



Effective Health Care

Steroid Therapies for Sudden Hearing Loss

Results of Topic Selection Process & Next Steps

The nominator, the American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF), is interested in a new evidence review to understand the effectiveness of corticosteroid therapy for sudden hearing loss. Specifically, the nominator is interested in oral, intratympanic, and transtympanic corticosteroids, and hyperbaric oxygen as initial and salvage therapies for sudden hearing loss in adults. The nominator plans to use a new Agency for Healthcare and Research Quality (AHRQ) review to inform their 2017 update to their current clinical practice guideline. However, due to limited program resources, the program will not develop a review at this time. No further activity on this topic will be undertaken by the Effective Health Care (EHC) Program.

Topic Brief

Topic Name: Steroid Therapies for Sudden Hearing Loss

Topic #: 0695

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Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

Summary of Key Findings:

- Appropriateness and importance: The nomination is both appropriate and important.
- Duplication: A new evidence review examining steroid therapy for sudden hearing loss would not be duplicative.
 - For key question 1, we identified existing evidence reviews examining benefits and harms of steroid treatment for idiopathic sudden sensorineural hearing loss. For key question 3, we identified existing evidence reviews examining the effectiveness of corticosteroids for salvage therapy in idiopathic sudden sensorineural hearing loss. For key question 5, we identified one existing evidence review examining the benefits and harms of hyperbaric oxygen treatment for idiopathic sudden sensorineural hearing loss. We did not identify existing reviews for key questions 2 or 4. Please see Table 2 below for more information.

- A bridge search for systematic reviews was conducted on December 20, 2016. This search identified no evidence reviews published since August 2016.
- Impact: The nomination has high impact potential due to the lack of current and consistent guidance on corticosteroid therapy for sudden hearing loss.
- Feasibility: A new evidence review examining steroid therapy for sudden hearing loss is feasible.
 - *Size/scope of review*: Our search of PubMed resulted in a total of 78 unique titles. Upon title and abstract review, we identified a total of 37 studies potentially relevant to the key questions in the nomination.
 - *ClinicalTrials.gov*: We identified 1 open or recently closed relevant clinical trial on ClinicalTrials.gov.
- Value: This nomination has high value potential because the nominator will use an AHRQ evidence review to inform their 2017 clinical practice guideline update.

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Introduction

Sudden hearing loss is the rapid impairment of hearing in one or both ears within a 72 hour period, affecting 5 to 20 per 100,000 population.¹ While 32-65% of cases recover spontaneously, many patients suffer long-term hearing impairment. The most common treatment is corticosteroids, but other treatment options are available and there is no uniformly accepted treatment.

Topic nomination 0695 was received on July 5, 2016. It was nominated by the American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF). After consulting the nominator, we combined a few of their proposed sub questions into one key question. The questions for this nomination are:

Key Question 1. What is the effectiveness of corticosteroid therapy (*ie*, oral or intratympanic) versus placebo or standard therapy as initial treatment for sudden hearing loss, and are the effects impacted by dosage, time since onset of hearing loss, and/or duration of therapy?

Key Question 2. What is the effectiveness of combined oral and intratympanic corticosteroid therapy versus placebo or standard therapy as initial treatment for sudden hearing loss?

Key Question 3. What is the effectiveness of salvage therapy (*ie*, systemic oral or intratympanic corticosteroids) versus placebo or standard therapy, and are the effects impact by dosage, duration of therapy, and/or level of hearing recovery (intratympanic steroids only)?

Key Question 4. After failure of initial corticosteroid therapy (*ie*, oral or intratympanic), what is the effectiveness of transtympanic steroid therapy for sudden hearing loss, and are the effects impacted by time since onset of hearing loss?

Key Question 5. What is the effectiveness of hyperbaric oxygen therapy versus placebo or standard therapy for sudden hearing loss?

To define the inclusion criteria for the key questions we specify the population, interventions, comparators, and outcomes, (PICO) of interest. See Table 1.

Table 1. Key Questions and PICOs

Key Question	1. What is the effectiveness of corticosteroid therapy (ie, oral or intratympanic) versus placebo as initial treatment for sudden hearing loss, and are the effects impacted by dosage, time since onset of hearing loss, duration of therapy	2. What is the effectiveness of combined oral <u>and</u> intratympanic corticosteroid therapy versus placebo as initial treatment for sudden hearing loss?	3. What is the effectiveness of salvage therapy (ie, systemic oral or intratympanic corticosteroids) versus placebo, and are the effects impacted by dosage, duration, level of persistent hearing loss (intratympanic only)	4. After failure of initial corticosteroid therapy (ie, oral or intratympanic), what is the effectiveness of transtympanic steroid therapy for sudden hearing loss, and are the effects impacted by time since onset of hearing loss?	5. What is the effectiveness of hyperbaric oxygen therapy versus placebo for sudden hearing loss?
Population	Adults with idiopathic sudden sensorineural hearing loss	Adults with idiopathic sudden sensorineural hearing loss	Adults with idiopathic sudden sensorineural hearing loss	Adults with idiopathic sudden sensorineural hearing loss	Adults with idiopathic sudden sensorineural hearing loss
Interventions	1. Oral corticosteroid therapy 2. Intratympanic corticosteroid therapy	Combined oral and intratympanic steroid therapy	1. Oral steroid therapy 2. Intratympanic steroid therapy	Transtympanic steroid therapy	Hyperbaric oxygen therapy
Comparators	Placebo	Placebo	Placebo	Placebo	Placebo
Outcomes	Improvement in hearing	Improvement in hearing	Improvement in hearing	Improvement in hearing	Improvement in hearing

Methods

To assess topic nomination 0695, Steroid Therapies for Sudden Hearing Loss, for priority for a systematic review or other AHRQ EHC report, we used a modified process based on established criteria. Our assessment is hierarchical in nature, with the findings of our assessment determining the need for further evaluation. Details related to our assessment are provided in Appendix A.

1. Determine the *appropriateness* of the nominated topic for inclusion in the EHC program.
2. Establish the overall *importance* of a potential topic as representing a health or "healthcare issue in the United States.
3. Determine the *desirability of new evidence review* by examining whether a new "systematic review or other AHRQ product would be duplicative. "
4. Assess the *potential impact* a new systematic review or other AHRQ product.
5. Assess whether the *current state of the evidence* allows for a systematic review or other AHRQ product (feasibility).
6. Determine the *potential value* of a new systematic review or other AHRQ product.

Appropriateness and Importance

We assessed the nomination for appropriateness and importance (see Appendix A).

Desirability of New Review/Duplication

We searched for high-quality, completed or in-process evidence reviews pertaining to the key questions of the nomination. Table 2 includes the citations for the reviews that were determined to address the key questions.

Impact of a New Evidence Review

The impact of a new evidence review was assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether a new review could influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.). See Appendix A.

Feasibility of New Evidence Review

We conducted a literature search in PubMed from August 2011 to August 2016. We reviewed all identified titles and abstracts for inclusion and classified identified studies by study design, to assess the size and scope of a potential evidence review. See Table 2, Feasibility Column, Size/Scope of Review Section for the citations of included studies.

We also searched Clinicaltrials.gov for recently completed or in-process unpublished studies. See Appendix B for the PubMed search strategy and links to the ClinicalTrials.gov search.

Value

We assessed the nomination for value (see Appendix A). We considered whether a partner organization could use the information from the proposed evidence review to facilitate evidence-based change; or the presence of clinical, consumer, or policymaking context that is amenable to evidence-based change.

Compilation of Findings

We constructed a table outlining the selection criteria as they pertain to this nomination (see Appendix A).

Results

Appropriateness and Importance

This is an appropriate and important topic. This topic represents a relatively uncommon condition, but affects people across the age and sex spectrum.

Desirability of New Review/Duplication

A new evidence review examining steroid therapies for sudden hearing loss would not be duplicative of an existing product. We identified one Cochrane evidence review² and one other evidence review examining oral or intratympanic steroids as initial treatment for sudden hearing loss. We identified two other evidence reviews examining oral or intratympanic steroids as salvage therapy.^{3,4} We did not identify any existing reviews for combined oral and intratympanic steroid treatment or for transtympanic steroid treatment. We identified one Cochrane review on hyperbaric oxygen treatment for sudden hearing loss.⁵ Although there are existing evidence reviews, none cover all key questions completely. See Table 2, Duplication column for the systematic review citations that were determined to address the key questions.

Impact of a New Evidence Review

A new systematic review on steroid therapies for sudden hearing loss may have high impact. There is a lack of current and consistent guidance on corticosteroid therapy for sudden hearing loss.

Feasibility of a New Evidence Review

A new evidence review examining steroid therapies for sudden hearing loss is feasible. We identified 20 published studies examining the effectiveness of corticosteroid therapy (KQ 1) (one in 2011,⁶ four in 2012,⁷⁻¹⁰ six in 2013,¹¹⁻¹⁶ two in 2014,^{17,18} and seven in 2015¹⁹⁻²⁵) and one ongoing clinical trial.²⁶ We identified nine published studies examining the effectiveness of combined oral and intratympanic corticosteroids for initial treatment of sudden hearing loss (KQ 2) (five in 2013,^{12,13,27-29} one in 2014,³⁰ two in 2015,^{20,21} and one in 2016³¹). We identified nine published studies for examining the effectiveness of salvage therapy (KQ 3) (two in 2011,^{32,33} one in 2012,¹⁰ one in 2013,³⁴ three in 2014,³⁵⁻³⁷ and two in 2015^{19,20}). We identified two published studies studying the effectiveness of transtympanic steroid therapy (KQ 4) (one in 2011³⁸ and one in 2013³⁹). We identified five published studies for KQ 5 (one in 2012,⁴⁰ two in 2013,^{11,41} one in 2014,⁴² and one in 2015⁴³), which examines the effectiveness of hyperbaric oxygen therapy.

We identified only one relevant clinical trial,²⁶ which suggests there may not be new treatments or effectiveness studies on the horizon. See Table 2, Feasibility column for the citations that were determined to address the key questions.

Table 2. Key questions with the identified corresponding evidence reviews and original research

Key Question	Duplication (Completed and In-Process Evidence Reviews)	Feasibility (Published and Ongoing)
KQ 1: Oral or intratympanic steroids as initial treatment	Total number of completed or in-progress systematic reviews - 2 <ul style="list-style-type: none"> • Cochrane Review – 1² • Other – 1³ 	<p><u>Size/scope of review</u> Relevant Studies Identified: 20</p> <ul style="list-style-type: none"> • RCT – 4^{7,8,12,15} • Retrospective cohort – 12^{9-11,13,16-21,24,25} • Pre-post – 3^{14,22,23} • Case-control – 1⁶ <p><u>ClinicalTrials.gov</u> Relevant Trials: 1</p> <ul style="list-style-type: none"> • Recruiting – 1²⁶
KQ 2: Combined oral and intratympanic	Total number of completed or in-progress systematic reviews – 0	<p><u>Size/scope of review</u> Relevant Studies Identified: 9</p> <ul style="list-style-type: none"> • RCT – 2^{12,28}

Key Question	Duplication (Completed and In-Process Evidence Reviews)	Feasibility (Published and Ongoing)
steroids as initial treatment		<ul style="list-style-type: none"> n-RCT – 2^{27,30} Retrospective cohort – 5^{13,20,21,29,31} ClinicalTrials.gov Relevant Trials: 0
KQ 3: Oral or intratympanic steroids as salvage treatment	Total number of completed or in-progress systematic reviews – 2 <ul style="list-style-type: none"> Other - 2^{3,4} 	<u>Size/scope of review</u> Relevant Studies Identified: 9 <ul style="list-style-type: none"> Prospective cohort – 1³⁴ Retrospective cohort – 7^{10,19,20,33,35-37} Pre-post – 1³² ClinicalTrials.gov Relevant Trials: 0
KQ 4: Transtympanic steroids as salvage treatment	Total number of completed or in-progress systematic reviews – 0	<u>Size/scope of review</u> Relevant Studies Identified: 2 <ul style="list-style-type: none"> RCT – 1³⁸ Case Control – 1³⁹ ClinicalTrials.gov Relevant Trials: 0
KQ 5: Hyperbaric oxygen treatment	Total number of completed or in-progress systematic reviews – 1 <ul style="list-style-type: none"> Cochrane - 1⁵ 	<u>Size/scope of review</u> Relevant Studies Identified: 5 <ul style="list-style-type: none"> RCT – 1⁴¹ Retrospective cohort – 3^{11,40,43} Pre-Post – 1⁴² ClinicalTrials.gov Relevant Trials: 0

Abbreviations: ISSNHL=Idiopathic Sudden Sensorineural Hearing Loss; KQ=Key Question; RCT=Randomized Controlled Trial

Value

The potential for value is high given the nominator will use an AHRQ evidence review to inform their 2017 clinical practice guideline update.

Summary of Findings

- Appropriateness and importance: The nomination is both appropriate and important.
- Duplication: A new evidence review examining steroid therapy for sudden hearing loss would not be duplicative.
 - For key question 1, we identified existing evidence reviews examining benefits and harms of steroid treatment for idiopathic sudden sensorineural hearing loss. For key question 3, we identified existing evidence reviews examining the effectiveness of corticosteroids for salvage therapy in idiopathic sudden sensorineural hearing loss. For key question 5, we identified one existing evidence review examining the benefits and harms of hyperbaric oxygen treatment for idiopathic sudden sensorineural hearing loss. We did not identify existing reviews for key questions 2 or 4. Please see Table 2 below for more information.
 - A bridge search for systematic reviews was conducted on December 20, 2016. This search identified no evidence reviews published since August 2016.

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- Value: This nomination has high value potential because the nominator will use an AHRQ evidence review to inform their 2017 clinical practice guideline update.

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Appendices

Appendix A: Selection Criteria Summary

Appendix B: Search Strategy & Results (Feasibility)

Appendix A. Selection Criteria Summary (

Selection Criteria	Supporting Data
1. Appropriateness	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the U.S.?	Yes, this topic represents a health care drug and intervention available in the U.S.
1b. Is the nomination a request for a systematic review?	Yes, this topic is a request for a systematic review.
1c. Is the focus on effectiveness or comparative effectiveness?	The focus of this review is on effectiveness.
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes, it is biologically plausible. Yes, it is consistent with what is known about the topic.
2. Importance	
2a. Represents a significant disease burden; large proportion of the population	This topic represents a relatively uncommon condition, but affects people across the age and sex spectrum.
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Treatment options for sudden hearing loss affects healthcare decision making, but as a relatively uncommon condition, it does not affect a large portion of the US population.
2c. Represents important uncertainty for decision makers	The AAO-HNSF provides clinicians guidelines for treating sudden hearing loss, and their guidelines are becoming outdated. There is now uncertainty for treatment pathways that need to be addressed by decision makers.
2d. Incorporates issues around both clinical benefits and potential clinical harms	The nomination focuses on benefits and harms for treatment options.
2e. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	The selection of treatment can potentially be high or low cost to payers and healthcare systems.
3. Desirability of a New Evidence Review/Duplication	
3. Would not be redundant (i.e., the proposed topic is not already covered by available or soon-to-be available high-quality systematic review by AHRQ or others)	We identified one Cochrane evidence review ² and one other evidence review examining oral or intratympanic steroids as initial treatment for sudden hearing loss. We identified two other evidence reviews examining oral or intratympanic steroids as salvage therapy. ^{3,4} We did not identify any existing reviews for combined oral and intratympanic steroid treatment or for transtympanic steroid treatment. We identified one Cochrane review on hyperbaric oxygen treatment for sudden hearing loss. ⁵ Although there are existing evidence reviews, none cover all key questions completely.
4. Impact of a New Evidence Review	

4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	Guidelines are available but are inconclusive in several areas due to lack of evidence. Guidelines will be updated which could be informed by a new evidence review.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	Yes, there is practice variation. Guidelines are available but do not cover all areas of practice due to limited evidence.
5. Primary Research/Feasibility	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	We identified 20 published studies for KQ1 (one in 2011 ⁶ , 4 in 2012 ⁷⁻¹⁰ , 6 in 2013 ¹¹⁻¹⁶ , 2 in 2014 ^{17,18} , and 7 in 2015 ¹⁹⁻²⁵) and one ongoing study. ²⁶ We identified 9 published studies for KQ2 (5 in 2013 ^{12,13,27-29} , one in 2014 ³⁰ , 2 in 2015 ^{20,21} , and one in 2016 ³¹). We identified 9 published studies for KQ3 (2 in 2011 ^{32,33} , one in 2012 ¹⁰ , one in 2013 ³⁴ , 3 in 2014 ³⁵⁻³⁷ , and 2 in 2015 ^{19,20}). We identified 2 published studies for KQ4 (one in 2011 ³⁸ , and one in 2013 ³⁹). We identified 5 published studies for KQ5 (one in 2012 ⁴⁰ , 2 in 2013 ^{11,41} , one in 2014 ⁴² , and one in 2015 ⁴³).
6. Value	
6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change	Yes, the AAO-HNSF will update their guidelines based on new evidence review.
6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	Yes, the AAO-HNSF will update their guidelines based on new evidence review.

Abbreviations: AAO-HNSF=American Academy of Otolaryngology – Head and Neck Surgery Foundation

Appendix B. Search Strategy & Results (Feasibility)

Topic: Sudden Hearing Loss Date: August 11, 2016 Database Searched: MEDLINE (PubMed)	
Concept	Search String
Sudden Hearing Loss	"Hearing Loss, Sudden/therapy"[Mesh]
	AND
Steroid treatment	"Steroids/therapeutic use"[Mesh]
	OR
Hyperbaric oxygen therapy	"Hyperbaric Oxygenation/therapeutic use"[Mesh]
	NOT
Editorials, etc.	(((((("Letter"[Publication Type]) OR "News"[Publication Type]) OR "Patient Education Handout"[Publication Type]) OR "Comment"[Publication Type]) OR "Editorial"[Publication Type])) OR "Newspaper Article"[Publication Type]
Limit to last 5 years; Humans; English	Filters activated: published in the last 5 years, Humans, English
N=78	
Systematic Review N=6	PubMed subsection "Systematic [sb]"
Randomized Controlled Trials N=66	Cochrane Sensitive Search Strategy for RCT's "(((((((groups[tiab])) OR (trial[tiab])) OR (randomly[tiab])) OR (drug therapy[sh])) OR (placebo[tiab])) OR (randomized[tiab])) OR (controlled clinical trial[pt])) OR (randomized controlled trial[pt])"
Other N=6	

ClinicalTrials.gov searched on August 11, 2016 \$

4 studies found for: **Recruiting** | Hearing Loss, Sudden \$

[https://clinicaltrials.gov/ct2/results?term=&recr=Recruiting&type=&rslt=&age_v=&gndr=&cond=\\$Hearing+Loss%2C+Sudden&intr=&titles=&outc=&spons=&lead=&id=&state1=&cny1=&state2=\\$&cny2=&state3=&cny3=&locn=&rcv_s=&rcv_e=&lup_s=&lup_e=\\$](https://clinicaltrials.gov/ct2/results?term=&recr=Recruiting&type=&rslt=&age_v=&gndr=&cond=$Hearing+Loss%2C+Sudden&intr=&titles=&outc=&spons=&lead=&id=&state1=&cny1=&state2=$&cny2=&state3=&cny3=&locn=&rcv_s=&rcv_e=&lup_s=&lup_e=$)

no studies found for: **Active, not recruiting** | Hearing Loss, Sudden \$

8 studies found for: **Completed** | Hearing Loss, Sudden \$

[https://clinicaltrials.gov/ct2/results?term=&recr=Completed&type=&rslt=&age_v=&gndr=&cond=\\$Hearing+Loss%2C+Sudden&intr=&titles=&outc=&spons=&lead=&id=&state1=&cny1=&state2=\\$&cny2=&state3=&cny3=&locn=&rcv_s=&rcv_e=&lup_s=&lup_e=\\$](https://clinicaltrials.gov/ct2/results?term=&recr=Completed&type=&rslt=&age_v=&gndr=&cond=$Hearing+Loss%2C+Sudden&intr=&titles=&outc=&spons=&lead=&id=&state1=&cny1=&state2=$&cny2=&state3=&cny3=&locn=&rcv_s=&rcv_e=&lup_s=&lup_e=$)