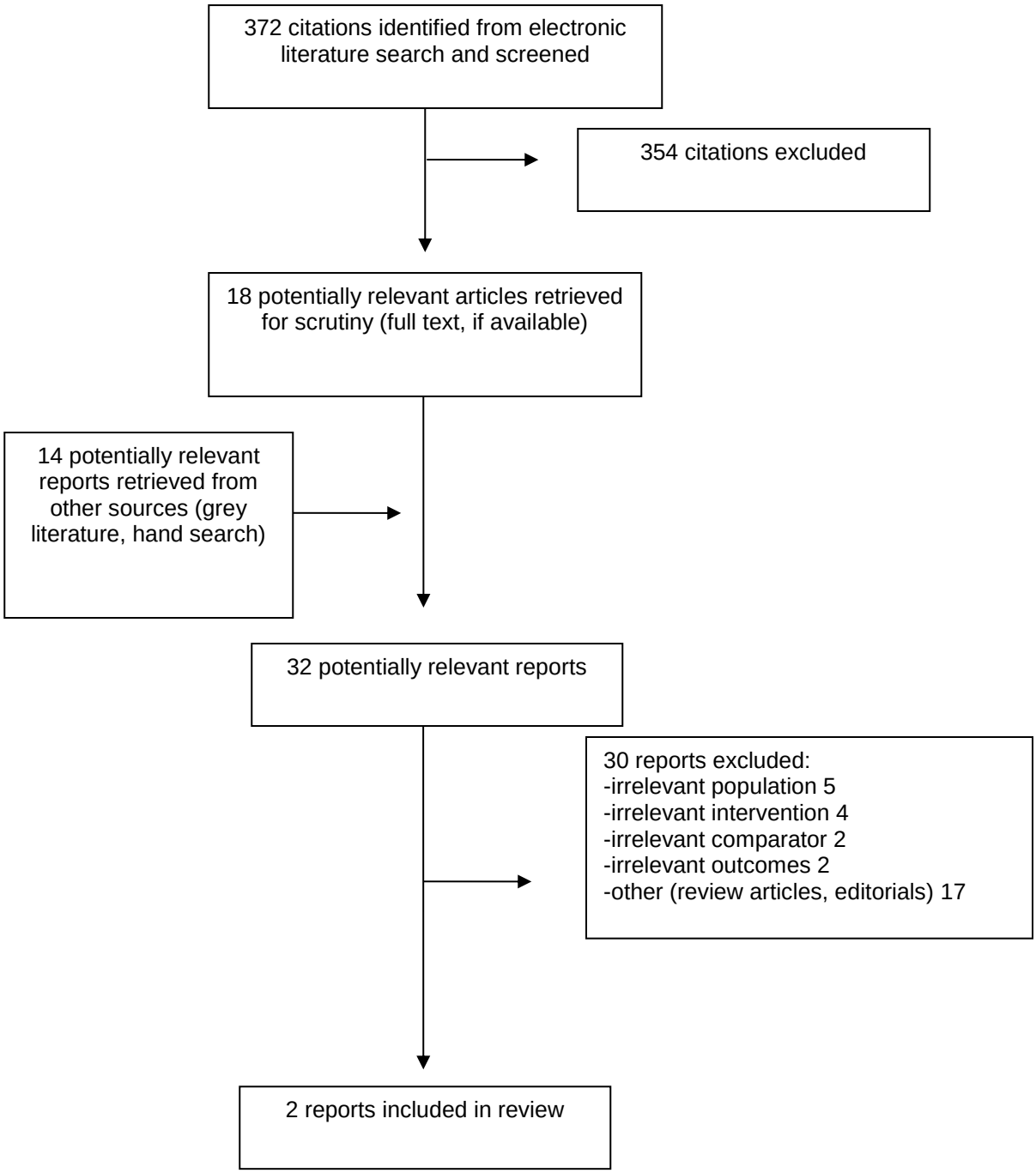
6. Omar Akhtar A, Singh H, Si F, Hodge WG. A systematic review and cost-effectiveness analysis of tonometer disinfection methods. *Can J Ophthalmol.* 2014;49(4):345-350.
7. Guideline for cleaning and care of surgical instruments. Denver (CO): Association of periOperative Registered Nurses (AORN); 2014: http://www.nascecme.com.br/assinante/GUIDELINE_FOR_CLEANING_AND_CARE_OF_SURGICAL_INSTRUMENTS.pdf. Accessed 2019 Jan 31.

Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Economic Evaluations

First Author, Publication Year, Country	Type of Analysis, Time Horizon, Perspective	Decision Problem	Population Characteristics	Intervention and Comparator(s)	Approach	Clinical and Cost Data Used in Analysis	Main Assumptions
Omar Akhtar 2014 Canada[6]	Cost-effectiveness analysis 1 year Hospital perspective	Ability of the interventions to avert cases of nosocomial EKC	Unclear	Alcohol swabs Bleach baths	Decision tree model	Clinical data obtained and modeled using 12 studies found from a systematic review Costs were obtained from a hospital in London, Canada	Clinical rate of EKC is based on studies with *in vitro* outcomes Population is 70,000 Entire pop Constant rate of EKC community cases regardless of disinfection method Rate of EKC nosocomial cases varies between the different disinfection method

EKC = epidemic keratoconjunctivitis

Table 3: Characteristics of Included Guidelines

Intended Users, Target Population	Intervention and Practice Considered	Major Outcomes Considered	Evidence Collection, Selection, and Synthesis	Evidence Quality Assessment	Recommendations Development and Evaluation	Guideline Validation
AORN: Guideline for Cleaning and Care of Surgical Instruments, 2014[7]						
Perioperative nurses where operative and other invasive procedures may be performed	Manufacturer's instructions for use and cleaning procedures	Cleaning of surgical instruments including the processing of ophthalmic instruments and special precautions as necessary to reduce the risk for transmitting prion diseases from contaminated instruments	Systematic search of databases for meta-analyses, systematic reviews, RCTs, non-randomized trials and studies, case reports, letters, reviews, and guidelines in English from January 2008 to June 2013. Additional hand searches were done as necessary	AORN Research or Non-Research Evidence Appraisal Tools	AORN Evidence-Rating Model was used to determine the strength of the recommendation which included the quality of the evidence, consistency of the evidence, and the potential benefits and harms.	Unclear

AORN = Association of periOperative Registered Nurses; RCT = randomized controlled trial

Appendix 3: Critical Appraisal of Included Publications

Table 4: Strengths and Limitations of Guidelines using AGREE II[4]

Item	Guideline
	AORN: Guideline for Cleaning and Care of Surgical Instruments, 2014[7]
Domain 1: Scope and Purpose	
1. The overall objective(s) of the guideline is (are) specifically described.	+
2. The health question(s) covered by the guideline is (are) specifically described.	+
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	+
Domain 2: Stakeholder Involvement	
4. The guideline development group includes individuals from all relevant professional groups.	?
5. The views and preferences of the target population (patients, public, etc.) have been sought.	?
6. The target users of the guideline are clearly defined.	+
Domain 3: Rigour of Development	
7. Systematic methods were used to search for evidence.	+
8. The criteria for selecting the evidence are clearly described.	+
9. The strengths and limitations of the body of evidence are clearly described.	+
10. The methods for formulating the recommendations are clearly described.	+
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	+
12. There is an explicit link between the recommendations and the supporting evidence.	+
13. The guideline has been externally reviewed by experts prior to its publication.	?
14. A procedure for updating the guideline is provided.	+
Domain 4: Clarity of Presentation	
15. The recommendations are specific and unambiguous.	+
16. The different options for management of the condition or health issue are clearly presented.	+
17. Key recommendations are easily identifiable.	+
Domain 5: Applicability	
18. The guideline describes facilitators and barriers to its application.	X
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	+

Table 4: Strengths and Limitations of Guidelines using AGREE II[4]

Item	Guideline
20. The potential resource implications of applying the recommendations have been considered.	X
21. The guideline presents monitoring and/or auditing criteria.	X
Domain 6: Editorial Independence	
22. The views of the funding body have not influenced the content of the guideline.	?
23. Competing interests of guideline development group members have been recorded and addressed.	X

Legend: + = Yes; X = No; ? = Unclear

Table 5: Strengths and Limitations of Economic Studies using the Drummond Checklist[3]

Item	Omar Akhtar et al. 2014[6]
Study Design	
1. The research question is stated.	+
2. The economic importance of the research question is stated.	+
3. The viewpoint(s) of the analysis are clearly stated and justified.	+
4. The rationale for choosing alternative programs or interventions compared is stated.	+
5. The alternatives being compared are clearly described.	+
6. The form of economic evaluation used is stated.	+
7. The choice of form of economic evaluation is justified in relation to the questions addressed	?
Data Collection	
8. The source(s) of effectiveness estimates used are stated.	+
9. Details of the design and results of effectiveness study are given (if based on a single study).	?
10. Details of the methods of synthesis or meta-analysis of estimates are given (if based on a synthesis of a number of effectiveness studies).	?
11. The primary outcome measure(s) for the economic evaluation are clearly stated.	+
12. Methods to value benefits are stated.	+
13. Details of the subjects from whom valuations were obtained were given.	X
14. Productivity changes (if included) are reported separately.	X
15. The relevance of productivity changes to the study question is discussed.	X
16. Quantities of resource use are reported separately from their unit costs.	+
17. Methods for the estimation of quantities and unit costs are described.	+
18. Currency and price data are recorded.	+
19. Details of currency of price adjustments for inflation or currency conversion are given.	X
20. Details of any model used are given.	+
21. The choice of model used and the key parameters on which it is based are justified.	+
Analysis and interpretation of results	
22. Time horizon of costs and benefits is stated.	+
23. The discount rate(s) is stated.	X
24. The choice of discount rate(s) is justified.	X
25. An explanation is given if costs and benefits are not discounted.	X
26. Details of statistical tests and confidence intervals are given for stochastic data.	X

Item	Omar Akhtar et al. 20146
28. The choice of variables for sensitivity analysis is justified.	+
29. The ranges over which the variables are varied and justified.	+
30. Relevant alternatives are compared.	+
31. Incremental analysis is reported.	+
32. Major outcomes are presented in a disaggregated as well as aggregated form.	+
33. The answer to the study question is given.	+
34. Conclusions follow from the data reported.	+
35. Conclusions are accompanied by the appropriate caveats.	+

+ = Yes; X = No; ? = Unclear

Appendix 4: Main Study Findings and Authors' Conclusions

Table 6: Summary of Findings of Included Economic Evaluations

Main Study Findings	Authors' Conclusion
Omar Akhtar, 2014[6]	
- compared to alcohol swabs, the ICER for peroxide bleach was $12,152 per EKC case averted	*"…based on health economic theory, alcohol swabs would still be the most logical method for cleaning tonometer tips…"* p. 349[6]

EKC = epidemic keratoconjunctivitis; ICER = incremental cost-effectiveness ratio

Table 7: Summary of Recommendations in Included Guidelines

Recommendations	Strength of Evidence and Recommendations
AORN: Guideline for Cleaning and Care of Surgical Instruments, 2014[7]	
"*Immediately after use during the procedure, ophthalmic instruments should be wiped clean with sterile water and a lint-free sponge and flushed or immersed in sterile water according to the manufacturer's written IFU*." p.831[7]	1: strong evidence
"The instrument manufacturer's written instructions for cleaning should be reviewed and followed." p.831[7]	2: moderate evidence
"Adequate time, an adequate number of personnel, and sufficient instrument inventory should be provided to permit thorough instrument cleaning and sterilization." p. 831[7]	2: moderate evidence
"Intraocular instruments should be cleaned in a designated cleaning area. Intraocular instruments should be cleaned separately from general surgical instruments." p.831 [7]	2: moderate evidence
"The scrub person should flush the irrigation and aspiration ports of phacoemulsification and irrigation/aspiration hand pieces and accessory reusable tips and tubing with sterile water according to the manufacturer's written IFU before disconnecting the hand piece from the unit." p. 832[7]	2: moderate evidence
"Cleaning products used to clean intraocular instruments should be selected and used in accordance with the instrument manufacturer's written IFU." p. 832[7]	
"After cleaning, ophthalmic instruments should be rinsed with a copious amount of water." p. 832[7]	2: moderate evidence
"A final rinse should be performed with sterile distilled or sterile deionized water." p. 832[7]	2: moderate evidence
"Records should be maintained of all cleaning methods, cleaning solutions, and lot numbers of cleaning solutions used with ophthalmic instruments." p. 833[7]	2: moderate evidence
	2: moderate evidence

IFU = instructions for use; OV = ophthalmic viscoelastic

Appendix 5: Additional References of Potential Interest

Studies with in vitro outcomes

Atkins N, Hodge W, Li B. A Systematic Review Regarding Tonometry and the Transmission of Infectious Diseases. J Clin Med Res. 2018;10(3):159-165.

Ragan A, Cote SL, Huang JT. Disinfection of the Goldman applanation tonometer: a systematic review. Can J Ophthalmol. 2018;53(3):252-259.

Guidelines with Unclear Methodology

Disinfection of Multi-Patient Contact Lenses in the Clinical Setting. 2018. https://www.aoa.org/documents/HPI/HPI_Report_Disinfection%20of%20Multipatient%20CLs%20in%20the%20Clinical%20Setting_2018.pdf

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Decontamination of Medical Devices. 2017. http://www.southernhealth.nhs.uk/_resources/assets/inline/full/0/42856.pdf

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